

I. INTRODUCTION

Effective protection and implementation of patent rights encourage investment in research and development studies. Patent holders contribute to the enhancement of technology by disclosing data about their inventions in return for being granted monopoly rights for a limited period of time. Such a disclosure is of utmost importance in respect of dissemination of information.

The strength of companies is not measured only by their productive capacity or tangible assets but increasingly by the value of their patent portfolios. Patents are considered to be primary means for controlling a globalised economy.

The present study concentrates on various systems of protection granted for patentable inventions in the European Community with special reference to pharmaceutical products and processes, alongside a preliminary overview of the other areas of intellectual property protection globally.

1.1. The Concept of Intellectual Property

Intellectual property means the legal rights arising from intellectual activity in the industrial, scientific, literary and artistic fields. Intellectual property rights provide an incentive, in the form of a temporary grant of exclusivity in the market, to invest time and money in research and development thereby putting the right-owner in a position to obtain a reward.¹

¹ Inge Govaere, *The Use and Abuse of Intellectual Property Rights in E.C. Law*, London, Sweet&Maxwell, 1996, p.16

1.2. Principal Characteristics of Intellectual Property Rights

1.2.1. Exclusivity

The principle of exclusivity implies that the right-owner is able to prohibit certain acts of third parties, for instance manufacturing and distribution, which would otherwise be lawful in the absence of intellectual property protection.

1.2.2. Territoriality

Although European Community harmonization measures and international conventions concerning intellectual property rights exist, it is still the national law that remains the principle source of the rights and obligations of the right-owner. This entails the scope of the intellectual property right being geographically limited to the territory of the Member State granting the protection.

The principle of territoriality is at times regarded as undermining the objectives of the single market of the E.C. and being contrary to the free movement of goods principle. It has been criticized that intellectual property protection allows for the creation of “islands” within the Community.²

1.2.3. Exhaustion of Rights

According to the principle of exhaustion of rights; the rights conferred through intellectual property protection upon the proprietor are deemed to be exhausted after the first sale by the right owner or with his consent. But at this point the question arises whether it amounts to a domestic or international exhaustion. This is often confined to first sales within the territory covered by the right which means ‘ domestic

² Govaere p.16, See G. Van Empel, Bescherming van de intellectuele eigendom (1987, Kluwer), p.16

exhaustion'. Accordingly national rights subject to such limitation can be used to prevent the importation of goods sold abroad by the national right-owner or goods which come from an associated enterprise ³ .

In various decisions, the European Court of Justice emphasized the significance of preventing the division of the market by use of national intellectual property rights. Once goods have been placed on the market anywhere within the Community by the person who owns the intellectual property rights represented by the goods, or with his consent, his specific intellectual property rights have been exhausted because he has been paid or had the opportunity of being paid, for those rights embodied in goods ⁴ . In *Centrafarm B.V. v Withrop B.V.* case, the European Court of Justice decided that national trade mark law could not be used to prevent the free circulation of goods throughout the Community which had been placed on the market in UK through subsidiaries. ⁵

Whatever the position in national law, the proprietor's exclusive right is deemed in Community Law to be exhausted by putting products into circulation anywhere within the common market. ⁶ This principle is being applied by the Court of Justice in cases relating to many forms of intellectual property .

The exhaustion of rights principle is not recognised internationally.⁷

1.3. Fields of Intellectual Property Rights and E.C. Harmonization Measures

Intellectual property is traditionally divided into two branches. "industrial property" and "copyright". ⁸

³ William Cornish / David Llewelyn, *Intellectual Property : Patents, Copyright, Trade Marks and Allied*, London, Sweet & Maxwell, 2003, p. 42

⁴ Terence Prime / David Booton, *European Intellectual Property Law*, Ashgate / Dartmouth , 2000, p.9,10

⁵ *Centrafarm B.V. v Winthrop B.V.* , Case 17/74 [1974] ECR 1147

⁶ Derrick Wyatt / Alan Dashwood, *The Substantive Law of the EEC*; Sweet & Maxwell, 1987, p.482

⁷ *Silhouette International v Hartlauer* [1998] F.S.R. 729.

⁸ WIPO, *Intellectual Property Handbook*, Geneva 2001, p. 3

According to Article 2(viii) of the Convention Establishing the World Intellectual Property Organization (WIPO),⁹ concluded in Stockholm on July 14, 1967; “intellectual property shall include rights relating to literary, artistic and scientific works, performances of performing artists, phonograms and broadcasts, inventions in all fields of human endeavour, scientific discoveries, industrial designs, trademarks, service marks, and commercial names and designations, protection against unfair competition, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.”

Literary, artistic and scientific works belong to the copyright branch of intellectual property.

The areas mentioned as performances of performing artists, phonograms, and broadcasts are usually called “related rights”, that is, rights related to copyrights.

The areas mentioned as inventions, industrial designs, trademarks, service marks and commercial names and designations constitute the industrial property branch of intellectual property. Inventions are new solutions to technical problems.

Art. 1.2 of the TRIPS Agreement states that, for the purposes of the Agreement, the term “intellectual property” refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II of the TRIPS Agreement, namely, copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs (topographies) of integrated circuits, and undisclosed information.

1.3.1. Copyright and Related Rights

Copyright law deals with the rights of intellectual creators. It is concerned with all forms of public communication, with printed publications and as well as with sound

⁹ WIPO promotes the protection of intellectual property throughout the world through cooperation among states and administers various multilateral treaties dealing with the legal and administrative aspects of intellectual property. The number of Member States was 181 as of December 31, 2004.

and television broadcasting, films for public exhibition in cinemas etc. And even computerized systems for the storage and retrieval of information.

Copyright law, protects only the form of expression of ideas, not the ideas themselves.

National copyright laws provide for the protection of literary, musical and artistic works, maps and technical drawings, photographic works, motion pictures, computer programs.

The original authors of works protected by copyright have exclusive rights of an economic character and they have also moral rights.

Acts such as ; copying or reproducing the work; distributing the work; renting the work; performing the work in public; making a sound recording of the work; making a motion picture of the work; broadcasting the work; translating the work; adapting the work can not be performed by the third persons without the authorization of the copyright owner ¹⁰. These acts constitute the exclusive rights of the copyright owner.

The right to claim authorship of the work and the right to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the work which would be prejudicial to the author's honour or reputation are stated as moral rights in the Berne Convention¹¹ .

Related Rights are the rights of performing artists in their performances, the rights of producers of phonograms in their phonograms, and the rights of broadcasting organizations in their radio and television programs.

¹⁰ WIPO, Intellectual Property Handbook, Geneva 2001, p. 43-44

¹¹ Andrew Christies – Stephen Gare, Blackstone's Statutes on Intellectual Property. Blackstone Press, 2001, p.416. "...The Berne Convention for the Protection of Literary and Artistic Works, adopted on September 9, 1886 in Paris. It sets out minimum standards of protection of the economic and moral rights of authors of literary and artistic works. The total number of Member States was 157, as of December 31, 2004."

They are labelled as “related” or “neighbouring” rights as distinct from “author’s rights”. They share many characteristics of the authors’ copyright. In this sense they are analogous. But they are somewhat closer to industrial property in the relative shortness of their duration.

The most important categories are; the right of performers to prevent fixation and direct broadcasting or communication to the public of their performance without their consent; the right of producers of phonograms to authorize or prohibit reproduction of their phonograms and the import and distribution of unauthorized duplicates thereof; the right of broadcasting organizations to authorize or prohibit rebroadcasting, fixation and reproduction of their broadcasts.

As a consequence of rapid technological developments, the need was felt for special protection of performers, producers of phonograms and broadcasting organizations. Unlike most international conventions, which follow national legislation, the Rome Convention¹² was an attempt to establish international regulations in a new field where few national laws existed. This meant that most States would have to draft and enact laws before adhering to the Convention.

In countries which are party to the Berne Convention, and in many other countries, the duration of copyright provided for by national law is the life of the author and not less than fifty years after the death of the author. In recent years, a tendency has emerged towards lengthening the term of protection to seventy years after death.

It was thought that a sufficient level of harmonization could be achieved in the field of copyright within the framework of international intellectual property conventions concluded by the Member States, in particular the Berne Convention for the Protection of Literary and Artistic Works.¹³

¹² Rome Convention 1961, International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, Done at Rome on October 26, 1961. It secures protection of performers on their performances, phonograms of producers of phonograms and broadcasts of broadcasting organizations. The total number of Member States was 79, as of December 31, 2004. Turkey adhered to the Rome Convention in 2004.

¹³ Govaere, p.55

The Berne Convention sets minimum standards of protection, leaving it to each Union country to enforce higher standards of protection. To remedy the distortions to intra-Community trade created by the different durations of copyright protection, a Directive extending the duration of copyright protection to 70 years post mortem auctores was adopted by the Council on October 29, 1993.¹⁴

The European intervention in the field of copyright and its neighbouring rights has been fragmented in the extreme.¹⁵ The areas of harmonizing intervention have been to give copyright protection to computer programs,¹⁶ for the protection of databases,¹⁷ creating rental and lending rights,¹⁸ as mentioned above extending the term of copyright protection, the co-ordination of rules concerning copyrights and neighbouring rights applicable to satellite broadcasts and cable programs,¹⁹ the creation of a resale right for the benefit of artist on resale of their work²⁰ and harmonization in the information society.²¹

1.3.2. Trademarks

A trademark is any mark that individualizes the goods of a given enterprise and distinguishes them from the goods of its competitors. As a result of changing modern advertising methods, trade marks perform other important duties such as indicating the quality of goods and promoting them in the minds of consumers.²²

Service marks fulfil essentially the same origin indicating and distinguishing function for services as trademarks do for goods.

¹⁴ Council Directive 93/98 of October 29, 1993 harmonizing the term of protection of copyright and certain related rights, [1993] O.J.L290/9

¹⁵ Prime / Booton, p.246-247.

¹⁶ Council Directive 91/250 of 14 May 1991 on the legal protection of computer programs ([1991]OJ.L 122/42)

¹⁷ Council Directive of 11 March 1996 on the legal protection of databases (96/9/EC) OJ L 77/20

¹⁸ Council Directive 92/100 of November 1992 on rental right and lending right and on certain rights related to copyright in the field of intellectual property ([1992] OJ L 346/61)

¹⁹ Council Directive 93/83 of 27 September 1993 on the co-ordination of certain rules concerning copyright and rights related to copyright applicable to satellite broadcasting and cable retransmission ([1993] OJ L248/15)

²⁰ Proposal for a European Parliament and Council Directive on the resale right for the benefit of an author of an original work of art COM(96) 97 final.

²¹ Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society.

²² Prime / Booton, p. 76

A collective mark can be owned by an association which itself does not use the collective mark but whose members may use the collective mark. The members may use the collective mark if they comply with the requirements fixed in the regulations concerning the use of the collective mark.

A certification mark may be used by anyone who comply with the defined standards.

Words, letters and numerals, devices, coloured marks, three-dimensional signs, audible signs, olfactory marks and other invisible signs e.g. signs recognized by touch may serve as trademarks.

According to Article 6quinquies B of the Paris Convention; trademarks may be denied registration if they are lacking distinctive character or if they are contrary to morality or public order and in particular, of such a nature as to deceive the public ²³ .

It is in the area of trademarks that “Europeanization” within the Community may be said to be complete. First attempts of such a cooperation can be traced back to the Paris Convention which came into force in 1884. The Convention obliges the signatories to obey four main principles in their national law; to protect well-known marks belonging to nationals of Convention countries, to prevent the registration and use of armorial bearings, flags, and emblems of the Convention countries, to provide effective protection against unfair competition and to accept for registration any trademark which has been duly registered in its country of origin. The last obligation was the most demanding one for the signatories. Although two provisions of the Convention concerning national treatment (Art.2) and the system of Convention priority (Art.4) have gained importance in practice, the Convention is quite loose to constitute an unifying instrument for trademarks on international basis.

²³ The Paris Convention for the Protection of Industrial Property, signed in 1883, in Paris, most recently revised in Stockholm, in 1967. It is one of the pillars of the intellectual property system. The total number of Member States was 168, as of December 31, 2004. It applies to industrial property in the widest sense, including inventions, marks, industrial designs, utility models, trade names, geographical indications and the repression of unfair competition.

The Madrid Agreement was signed in 1891. It is a special arrangement under the Paris Convention and therefore only the parties to the Paris Convention can become parties to this subsequent agreement. This system gave the applicants whose trademarks are registered in their home country the opportunity to obtain protection in other Contracting countries for a uniform period of twenty years by filing only one application in one language. The trademark is entered on the International Register, operated by the Central Registration Bureau based in Geneva. The existence of the trademark in each country rests upon its national trade mark law. The scope of protection and issues of infringement are dealt with national law of each Contracting State. The solutions provided by the Madrid Agreement in some important issues were so limited that the United States, UK, Denmark and Ireland did not join it. There were only twenty nine Signatories .

Protocol Relating to the Madrid Agreement concerning the International Registration of Marks was concluded in 1989. The aim was to make Madrid Agreement system more attractive to the Member States of the European Community, which had stood outside the system and to make the Madrid system link with the Community Trademark provision. New features were added which rendered the system for international registration of marks more flexible and compatible with the domestic legislation of these countries.²⁴

The Council Regulation creating the Community Trademark was enacted in order to enhance further E.C. harmonization in the field of trademarks ²⁵ . Its aim is to create uniform trademark protection and specialized Community institutions such as the Community Trade Mark Office where natural or legal persons can register their marks as Community Trademarks. The said Office of Harmonization in the Internal Market (OHIM) was established in Alicante in Spain. In order to comply with the TRIPS Agreement the Regulation was amended by Council Regulation EC/3288/94 in December 1994 and is applicable as of 1 January 1996.²⁶ Later, the Commission

²⁴ The total number of Member States party to the Madrid Agreement was 56 and to Madrid Protocol was 66, as of December 31, 2004.

²⁵ Council Regulation 40/94 on the Community Trademark [1994] O.J.L 11/1, as amended by Regulation 3288/94[1994] O.J.L349

²⁶ Council Regulation No 3288/94 of 22 December 1994 amending Regulation (EC) No 40/94 on the Community Trademark for the Implementation of the Agreements Concluded in the Framework of the Uruguay Round, OJL 349, 31/12/1994 P.0083-0084

also adopted Regulation EC/2868/95 for the implementation of the Council Regulation and the determination of the application procedure, which came into force on the 22 December 1995 according to its Article 3.²⁷

The concurrent existence of the national trademark laws has weakened the effective implementation of the Community Trademark. In order to lessen these adverse effects; a Council Directive was issued to approximate the national laws of the Member States.²⁸ The Directive was adopted by the Council by a qualified majority pursuant to Article 95 (ex100a) ECT. It consists of mandatory and optional provisions. It merely concerns the approximation of a limited number of national provisions; especially provisions of national laws which most directly affect the functioning of the internal market and not a full harmonisation of national trademark law.²⁹ In the Recitals to the Directive, it is clearly stated that ‘ it does not appear to be necessary at present to undertake fullscale approximation of the trade mark laws of Member States and it will be sufficient if approximation is limited to those national provisions of law which most directly affect the functioning of the internal market’ .

1.3.3. Industrial Designs and Integrated Circuits

a. Industrial Designs

Industrial design refers to the creative activity of achieving a formal or ornamental appearance for mass-produced items, that satisfies both the need for the item to appeal visually to potential consumers, and the need for the item to perform its intended function efficiently .

²⁷ Commission Regulation No EC/2868/95 of 13 December 1995 Implementing Council Regulation (EC) No EC/40/94 on the Community Trademark, OJ L 303, 15/12/1995 P 0001-0032

²⁸ First Council Directive 89/104 of December 21, 1988 to approximate the laws of the Member States relating to trademarks [1989] O.J.L40/1. See also Council Decision 92/10 December 19, 1991 postponing the date on which the national provisions applying Directive 89/104 to approximate the laws of the Member States relating to trademarks are to be put into effect [1992] O.J.L6/35

²⁹ Gregor Grubhofer, ‘Protection of Trademarks in the EC’ LL.M. Thesis, Marmara University European Community Institute Department of European Union Law, Istanbul – 2003, p. 54.

The subject matter of the legal protection of industrial designs is not articles or products, but rather the design which is applied to or embodied in such articles or products.

Designs which are dictated solely by the function which the article is to perform shall be excluded from protection. Article 25.1 of the TRIPS Agreement provides that Members of the WTO may provide that industrial design protection shall not extend to designs dictated essentially by technical or functional considerations.

It is a requirement of all industrial design laws that protection through registration shall be granted only to designs which are novel. And a design can be only protected if it is capable of being used in industry, or in respect of articles produced on a large scale.

Industrial design registration grants the proprietor the exclusive right to prevent the unauthorized exploitation of the design in industrial articles.

Term of protection for an industrial design varies from country to country. The usual term goes from 10 to 25 years, often divided into terms requiring the proprietor to renew registration in order to obtain an extension of the term.

It is in the area of industrial design that national laws are most varied. On the other hand present arrangements for the international protection of designs are totally unsatisfactory. Art.5 of the Paris Convention for the Protection of Industrial Property requires the protection of industrial designs in all countries but does not contain any requirements as to substantial rights. The Berne Convention on the Protection of Literary and Artistic Works leaves the protection of designs to the discretion of the members of the Bern Union by either copyright law or specific legislation, but it lacks specific binding provisions. The Hague Agreement concerning the International Deposit of Industrial Designs 1925 is slightly better. It is aimed at facilitating the industrial design application in a number of countries by providing for a centralised international deposit system. Two acts of the Hague Agreement are currently in force, the 1960 Act and the 1934 Act. A further Act, the Geneva Act, was

adopted on July 2, 1999 which renamed the Hague Agreement for the International Registration of Industrial Designs.³⁰

The Commission issued in 1991 the Green Paper on the Legal Protection of Industrial Designs which forms the basis for the current proposals for a Council Regulation on the Community Design, and a Council Directive on the approximation of national design law.³¹ The Directive has entered into force.³² This Directive accepted the principle of subsidiarity and recognised that the approximation to be achieved by harmonization does not need to extend to all aspects of the national protection laws. It was considered sufficient to bring into line those features that are necessary for the co-existence of specific national and Community design protection.

The Community Design Regulation has also entered into force.³³ The Regulation has many similarities to the Trade Mark Regulation. Its main objective is to create a single Community wide-design without any separate formalities in each State, principally based on registration, but it also provides a short term unregistered protection for such designs as fashion of short-lived usefulness.

b. Integrated Circuits

Article 2 of the Treaty on Intellectual Property in Respect of Integrated Circuits (IPIC Treaty)³⁴ defines the term “integrated circuit” as a product, in its final form or an intermediate form, in which the elements, at least one of which is an active element, and some or all of the inter-connections are integrally formed in and/or on a piece of material and which is intended to perform an electronic function. The contracting parties to the Treaty must provide protection of integrated circuits, whether or not the integrated circuit concerned is incorporated in an article, against unlawful acts such as the reproduction of the layout-design, and the importation, sale

³⁰ http://www.wipo.int/treaties/en/registration/hague/summary_hague.html

³¹ [1993] O.J.C345/14 (proposal directive); [1994] O.J.C29/20 (proposal regulation)

³² Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998 on the Legal Protection of Designs.

³³ Council Regulation (EC) No.6/2002 of 12 December 2001 on Community Designs OJL 3, 5.01.2002.

³⁴ IPIC Treaty was adopted at a Diplomatic Conference, held at Washington D.C., in 1989. The Treaty is open to Members of WIPO or the United Nations and to intergovernmental organizations meeting certain criteria.

or other distribution for commercial purposes of the layout-design or an integrated circuit in which the layout-design is incorporated.

The development of such topographies requires a considerable amount of investment and topographies of semi-conductor products were not sufficiently protected in all Member States of the Community. Therefore there was a need to enact a secondary legislation in the European Community. The Council Directive 87/54/EEC was adopted for the legal protection of topographies of semiconductor products.³⁵ In the recitals of the Directive it is stated that the Community's legal framework on the protection of topographies of semiconductor products can in the first instance be limited to certain basic principles by provisions specifying whom and what should be protected, the exclusive rights of the owner to authorise or to prohibit certain acts, exceptions to these rights and the term of protection.

1.3.4. Geographical Indications

A geographical indication identifies a geographical area in which one or several enterprises are located which produce the kind of product for which the geographical indication is used.

Each and every enterprise which is located in the area to which the geographical indication refers has the right to use the said indication for the products originating in the said area. Such use is possibly subject to compliance with certain quality requirements.

Geographical indications can be protected on the national level through registration as collective and/or certification mark or an action for unfair competition.

Three multilateral treaties administered by WIPO contain provisions for the protection of geographical indications. They are namely; the Paris Convention for the Protection of Industrial Property, the Madrid Agreement for the Repression of False

³⁵ Council Directive 87/54/EEC of 16 December 1986 on the Legal Protection of Semiconductor Products.

and Deceptive Indications of Source on Goods and the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration.

Apart from those multilateral treaties; protection can be provided at International level through the provisions of bilateral agreements where contracting parties draw up a list of geographical indications and undertake to protect the geographical indications of the respective contracting parties.

Part II, Section 3 of the TRIPS Agreement is dedicated to geographical indications.

The EC Council Regulation on the Protection of Geographical Indications was adopted.³⁶ Its objective is to lay down common rules on the protection of geographical indications and designations of origin so as to add value to certain specific high-quality products from a geographical area and to promote in a rural development context the diversification of agricultural production.³⁷

1.3.5. Enforcement of Intellectual Property Rights

For ensuring the effective enforcement of intellectual property rights within the European Community and at its external borders, a number of legislative measures have been taken in the last ten years.

The Customs Regulation allowing border control of imports of fake goods was adopted in 1994.³⁸ A Directive³⁹ harmonising the enforcement of intellectual property rights within the Community and a Regulation⁴⁰ improving the mechanisms for

³⁶ EC Council Regulation No.2081/92 of July 14, 1992, on the Protection of Geographical Indications and Designations of Origin for Agricultural Products and Foodstuffs amended by Council Regulation (EC) No 535/97 of 17 March 1997 [Official Journal L 83, 25.03.1997]

³⁷ <http://europa.eu.int/scadplus/printversion/en/lvb/121097.htm>, retrieved on 24.10.2004.

³⁸ EC No 3295/94.

³⁹ Directive 2004/48/EC, of the European Parliament and of the Council of 29 April 2004 on the Enforcement of Intellectual Property Rights (Official Journal of the EU L 157 of 30 April 2004).

⁴⁰ Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing intellectual property rights and the measures to be taken against goods found to have infringed such rights. (Official Journal of the EU L 196 of 02.8.2003)

customs action against counterfeit or pirated goods set by the previous Customs Regulation were enacted. This Regulation extends Europol's powers to cover piracy and counterfeiting.

However the rightholders can not benefit from these internal instruments when violations occur in third countries and fake goods are either consumed domestically or exported to third countries. In order to overcome this, the European Commission decided to adopt a strategy paper for the enforcement of intellectual property rights in third countries. The Enforcement Strategy is a Communication of the Commission determining the priorities and optimising the use of resources in order to obtain the most effective results in terms of IPR enforcement in third countries. The Strategy Paper does not impose any additional , TRIPS plus obligations on any developing country.

The European Commission issued the results of a survey on issues regarding the enforcement of IPR in third countries in July 2003. China, Thailand, Russia, Indonesia, Brazil, Turkey and South Korea were considered as most problematic countries where production of pirated and counterfeiting goods in terms of domestic consumption and export reached worrying dimensions.

II. PATENTS

A patent is the right granted by the State to an inventor to exclude others from commercially exploiting the invention for a limited period, in return for the disclosure of the invention, so that others may gain the benefit of the invention.

Patent protection confers a temporary exclusive right on the invention of a new industrial product or process that fulfils the stringent conditions for protectability. The right which they accord is to prevent all others not just imitators, but even independent devisers of the same idea from using the invention for the duration of the patent.

In common with other intellectual property rights, a patent is a form of personal property that may be assigned, licensed or charged by way of a mortgage.

A patent is a document, issued upon application by a government office (or a regional office acting for several countries) which describes an invention and creates a legal situation in which a patented invention can normally be exploited with the authorization of the owner of the patent.

Despite the advantages of the EPC and PCT which shall be scrutinized in the following sections, there is a need for a worldwide patent system, due to increasing costs and complexity of obtaining and litigating patents. Such a system should give rise to a single patent enforceable within every country within a single framework. Although it is unlikely to establish such a system in a short term, a similar aim can be achieved by harmonizing patent grant and enforcement. The Patent Law Treaty⁴¹(PLT), adopted at Geneva on June 1, 2000, shall satisfy this need through harmonising global formalities for obtaining a patent to a limited extend. However the

⁴¹ www.wipo.int/treaties/en/ip/plt/trdocs_wo038.html, retrieved on 03.6.2005. World Intellectual Property Organisation, Treaties and Contracting States. Patent Law Treaty has entered into force in Croatia, Denmark, Estonia, Kyrgyzstan, Nigeria, Republic of Moldova, Romania, Slovakia, Slovenia and Ukraine on 28.4.2005.

conclusion of the Substantive Patent Law Treaty in future, which has been still under negotiation at the WIPO, can be considered as a great success for the achievement of long term goals in respect of establishing a worldwide patent system. In contrast with the PLT which relates only to formalities, the SPLT is aimed at harmonising substantive requirements such as novelty, inventive step, non-obviousness, industrial applicability, utility, sufficient disclosure, unity of the invention, claim drafting and interpretation.

2.1. Historical Perspective

Individual monopoly grants date back to thirteenth and fourteenth centuries and can be found in the records of various European territories. Letters patent were open letters with the King's Great Seal on the bottom granting rights often to foreign weavers and other craftsmen allowing them to practice their trade. The first letters patent were granted in 1311 to John Kepme, a Flemish weaver who wanted to practise his trade in England.⁴²

The world's first patent statute was passed in Venice in 1474.⁴³ Around one hundred patents have been granted under this Statute in a wide variety of technical fields including windmills, mud excavation, brick-making, wood-sawing, keel-laying, glass-pouring and working intaglio (carving) in glass. Even in this early stage of the history novelty and non-obviousness of the invention were required to obtain a patent.

In the United Kingdom, the Statute of Monopolies was passed in 1624. In the United States the constitutional provisions of 1787 provided for the grant of exclusive rights to the inventor. Abraham Lincoln was cited as saying "The patent system added the fuel of interest to the fire of genius".

⁴² David Bainbridge, Intellectual Property, Financial Times, Pitman Publishing, 1999, p.320

⁴³ Brian C. Reid, A Practical Guide To Patent Law, 1999, London, Sweet & Maxwell, p.1

2.2. European Intervention In the Field of Patent Rights and Associated Areas

European intervention in the field of patent rights and associated areas of intellectual property has been extensive and quite fragmented. Not all the intervention has been through the European Community, some of the interventions have been broad and general such as the European Patent Convention.

The interventions can be listed as: the European Patent Convention,⁴⁴ the proposal for a Community patent regime,⁴⁵ the proposal for a European Utility Model, Regulation on Plant Variety Rights,⁴⁶ Directive on the legal protection of biotechnological inventions,⁴⁷ the Regulations introducing supplementary protection certificates for medicinal⁴⁸ and agrochemical⁴⁹ products.

The recent developments concerning the Community Patent shall be examined in Section (V) in details.

2.3. Patent Protection in International Treaties and Conventions.

2.3.1. Paris Convention for the Protection of Industrial Property

A diplomatic Conference was convened in Paris in 1883, which ended with final approval and signature of the Paris Convention for the Protection of Industrial Property.

⁴⁴ Convention on the Grant of European Patents (European Patent Convention) Munich, 5 October 1973.

⁴⁵ Convention for the European Patent for the Common Market (the Community Patent Convention) [1989]O.J.L.410/1.

⁴⁶ Council Regulation (EC) No.2100/94 of 27 July 1994 on Community plant variety rights, [1994] OJ L227/1 which came into force September 1994.

⁴⁷ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

⁴⁸ Regulation 1768/92 OJ L182/1, which came into force on 2 January 1993.

⁴⁹ Regulation 1610/96 [1996] OJ L 198/30, which came into force in February 1997.

Principal provisions of the Paris Convention are “National Treatment” and “The Right of Priority”.

National treatment means that, as regards the protection of industrial property, each country party to the Paris Convention must grant the same protection to nationals of the other member countries as it grants to its own nationals.

The right of priority means that, on the basis of a regular application for an industrial property right filed by a given applicant in one of the member countries, the same applicant may, within a specified period of time (six or 12 months) , apply for protection in all the other member countries. For patents and utility models the priority period is 12 months, for industrial designs and trademarks it is six months.

Provisions Concerning Patents are mentioned below :

a. Independence of Patents

The rule concerning the “independence” of patents for inventions is contained in Article 4bis of the Paris Convention.

Patent for invention granted in member countries to nationals or residents of member countries must be treated as independent of patents for invention obtained for the same invention in other countries, including non-member countries. This principle means that a patent for an invention cannot be refused, invalidated or otherwise terminated in any member country on the ground that a patent for the same invention has been refused or invalidated , or that it is no longer maintained or has terminated, in any other country.

b. The Right of the Inventor to be Mentioned

According to Art.4 ter of the Paris Convention; an inventor shall have the right to be mentioned as such in the patent application.

c. Importation, Failure to Work and Compulsory Licences

The questions of importation of articles covered by patents, of failure to work the patented invention and of compulsory licences, are dealt with in Article 5A of the Convention.

With respect to importation, the provision states that importation by the patentee, into the country where the patent has been granted, of articles covered by the patent and manufactured in any of the countries of the Union will not entail forfeiture of the patent. This article applies to patentees who are entitled to benefit from the Paris Convention and who, having a patent in one of the countries of the Paris Union, import to this country goods (covered by the patent) which were manufactured in another country of the Union. In such a case, the patent granted in the country of importation may not be forfeited as a sanction for such importation.

With respect to the working of patents and compulsory licenses, the essence of the provisions contained in Article 5A is that each country may take legislative measures providing for the grant of compulsory licenses. These compulsory licenses are intended to prevent the abuses which might result from the exclusive rights conferred by a patent for invention, for example failure to work or insufficient working.

Compulsory licenses on the ground of failure to work or insufficient working are the most common kind of coercive measures against the patent owner to prevent abuses of the rights conferred by the patent for invention.

d. Grace Period for the Payment of Maintenance Fees

Article 5bis provides for a grace period for the payment of maintenance fees for industrial property rights and deals with the restorations of patents in case of non-payment of fees. The grace period is six months, and is established as a minimum period, leaving countries free to accept a longer period.

e. Patents in International Traffic

Another common rule of substantive importance, containing a limitation of the rights of the patent owner in special circumstances, is contained in Article 5ter. It deals with the transit of devices on ships, aircraft or land vehicles through a member country in which such device is patented.

Where ships, aircraft or land vehicles of other member countries enter temporarily or accidentally a given member country and have on board devices patented in that country, the owner of the means of transportation is not required to obtain prior approval or a licence from the patent owner. Temporary or accidental entry of the patented device into the country in such cases constitutes no infringement of the patent for invention.

The device on board the ship, aircraft or vehicle must be in the body, in the machinery, tackle, gear or other accessories of the conveyance, and must be used exclusively for operational needs.

f. Inventions Shown at International Exhibitions

The principle stated in Article 11 of the Paris Convention is that member countries are obliged to grant, in conformity with their domestic legislation, temporary protection to patentable inventions, utility models, industrial designs and trademarks in respect of goods exhibited at official or officially recognized international exhibitions held in the territory of any member country.

Temporary protection may be provided by various means. One is to grant a special right of priority, similar to that provided for in Article 4. This priority right would start from the date of the opening of the exhibition or from the date of introduction of the object at the exhibition. It would be maintained for a certain period, say twelve months, from that date, and would expire if the application for protection does not follow the exhibition within that period.

Another means which is found in a number of national laws, in particular with respect to patents for invention, is that of prescribing that, during a certain period of, say, twelve months before the filing or priority date of a patent application, a display of the invention at an international exhibition will not destroy the novelty of the invention.

2.3.2. Patent Cooperation Treaty (PCT)

The PCT shall be examined in details in section (IV).

2.3.3. European Patent Convention (EPC)

The European Patent Convention shall be examined in details in section (III).

2.3.4. The Strasbourg Agreement Concerning the International Patent Classification

The IPC is based on an international multilateral treaty administered by WIPO. It was concluded in 1971 and amended in 1979.⁵⁰ The IPC is a means for obtaining an internationally uniform classification of patent documents.

The Classification subdivides technology into 8 sections, 20 subsections, 118 classes, 624 subclasses and over 67.000 groups. Each of the sections, classes, subclasses, groups and sub-groups has a title and a symbol, and each of the subsections has a title. The symbol or symbols of at least the subclass or subclasses to which the technical invention described in any patent document belongs are indicated generally on the patent document by the industrial property office of the country where the application is filed.

⁵⁰ http://www.wipo.int/treaties/en/classification/strasbourg/summary_strasbourg.html

The IPC is an effective search tool for the retrieval of relevant patent documents by industrial property offices and other users in order to establish the novelty and assess the inventive step of patent applications. It also serves as a basis for investigating the state of the art in given fields of technology.

There are two authentic versions of the IPC, in English and German, published by the WIPO.

The IPC Union Assembly meets once every two years for the adoption of the Union's biennial program and budget. An Intergovernmental Committee of Experts revises the IPC to keep it up to date. IPC is continuously revised and a new edition is published every five years.⁵¹ All states party to the Agreement are the members of the IPC Union Assembly and the Committee of Experts.⁵²

It is open to States party to the Paris Convention for the Protection of Industrial Property.

2.3.5. The Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS")

The General Agreement for Tariffs and Trade (GATT) was set up in 1948 to deal with multilateral trade issues. The latest round of GATT negotiations, the Uruguay Round was concluded in April 1994, and led to the establishment of the World Trade Organisation.

The Agreement embodying the results of those negotiations, the Agreement establishing the World Trade Organization ("WTO Agreement"), was adopted on April 15, 1994, in Marrakech.

Those negotiations included, for the first time within the GATT, discussions on aspects of intellectual property rights related to international trade. The result of those

⁵¹ The current (seventh) edition is in force until December 2005.

⁵² WIPO Intellectual Property Handbook, WIPO Publication No.489 (E), Geneva 2001, p.305-306.

negotiations, contained in an Annex to the WTO Agreement, was the Agreement on Trade-Related Aspects of Intellectual Property Rights (the “TRIPS” Agreement).⁵³

The WTO Agreement, including the TRIPS Agreement (which is binding on all WTO Members) entered into force on January 1, 1995. The former Agreement established a new organization, the World Trade Organization, which began its work on January 1, 1995.

a. Basic Principles

Articles 1-8 of TRIPS include the basic principles of national treatment and most favored nation treatment.

According to the principle of national treatment; each Member State must give to the nationals of other Member States treatment no less favourable than that given to its own nationals. According to the principle of most favoured nation treatment, each Member State must give to the nationals of all Members the same privileges as are given to nationals of any Member.⁵⁴

Unlike other provisions of TRIPS, these articles could not be delayed beyond 1 January 1996 by any Member State, whatever its state of development.

b. Provisions Relating Specifically to Patents

The essential elements of the standards concerning the availability, scope and use of the patent rights include the following :⁵⁵

- Patents shall be available for products and processes in all fields of technology, including product patents for pharmaceuticals provided that they

⁵³ www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.

⁵⁴ Philip W. Grubb, Patents for Chemicals, Pharmaceuticals and Biotechnology, Oxford University Press Inc., New York, 1999, p.30-31.

⁵⁵ Vildan Kayacan, İlaçta Patent Korumasının Etkileri ve Koruma Tedbirleri, Hacettepe Üniversitesi Sağlık Bilimleri Enstitüsü, Bilim Uzmanlığı Tezi, Ankara, 2000, p.17-19

are new, involve an inventive step and are capable of industrial application (Article 27.1);⁵⁶

- Members may exclude inventions, the prevention within territory of the commercial exploitation of which is necessary to protect ordre public (public safety), including to protect human, animal or plant life or health or to avoid serious prejudice to the environment , provided that such exclusion is not made merely because the exploitation is prohibited by their law (Article 27.2);
- Members may further exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals, plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes (Article 27.3);
- Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof (Article 27.3);
- Patents shall be available and patent rights enjoyable without discrimination as to place of invention, the field of technology and where products are imported or locally produced (Article 27.1);
- Exclusive rights shall include , for products , the right to prevent third parties from making, using, offering for sale, selling or importing the patented product, and for processes , the right to prevent third parties from using the process and from using, offering for sale, selling or importing for those purposes the product obtained directly by that process (Article 28.1), subject to certain allowable exceptions (Article 30);

⁵⁶ Grubb, p.32 "...When the WTO came into existence on 1 January 1995, it was probably true to say that not a single Member country had a patent law which was completely in accordance with TRIPS... In case of some countries, such as India, Argentina, Brazil and Turkey, a patent protection for pharmaceuticals was totally or effectively lacking, and major revisions were needed".

- Patents shall be assignable, transferable and shall be available for licensing (Article 28.2) certain conditions are imposed concerning the disclosure of the invention in a patent application (Article 29);
- Any use allowed without authorization of the right-owner (commonly known as a compulsory license) , and such use by the government, is made subject to certain enumerated conditions (Article 31); such use in the case of semiconductor technology is limited to certain enumerated purposes (Article 31(c));
- Judicial review shall be available for any decision to revoke or forfeit a patent (Article 32);
- The term of protection shall be at least 20 years from the date of the filing of the application (Article 33);
- The burden of proof concerning whether a product was made by a patented process shall in certain cases be placed on the alleged infringer (Article 34) where a Member had not made available, as of the date of entry into force of the WTO Agreement (that is, January 1, 1995) , patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member must provide as from the date a means by which applications for patents for such inventions can be filed

c. Provisions on Enforcement of IP Rights

Part III of the TRIPS Agreement (Articles 41 – 61) deal with the enforcement of IP rights. Member States must provide fair, effective and equitable enforcement procedures that are not unnecessarily costly. Judicial authorities must be authorised to order the production of evidence, to give orders for injunctions, costs, damages and destruction or confiscation of infringing goods. Judges must have the power to issue orders for preliminary and interlocutory injunctions in cases where necessary without notifying the defendant in advance.

2.3.6. Patent Law Treaty

The Patent Law Treaty was concluded in 2000. The Patent Law Treaty (PLT) is aimed at harmonising formal procedures in respect of national and regional patent applications. With a significant exception for the filing date requirements, the Patent Law Treaty provides a maximum set of requirements which the office of a contracting party may apply. The national patent office may not lay down any further formal requirements in respect of matters dealt with this Treaty.

The total number of Contracting States was 9 as of December 31, 2004.⁵⁷

2.4. Term of Protection

The grant of a patent effectively gives the inventor a monopoly to work the invention to the exclusion of others for a period of time, generally twenty years counted from the filing date.⁵⁸

The period of protection is very short compared with other forms of “property”, especially copyright.

According to Art.63 (2) of the European Patent Convention; Supplementary Protection Certificate (SPC) offers an extension of protection for a maximum period of five years, for inventions in the field of medical and plant protection products in order to at least partially restore patent term lost during the product development and regulatory review, as well as effective date protection and adequate means of enforcement.⁵⁹ To obtain Supplementary Protection Certificate the invention must

⁵⁷ The PLT will enter into force three months after ten instruments of ratification or accession by states have been deposited with the Director General of WIPO.

⁵⁸ Article 33 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of April 15, 1994

⁵⁹ Supplementary Protection Certificates Act 1996 (BGBl.no.11/1997) as amended by BGBl.no.143/2001; Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the Creation of a Supplementary Protection Certificate for Medicinal Products (OJ EC L 182/1992, 1) ; Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the Creation of a Supplementary Protection Certificate for Plant Protection Products (agro-chemicals) .

be protected by a basic patent in force.⁶⁰ Supplementary Protection Certificates shall be dealt in detail in Section 3.5.9 .

After the expiry of the patent, the invention falls into public domain and anyone is free to make use of it.

2.5. A Patent May Relate to a Product or Process

An “invention” providing a solution to a specific problem in the field of technology may relate to a product or process. Article 27.1 of the TRIPS Agreement requires Member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to normal tests of novelty, inventiveness and industrial applicability.⁶¹

The invention might concern a new or an improved product, for example, a new type of window lock or an improvement to the design of scaffolding clams. Alternatively, the invention may concern some industrial process, such as a new method of rustproofing motor car bodies or an improved method of making printed circuit boards for electronic equipment. Because of the strength of this form of property right, high standards are required – the invention must be new and it must involve an inventive step, that is it must be more than merely an obvious application of technology. Furthermore, the invention must be capable of industrial application.⁶²

2.6. The Application of Exhaustion of Rights Doctrine to Patents

The European Court of Justice has repeatedly stated, as a general principle, that “the proprietor of an industrial or commercial property right protected by the legislation of a Member State may not rely on that legislation in order to oppose the importation of a product which has lawfully been marketed in another Member State

⁶⁰ <http://www.patentamt.at/GBTAUT8.htm>

⁶¹ http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

⁶² Bainbridge, p.317

by, or with the consent of, the proprietor of the right himself or a person legally or economically dependent on him.”⁶³

The leading case on the application of the exhaustion of rights principle to patents is *Centrafarm v. Sterling Drug*.⁶⁴ Sterling Drug was a company based in New York which held patents including the United Kingdom and the Netherlands. The subject-matter of the patents were the method for preparing a drug for the treatment of urinary-tract infections. Centrafarm, a company famous in the annals of the European Court as a parallel importer of pharmaceutical products, imported this drug into Holland from England and Germany without the agreement of Sterling Drug. The drug was considerably cheaper in England than it was in Holland, and this was the motivation for Centrafarm’s actions. The drugs had been placed on the market in England and Germany by subsidiaries of Sterling Drug. Sterling Drug brought a case against Centrafarm, Sterling Drug alleged that its patent rights have been infringed and tried to obtain injunctive relief against Centrafarm.

The ECJ’s judgement in this case defines the existence or specific subject-matter of the patent as being the right of the patent-holder itself or through its licensees, to market the product initially and, as a necessary corollary, the right to bring actions for any infringement of this right. The Court says that this is the reward for inventiveness which the patent is designed to secure. This is not affected by Community Law. But once the product has been marketed within the Community then Community law will make an impact on the exercise of the right. The ECJ developed the exhaustion of rights doctrine to give expression to the limitations imposed on the exercise of the right. The Court stated in its judgement that the exercise by a patentee of the right given him by the laws of a Member State to prohibit the marketing in that State of a product protected by the patent and put on the market in another Member State by such patentee or with his consent would be incompatible with the rules of the EEC Treaty relating to the free movement of goods

⁶³ Wyatt / Dashwood, p.482, see among many instances, Case 144/81 *Keurkoop v. Nancy Kean Gifts* [1982] E.C.R. 2853 at p.2873

⁶⁴ Case 15/74, *Centrafarm BV v. Sterling Drug Inc.* [1974] ECR 1147, [1974] 2 CMLR 480

in the Common Market. Otherwise this will constitute an obstacle to the free movement of goods.⁶⁵

The Court also considered the circumstances in which the use of a patent to block the importation of protected products from another Member State might be justified. Two cases of possible justification were mentioned : where the product is not patentable in the Member State of importation and where a patent exists in each of the Member states in question but the original proprietors of patents are legally and economically independent of each other.⁶⁶

If the patentee chooses to market the goods in a State where there is no patent protection available, then it cannot use its patent rights in a different country to prevent the import of these products. This is evident from *Merck v. Stephar*.⁶⁷ The plaintiff in the national proceedings, Merck, was the holder in the Netherlands of patents relating to a drug used mainly in the treatment of high blood pressure. The defendant Stephar had imported the drugs into the Netherlands from Italy where, they were not patentable, but had been placed on the market by Merck nonetheless. Merck argued that Centrafarm should be distinguished since in that case it had not been able to obtain patent protection in Italy, and hence its sales in that country did not secure it any monopoly return. The ECJ was unconvinced and stated :

“It is for the proprietor of the patent to decide , in the light of all circumstances, under what conditions he will market his product, including the possibility of marketing it in a Member State where the law does not provide patent protection for the product in question. If he decides to do so he must accept the consequences of his choice as regards the free movement of the product within the Common Market, which is a fundamental principle forming part of the legal and economic circumstances which must be taken into account by the proprietor of the patent in determining the manner in which his exclusive right will be exercised.”

⁶⁵ Paul Craig / Grainne De Burca, EU Law, Text, Cases, and Materials, Oxford University Press, 1998, p.1029-1031

⁶⁶ Wyatt / Dashwood, p.483

⁶⁷ Case 187/180 [1981] E.C.R.2063; [1981] 3 C.M.L.R.463.

The ECJ has emphasized that the patent owner's choice is of great significance and he must bear the consequences of his choice. In the above mentioned case he could have chosen not to market his products in a country such as Italy, in which patent protection was not available at the time, with the consequence that it can not use its Dutch patent rights to prevent the import of any such goods from Italy into Holland. It can choose to make possible gains from the Italian market by consenting to the manufacture of its goods in that country, but then it can not legally prevent the import of the goods into Holland.

Where the consent of the patent owner does not exist the import of goods can be prevented. This will be so where the goods were initially marketed by a third party without the consent of the patentee; where the initial sale was made because of a legal obligation imposed by national or Community law; or where that sale was the result of a compulsory license, as demonstrated by the *Pharmon* case itself.

In such a case an owner of parallel national patents shall be entitled to resist the importation into one of the Member States concerned of products manufactured under a compulsory license issued in respect of his patent in the other Member State since he is deprived of his monopoly by an official decision to grant licenses to third parties in return for a reasonable royalty. In *Pharmon v. Hoechst*,⁶⁸ parallel patents in a medicinal drug were owned by Hoechst in Germany, the Netherlands and the United Kingdom. A compulsory license for the manufacture of the drug had been obtained in the United Kingdom and Pharmon had purchased a consignment from the licensee with a view to selling it on the Dutch market. Hoechst was anxious to prevent this. Pharmon rested its case on the exhaustion of rights principle, arguing that Hoechst entered the British market being aware of the legal consequences arising from the registration of a parallel patent. It was, however, rejected by the Court on the ground that the compulsory character of a license meant the holder of the patent could not be regarded as having consented to the actions of the licensee.

⁶⁸ Case 19/84 [1985] 3 C.M.L.R.775.

(III) EUROPEAN PATENT SYSTEM

3.1. Introduction

The introduction of the European Patent Convention was a reaction against the failure of international co-operation to introduce an effective transnational system of patent protection, particularly in the European region.⁶⁹

The European patent system is primarily concerned with the granting of European patents, with their validity but not with their enforcement.⁷⁰

The European Patent Convention (the EPC) was signed in Munich on 5 October 1973 and entered into force on 7 October 1977, in coexistence with individual national patent laws.

The EPC is linked to the Patent Cooperation Treaty (PCT), an international treaty which offers a unitary, simplified filing procedure, followed by an international search and, at the applicant's option, an international preliminary examination, for over 100 countries. The PCT is administered by the World Intellectual Property Organization in Geneva. By agreement with WIPO, the EPO acts under the PCT as a receiving Office, an International Searching Authority and a Preliminary Examination Authority. European patents may be granted on the basis of international applications filed under the PCT.

Currently, 29 countries have signed the EPC. Contracting States are : Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, the United Kingdom, Greece, Hungary, Ireland, Iceland, Italy, Liechtenstein, Luxembourg, Monaco, the Netherlands, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, Turkey.

⁶⁹ Prime / Booton, p.177

⁷⁰ Gerald Paterson, A Concise Guide To European Patents: Law and Practice, London, Sweet & Maxwell, 1995, p.1.

On the other hand, under the extension system, extension agreements have entered into force for Bosnia and Herzegovina, Latvia, Albania, Former Yugoslav Republic of Macedonia, Croatia, Serbia and Montenegro.⁷¹ Under the extension system, extension of protection to each one of these States is deemed to be requested for any European patent application filed on or after the respective date of entry into force of the extension agreement for each such State, subject to payment of an extension fee within a time limit.

The main objectives of the EPC , as set out in its preamble, are “ to strengthen co-operation between the States of Europe in respect of the protection of inventions”, and “that such protection may be obtained in those States by a single procedure for the grant of patents and by the establishment of certain standard rules governing patents so granted.”

Although the Contracting States to the EPC are not obliged to bring their national laws into conformity with the EPC, the majority of the States have changed their national laws since the harmonization of patent law within Europe is the main purpose. Therefore, many provisions of the EPC, concerning procedural and substantive law have counterparts in national patent laws of the Contracting States.

The EPC is a pragmatic response to the need for industry and commerce to reduce the cost of securing patent protection across national boundaries within Europe. Consequently, countries which are not members of the European Community, may participate in the EPC and there is no necessary correlation between participants in the Convention and membership of the Community.

3.2. The functioning of the European Patent Office

The European Patent Office grants European patents for the contracting states to the EPC. It is the executive arm of the European Patent Organisation, an

⁷¹ <http://www.european-patent-office.org/epo/members.htm> retrieved on 09.11.2004

intergovernmental body set up under the EPC, whose members are the EPC contracting states. The activities of the EPO are supervised by the Organization's Administrative Council, composed of delegates from the contracting states.⁷²

The mission of the EPO is to support innovation, competitiveness and economic growth for the benefit of the citizens of Europe. Its task is to grant European patents for inventions, on the basis of a centralized procedure. By filing a single application in one of the three languages (English, French and German) it is possible to obtain such protection in several or all of the EPC contracting states.

It is responsible for the practical functioning of the European patent system. It also proposes legal and administrative measures to guarantee that the system operates smoothly.

The EPO is directed by its President, who is responsible for its activities to the Organisation's Administrative Council.

The EPO consists of five Directorates General. DG 1 and DG 2 are responsible for European patent applications . Formalities examination, prior art searching, publishing applications, carrying out substantive examination and opposition procedures are main duties. DG 3 consists of the boards of appeal which give decisions in cases of appeals filed in the course of formalities examination, substantive examination and opposition proceedings. DG 4 handles matters concerning general administration, staff, finance and patent information. DG 5 handles legal matters, international affairs, public relations and technical co-operation.

The EPO is entirely self-financing. Its operating and capital expenditures are financed by procedural fees and a proportion of the renewal fees for granted European patents.

⁷² Mehmet Özcan, Avrupa Birliğinde Fikri ve Sınai Haklar, Ankara 1999, Nobel Yayın Dağıtım Ltd.Şti., pp.186-187

The EPO has been co-operating closely with the Japanese Patent Office and the United States Patent and Trademark Office closely since 1983 on serious projects involving automation and data-bases. They formed the Industry Trilateral, a unique platform whose aim is to increase industry's cooperation efforts on Intellectual Property discussions. The Industry Trilateral brings together industry representatives from the United States, Japan and Europe.

3.3. Important Characteristics of the EPC

3.3.1. A “first-to-file” System

The European patent system is a “first-to-file” system, unlike the American patent system, which is a first to invent system. In this sense, if two or more persons invent the same product or process independently of each other, the person who first files a European patent application can only obtain a European patent.

Upon the filing of a European patent application, a filing date shall be received at the EPO. Patentability requirements; novelty and inventive step are assessed in relation to the state of the art at the filing date. If priority is claimed from an earlier patent application under the Paris Convention, then the priority date counts as the filing date.

The contents of such a European patent application become part of the state of the art on its filing date with respect to a later filed European patent application for the purpose of assessing its novelty.⁷³

A “first-to-file” system is applied in patent applications throughout the world except the USA. The USPTO is reluctant to abandon its “first-to-invent” system. Their insistency on applying such a different criterion for deciding to whom a patent should

⁷³ Paterson, A Concise Guide To European Patents, p.2

be granted is a big impediment to harmonisation efforts made in respect of substantive points of patent law.

3.3.2. Early Publication of a European Patent Application

According to Art.93(1) of the EPC; a European patent application shall be published as soon as possible after the expiry of a period of eighteen months from the date of filing, or if priority has been claimed, as from the date of priority on condition that the filing fee and the search fee have been paid. Nevertheless, at the request of the applicant, the application may be published before the expiry of the period referred to above (EPC Art.93(1) second sentence).

This article serves the function of making the information contained in European patent applications available to the public at an early stage. Reasons for such an early publication can be to obtain rights under Art. 67 EPC with respect to third parties, or to prevent a third party to come too close with his later filed application: only novelty is required with respect to a not yet published publication, but inventive step with respect to a published application.⁷⁴

According to Art.67(1) EPC, a European patent application provisionally confers upon the applicant such protection as is conferred by the granted patent in the designated Contracting States. In other words; the application after publication gives the same rights as the granted patent, but provisionally.⁷⁵

On the other hand, the patent application becomes from the publication date full state of the art in the sense of Art.54(2) EPC for all patent applications with a later priority date.⁷⁶

⁷⁴ Derk Visser, The Annotated European Patent Convention, Eleventh Revised Edition, Updated till 31 December 2003, H.Tel Publisher, Veldhoven, p. 165-166.

⁷⁵ Visser, p. 98.

⁷⁶ Bernd Hansen/ Fritjoff Hirsch, Protecting Inventions in Chemistry, Wiley-VCH Verlag GmbH, Weinheim, 1997, p.11.

3.3.3. Nature of a European Patent: a Bundle of National Patents

Upon filing a European patent application at the EPO, the applicant designates the Contracting States in which patent protection is desired. Upon grant, a European patent has a uniform term of protection of 20 years for all Contracting States as from the date of filing of the application according to Art.63.

Except the centralised opposition procedure stated in Art. 99, the EPO's role ceases when the patent is granted, each patent within the bundle having the same status as a patent created by the appropriate national Office.

After grant, the resulting bundle of national patents may only be challenged and enforced individually within the national jurisdiction of the designated Contracting States.⁷⁷ Matters of infringement and revocation are left to national laws and procedures, although the grounds on which revocation may take place under national law are provided by the terms of the Convention. The finding of a national court on one of the patents within the bundle does not affect any of the other patents, which are controlled by different laws and courts.

As a result of being a bundle of national patents, a European patent is enforceable in a country-by-country basis, each being subject to national legislation of the Contracting State. National jurisdictions of the Contracting States may render different decisions in infringement cases where the disputed subject-matter is the same European patent granted by the EPO. This situation gives rise to high litigation costs and revocation costs, forum shopping and legal uncertainty (e.g. a European patent may be upheld in France while revoked in Germany). The European Patent Litigation Agreement (EPLA)⁷⁸ shall remedy these shortcomings by enabling each Member State to cede to a central patent court the jurisdiction to decide the infringement and validity of a European patent in force in that member state. A workable litigation is already needed for the users of the European patent system.

⁷⁷ Reid, p. 181.

⁷⁸ www.european-patent-office.org/epo/epla/-7k, European Patent Office, Litigation of European Patents, retrieved on 03.6.2005. The EPLA is a proposed patent law agreement aimed at creating an optional protocol to the EPC which would commit its signatory states to an integrated judicial system, including uniform rules of procedure and a common appeal court.

European patents shall be granted even after Community patents become available . Therefore further efforts should be made for the conclusion and implementation of the EPLA which shall redouble the reliability of European patents by creating a central judicial system.

3.4. The First and Second Instance Departments of the EPO

According to Art.15 of the EPC; a Receiving Section, Search Divisions, Examining Divisions, Opposition Divisions, a Legal Division, Boards of Appeal and an Enlarged Board of Appeal are set up within the European Patent Office for implementing the procedures laid down in the European Patent Convention.

3.4.1. The First Instance Departments of the EPO

The first instance departments of the EPO are; the Receiving Section, the Examining Divisions, the Opposition Divisions; and the Legal Division.

According to Art.16 EPC; the Receiving Section is responsible for the examination on filing and the examination as to formal requirements of each European patent application.

According to Art.17 EPC; Search Divisions shall be responsible for carrying out search and drawing up European search reports.

According to Art.18 EPC; Examining Division is responsible for the substantive examination of each application as to whether the invention meets the requirements for patentability.

In 1990 the EPO started the BEST Project (Bringing Examination and Search Together), which aims at improving quality and efficiency of search and examination.

Under BEST both the search and the examination are performed by the same examiner.⁷⁹

Upon the grant of a European patent, any person may file an opposition against it within nine months, on one or more grounds specified in the EPC. According to Art. 19, an Opposition Division is responsible for the examination of such oppositions against any European patent.

According to Art.20 EPC; the Legal Division is responsible for decisions concerning entries in the Register of European Patents and in respect of registration on, and deletion from, the list of Professional representatives.

3.4.2. The Second Instance Departments of the EPO

According to Art.106 EPC, decisions of the Receiving Section, Examining Divisions, Opposition Divisions and the Legal Division are subject to appeal. The appeal procedure before a Board of Appeal is the final instance of the grant and opposition procedure of the EPO. If a European patent application is refused or a European patent is revoked by a decision of a Board of Appeal, no further appeal is possible either within or outside the EPO.⁸⁰

The more important of decisions of the Boards of Appeal, concerning points of law and interpretation of the EPC, are published in the Official Journal of the EPO ("O.J.EPO"), which is issued monthly.

To ensure a uniform application of the law, a Board of Appeal or the President may refer important points of law to an Enlarged Board of Appeal.

⁷⁹ Visser, p. 20

⁸⁰ Paterson, A Concise Guide to European Patents, p.4

a. The Boards of Appeal

The Boards of Appeal are administratively organised as one of five Directorates-General within the EPO. According to Art.21 EPC; the Boards of Appeal shall be responsible for the examination of appeals from the decisions of the Receiving Section, Examining Divisions, Opposition Divisions and of the Legal Division. Members of the Boards of Appeal are either technically or legally qualified.

Art. 23(3) EPC clearly states that the members shall not be bound by any instructions in their decisions.⁸¹ They act as courts with the task of ensuring that the provisions of the EPC are applied in each individual case. According to Art.23 (3); they shall comply only with the provisions of this Convention. They are not bound to follow previous interpretations of the EPC as set out in earlier Board of Appeal decisions, but they usually do so.

While interpreting the EPC , the Boards of Appeal (including the Enlarged Board of Appeal) apply the Vienna Convention;⁸² Articles 31 to 33 of this Convention contain a clear and relatively short statement as to how an international treaty such as the EPC should be interpreted.

Additionally, the Boards of Appeal have applied a number of internationally recognized “general principles of law” when deciding the cases before them. The principle of good faith (between the EPO and parties before it),⁸³ equality of treatment of parties,⁸⁴ the right of a fair hearing⁸⁵ and the duty to give reasons for decisions⁸⁶ have been applied in various cases.⁸⁷

⁸¹ Gerald Paterson, The European Patent System, The Law and Practice of the European Patent Convention, London, Sweet & Maxwell, 1997, p.4

⁸² Convention on the Law of the Treaties – signed Vienna, 1969.

⁸³ J 10/84 O.J.EPO 1985,71.

⁸⁴ G 1/86 O.J.EPO 1987, 447.

⁸⁵ J 20/85 O.J. EPO 1987, 102; G5/91 O.J. EPO 1992, 617.

⁸⁶ T 182/88 O.J. EPO 1990, 287.

⁸⁷ Paterson, The European Patent System, p.6

b. The Enlarged Board of Appeal

The Enlarged Board of Appeal is not a further instance, but a special department ensuring the uniform application of the EPC. Its decisions and opinions obtain a G number (from the German 'Grosse Beschwerdekammer').⁸⁸

It consists of five legally qualified members and two technically qualified members. One of the legally qualified members shall be the chairman.

It is responsible for deciding important points of law which are referred to it by Boards of Appeal or by the President of the EPO under the conditions laid down in Article 112 (1) (a)(b) EPC.

The Enlarged Board of Appeal only settles points of law in pending appeals, not the complete appeal case. The final decision in a case is always up to the Board of Appeal. A decision of a Board of Appeal cannot be contested before the Enlarged Board of Appeal because the Enlarged Board of Appeal is not a second instance for decisions taken by the Board of Appeal.⁸⁹

In the event of divergent interpretations of the EPC by different Boards of Appeal in different decisions, the Enlarged Board of Appeal may be asked to decide on the important point of law in issue. Under Article 112(3) EPC the decision of the Enlarged Board of Appeal shall be binding on the Board of Appeal in respect of the appeal in question.

⁸⁸ Visser, p.26

⁸⁹ Visser, p.217.

3.5. Procedure for Granting a European Patent

3.5.1. Filing a Patent Application

a. Contents of a Patent Application

According to Art. 78 EPC, a European patent application shall contain; a request for a patent (R26); a description of the invention (Art.83, R27, 27a, 28 and 28a); one or more claims (Art.84 and R29 and 31 as well as Art.82 and R30); any drawings referred to in the description or the claims (R32) and an abstract (Art.85 and R33).

Upon the receipt of the application, the Receiving Section of the EPO must pursue an examination as to formal requirements to determine whether the application fulfils the conditions to be allocated a filing date. In order to be allocated a filing date according to Art. 80; the application must contain an indication that a European patent is sought; the designation of at least one Contracting State; information identifying the applicant and a description and one or more claims. These designations may be afterwards withdrawn but never added to.⁹⁰

Absence of the abstract does not preclude according a filing date.

Since 8 December 2000 electronic filing has been possible on a permanent basis within the framework of epoline.⁹¹ Electronic filing is possible offline in a physical media (CD-R) or online, at the EPO's computer servers at the address <https://secure.epoline.org>.⁹²

⁹⁰ Cornish / Llewelyn, p.153.

⁹¹ The first set of regulations was published in a supplement to OJ 4/2001.

⁹² Additional information is available on the EPO's website (www.european-patent-office.org/epoline)

The Receiving Section examines further whether the filing fee and the search fee have been paid in due time.⁹³ If filing and search fees have not been paid in due time, the application is deemed to be withdrawn.

If a filing date cannot be accorded, the Receiving Section must give the applicant the opportunity to correct the deficiencies in accordance with Implementing Regulations. If the applicant fails to remedy these deficiencies, the application may not be dealt with as a European patent application.

If an application is given a filing date; it must be examined as to formal requirements, it must be the subject of a search report of previous registrations and then published.⁹⁴

b. Place and Time of Filing

Article 75(1) states that; an applicant has the choice of filing his European patent application with the EPO or with a national authority of a Contracting State.

An applicant may file his European patent application with one of the EPO filing offices in Munich, the branch at the Hague and the sub-office of the EPO in Berlin. The EPO sub-office in Vienna is not a filing Office for the purpose of Art.75(1).⁹⁵

All Contracting States except the Netherlands allow applicants to file European patent applications with their national authorities.⁹⁶ For instance an application made for a European patent designating a number of contracting states to the EPC can be handled by the Patent Office in London.⁹⁷ An application filed in this way shall have the same effect as if it had been filed on the same date at the European Patent Office.

⁹³ Filing and search fees must be paid within one month of filing the application. The time limit runs from the date on which it is possible to accord a filing date.

⁹⁴ Prime / Booton, p.201.

⁹⁵ Visser, p.110-111

⁹⁶ Margerete Singer / Dieter Stauder, European Patent Convention, A Commentary, Volume 1, Substantive Patent Law – Preamble, Articles 1 to 89, Thomson-Sweet & Maxwell- Karl Heymanns Verlag KG, 2003, p.279.

⁹⁷ Bainbridge, p.327.

The national authorities are only responsible for receiving the application. They do not examine whether the received documents fulfil the formal requirements set out in Articles 90 and 91 EPC. They do not accept payments or any further correspondence.

The date of filing an application is the date of receipt of documents in accordance with Article 80 EPC, either directly at the EPO or at a competent national authority.

If further documents other than the application are subsequently filed with a national authority and forwarded by that authority to the EPO, the date of receipt is considered to be the date of receipt at the EPO, not by the national authority.

c. Languages

According to Article 14(1) EPC, a patent application must be filed in one of the three languages of the European Patent Office. These are English, French and German.⁹⁸

According to Article 14(2) EPC, natural or legal persons residing or having their principal place of business within the territory of a Contracting State, having a language other than three official languages of the EPO, and nationals of that State who reside abroad, may file European patent applications in an official language of that State. These official languages of the Contracting States are also called admissible non-EPO languages (ADNELs).

A translation in one of the official languages of the EPO must be filed within the time limit prescribed in the Implementing Regulations.⁹⁹

⁹⁸ This fundamental principle was confirmed in decision J 18/96 (O.J.EPO 1998, 403, point 2.2).

⁹⁹ The translation into one of the three official EPO languages has to be filed within three months after the receipt of the European patent application but at least thirteen months after the priority date (para.2 in conjunction with R 6(1)). If the translation is not filed in due time, the application is deemed to have been withdrawn (Art.90(3)EPC). The failure to comply with the time limit for filing the translation can be remedied by an application for restitutio under Art.122.

A patent application filed in a non-admissible language will not be accorded a filing date.

When the applicant selects the official EPO language for the European patent application or its translation, he determines the language of the proceedings which is subsequently to be used in all procedures before the EPO. The language of the proceedings can not be changed during the proceedings.

The Agreement on the application of Art.65 on the grant of European patents was signed by ten EPC Contracting States but it has not entered into force yet. The Contracting States should do their best so that the Agreement enters into force as soon as possible since it will reduce the translation costs at a considerable rate.

d. Representation

As stated in Article 133(1), it is not an obligation to appoint a representative in proceedings established by European Patent Convention. However if a person does not have his residence or principle place of business in one of the Contracting States, he must be represented by a professional representative according to Article 133(2) in all proceedings other than in filing the European patent application.

Professional representatives can be natural or legal persons whose names are entered on the list of the European Patent Office. In order to qualify as a professional representative in accordance with Article 134(2) , one must be a national of the Contracting States, must have his place of business or employment within the territory of one of the Contracting States and he must have passed the European qualifying examination.

e. Persons Entitled to Apply

Article 80 requires that an information identifying the applicant must be contained in the application document. Otherwise it shall not be allocated a filing date.

Article 60(1) states that the inventor or his successor are entitled to a European patent . If there are two or more persons who made and filed the same invention independently, the person who first filed the application is entitled to a European patent according to the “first-to-file” principle enshrined in Article 60(2) EPC. The earlier application only enters into effect if it has been published and only with the effect for the countries designated in the earlier European application (Art.54(3) and (4)).¹⁰⁰

If several persons are involved in the creation of an invention, they are co-inventors of this joint invention. There aren't any provisions in the EPC concerning the status of co-inventors. Co-inventors have the same legal status of individual inventors.¹⁰¹

The EPC does not either define the successor in title. Succession in title is determined according to the national law whose application is determined according to private international law.

In European patent applications, the EPO does not investigate if the applicant is entitled to a European patent. This issue is left to the appropriate national courts. So long as the EPO has not granted the European patent, the Protocol on Jurisdiction and the Recognition¹⁰² gives jurisdiction to the Contracting States agreed by disputants; if not agreed, then in employer-employee disputes to the State where employed; and in other cases, to the applicant's State; or otherwise to the claimant's State; and if none of these tests provides a Contracting State, then to Germany. Once the patents have been granted, the question has to be dealt by the legislation of each designated country, not by the Protocol on Jurisdiction and Recognition.¹⁰³

¹⁰⁰ If simultaneous inventions have the same application and priority date, each applicant is entitled to the European patent for his own application. In this sense, dual patenting is possible.

¹⁰¹ Singer / Stauder, EPC, Vol.1, p. 186 “Art.81 EPC assumes the equal treatment of all inventors for the purpose of the mention of the inventor.”

¹⁰² Protocol on Jurisdiction and the Recognition of Decisions in respect of the Right to the Grant of a European Patent (Protocol on Recognition) of 5 October 1973. The Protocol is an integral part of the EPC (Article 164(1) EPC) which serves to realize the material claims of Art.61 on the European patent. It governs the competence of the national courts in Section I and the recognition of their decisions in Section II. This Protocol only applies to European patent applications but not to granted patents.

¹⁰³ Cornish / Llewelyn, p.147.

If a European patent has been challenged successfully by the lawful applicant, Article 61 (1) offers him three choices. He can either prosecute the application of the third party as his own application or he can file his own patent application for the same invention or he can withdraw the application of the third party according to appropriate circumstances envisaged in Article 61(1) EPC. In one of its decisions, the Enlarged Board of Appeal held that it was not a prerequisite that the original unlawfully made application be pending before the EPO at the time a new application is filed by the lawful applicant under Article 61(1)(b).¹⁰⁴ Such lawful applicant may file a new European patent application pursuant to Art.61(1)(b) EPC even if at the time of filing the earlier unlawful application is no longer pending before the EPO.

3.5.2. The Search Report

The EPO established the BEST Project (Bringing Search and Examination Together) to improve the quality of the search and examination proceedings in respect of European patent applications. In this project, one single examiner carries out both the search and the substantive examination.¹⁰⁵

EPO's PACE Programme has accelerated the search procedure. An applicant receives a search report no later than six months after the date of filing.

If a European patent application has been accorded a filing date, the Search Division must prepare the European search report on the basis of the claims, with due regard to the description and any drawings, in the prescribed form under Article 92 EPC (Examination Guidelines¹⁰⁶ B-III, 3.1; see also Art.15(3), R 33.3 (a) PCT).

¹⁰⁴ Paterson, The European Patent System, p.84-85 - Decision G3/92 (LATCHWAYS/Lawful applicant) O.J EPO 1994, 607.

¹⁰⁵ The legal basis for BEST is provided by the revised Art.16 to 18 EPC 2000 which are to be applied provisionally (Art.6 of the Ct revising the EPC).

¹⁰⁶ www.european-patent-office.org/legal/guidelines/e/, retrieved on 03.6.2005. "Guidelines for Examination in the European Patent Office" published by the European Patent Office. The main body of these Guidelines comprises five parts; Part A: Guidelines for Formalities Examination; Part B: Guidelines for Search; Part C: Guidelines for Substantive Examination; Part D: Guidelines for Opposition Procedure; Part E: Guidelines for General Procedural Matters.

The search should relate to the technically inventive subject-matter to which the claims are directed or to which they might be directed after amendment.

A search undertaken by EPO shall cover a considerable amount of patents from major patenting countries and a range of the most important technical literature,¹⁰⁷ listed in EPO's Guidelines B IX.¹⁰⁸

The search focuses, first of all, on all published documents that is directly relevant to the technical field in the same patent classification unit as the invention itself. If the examiner decides to carry out further search, he extends his search to similar technical fields outside the particular patent classification unit.

The filing date, accorded to the patent application has to be taken into account with regard to search. If priority is claimed from an earlier patent application, the state of the art between the priority date and the filing date is taken into account.

After it has been drawn up, the European search report shall be sent to the applicant with copies of any cited documents. (Art.92(2))

3.5.3. Publication of the Application

A European patent application must be published as soon as after the expiry of a period of eighteen months from the date of filing, or if priority has been claimed, as from the date of priority.¹⁰⁹ At the request of an applicant; the application may be published before the expiry of this period provided that the filing fee and the search fee have been validly paid (Art.93(1)).

¹⁰⁷ The search documentation of the EPO is a collection of more than 28 million documents, consisting of patent documents from different countries and articles from specialised journals and literature.

¹⁰⁸ Cornish / Llewelyn, p.155.

¹⁰⁹ The details of the publication are governed by the Implementing Regulations: R 48 (Technical preparation for publication), R 49 (Form of the publication of the European patent applications and European search reports) and R 50 (Information about publication) and Examination Guidelines A-VI,1.

Reasons for such an early application can be to obtain rights under Article 67 with respect to third parties, or to prevent a third party to come too close with his later filed application.¹¹⁰

According to Article 92(3) the publication must contain the description, the claims and any drawings as filed, the European search report and the abstract, in so far as the latter are available before the termination of the technical preparations for publication. If the search report is not available at the time it shall be published separately.

As well as the original claims the publication must cover the new and amended patent claims that are filed under R 86(2) after the receipt of the European search report (R 49(3)).

All European patent applications are published as printed documents and subsequently on CD-Rom (Espace). They are accessible on their date of publication on the Internet and at the same time available for public inspection.

3.5.4. Request for Examination

A request for examination must be filed by the applicant up to the end of six months after the date on which the European Patent Bulletin mentions the publication of the European search report. After the expiry of this time limit, a request may still be filed within a period of grace of one month (R 85(b)).

The purpose of the request is to have the application examined and assessed as to whether it meets the substantive and formal requirements of the EPC.

A request for examination can not be withdrawn. If the applicant does not wish to pursue any further substantive examination proceedings, he can withdraw his patent application but not his request for examination (Art.94(2) EPC).

¹¹⁰ Visser, p. 165 "...only novelty is required with respect to a not yet published application, but inventive step with respect to a published application."

If the applicant fails to make a request for the examination or pay the examination fee within the specified period, the application is deemed to be withdrawn upon the expiry of six-month period (Art.94(3) EPC).¹¹¹

3.5.5. Substantive Examination Procedure

Art.96 EPC sets out important principles which enable the applicants to participate actively in the examination procedure. If the application or the invention does not satisfy the requirements of the EPC, the Examining Division invites the applicant to submit his observations.¹¹²

a. Extent of the Examination

The Examining Division carries out the examination to find out whether a European patent application fulfils the requirements of the EPC (Articles 94(1) and 96(2) EPC.), for the grant of a patent. The scope of the examination refers to matters such as whether the subject-matter is within the patentable field; whether in the light of the search report, the invention is novel and inventive; whether there is a sufficient description and the claims meet the criteria.¹¹³ The Examining Division is not bound with the findings of the Search Division.¹¹⁴

The Examining Division does not have to examine the reservations which were made by the Contracting States upon joining the EPC under Article 167(2). These reservations are part of national laws and they may relate to patentable subject matter, such as reservations concerning chemicals, pharmaceuticals or food products.¹¹⁵

¹¹¹ Prime / Booton, p.203.

¹¹² Details of the procedure are set out in R 51 (examination Procedure), R 69 (Noting of loss of rights), R 70 (Form of communications and notices), Art.119 (Notification), Examination Guidelines C-VI.

¹¹³ Cornish / Llewelyn, p.156.

¹¹⁴ Margarete Singer / Dieter Stauder, A Commentary, Volume 2, Procedural Patent Law – Article 90 to Article 178, Thomson-Sweet & Maxwell, Carl Heymanns Verlag KG, 2003, p.61 “The Examining Division can decide that the application lacks unity of the invention and does not comply with Art.82, even though the Search Division did not raise any such objection under R 46(1) . (T 178/84, OJ 1989, 157).”

¹¹⁵ Paterson, A Concise Guide to European Patents, p.13.

According to Article 18 EPC, the Examining Division consists of three technically qualified examiners. Before a decision is taken concerning a European patent application, as a general rule, one member of the Examining Division shall be entrusted with its examination. But oral proceedings shall take place before the Examining Division itself. In cases where it is necessary, the Examining Division shall be enlarged by the addition of a legally qualified examiner.

b. Communications and observations in reply

According to Article 96(2) EPC, the applicant must be given an opportunity to comment on all deficiencies found in the application by the examiner. In such a case the Examining Division invites the applicant as often as necessary to file his observations in reply within a fixed period. This fixed period for the first communication is normally between two or four months. If the applicant fails to reply to this first communication in due time, the application shall be deemed to be withdrawn.

For example if the examiner does not find an inventive step, he does not have to prove the lack of inventive step. The burden of proof is on the applicant's shoulders. The applicant must prove the existence of the inventive step in his reply to the invitation.¹¹⁶ If the examiner and the applicant cannot agree, the issue may be raised in a formal hearing before the full Examination Division with a right of appeal.

The expression in Article 96(2) "as often as necessary" indicates that in case of absence of a legal obligation to invite further observations, it is left to the discretion of the Examining Division to whether or not to invite further observations from an applicant before issuing a decision which adversely affects him.¹¹⁷

¹¹⁶ Visser, p.173.

¹¹⁷ Paterson, The European Patent System, p.87. In Decision T 640/91 (NIPPON/Examination procedure) O.J. EPO 1994, 918, it was held that : "The requirement in Article 96(2) EPC that the Examining Division shall invite the applicant to file his observations "as often as necessary" implicitly recognises that in certain circumstances, there is a legal obligation upon the Examining Division to invite further observations from the applicant before issuing a decision which adversely affects the applicant."

c. Amendments

The possibility to amend an application serves to meet objections raised by the EPO in grant and opposition proceedings.

Under Article 123(1), an applicant shall be allowed at least one opportunity to amend the description, claims and drawings.

Applicants often amend their applications in two instances; after the receipt of the search report to adapt the application to a closer state of the art (R 86(2)), and after receipt of the first communication from the Examining Division in reply to its arguments (R 86(3)).

An amendment is not admissible that contains subject-matter which extends beyond the content of the application as filed.¹¹⁸

Legal Advice No. 15/84 states that : “under Article 113(2) EPC, the EPO is bound by the applicant’s submissions: The European patent may be granted only on the basis of a text which is without formal or substantial deficiency submitted or agreed by the applicant in its entirety.”¹¹⁹

The Board of Appeal considered the effect of failure to take account of requested amendment in its Decision T 647/93 (HITACHI MAXWELL/Procedural violation) . In this case, the applicant filed a request for amendment of claim 1 in order to overcome objections raised by the Examining Division. The Examining Division issued a decision refusing the application. The decision was clearly based upon a text of claim 1 which did not include all the amendments which were requested by the applicant. The Board of Appeal held that Article 113(2) EPC had been violated and the EPO should have considered and decided upon the European patent application only in the text submitted to it, or agreed by the applicant.¹²⁰

¹¹⁸ Paterson, A Concise Guide to European Patents, p.15-16.

¹¹⁹ Legal Advice No. 15/84, O.J.EPO 1984, 491.

¹²⁰ Decision T 647/93 (HITACHI MAXWELL/Procedural violation) O.J. EPO 1995, 132.

d. European divisional applications¹²¹

Under Article 76(1) EPC, an applicant may divide an application by filing one or more divisional applications.¹²² There are two kinds of European divisional applications. The first one is voluntary division where a divisional application may be filed of the applicant's own volition; the second one is mandatory division where a divisional application is filed at the request of the EPO to overcome an objection under Art.82 that the application lacks unity.¹²³ Several divisional applications may arise from a single parent application. The applicant of the parent application is considered to be entitled to apply for the divisional application.¹²⁴

A divisional application may be filed only in respect of subject matter which does not extend beyond the content of the earlier application as filed. It is regarded as a new European patent application and its procedure is independent from the procedure of the patent application. It has to be searched, published and examined. It passes through each stage of the procedure again, including examination on filing and examination as to formal requirements. But it is deemed to have been filed on the date of the filing of the earlier application and shall have the benefit to any right to priority.

e. Applications Containing More than One Invention

Article 82 EPC defines unity of the invention in terms of a linked group of inventions forming a single general inventive concept.¹²⁵ It is supplemented by R 30 (Unity of invention), R 46 (European search report where the invention lacks unity) and Rule 25 (Provisions for European divisional applications). According to this article, the European patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. It is

¹²¹ For details about division of application ; see R 25 (Provisions for European divisional application), R 6 (Time limits and reduction of fees), R 37(3) (Payment of renewal fees), R 42(2) (Subsequent identification of the inventor), R 85 a (extension of time limits).

¹²² See for the implementation : R.4 : Language of the European divisional application, R.25 : Provisions for filing of a European divisional applications.

¹²³ Visser, p.76-78

¹²⁴ Singer / Stauder, EPC, Vol.1, p.285-286.

¹²⁵ Visser, p.126.

possible to have claims for process, the apparatus to operate it and its products; or for products, processes for making them and use of the products.¹²⁶

Unity of the inventions must be examined on the basis of the inventions claimed. The original claims constitute the basis during the search. During the substantive examination, the basis is provided by the claims valid at the time.

The different inventions shall be linked by a single general inventive concept if there is a technical relationship among them expressed by one or more of the same or corresponding technical features.¹²⁷

Unity of the invention is first examined during the search. If the Search Division considers that the application does not comply with the unity of invention set out in Article 82 EPC, a partial search report is drawn up for the invention or group of inventions first defined in the claims. With notification of the partial search report, the Search Division invites the applicant to pay further search fees to search the further inventions in the application and also informs him that only the part of the application that relates to the inventions for which search fees have been paid will be searched.¹²⁸

If the applicant pays these additional search fees, after the receipt of the search report he may choose which invention to put forward in the claims of the application. And he may file divisional applications in respect of other inventions which have been covered by the search report.

According to the decision of the Enlarged Board of Appeal “if an applicant who fails to pay further search fees, he cannot pursue that application for the subject-matter in respect of which no search fees have been paid. He must file a divisional application in respect of such subject-matter if he wishes to seek protection for it”.¹²⁹

¹²⁶ See for the implementation : R.30 : Unity of invention.

¹²⁷ Singer / Stauder, EPC, Vol.1, p.346-347.

¹²⁸ See for the implementation : R.46: European search report where the invention lacks unity.

¹²⁹ Paterson, The European Patent System, p.91. Enlarged Board of Appeal - Opinion G2/92 (Non-payment of further search fees) O.J.EPO 1993, 591.

Lack of unity may not be objected to in opposition procedures. Lack of unity does not provide a ground for the invalidation of a European patent in national proceedings.

f. Withdrawal of an application

According to Article 67(4) EPC, withdrawal of a European patent application has a retroactive effect. Such a withdrawn application shall never be deemed to have conferred any protection upon the applicant. In other words, when the published European patent application ceases to have effect, the protection ceases to apply retroactively. In respect of the countries whose designations are withdrawn, protection shall also cease to apply retroactively.

The date of withdrawal must be entered in the Register of Patents.¹³⁰ It must also be published in the Patent Bulletin under Article 129(a) , for reasons of legal certainty.

Withdrawal of a European patent application is binding on the applicant. Legal Advice No.8/80 excludes the possibility of retraction of a withdrawal once made.¹³¹

3.5.6. Observations by third parties

Any person may file observations concerning the patentability of an invention in a European patent application under Article 115 EPC, following the publication of the application before the end of a possible opposition procedure without paying any fees.

Such observations must be submitted in writing and must include a statement of the grounds on which they are based. Such a person filing observations does not become a party to the examination proceedings before the EPO. The EPO will not inform the third party about the outcome of the proceedings. He may not either raise

¹³⁰ See for the Implementation : R.92(1)(n) Entries in the Register of European Patents.

¹³¹ Legal Advice No. 8/80 OJ.EPO 1981, 6; see also J 15/86 O.J. EPO 1988, 417.

an appeal. He can only inspect the patent application file when he wants to find out whether his observations have been taken into account.

Only patentability questions (Art.52-57) can be raised according to Article 115 (1), not e.g. lack of unity (Art.82) or insufficient disclosure (Art.83).¹³²

Observations filed by third parties shall be communicated to the applicant so that he can submit his comments (Art.115(2)EPC).

This procedure is useful especially in such cases where competitors of the applicant makes EPO aware of the grounds that hinder patentability of an invention, without waiting for possible grant of the patent or the consequent opportunity to commence opposition procedures.¹³³ These observations of the third parties shall be taken into account during the examination, opposition or appeal procedure.

The EPO may also take up the contents of such observations as objections to the grant of a patent and examine the facts of its own motion under Article 114(1) EPC.¹³⁴

3.5.7. Suspension of Examination Proceedings

The Examining Division may suspend examination proceedings in case of the existence of pending Enlarged Board of Appeal proceedings or pending proceedings concerning entitlement to grant.¹³⁵

If a decision of the Examining Division depends on the outcome of proceedings before the Enlarged Board of Appeal on a legal question as set out in Article 112 EPC, the further examination of the matter is suspended until the matter is resolved by the Enlarged Board of Appeal.

¹³² Visser, p. 226.

¹³³ Paterson, A Concise Guide to European Patents, p.19.

¹³⁴ Singer / Stauder, EPC, Vol.2, p.319 "... Third party observations are considered by the EPO of its own motion in exercise of its discretion under Art.114(1). (T 69/91, OJ 1993, 408, point 16)."

¹³⁵ Paterson, A Concise Guide to European Patents, p.19.

On the other hand, according to Implementing R.13(1); if a third party provides proof to the EPO that he has started proceedings against the applicant in order to obtain a judgement that he is entitled to the grant of a European patent, the EPO shall stay the proceedings unless the third party consents to continuation.

3.5.8. Preparation for Grant and Late Requests for Amendment

When the Examining Division is of the opinion that the application is ready for grant, it must obtain the applicant's approval of the text as required by Art.97(2)(a), which is based on Article 113(2), before it can take a decision.

The approval procedure is set out in R.51(4). The Examining Division informs the applicant of the version of the text in which it intends to grant the patent. This text is based on the requests filed by the applicant and it comprises editorial amendments made by the Examining Division.¹³⁶ At the same time the Examining Division invites him to pay the fees for grant and printing and file a translation of the claims in the two official EPO languages other than the language of the proceedings.

The payment of the fees for grant and printing and the filing of the translations must be effected within a period. This period may not be less than two months or more than four months. If the applicant pays the fees and files the translations in due time, he is deemed to have approved the text intended for grant implicitly

If the applicant additionally files amendments and/or corrections, the procedure set out in Rule 51(5) will be followed. If the Examining Division does not consent to these amendments, it must give reasons and also invite the applicant to submit his observations and any amendments considered necessary by the Examining Division before reaching a decision. If the applicant submits such amendments, he shall be deemed to have approved the grant of the patent as amended.

¹³⁶ Examination Guidelines C-VI 15.1

According to Rule 51(8), if the fees are not paid in due time or the translations are not filed in due time, the European patent application shall be deemed to be withdrawn.

3.5.9. Term of Protection for a European Patent: Supplementary Protection Certificates

According to Art.63(1) EPC, the protection term for a European patent shall be 20 years beginning from the date of filing of the application. A patent continues for the full 20 years provided that the renewal fees are paid within due time.

Where the patent is originally granted by the European Patent Office, Article 63(2) EPC confers the power to grant “supplementary protection certificate” to national patent authorities.¹³⁷ The enactment of the Hatch/Waxman Act¹³⁸ in the USA, and the extension provisions in Japan¹³⁹ resulted in the extension of patent protection term beyond 20 years in European countries by the enactment of the EC Regulation 1768/92 concerning the Creation of a Supplementary Protection Certificate for Medicinal Products.¹⁴⁰ This Regulation has entered into force on 2 January 1993. Introduction of patented pharmaceuticals may be delayed for a long time until Government authorities complete safety tests for the grant of marketing authorisation. Therefore SPCs cover only the marketed pharmaceutical product for which regulatory approval had been obtained.

The SPC is based on a basic patent which can be any national patents or the national parts of a European patent in or with effect for an EC Member State. The EC Regulations regarding the grant of SPC are independent of the European Patent Convention. Member States of the EU and Contracting States of the EPC are not the same.¹⁴¹

¹³⁷ See also section 2.4 above.

¹³⁸ Drug Price Competition and Patent Term Restoration Act of 1984.

¹³⁹ Grubb, p. 148.

¹⁴⁰ OJ EC L 182/1992,1.

¹⁴¹ Hansen / Hirsch, p. 293-294.

However, Art.63 EPC has been amended to allow the Contracting States to extend the term of a European patent or to grant corresponding protection upon the expiry of a European patent if the subject-matter of a European patent is a product or process of manufacturing a product or a use of a product which has to undergo an administrative authorisation procedure required by law before it can be put on the market.¹⁴² Where the patent is originally granted by the European Patent Office, Article 63(2) EPC confers the power to grant “supplementary protection certificate” to national patent authorities.

The SPC is issued for the active ingredient protected by the basic patent and used in an authorised finished medicinal product. The protection of the certificate corresponds with that of the basic patent, except that it is restricted to a particular ingredient¹⁴³ and that protection covers the use of the active ingredient as a medicinal product and not for other purposes (such as a dye).

So far as European Union countries are concerned, Council Regulation 1768/92 requires national patent authorities to grant SPCs for patented products which have been authorised for marketing as a medicine under control procedures.

Afterwards SPCs are extended to agro-chemicals (plant protection products) by the EC Regulation 1610/96. The Regulation entered into force on 8 February 1997. The provisions of the EC Regulation 1619/96 for agro-chemicals are similar to the provisions of the EC Regulation 1768/92 for medicinal products.

The dates of entry into force of both EC Regulations apply to all Members States¹⁴⁴ of the European Union. Both Regulations create the legal framework and are directly applicable in the EU Member States.

¹⁴² Grubb, p.149 “Note that this provision is not limited to pharmaceutical products”.

¹⁴³ Singer / Stauder, EPC, Vol.1, p.207 “...the basic patent for example protect a whole range of substances based on a broad formula.”

¹⁴⁴ Only in Member States whose national legislation did not, in January 1990, provide for the patentability of medicinal products and plant protection products (Spain, Greece and Portugal), the Regulations shall apply as of 2 January 1998.

A patent owner should apply for a SPC within six months of either the date of marketing authorization or the date of patent grant, whichever is the later (Art.7, Reg.1768/92).

The term of a SPC shall start upon the expiry of the basic patent and shall be calculated according to the period of delay between the date of patent filing and the date of grant of the first marketing authorisation in the European Economic Area (EEA, i.e. the EU plus Norway, Iceland and Liechtenstein), reduced by five years, up to a maximum duration of five years (Art.13, Reg.1768/92).¹⁴⁵ In this sense a delay of six years gives a further year's supplement; and each additional year's delay gives a further year's supplement up to a maximum of five years.

On May 1 2004 Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia joined the European Union. On accession, EU legislation is applied to SPCs granted in accordance with the national legislation of all the acceding countries (except Hungary) prior to the date of accession. Transitional arrangements for the "cut-off-date"¹⁴⁶ were agreed with the acceding countries on an individual basis which vary from state to state.

There are various judgements of the ECJ concerning the application of the EC Regulations 1768/92 and 1610/96. In Case C-392/97, the Court decided that a SPC granted in respect of an active ingredient having a valid marketing authorisation extends to all derivatives of the active ingredient (such as salts and esthers), provided that they are protected by the basic patent. The ECJ also emphasized in its judgement that national patent law is to be applied for the determination of the scope of the basic patent.¹⁴⁷

¹⁴⁵ Grubb, p.149 "This has the effect that if marketing authorization is first granted between five and ten years from the patent filing date, the effective patent life (from marketing authorization to SPC expiry) will be 15 years".

¹⁴⁶ The "cut-off-date" is the date after which the relevant marketing authorisation must have been obtained for the SPC regime to apply. For example, in Poland the SPC Regulation is applied to medicinal products for which the first authorisation must have been obtained after 1 January 2000. In Slovenia, SPC Regulation covers medicinal products for which the first authorization to place it on the market was obtained after 1 January 2000. In each case, a SPC application must be lodged within 6 months of the date of accession i.e. 31 October 2004

¹⁴⁷ Singer / Stauder, EPC, Vol.1, p.209, Case C-392/97, Farmitalia Carlo Erba, ECR 1999 I 5553.

Korea, Taiwan, Israel and Australia have also introduced patent term extensions to compensate for regulatory delay.¹⁴⁸

3.5.10. Renewal fees for European patent applications : Time-limit

Renewal fees shall be due in respect of the third year and each subsequent year, calculated from the date of filing of the application. (Art. 86(1)).

Renewal fees are of a fund-raising character, they do not entitle the payer to a service rendered by the EPO.¹⁴⁹ The renewal fee may be paid up to one year before the due date. If it is not paid on or before the due date, it may be validly paid within six months of the said date, provided that the additional fee is paid at the same time. The surcharge for late payment fee is called an “additional fee”. (Art.86(2))

According to Article 86 (3); non-payment of the renewal fee results in the application being deemed withdrawn. The withdrawal takes effect at the end of the six month additional period.

The last renewal fee shall be paid to the EPO in respect of the patent year in which the mention of the grant is published (Art.86 (4) EPC)

Renewal fees for the following years are to be paid to the national offices as stated implicitly in Art. 141(1) and Art. 39 (1) EPC.¹⁵⁰

3.6. Opposition Procedure

According to Art. 99 EPC, any person may launch an opposition against a European patent within nine months of grant. It is a post-grant opposition

¹⁴⁸ Grubb, p.150.

¹⁴⁹ Visser, p.135-136.

¹⁵⁰ Visser, p.139

procedure,¹⁵¹ under Articles 99 to 105 EPC, which may give rise to the revocation of the complete bundle of national patents. In other words opposition procedure applies to the European patent in all Contracting States in which the patent has effect.¹⁵²

The opposition procedure has created a centralised patent granting procedure. It constitutes an exception to the general rule that a granted patent is no longer subject to EPO jurisdiction.¹⁵³

The opposition procedure¹⁵⁴ which must be followed by the Opposition Division is dealt with comprehensively in the Guidelines and a guidance entitled Opposition Procedure in the EPO.¹⁵⁵ The filing of an opposition at the EPO does not suspend the effect of grant of the European patent.

Any natural or legal person may file an opposition regardless of where this person has his place of residence or business without having to prove that he has a specific interest¹⁵⁶ in the subject matter of the patent.¹⁵⁷

The subject of the opposition is the legally valid granted patent.

A notice of opposition has to be filed within nine months from the publication of the mention of the grant of the European patent (Art.99 EPC and R 55). If an opponent does not respect this time limit, re-establishment of rights according to Art.122 EPC shall not apply since Art.122 EPC only protects the applicant and patent proprietor who fail to comply with time limits.

¹⁵¹ For further details see R 55 (content of the notice of opposition), R 56 (rejection of the notice of opposition as inadmissible).

¹⁵² Singer / Stauder, EPC, Vol.2, p.104-105 "However, in cases where the European patent has different legal effects since it has different sets of claims for different designated contracting states, the opposition can affect some states, rather than other to a greater or lesser extent, or not at all, particularly when the European patent is not substantively contested in its entirety."

¹⁵³ Singer / Stauder, EPC, Vol.2, p.90, G 4/91, OJ 1993, 339 and 707.

¹⁵⁴ T 198/88 O.J. EPO 1991, 254. "the opposition procedure is an independent procedure which takes place after the grant procedure; it is a separate procedure in which a patent may be limited or revoked...the opposition procedure is not part of the grant procedure". G 7, 8/91 O.J.EPO 1993, 346 and 356, stated that the opposition procedure is a purely administrative procedure.

¹⁵⁵ O.J. EPO 1998, 471.

¹⁵⁶ G 3/97 and G 4/97, OJ 1999, 245 and 270.

¹⁵⁷ A notice of opposition can be filed at the EPO filing offices in Munich, the Hague or Berlin. A notice of opposition filed at the national patent offices are not admissible.

A notice of opposition must be “a written reasoned statement” and filed in one of the official languages of the EPO. The opposition fee has to be paid within nine months period. Otherwise an opposition shall be deemed not to have been filed.

R 55 prescribes the essential content¹⁵⁸ of a notice in order to be admissible. It should contain identity of the opponent, the contested patent, extent to which the patent is opposed,¹⁵⁹ grounds of opposition together with the facts and evidence in support of the grounds and the representative.

Exclusive grounds of opposition are set out in Article 100 EPC. They are; unpatentable subject-matter under Articles 52 to 57 EPC,¹⁶⁰ inadequate disclosure under Article 183 EPC and unallowable amendments (addition of subject-matter) under Article 123(2) EPC.¹⁶¹

Art.99 (3) EPC states that an opposition maybe filed even if the European patent has been surrendered or has lapsed for all the designated states since the surrender of a patent has ex nunc effect. After surrender or lapse have taken legal effect, right conferred by the European patent can still be exercised.

According to Art.99 (4) EPC; the parties to the opposition proceedings are the patent proprietor and the opponent.

The notice of opposition must indicate legal and factual reasons why the alleged grounds of opposition should succeed. If the facts and evidence cannot

¹⁵⁸ Paterson, A Concise Guide to European Patents, p.30-31. Contents which are not essential within the nine-month period are “the name and address of the opponent”; “the State in which his residence or principal place of business is located”; “the number of the opposed European patent”; “the name of the proprietor”; “the title of the invention”. Such requirements may be fulfilled within a period fixed by the Opposition Division, which may expire outside the nine-month limit.

¹⁵⁹ e.g. the number of claims which are opposed, whether the opposition concerns the entire patent or only a part of it.

¹⁶⁰ Under Articles 52 to 57 EPC including:

- (i) excluded subject matter, Articles 52 and 53 EPC;
- (ii) lack of novelty, Article 54 EPC;
- (iii) lack of inventive step, Article 56 EPC;
- (iv) not susceptible of industrial application, Article 57 EPC;

¹⁶¹ According to Art.123(2) EPC, the European patent application and the European patent may not be amended in such a way that they contain subject-matter which extends beyond the content of the application as originally filed.

support the grounds of opposition alleged, the opposition is inadmissible. If at least one of the alleged grounds is properly substantiated, the opposition is admissible.¹⁶²

If an opposition is based on prior use, the notice of opposition must indicate all the facts which make it possible to determine the date of prior use, what has been used and the circumstances relating to the prior use.

A notice of opposition shall be first examined by a Formalities Officer of the Opposition Division for admissibility. If it is held admissible, it shall be communicated to the patent proprietor under R 57(1). The patent proprietor is entitled to contest the admissibility of the opposition in his observations in reply. Such contentions are decided in inter partes proceedings by the Opposition Division. It is a prerequisite for a substantive examination that an opposition fulfils the admissibility criteria. If an opposition is held inadmissible, its substance cannot be examined.

Preliminary examination of a notice of opposition for admissibility is followed by substantive examination which is governed by R 57. According to Art.101(1), if the opposition is admissible, the Opposition Division shall examine whether the grounds for opposition laid down in Art.100 EPC prejudice the maintenance of the European patent. In principle the Opposition Division examines only grounds of opposition which have been properly substantiated in the notice of opposition. But in exceptional cases it may apply Article 114(1) EPC and consider other grounds of opposition which prima facie appear to prejudice the maintenance of the patent.¹⁶³

During the examination of the opposition, the Opposition Division shall invite the parties, as often as necessary to file observations on communications from another party or issued by itself (Art.101(2) EPC).

Even though an opposition is withdrawn; EPO may carry on with opposition proceedings of its own motion where it is convinced that the patent cannot be

¹⁶² Paterson, A Concise Guide to European Patents, p.29-30.

¹⁶³ G10/91 O.J.EPO 1993, 420.

supported at least in its granted form (R 60(2)).¹⁶⁴ The same shall apply in the event of death or legal incapacity of an opponent.

The final outcome of opposition proceedings may amount to the revocation of the patent (Art.102(1)EPC); rejection of the opposition (Art.102(2)EPC);¹⁶⁵ maintenance of the patent in amended form (Art.102(3)EPC).

Where the nine month opposition period of Art.99(1) has often lapsed before the infringement is raised, Art.105 EPC enables an assumed infringer to intervene as opponent in a pending opposition procedure or opposition appeal proceedings. The intervention can be based on one of the grounds stated in Article 100 and even on a new ground, as otherwise intervention would have no point. He must give notice of intervention within three months of the date on which the infringement proceedings are instituted.¹⁶⁶ A notice of intervention must meet the same requirements for admissibility as a notice of opposition.

It is also possible for a third party to file observations concerning the patentability of an invention under Art. 115 EPC, when opposition proceedings are pending.

Opposition proceedings at the EPO and revocation proceedings in national courts may be pending at the same time. In such a case a vital question arises whether one of these proceedings should be stayed in order to avoid duplication. There are different approaches concerning this matter in Contracting States.

¹⁶⁴ Cornish / Llewelyn, p.160.

¹⁶⁵ The patent maintained unamended.

¹⁶⁶ Paterson, A Concise Guide to European Patents, p. 40 "... the assumed intervener must prove either that proceedings for infringement of the European patent have been instituted against him or he has instituted court proceedings for a declaration of non-infringement."

3.7. Appeal Procedure

The appeal procedure is a special procedural phase (Art.106-112 EPC, R 64-67)

The EPC gives the parties to the proceedings to lodge an appeal against the decisions issued by the departments of the first instance mentioned in Article 106 EPC.

The appeal procedure before a Board of Appeal is the final instance of the grant and opposition procedure of the EPO. There is no form of legal redress against their decisions.¹⁶⁷ However under Art.22(1)(c), 112a EPC 2000¹⁶⁸ the Enlarged Board of Appeal will be competent to decide on petitions for review of decisions of the boards of appeal. Such a petition may be filed on the grounds of a fundamental procedural deficiency that occurred in appeal proceedings or if a criminal act might have influenced the decision.

The appeal procedure is to be considered a judicial procedure.¹⁶⁹ The boards of appeal form the judicial body of the EPO.¹⁷⁰

The boards of appeal are responsible for issuing decisions in appeal proceedings. The competence and composition of the Technical and Legal Boards of Appeal are governed by Art.21(2)-(4) EPC.¹⁷¹ According to the decision of the

¹⁶⁷ G1/97 O.J. EPO 2000, 322.

¹⁶⁸ www.european-patent-office.org/epo/an_rep/2001/html/5_e.htm, retrieved on 03.6.2005. A diplomatic conference was held in November 2000 in Munich to revise the Convention, amongst other things to integrate in the EPC new developments in international law, especially those of the TRIPS Agreement and of the Patent Law Treaty, and to add a level of judicial review of the Board of Appela decisions. The revised Convention, known as the EPC 2000 has not entered into force yet. Twelve Contracting States have ratified the EPC 2000, as of April 2005. EPC 2000 shall enter into force two years after ratification by the fifteenth state, or on the first day of the third month after ratification by the last of all the contracting states, if it takes place earlier.

¹⁶⁹ G7, 8/91 O.J. EPO 1993, 346 and 356; G 9, 10/91 O.J. EPO 1993, 408 and 420.

¹⁷⁰ Singer / Stauder, EPC, Vol.2, p.189 "... The status of boards of appeal and the Enlarged Board of Appeal as courts has already been acknowledged by the GB-House of Lords (decision of 26 October 1995-Merrel Dow Pharma v. H.N. Norton, [1996] R.P.C.76=GRUR Int. 1996, 825, 826 – Terfenadine); Grubb, p.127 "...The judge held that the EPO Boards of Appeal are really judicial in nature, their members being judges in all, and that there was no violation of TRIPS Art.32 which requires judicial review of any decision to revoke a patent."

¹⁷¹ Singer/ Stauder, EPC, Vol.2, p. XIII. "...Case numbers of decisions of the EPO Boards of Appeal indicate the nature of the board (J for the Legal Board, T for Technical Boards), the serial number in the year in question, and the year in which the appeal was filed. Cases are identified as follows:
Enlarged Board of Appeal : G (previously Gr), e.g. G 1/88

Enlarged Board of Appeal; Legal Boards of Appeal (Art.21(3)(c)EPC) is only competent when the appeal concerns a decision issued by an examining division consisting of fewer than four members and when the decision does not concern the refusal of a European patent application or the grant of a European patent; in all other cases a technical board of appeal has the competence .¹⁷²

The provisions of the EPC are the only binding legal source for the members of the Board. They may overrule the Guidelines or declare the Implementing Regulations void which contradict the EPC provisions.¹⁷³

The most important provisions with regard to the appeal and appeal proceedings are Art.21-24 EPC, 106-112 EPC, R 64-67, the Rules of Procedure of the Boards of Appeal (RPBA, as last amended in 2002, see OJ 2003, 60; version consolidating all amendments OJ 2003, 89), the Rules of Procedure of the Enlarged Board of Appeal (RPEBA, as last amended in 2002, see OJ 2003, 58; version consolidating all amendments OJ 2003, 83), the decision of the Presidium of the Boards of Appeal 31 May 1985 concerning the transfer of functions to the Registrars of the Boards of Appeal (OJ 1985, 249; amendments see OJ 2002, 590). The amount of the appeal fee is laid down in Art.2 No.11 RFees. Under the EPC 2000 some details of the appeal procedure have been transferred to the Implementing Regulations; this is true for Arts.106, 108 and 110 EPC.¹⁷⁴

3.7.1. Decisions Subject to Appeal

Due to an exhaustive list of appealable decisions in Art.106(1) EPC, all final decisions of the Receiving Section, Examining Divisions, Opposition Divisions and the Legal Division may be subject to appeal. Since it is assumed that the search division which is only responsible for drafting search reports does not issue

Legal Board of Appeal: J, e.g. J 3/86

Technical Board of Appeal: T, e.g. T 385/86

Technical Board of Appeal dealing with PCT protests: W, e.g. W 31/88

Board of Appeal in disciplinary matters: D, e.g. D 3/87

¹⁷² G 2/90, O.J. EPO 1992,10.

¹⁷³ Grubb, p.126.

¹⁷⁴ Singer / Stauder, EPC, Vol.2, p.192

decisions, it is not mentioned in Art.106(1) EPC. An appeal can be also filed against interlocutory decisions provided that separate appeal is allowed.¹⁷⁵

All appealable decisions must be reasoned. All written first instance decisions consist of a “Summary of Facts and Submissions” and “Reasons for the Decision” ending with a statement what has been decided, the “order”.

a. Decisions

Decisions which may be appealed, must be distinguished from communications and notifications.¹⁷⁶ Communications and notifications cannot be subject to an appeal. Whether a document constitutes a decision within the meaning of Article 106(1) EPC depends on the substance of its contents, not upon its form.¹⁷⁷ If the Board of Appeal interprets that the document does not constitute a decision, but merely a communication or a notification, the appeal shall be deemed to be inadmissible.

b. Noting of a Loss of Rights

Loss of rights may arise automatically in the course of the granting proceedings if the European patent application is deemed to be withdrawn because of the applicant’s failure to perform procedural actions at all, or in due time.

The EPO notifies the applicant that a loss of rights has occurred. A notification of loss of rights under R.69(1) is not a decision. This communication is merely information from the EPO. Since it is not a decision, an appeal cannot be filed against it.¹⁷⁸ But if the applicant does not consent to the finding of EPO concerning the loss of rights, he must ask for a decision from the EPO under R.69(2) within two months from the notification. If the EPO decides that the loss of rights has occurred, an

¹⁷⁵ Hansen / Hirsch, p.3.

¹⁷⁶ A communication invites observations in reply and a notification normally gives notice of some event, without inviting observations in reply.

¹⁷⁷ J 8/81 O.J. EPO 1982, 10.

¹⁷⁸ Singer / Stauder, EPC, Vol.2, p.196, J 13/83 of 3 December 1984.

appeal can be only lodged against this decision under R 69(2).¹⁷⁹ If the decision concerning the loss of rights is issued by a board of appeal, one cannot file an appeal against such a decision since a board of appeal is not included in Art.106(1) EPC.

c. Suspensive Effect

According to Article 106(1) EPC, appeal shall have a suspensive effect. This means that the contested decision does not take effect until the final decision is delivered by the competent board of appeal. Since an appeal suspends the enforcement of a first instance decision, a patent revoked by an Opposition Division shall exist as long as the decision is on appeal.¹⁸⁰ The suspensive effect occurs only if the notice of appeal has been validly filed and the fee for appeal has been paid in accordance with Article 108 EPC.

As a result of suspensive effect, a European patent application continues to exist throughout the appeal proceedings despite the decision of the first instance department that it is deemed to have been withdrawn or has been refused.¹⁸¹

If a European patent application is published in accordance with Art.93, the publication should contain a warning of the matters still pending.¹⁸²

d. Decisions Relating to Lapsed or Surrendered Patent

Even when a European patent application has lapsed or surrendered in all the designated countries due to non-payment of the renewal fees, an appeal may be filed against a decision of the opposition division.

¹⁷⁹ Visser, p.201.

¹⁸⁰ Grubb, p.127.

¹⁸¹ Singer/Stauder, EPC, Vol.2, p.106 “For this reason the application must, e.g., be published in accordance with Art.93; or the application still confers the provisional protection prescribed in Art.67; or the renewal fees due must be paid in accordance with Art.86.”

¹⁸² J 3/81, O.J. EPO 1982,100.

e. Interlocutory Decisions

Art.106(3) EPC provides that a decision which does not terminate proceedings as regards one of the parties can only be appealed together with the final decision, unless the decision allows separate appeal.

An interlocutory decision is issued when the matter in question shall form the basis of further proceedings. Since an interlocutory decision does not terminate proceedings, in general it can not be appealed separately. Decisions about taking evidence, refusal of requests regarding impartiality are interlocutory decisions. These decisions can be only contested within the context of an appeal against a final decision.

An interlocutory decision is appealable only if the decision indicates so. The most common separately appealable interlocutory decision is the maintenance of the European patent in amended form by the opposition division (Art.102(3) EPC).¹⁸³

It is also possible to file an appeal against a decision concerning the admissibility of an opposition separately.¹⁸⁴

A separate appeal can also be filed against an interlocutory decision in ex parte proceedings concerning the validity of the claimed priority since the state of the art at the time of priority is decisive for patentability. "...A separate appeal may be lodged against an interlocutory decision regarding the admissibility of a notice of opposition."¹⁸⁵

f. Decisions Regarding the Apportionment of Costs

According to Art.106(4) EPC; the apportionment of costs of opposition proceedings cannot be the sole subject of an appeal.

¹⁸³ Visser, p.203, "...without the possibility of appeal on the interlocutory decision in the opposition procedure, the proprietor would have to make all necessary translations of the patent and thereby run the risk that the translations are in vain when the amended patent is revoked in a subsequent procedure.(T 244/85)"

¹⁸⁴ Grubb, p.128.

¹⁸⁵ Singer / Stauder, EPC, Vol.2, p.203 T 10/82, O.J.EPO 1983, 407; T 376/90, O.J.EPO 1994, 906.

This article provides that the apportionment of costs can only be challenged in connection with another finding of the Opposition Division. If a party loses in an opposition procedure and is ordered to pay the costs of another party in accordance with Art.104(1) EPC, the party can appeal the decision concerning the apportionment of costs while he is appealing the decision of the Opposition Division.¹⁸⁶

g. Decisions Fixing Costs

The amount of costs to be repaid on the apportionment of costs is fixed by the Registry of the Opposition Division. This decision is appealable if only the fixed amount is greater than the appeal fee itself.(Art.106(5) EPC in conjunction with Art.11 RFees and Art.2 No.11 RFees).

3.7.2. Persons Entitled to Appeal and to Be Parties to Appeal Proceedings

a. Persons Entitled to Appeal

Art.107 EPC provides that all parties involved in the first instance proceedings before the EPO are entitled to file an appeal if they were adversely affected by the decisions of the department of the first instance.¹⁸⁷

In the opposition proceedings (inter partes proceedings) the proprietor and the opponents are parties to appeal proceedings. Multiple appeals are possible if more than one party to opposition proceedings is adversely affected by the decision of an opposition division.¹⁸⁸

¹⁸⁶ In T 154/90, O.J.EPO 1993, 505, the opponent attacked the maintenance of the patent in amended form and simultaneously the decision on the apportionment of costs.

¹⁸⁷ As an exception, a person intervening under Art.105 may become party to an opposition appeal although he was not a party to opposition proceedings.

¹⁸⁸ Paterson, A Concise Guide to European Patents, p.47 "... For example, if a patent is maintained in amended form in accordance with an auxiliary request, the patentee is adversely affected by the decision not to maintain the patent as granted, and the opponent as adversely by the decision not to revoke the patent. In such a case both the patentee and the opponent may file an appeal."

In grant procedure (ex parte proceedings), all decisions of the examining division are subject to appeal and only the applicant(s) are involved in appeal proceedings. If there are more than one applicant (Art.59 EPC), each of them is entitled to file an appeal against the decision separately.

Appeal is not open to persons who have filed their observations concerning the patentability of an invention under Art.115(1) EPC.

b. Adverse Affection

The result of the first instance proceedings expressed in the order of the decision must be compared with the party's final main request. A party is deemed to have been affected adversely by a decision if such a decision is inconsistent with what he has specifically requested.¹⁸⁹ A party is adversely affected unless his requests have been met in full.

An applicant is only adversely affected in grant procedure if a decision does not agree with his explicit request.¹⁹⁰

Both parties (proprietor and opponent) in an opposition procedure are adversely affected if an opposition results in the patent being maintained on the basis of claims as auxiliary requests but not the main request.¹⁹¹

c. Parties as of Right (Automatically Parties to Proceedings)

Parties to proceedings before the department of the first instance that do not file an appeal, or are not entitled to file an appeal since they are not adversely

¹⁸⁹ J 12/85 O.J.EPO 1986, 155.

¹⁹⁰ If the applicant does not agree to the text of the application to be granted according to Art.113(2), he can appeal the decision to grant, because change in the description may influence the scope of the protection according to Art.69, resulting in adverse affection.

¹⁹¹ The patent proprietor is adversely affected since his claims in the high-ranking requests are refused (T 234/86, O.J.EPO 1989). On the other hand an opponent requesting the revocation of the entire patent is adversely affected too.

affected, are, nevertheless, automatically parties to proceedings according to Art.107 EPC, second sentence.¹⁹²

If an opponent as a sole appellant withdraws his appeal, the proceedings shall be terminated, even if the Board of Appeal considers the patent invalid.¹⁹³

The rights of parties as of right are restricted compared with those of an appellant. For example, if the sole appellant who paid the appeal fees withdraws his appeal, a party as of right has no right to continue the proceedings.¹⁹⁴

d. The Principle of the 'Prohibition of Reformatio in Peius'

The Boards of Appeal have introduced the principle of the 'prohibition of reformatio in peius' in appeal proceedings. It means the prohibition to put a person in a worse position. As a result of this principle, the Boards of Appeal may not go beyond a request of an appealing party and put it in a worse position than it was in before it applied.

This principle refers to contentious, inter partes proceedings after grant. It cannot be applied to appeal in grant proceedings since they are ex parte proceedings.¹⁹⁵

Decisions of the Enlarged Board of Appeal have established the principles that where a party appeals a decision of the Opposition Division, he can not put himself in a worse position by appealing.¹⁹⁶

¹⁹² Singer / Stauder, EPC, Vol.2, p. 214 "This is of significance to all inter partes proceedings , in particular, opposition appeal proceedings. Under Art.107, second sentence, even an opponent whose appeal was inadmissible is a party to appeal proceedings providing another opponent filed an admissible appeal (T 643/91 of 18 September 1996)".

¹⁹³ Grubb, p.128, G 8/93, O.J.EPO 1994, 887, Serwane/Withdrawal of opposition.

¹⁹⁴ Grubb, p.128, G 2/91, O.J.EPO 1992, 206, Krohne / Appeal fees.

¹⁹⁵ If an appeal is filed against a decision refusing a patent application, a Board of Appeal is competent to examine whether the application meets the requirements of the EPC, even if the Examining Division has not considered the requirements or regarded them as having been met.

¹⁹⁶ Grubb, p.128 G 9/92, G 4/93, O.J.EPO 1994, 875, BMW(Motorola)/Non-appealing party.

If the Opposition Division decides to maintain the patent in a narrower scope, both the patent owner and the opponent may appeal this decision since they are both adversely affected. In this case:¹⁹⁷

- If only the patent owner appeals, the patent can not be limited further or revoked entirely.
- If only the opponent appeals, the patent can not be broadened further or restored to its original scope.

3.7.3 Form of Appeal and Time Limit

a. Form of the Notice of Appeal and the Statement of Grounds of Appeal

The form of the notice of appeal must meet the requirements envisaged in R 36 (form of subsequently filed documents). It must be filed within two months of the notification of the appealed Decision at the EPO in Munich, The Hague or Berlin.

The essential contents of the notice of appeal are set out in R 64 (content of the notice of appeal). A notice of appeal must contain the name and address of the appellant, a statement identifying the decision which is impugned¹⁹⁸ and the extent to which amendment or cancellation of the decision is requested.¹⁹⁹ There is no need to give further details at this stage.

An appeal can be filed in any official language of the EPO (English, French or German) . This is subject to Article 14(2) and 4 EPC.

As the next step, a complete statement of grounds must be filed within four months of the notification of the first instance department. The statement of grounds of appeal must be well-drafted. It should not confine itself to an assertion that the

¹⁹⁷ Grubb, p.128.

¹⁹⁸ If the impugned decision is not identified sufficiently, under R 65, the Board will consider the appeal as inadmissible unless this deficiency is rectified within the two month appeal period.

¹⁹⁹ In the absence of such a statement , a notice of appeal may be interpreted as being against the entire contents of the first instance decision. (e.g. T 7/81 O.J. EPO 1983, 98)

impugned decision is incorrect but it should state the legal and factual reasons why the decision should be set aside.²⁰⁰ The sufficient content of a statement of grounds of appeal has been developed through the case law of boards of appeal. It is evident from the formulation of Article 108 EPC that the grounds of appeal should contain something more than the notice of appeal since it provides an additional two months, beyond the two-month period prescribed for filing a notice of appeal. Many appeals were held inadmissible due to an inadequate statement of grounds.²⁰¹

If a decision of a department of first instance concerns a number of subject-matters, the decision with regard to the parts that are not impugned by the appeal becomes final (J 27/86 of 13 October 1987).²⁰²

An appeal can be withdrawn entirely or partially. The consent of the board of appeal is not required. The withdrawal of the appeal by a sole appellant terminates the appeal proceedings in ex-parte and as well as inter partes proceedings as far as substantive matters are concerned.²⁰³

Only appellants who have paid the appeal fee may independently continue the appeal proceedings even if the other appellant(s) withdraws his appeal. In this case appeal proceedings shall be continued when there is at least one further party (as appellant) to appeal proceedings.²⁰⁴ A party to appeal proceedings by virtue of Art.107, second sentence, may not continue appeal proceedings on his own once the last remaining appeal has been withdrawn.²⁰⁵

There are ancillary issues such as requests for refund of the appeal fee²⁰⁶ or requests for apportionment of costs²⁰⁷ which may remain to be decided after the withdrawal of an appeal.

²⁰⁰ Singer / Stauder, EPC, Vol.2, p.226 "...If an opposition has been rejected on the grounds of insufficient substantiation, but the statement of grounds of appeal merely dispute patentability, without elaborating on the admissibility of the opposition, the appeal is inadmissible for lack of an adequate statement of grounds of appeal (T 213/85, OJ 1987, 482)".

²⁰¹ T 220/83, O.J.EPO 1986, 249, Huls/Grounds for appeal; T 145/88, O.J.EPO 1991, 251, Nicolon/Statement of grounds.

²⁰² Singer / Stauder, EPC, Vol.2, p.225.

²⁰³ G 8/91, O.J.EPO 1993, 346.

²⁰⁴ G 2/91, O.J.EPO 1992, 206.

²⁰⁵ G 2/91; G8/91, O.J.EPO 1993, 346.

²⁰⁶ T 41/82, O.J.EPO 1982, 256 point 6; J 12/86, O.J.EPO 1988, 83.

In cases where the opponent is the sole appellant, the withdrawal of an opposition during the appeal proceedings is equal in effect to a withdrawal of appeal . Proceedings relating to substantive issues shall be terminated even if the Board of Appeal considers that the requirements set out in EPC for the maintaining of a European patent are not satisfied. The consent of the proprietor shall not be sought either.²⁰⁸

An appeal cannot be filed conditionally. For this reason an appeal filed as an auxiliary request, e.g. conditional on the main request for the re-establishment of rights not being allowed by the first instance, is not admissible. (J 16/94, O.J.EPO 1997, 331; T 460/95, O.J.EPO 1998, 587).²⁰⁹

b. Time Limit

Notification of the decision rendered by the department of the first instance is according to Art.119 EPC, R.78(1), deemed to be received in all cases on the 10th day following its posting. The two month time limit for filing the notice of appeal runs from the tenth day, even this day is a Saturday or Sunday.

Within four months after the date of notification of the decision, a written statement setting out the grounds of appeal must be filed.

As compared with other time periods fixed, the time period for filing notice and grounds cannot be extended by the EPO. But a failure to meet 2 or 4 month time limit can be remedied with *restitutio in integrum* (request for the re-establishment of rights) under Art.122 EPC for the applicant and proprietor.²¹⁰

²⁰⁷ T 323/89, O.J.EPO 1992, 169.

²⁰⁸ Singer / Stauder, EPC, Vol.2, p.231, G 8/93, O.J.EPO 1994, 887; T 323/89; O.J.EPO 1992, 169.

²⁰⁹ Singer / Stauder, EPC, Vol.2, p.221.

²¹⁰ The two month time limit is excluded from *restitutio* for the opponent in order to warn the applicant or proprietor not later than two months that an appeal has been lodged and his rights may be in jeopardy. But an opponent as appellant can apply for *restitutio* in the four month time limit.

c. Appeal Fee

An appeal fee must be paid within two months after the date of notification of the decision. A notice of appeal without payment has no legal effect, it shall be deemed not to have been filed.²¹¹

In the event of parallel appeals or opposing appeals, each appellant must pay an appeal fee (G 2/19, O.J.EPO 1992, 206).²¹²

The amount of the appeal fee is fixed in Rfees 2 (11).

3.7.4 Examination for Admissibility

According to R.65(1), if the appeal does not comply with Articles 106 to 108 EPC and with R 1, paragraph 1, and R 64, sub-paragraph (b), the Board of appeal shall reject it inadmissible, unless each deficiency has been remedied before the relevant time limit laid down in Art.108 EPC has expired.

As a result of this examination for admissibility it will be decided if the appeal may go forward for substantive examination. If an appeal is inadmissible, the Board of Appeal may not examine whether the appeal is allowable (Article 110(1) EPC)

3.7.5 Interlocutory Revision

Article 109(1) EPC envisages that the first instance department shall initially consider the notice of appeal and the statement of grounds of appeal. If it considers the appeal to be admissible and well-founded, it shall rectify its decision by

²¹¹ If the paid amount falls short by a small amount, the fee is regarded as paid in time, if the circumstances justify overlooking the amount lacking (Rfees9(1)).

²¹² In case of a parallel appeal, number of opponents lodge appeals and in case of opposing appeal, patent proprietor and opponent both file appeals against the maintenance of the patent according to an auxiliary request.

interlocutory revision within three months after the receipt of the statement of grounds.²¹³

It is possible to settle an appeal against the decision of the Examining Division refusing the application, through an interlocutory revision, if the appellant agrees with all proposals of the Examining Division he has rejected before.

As a general rule; interlocutory revision is not possible in inter partes proceedings, in proceedings where there are opposing parties (Art.109(1)EPC).²¹⁴ In these cases the first instance department sends the notice of appeal directly to the Board of Appeal. However, in opposition proceedings, the interlocutory revision is only admissible under special procedural circumstances, e.g. if an opposition or an intervention regarded as admissible, and the decision is appealed, or if all oppositions are withdrawn and the proprietor appeals.²¹⁵

Interlocutory revision is admissible when the appellant is the only party involved in the proceedings, i.e. in ex parte proceedings before the Receiving Section, the Legal Division and the Examining Division. In grant proceedings an interlocutory revision is admissible even if there are several applicants in the proceedings as joint applicants, provided that they are not in dispute with each other.

Art. 109(2) EPC states that “if the appeal is not allowed within three months after the receipt of the statement of grounds, it shall be remitted to the Board of Appeal without delay, and without comment as to its merits”. According to this article; if interlocutory revision is not admissible, the appeal must be remitted to the Board of Appeal as soon as possible. If interlocutory revision is admissible, the first instance department should decide within a three months period whether or not to grant interlocutory revision. If interlocutory revision is not granted within this prescribed period, the first instance department should remit the case to the board of appeal without delay and without making any comments on the merits of the appeal request.

²¹³ Singer / Stauder, EPC, Vol.2, p.234 “Examination Guidelines E, XI-7 gives examples of situations in which interlocutory revision could be granted.”

²¹⁴ Interlocutory revision is not possible in appeals against decisions regarding mention of the inventor (R.19), suspension of the proceedings (R.13) or registering a transfer (R.20) since there are opposing parties. In these cases the department of the first instance must send the case directly to the Board of Appeal.

²¹⁵ Singer / Stauder, EPC, Vol.2, p.233. (Examination Guidelines E, XI-7; cf also T 168/03 of 7 March 2003).

An application for the re-establishment of rights into a time period relating to the appeal itself does not lie within the jurisdiction of the first instance.²¹⁶

If the first instance department issues an adverse decision at the end of the interlocutory revision, the appellant is entitled to lodge an appeal against this decision. At the same time the appellant preserves the possibility of consideration of the merits of the case by two instances.

3.7.6. Substantive Examination of an Appeal

Following due filing of the notice of appeal and the statement of grounds of appeal, interlocutory revision under Article 109 EPC and the examination for admissibility under Rule 65 EPC, an appeal is ready for substantive examination and decision under Articles 110, 111 and R 66 EPC. If the appeal is considered admissible, the Board of Appeal proceeds to check whether it is allowable.

The assessment of the notice of appeal shall be carried out according to Art.110(1), R 64 and R 65 EPC.

An appeal shall be deemed to be admissible if it does not contain any of the deficiencies listed in R.65. According to R.65(1); if the appeal does not comply with Articles 106 to 108 EPC and with R 1, paragraph 1, and R 64, sub-paragraph (b), the Board of Appeal shall reject it as inadmissible, unless each deficiency has been remedied before the relevant time limit laid down in Art.108 EPC has expired.

Art.110 EPC states that if the appeal is admissible, the Board of Appeal shall examine whether it is allowable. An appeal shall be allowable if the grounds on which the appeal is based justifies rectification of the impugned decision.

The examination of allowability has been worked out in Art.110(2) EPC.

²¹⁶ T 473/91, O.J.EPO 1993,630

R 66 deals with the examination of appeals and states that in proceedings before departments of second instance the same rules apply as in proceedings before the first instance, especially the general procedural rules in Art.113-126 EPC: fair hearing, examination of its own motion, oral proceedings, taking of evidence, and R.26-36: filing of documents.²¹⁷

The appeal procedure is in principal in writing but it includes also oral proceedings on request of one of the parties or the Board of Appeal.

Due to the above mentioned principle of fair hearing , in the course of appeal proceedings, the Board of Appeal invites the parties to file their observations as often as necessary to the questions and opinions of the Board of Appeal (Art. 110(2) EPC).

Extent of examination depends on the content of the appeal. In an appeal from a grant refusal, the Board of Appeal exercises a wider scope of power in respect of examination. Not only does it examine whether the application meets the requirements of the EPC but also examines the requirements the Examining Division did not consider or regarded as having been met. But in opposition appeal the Board of Appeal may not examine the subject matter which is not covered by the extent of the opposition as stated in the notice of opposition.

In order to avoid unnecessary delays, Art. 110 (3) EPC provides that if the applicant fails to reply in due time to an invitation under paragraph 2, the European patent application shall be deemed to be withdrawn. This provision does not apply to inter partes proceedings. It is not also applicable to appeals raised against decisions taken by the Legal Decision since such decisions relate to transfers of right and not to the grant of an application.²¹⁸

²¹⁷ Visser, p.212.

²¹⁸ Visser, p.214.

3.7.7. Decisions in Respect of Appeals

The Board of Appeal reviews the decision of the first instance department during appeal proceedings. The decision of the Board of Appeal may be either interlocutory, not terminating proceedings or final, terminating proceedings.

a. The Board of Appeal May Reach a Decision as to the Merits of the Case itself

According to Article 111 (1) EPC, the Board of Appeal may exercise any power within the competence of the department which was responsible for the appealed decision.²¹⁹

If the Board of Appeal finds a notice of appeal well founded, it sets aside the decision of the first instance department. For example the Board of Appeal may order the grant of a patent or to maintain it in an amended form, which has been refused by the Examining Division or revoked by the Opposition Division due to lack of inventive step if the grounds of appeal are well substantiated. In such cases the Board of Appeal orders the first instance department to grant a European patent in a precisely specified form.

If the appellant has filed auxiliary claims besides main set of claims, the Board of Appeal shall decide first on the main set of claims. If it concludes that the main set of claims are not allowable, then it will examine the auxiliary set of claims.

In opposition appeal proceedings, the Board of Appeal may decide for the revocation of the patent or the rejection of the opposition if the appeal is well founded.

If the Board of Appeal concludes that the appeal is not allowable, it will dismiss the appeal.

²¹⁹ Rule 66(1) provides that the provisions relating to proceedings before the first instance shall be applied mutatis mutandis in the appeal proceedings.

b. The Board of Appeal Can Remit the Case to the First-Instance Department for Further Prosecution

According to Art.111(1) EPC; a Board of Appeal may remit a case to the department which was responsible for the decision.

The first instance department may not take a particular decision itself but it continues the examination on the basis of the decision taken by the Board of Appeal. It is bound by the ratio decidendi of the board's decision in so far as the same facts obtain.

In case of fundamental deficiencies in proceedings before the first instance²²⁰ and in the presence of new facts or evidence²²¹, the remittal is possible. A case shall also be referred back to the first instance when a decision of the examining division is set aside in which the division failed to take account of every aspect of patentability. Substantial amendments to the patent claims can also result in the remittal of the case, especially where the amendments are so substantial as to require a new examination on the basis of a new search in a different patent classification.²²²

c. Binding Effect of a Decision

Art.111(2) EPC defines the extent to which the judgement of the Board of Appeal is binding on the first instance department.²²³ The decision of the Board of Appeal has a binding effect on the first-instance department only with regard to the particular case in question. However to the extent that the facts and evidence are not the same, the binding effect does not apply.

²²⁰ Singer / Stauder, EPC, Vol.2, p.264 "... for example when the principle of the right to be heard is violated (T 125/91 of 3 February 1992) ”.

²²¹ Singer / Stauder, EPC, Vol.2, p.264 "... for example, a new, relevant prior art document becomes known which was not considered during the examination by the department of first instance, and casts doubt on the patentability of the invention in suit. A remittal is particularly appropriate where the new prior art document endangers the validity of the patent (T 326/87, OJ 1992, 522)".

²²² T 63/86, O.J.EPO 1988, 224

²²³ A reference is made to the ratio decidendi, these are the facts and elements of the board's reasoning that determine the outcome of the judgement (T 934/91, O.J.EPO 1994, 184)

The decision of the Board of Appeal does not have any binding effect on other cases but may serve as a guiding principle. Art.15 of the Rules of Procedure of the Boards of Appeal stipulates, that, where a Board departs from an earlier decision on a point of law, the Board must explain the departure in the reasons for the decision and inform the President.

The binding effect does not extend to any subsequent department. By way of exception a decision issued by the Legal Boards of Appeal concluding an appeal against a decision of the Receiving Section is binding not only on the Receiving Section but also on the Examining Division. The aim of this provision is to prevent the procedural problems decided by the Legal Board of Appeal from being raised again by the Examining Division; according to Art. 94(1) and 96(2) EPC procedural requirements are also to be examined by the Examining Division.

d. Finality of a Decision

A decision of the Board of Appeal becomes formally *res judicata* as soon as it is issued. It is no longer open to appeal. The principle of *res judicata* is based on public policy that there should be an end to litigation.²²⁴

They are also binding on a Board of Appeal and on the parties to the proceedings.²²⁵ Once a decision has been issued, whether orally or in writing, it is final and it cannot be cancelled or changed by the instance which issued it.²²⁶

Neither an Examining Division nor a Board of Appeal has power to reopen examination of claims which have been previously refused by the Board of Appeal.

Decisions of the EPO in proceedings for grant, grant appeal, opposition and opposition appeal have no *res judicata* effect on revocation proceedings pursuant to Art. 138 held before national courts, even if the parties are the same.²²⁷

²²⁴ Visser, p.215

²²⁵ T 934/91, O.J.EPO 1994, 184.

²²⁶ R 89 states that only linguistic errors, errors of transcription and obvious mistakes may be corrected.

²²⁷ Visser, p. 217

e. Reimbursement of Appeal Fees

Even in the absence of a request, the Board of Appeal is obliged to decide for the reimbursement of the appeal fee in accordance with R 67 in the event of interlocutory revision or when the Board deems an appeal to be allowable and when reimbursement is equitable by reason of substantial procedural violation caused by the first instance division.²²⁸ Failure to respect a party's right to be heard,²²⁹ failure to consider claims or requests by parties,²³⁰ failure by the first instance department to carry out the decision handed down by the Board of Appeal, failure to take account of the suspensive effect of an appeal,²³¹ notification of a decision without any reasons for the decision²³² can be listed as examples for procedural violations.

f. Form and Language of a Decision

The content, form and notification of decisions issued by the EPO are laid down in general terms in R 68. R 66(2) stipulates the constituents that must be present in a decision issued by a board of appeal.²³³

In principle, the decision of the board of appeal is to be drafted in the language of the proceedings. It is also possible to issue decisions in a different official language of the EPO provided that all the parties give their consent.

²²⁸ Unless these requirements are met in full, the Board of Appeal may not order the reimbursement of appeal fees (T 41/82, O.J.EPO 1982, 256)

²²⁹ J 7/82, O.J.EPO 1982, 391

²³⁰ For example if a publication was made despite withdrawal of the European patent application (J 5/81; O.J.EPO 1982, 155)

²³¹ J 5/81, O.J.EPO 1982, 155

²³² T 493/88, O.J.EPO 1991, 380

²³³ According to R 66(2); the decision shall contain :

- (a) a statement delivered by the Board of Appeal;
- (b) the date when the decision was taken;
- (c) the names of the Chairman and of the other members of the Board of Appeal taking part;
- (d) the names of the parties and their representatives;
- (e) a statement of the issues to be decided;
- (f) a summary of the facts;
- (g) the reasons;
- (h) the order of the Board of Appeal, including, where appropriate, a decision on costs.

g. Publication of the Decision Data and the Board of Appeal Decision

Both the refusal and the grant of a patent are entered in the Register of European Patents and also published in the European Patent Bulletin.

When the Board of Appeal considers that a decision is of general interest, this decision shall be published in the three official EPO languages in the Official Journal of the European Patent Office.²³⁴

3.7.8. Decision or Opinion of the Enlarged Board of Appeal

The Board of Appeal is the last instance in the proceedings. Since the Enlarged Board of Appeal does not carry out the function of a second instance, a decision of the Board of Appeal cannot be contested before it. The Enlarged Board of Appeal does not act as a third instance.²³⁵

Under EPC 2000, the Enlarged Board of Appeal will be responsible for deciding on petitions for review of decisions of the Board of Appeal. Such petitions shall be reviewed if a party to the appeal proceedings can in accordance with Art. 112a prove that he has been adversely affected by one of the fundamental procedural defects defined in Art.112a(2) or the Implementing Regulations. Parties shall have the right to file petitions for review in case of criminal acts which may have had an impact on a board of appeal decision.²³⁶

According to Art. 112 EPC; the Enlarged Board of Appeal's main function is to ensure uniform application of law. It settles important points of law in pending appeals. However it may not settle the entire case since the Board of Appeal is solely competent to reach a final decision.

²³⁴ The headnote of a published decision does not constitute a part of the decision and is binding neither on the Board of Appeal that issued the decision nor on first instance departments.

²³⁵ Grubb, p.127 "...Unlike the procedure in the British or US Patent Offices, there is no further appeal from the EPO to the courts, for example to the European Court of Justice."

²³⁶ Singer / Stauder, EPC, Vol.2, p.279.

As to the composition of the Enlarged Board of Appeal, it consists of seven members; five legally qualified and two technically qualified members. One of the legally qualified members shall be the Chairman. The competence of the Enlarged Board of Appeal is determined by Art.22 EPC. The members of the Enlarged Board of Appeal may not be members of the first instance departments and are often members of Boards of Appeal.

Procedure of the Enlarged Board of Appeal is governed primarily by the “Rules of Procedure of the Enlarged Board of Appeal” (RPEBA).²³⁷ These Rules of Procedure are adopted by the Enlarged Board itself (Art. 23(4) and R 11 EPC). They are generally similar to those of the Boards of Appeal.

Art. 112(1) EPC stipulates that a question can be referred to the Enlarged Board of Appeal either by a Board of Appeal or by the President. The parties to the proceedings may even request a Board of Appeal to refer a question to the Enlarged Board of Appeal but it is at the discretion of a Board of Appeal to grant or refuse such a request.

a. Referral of a Point of Law by a Board of Appeal

According to Art.112(1)(a) EPC; a Board of Appeal may refer a legal question to the Enlarged Board of Appeal whether of its own motion or on parties’ request in order to ensure uniform application of law or to clarify an important point of law when it considers that a decision by the Enlarged Board of Appeal is required.²³⁸

In this case the proceedings shall be suspended until the decision of the Enlarged Board of Appeal is rendered.²³⁹ Its decision shall be binding on the Board of Appeal in accordance with Art.112(3) EPC. Substantive decision of a Board of Appeal shall be based on the Enlarged Board’s findings. The binding effect does not

²³⁷ A consolidated version of the Rules of Procedure of the Enlarged Board of Appeal is published in O.J.EPO 2003, 83. It includes the amendment by the Enlarged Board of 28.10.2002, which was approved by the Administrative Council under Art.23(4) EPC in its decision of 12.12.2002 (O.J.EPO 2003, 58).

²³⁸ Singer / Stauder, EPC, Vol.2, p.281 “...For example , it was a question of fundamental importance that prompted the Enlarged Board of Appeal’s decision concerning a second medical use, among others G 5/83, OJ 1985, 64 as well as the decision G 1/88, O.J.EPO 1989, 189 concerning the way in which the opponent’s silence in response to a communication under R 58(4) is to be construed.”

²³⁹ T 166/84, O.J.EPO 1984, 489

extend to other decisions which have already become final. The decision does not either affect other cases handled by the Board of Appeal even though in which the same question arises.

However every Enlarged Board opinion or decision has a binding effect upon subsequent individual Boards of Appeal, having regard in particular to Article 16 RPBA. According to Art.16 RPBA; if a board of appeal considers it necessary to depart from an interpretation or explanation of the EPC contained in an earlier decision or opinion of the Enlarged Board of Appeal, it must refer the case anew to the Enlarged Board of Appeal. However in case of violation of this provision there is no sanction to be imposed.²⁴⁰

A referral to the Enlarged Board of Appeal is not necessary in cases where an unambiguous answer to a legal question can be found by reference to the EPC,²⁴¹ or the Board of Appeal sees no reason to deviate from the case law established in earlier decisions.²⁴²

b. Referral of a Point of Law by the President of the EPO

Art.112(1)(b) EPC states that; when a point of law arises where two different Boards of Appeal have given divergent decisions on the same point, the President of the European Patent Office is entitled to refer a matter to the Enlarged Board of Appeal.²⁴³

In such cases the Enlarged Board of Appeal does not reach a decision concerning the proceedings which led to the contradictory decisions since those proceedings have already been closed. It only renders an opinion on points of law referred to it by the President acting in fact as an advisory body and such an opinion becomes effective only for future cases. It does not have any retrospective effect on

²⁴⁰ Paterson, A Concise Guide to European Patents, p.71

²⁴¹ J 5/81, O.J.EPO 1982, 155.

²⁴² J 47/92, O.J.EPO 1995, 180.

²⁴³ Singer / Stauder, EPC, Vol.2, p.284 "...The crucial factor for the application of this provision should be that the two decisions are contradictory in their constructions of the law, and not that the divergent decisions are taken by two separate boards of appeal."

the contradictory decisions. However in accordance with Art.16 RPBA, there is an indirect binding effect for future cases before the boards of appeal.

3.8. Contents of a European Patent Application

Art.78(1) EPC lays down 5 integral parts of a European patent application :

- (a) a request for the grant of a European patent (R 26);
- (b) a description of the invention (Art.83 EPC and R 27, 27a, 28 and 28a);
- (c) one or more claims (Art.84 EPC and R 29 and 31, as well as Art.82 EPC and R 30);
- (d) any drawings referred to in the description or the claims (R 32, Art.83 EPC);
- (e) an abstract (Art.85 EPC and R 33).

Items a), b) and c) are checked in the course of examination of Art.90 EPC for according a filing date (Art.80 EPC). Items a) to e) i.e. all documents making up the application, are checked during the subsequent formalities examination (Art.91 EPC)

3.8.1. Request for Grant

R 26 lays down the requirements for the request for grant. The request for the grant of a European patent shall be filed on a form drawn up by the European Patent Office (O.J.EPO 2002, 375).

3.8.2. Drawings

Drawings mean technical drawings of any kind, including perspectives, exploded views, sections and cross-sections, details on different scale, flowsheets and diagrams etc. R.32 defines the form of the drawings

Art.78(1) EPC does not state when drawings are necessary. However drawings are part of the substantive contents of an application. The applicant should determine the necessity of drawings in respect of complying with Art. 83 EPC (sufficiency of disclosure of the invention) or facilitating an understanding of the invention. The decisive point will be that the application should be filed to disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.²⁴⁴

3.8.3. Abstract

Art.85 EPC states that an abstract is of an informative character and merely serves for use as a technical information. It informs the public of the technical information disclosed in the application. It is not part of the substantive contents of an application and cannot be taken into account when determining what subject of matter is contained in the application as filed.

R 33 defines the form and content of the abstract.²⁴⁵ In accordance with R 33(2), the abstract must contain a concise summary of the invention disclosed in the description, the claims and the drawings to render it possible to understand both the problem and the solution and the principal uses of the invention. It must also indicate the title of the invention.

The Receiving Section examines whether the applicant has filed the abstract within the context of the examination as to formal requirements (Art. 91(1)(c)). If there is no abstract among the filed documents, a period of at least two months is given to file the abstract (R 41(1), R 84). If the applicant fails to remedy this failure within this period, the Receiving Section refuses the application (Art.91(3))

²⁴⁴ The drawing is accorded the same significance when addressing the question of disclosure of the invention as the other parts of the application (T 169/83, O.J.EPO 1985, 193)

²⁴⁵ The EPO has given some additional information on drafting the abstract in O.J.EPO 1979, 293.

3.8.4. Description and Sufficiency

R 27(1) defines the content of a description of a European patent. This rule ensures that the technical information in the application should be sufficient for the skilled person to put the invention into practice as required by Art.83 EPC and to enable a reader to understand the contribution to the art.

The description must disclose an invention which satisfies Art. 52 EPC “requirements for patentability”, provide a sufficient disclosure of how to carry out the invention (Art. 83 EPC), support the claims (Art. 84 EPC).

R 27(1) stipulates the content of the description as follows :

- the technical field of the invention;
- the prior art;²⁴⁶
- a disclosure of the invention facilitating the identification of the problem and the solution to said problem;
- a brief description of the figures and drawings;
- description of at least one way of carrying out the invention;²⁴⁷
- how the invention is capable of industrial exploitation.

Failure to act in accordance with R 27(1) may amount to the refusal of the European patent application under Art. 97(1) EPC. Although R 27(1) has a mandatory character, a departure is permitted under R 27(2) to the extent that, owing to the nature of the invention, a different manner or a different order would afford a better understanding and a more economic presentation.

Art. 83 EPC stipulates that a European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a

²⁴⁶ An applicant must indicate explicitly the background art known to him by mentioning it and/or quoting documents which reflect it (T 11/86, O.J. EPO 1983, 479). This information facilitates understanding the invention and is particularly necessary to an objective assessment of the problem. Not only the documents which are known to the applicant but also those documents which are identified in the course of proceedings are included under the prior art (T 11/82, O.J.EPO 1983, 479, established case law)

²⁴⁷ Where appropriate, the description should use examples and refer, if necessary , to drawings. For example where a new technical method is disclosed, a single example may be sufficient to enable the skilled person to achieve the desired effect for the whole range claimed (T 292/85, O.J.EPO 1989, 275)

person skilled in the art²⁴⁸ using his common general knowledge²⁴⁹ without undue burden. The invention is then reproducible. The decisive point in determining the sufficiency of the disclosure is that a person skilled in the art must be able to perform the claimed invention, either on the basis of the information in the application on its own, or supplemented when appropriate by information which is part of the common general knowledge of such skilled person.²⁵⁰ The disclosure of an invention is only sufficient if the skilled person can reasonably expect that substantially all embodiments of a claimed invention can be put into practice.²⁵¹

In some cases it has been held that an invention is sufficiently disclosed if at least one way is clearly indicated enabling the skilled person to carry out the invention.²⁵²

Exact repeatability of a process is not required. As long as the description of the process enables the invention to be put into practice, there is no lack of sufficiency.²⁵³

The disclosure of the invention is one of the requirements for patentability. Due to lack of disclosure, a European patent may be revoked in national proceedings under the law of a Contracting State with effect for its territory, under Art.138(1)(b) EPC.

Anyone who alleges that the invention cannot be carried out has the burden of proof. Since mere allegations do not suffice, the opponent should submit the proof by presenting comparative tests.²⁵⁴

²⁴⁸ “Person skilled in the art” means the average skilled person who is expected to have the same qualifications as the relevant skilled person referred to under Art.56 for assessing inventive step (T 60/89 O.J.EPO 1992, 268)

²⁴⁹ Information which can only be obtained after a comprehensive search is not to be regarded as part of common knowledge. (T 206/83 O.J. EPO 1987, 5). Known source materials such as encyclopedias and common reference works are for example included under general knowledge.

²⁵⁰ Paterson, A Concise Guide to European Patents, p.88-89

²⁵¹ T 292/85 O.J. EPO 1989, 275; T409/91, O.J. EPO 1994, 653.

²⁵² T 292/85 O.J.EPO 1989, 275.

²⁵³ Paterson, A Concise Guide to European Patents, p.91 “Generally applicable chemical or biological processes are not insufficiently described for the sole reason that some starting materials or genetic precursors, e.g. a particular DNA or a plasmid, are not readily available to obtain each and every variant of the expected result of the invention, e.g. the product, provided the process as such is reproducible (T 292/85 O.J. EPO 1989, 275).

²⁵⁴ T 182/89, O.J.EPO 1991, 391, with further references; T 16/87, O.J.EPO 1992, 212

Not only the description but also other parts of the application, i.e. the claims and the drawings (Art.78(1) EPC) may also contribute to the disclosure. The abstract and the priority documents²⁵⁵ are not the place for disclosure.

The disclosure of the invention must take place in the original documents of the application since the disclosure on the date of filing defines the content of the European patent application. Later additions to the disclosure are not admissible pursuant to Art.123(2) EPC because they constitute an extension of the content. Such later additions also provide grounds for opposition and revocation (Art.100(c), Art.138(1)(c) EPC). On the other hand it is not possible to remedy deficiencies in the disclosure unless an amendment of the claims makes it possible for the disclosure to be examined on a different basis.

The disclosure of the invention must enable a person skilled in the art to understand the problem and its solution and to carry the invention out. In case of a product it must be possible to produce it. The starting material must be available or made available by the applicant and the production process must be known to him or disclosed in the application.²⁵⁶ In the case of a process, the means for the process and the steps of the process belong to the disclosure.

According to R 28(1); in inventions involving new strains of micro-organisms, an applicant is obliged to deposit biological material which can not be described in writing in the patent application with a recognised depositary institution. The object of such a deposit is to enable skilled person to carry out the invention.²⁵⁷ The applicant should deposit the sample with a recognised depositary institution²⁵⁸ no later than on the date of filing the application.²⁵⁹ Upon request, the biological material can be

²⁵⁵ G 11/91, O.J.EPO 1993, 125

²⁵⁶ In the case of product claims in the field of biology, a sample of biological material may be made available to the public in accordance with R 28 (Deposit of biological material).

²⁵⁷ Singer / Stauder, EPC, Vol.1, p.372 "... The deposit is an alternative to the description. It is not a formal requirement. The deposit of the biological material is only required when the material mentioned is necessary to carry out the invention (T 418/89, O.J.EPO 1993, 20)"

²⁵⁸ The applicant should identify the depositary institution and the accession number of the deposited biological material.

²⁵⁹ A recognised depositary institution can be an international depositary authority under the Budapest Treaty, which the EPO applies (see O.J.EPO 1980, 380) or an institution in accordance with R 28. The depositary institutions recognised by the EPO are published annually in the Official Journal in the Synopsis of the territorial field of application of international patent treaties.

made available to third parties as of the day of publication of the European Patent application provided that the third parties use it only for experimental purposes.

3.8.5. The claims

A specification is a very important document in a patent application which should contain a description of the invention, one or more claims together with any drawings needed to illustrate the invention.²⁶⁰ The construction of claims can not be considered in isolation from the rest of the specification. The direction of Art.69 EPC is that description and drawings are to be used to interpret the claims of the granted European patent.

Art. 84 EPC prescribes that the claims must define the matter for which protection is sought. This article is supplemented by R 29.

A European patent application shall include a statement of the claims defining the invention for which protection is required. The extent of protection conferred by a European patent is determined by the terms of the claims. R 29(1) states that the claims must define the matter for which protection is sought in terms of the technical features of the invention. These technical features may be structural or functional. While defining technical features, references may only be made to the description or the drawings in compliance with R 29(6) if it is absolutely necessary, i.e. if the information contained in the claims does not suffice to define the scope of protection sought in a clear manner.²⁶¹ The English practice of conventional claims including a general reference back to the description is not allowed.

Under R 29(1), where appropriate; a claim must consist of two parts: the preamble and a characterising portion. It is deemed to be appropriate where the clearly defined state of the art and the claimed subject matter can be distinguished by

²⁶⁰ Bainbridge, p.328

²⁶¹ Singer / Stauder, EPC, Vol.1, p.381 "If the application contains drawings, the technical features mentioned in the claims should be followed by reference signs."

way of additional technical features.²⁶² The preamble consists of the designation of the subject-matter of the invention and the technical features required for the definition of the claimed subject-matter, which are known from the prior closest art. The characterising portion contains other features for which protection is sought (R 29(1)(a) and (b)) .

Claims may be written in independent form or may refer back to an earlier claim. As stated by Rule 29(3), an independent claim must contain all essential features of the invention for which protection is sought. These essential features must distinguish the invention from the closest prior art²⁶³ and enable a skilled person to carry out the claimed process or define the claimed product. This independent claim may be followed by one or more dependent claims concerning particular embodiments of that invention. In accordance with R 29(4), a dependent claim must contain by way of reference all features of another claim and then state additional features for which protection is sought in connection with the other claim. Claims which are dependent on a dependent claim are also admissible. If a main claim is novel then so is any claim depending upon it, even if the additional feature in the dependent claim may itself be obvious.

Chemical products are characterised by their structural formula, as the product of a process or by way of their properties.²⁶⁴

The formulation of the claims may be amended before or during the procedure for substantive examination under Art.123 EPC provided that such an amendment does not extend the subject-matter of the application.

Generally two types of claiming; “fence-post” claiming and “sign-post claiming” are favoured by patent systems. Sign-post claims intend for specifying the essential inventive concept in the specification and distinguish what’s new from what’s old. In

²⁶² T 13/84, O.J.EPO 1986, 253.

²⁶³ T 1055/92, O.J.EPO 1995, 214.

²⁶⁴ Singer / Stauder, EPC, Vol.1, p.379 “Parameters are measured values of the properties of a substance. They may be used to characterise the substance if another definition is not possible or not appropriate and the parameter can be clearly and reliably determined using common methods (T 94/82, O.J.EPO 1984, 75). Unusual parameters can present competitors with unreasonable difficulties in assessing the protected subject-matter and are possibly employed to disguise lack of novelty”

the European patent system, the “fence-post” method has been chosen. Fence-posts are set by the use of words, chemical and mathematical symbols and by reference to drawings. According to Art.69(1) EPC; the extent of protection is fixed by “the terms of the claims”²⁶⁵ using the description and drawings to interpret them.²⁶⁶

A set of valid claims which give the widest scope to the invention creates an ideal situation for an applicant.²⁶⁷

While drafting a patent application, a patent attorney should consider the limitations imposed by the prior art at the time of drafting and claim each invention as broadly as possible.²⁶⁸

Under R 29(2) categories of claims are mentioned as product, process, apparatus or use. Furthermore R 29(2) states that a European patent application may contain more than one independent claim in the same category provided that the subject-matter of the application involves a plurality of inter-related products; different uses of a product or apparatus or alternative solutions to a particular problem, where it is not appropriate to cover these alternatives by a single claim. The applicant should also comply with the principle of unity of the invention under Art. 82 EPC.

The basic distinction is between product or substance claims and process, method or use claims. The first category concerns claims to things and the rights conferred on the proprietor are infringed by means of making, selling and using the things claimed. The second category contains procedures for conducting activities and the rights are infringed by third parties through performing the activity.

²⁶⁵ Visser, p.101 “The English version of Art.69 (1) refers to ‘terms’, whereas the German version refers to ‘Inhalt’, suggesting a broader interpretation”.

²⁶⁶ Cornish / Llewelyn, p.166. “The Protocol on the Interpretation of Art.69 (of the Convention) requires Art.69 to be read as defining a middle position which combines a fair protection for the patentee with a reasonable degree of certainty for third parties.”

²⁶⁷ Bainbridge, p.330 “Patent agents use language designed to maximise the protection afforded by the patent when granted.”

²⁶⁸ Grubb, p.311 “It is always better to start out with claims which are too broad rather than too narrow, so long as basis exists in the specification for the restrictions which may have to be made when new prior art is found, or when the inventor finds that part of his invention does not work”.

If an applicant cannot characterise a product by its composition, structure or other verifiable parameters, the applicant has an option of defining the product by way of the process for its preparation. This is called "product-by-process claims".²⁶⁹ This is also applicable to living matter as a product of a biological process.²⁷⁰ Under European Law, product-by-process claims are allowable provided that the product is patentable per se and can only be defined by its method of production.²⁷¹

Claims must be clear and concise for a third party.²⁷² This condition is sought for the choice of the category of the claims, the terminology, the number and order of the claims. Consistent terminology should be used throughout the description and claims. Clear formulating provides competitors with legal certainty for estimating what type of uses infringe the patented invention.

Disclaimers are used to remove a particular subject-matter explicitly from the content and protective scope of the claims. Under European Law, the use of disclaimers is allowed to distinguish the subject-matter of the invention from a citation which is damaging novelty or to exclude non-inventive variants or variants which are not industrially applicable.²⁷³

In conformity with R 29(1); disclaimers define the area which is not intended to be covered by the claim. Disclaimers can only be allowed if they serve to the formulation of claims in the most concise definition. Disclaimers are admitted as a part of consistent practice in order to establish novelty²⁷⁴ since an applicant may not be able to recognize conflicting issues under Art.54(3) EPC at the time of preparing his application.

Art. 52(4) and 54(5) EPC prescribe special rules concerning the formulation of claims for the protection of pharmaceuticals..

²⁶⁹ T 150/82, O.J.EPO 1984, 309; T 219/83, O.J.EPO 1986, 211; T 248/85, O.J.EPO 1986, 261.

²⁷⁰ T 320/87, O.J.EPO 1990, 71.

²⁷¹ Grubb, p.308, T 219/83, O.J.EPO 1986, 211, Basf/Zeolites.

²⁷² EPO Guidelines, C III.4.

²⁷³ Hansen / Hirsch, p.177.

²⁷⁴ T 4/80, OJ 1982, 149; T 170/87, OJ 1989, 441

Patents are also available for second uses of known substances or compositions for medicinal use. However, great care must be taken in drafting the claims in such cases. A certain form of claims has become widely acceptable, known as a “Swiss type claim”.²⁷⁵

A typical claim for a first medical use of a known product might take the form:
Substance or composition X,...

...for use as a medicament
... for use as an antibiotic; or
... for use in treating disease Y.²⁷⁶

According to R 29(5); the number of claims must be reasonable in consideration of the nature of the invention. A multiplicity of trivial claims will be objected to. Also a large number of claims amounts to payment of high claim fees since Rule 31 prescribes that a fee is to be paid for each claim from the eleventh claim onwards.²⁷⁷

The claims must be supported by the description. The claims and the description should be consistent with each other, so that the claims may be interpreted on the basis of the description. If they are inconsistent, the description must be adjusted to the claims or vice versa . The scope of the claims should not go beyond the scope justified by the description and the drawings.²⁷⁸

3.9. Amendment

Art. 123 EPC and Rules 86 to 88 EPC²⁷⁹ govern the amendments of the description, claims and drawings of a patent application or patent, which can be

²⁷⁵ Bainbridge, p. 330-331 “ In Eisai ([1985] OJ EPO 64), the Enlarged Board of Appeal approved such a type of claim, which normally takes the form:

Use of a substance or composition X for the manufacture of a medicament for a specified new and inventive therapeutic application.

²⁷⁶ Bainbridge, p.331

²⁷⁷ The amount of claim fees is set out in Art.2 No.15 Rules Relating to Fees.

²⁷⁸ Singer / Stauder, EPC, Vol.1, p.391-392 “...The scope of the patent monopoly defined in the claims must correspond to the applicant’s contribution to the prior art (T 409/91, O.J.EPO 1994, 653)”

²⁷⁹ R 86 (Amendment of the European patent application) lays down temporal limits.

carried out both after filing and after grant. Art. 123(1) states that in any case an applicant or a patent proprietor shall be allowed at least one opportunity of amending the description, claims and drawings of its own volition.

It is not possible for an applicant to have a full knowledge of all prior art or the ways in which the invention may be carried out, at the time of drafting his application. An applicant becomes aware of the prior art after the receipt of the search report or in the course of the examination or opposition proceedings. The third parties may take advantage of this situation and challenge the validity of a patent by alleging the lack of inventive step. Therefore an amendment offers a unique possibility of meeting the objections of the EPO in grant and opposition proceedings, especially curing invalidity, having regard to previously prior art.

Amendments must be distinguished from “corrections” which clarify a technical teaching rather than amending it and also from “disclaimers” which define the area which is not intended to be covered by the claims.²⁸⁰

Where a patent application contains several different subject-matters, the applicant is not allowed to incorporate any subject-matter which neither forms a single general inventive concept with the subject-matter searched, nor has been the object of a search itself. The applicant is not allowed to continue his application with regard to subject-matter for which no search fee has been paid and no search has been performed.

An applicant may not make any amendments to the application documents that constitute the disclosure of the invention until the receipt of the search report. An applicant has the opportunity to amend his application in two instances: after receipt of the search report to adapt the application to a closer state of art and after receipt

R 87 (Different claims, description and drawings for different states) deals with prior rights.

R 88 (Correction of errors in documents filed with the European Patent Office) deals with corrections.

R 89 (Correction of errors in decisions) deals with the extent of permitted correction of errors in decisions.

R 57a (Amendment of the European patent) deals with amendments which shall be considered admissible in the course of opposition proceedings. As long as these amendments correspond with the grounds set out in Art. 100 EPC they do not have to be evoked by the opponent.

Examination Guidelines A, V 2; C, VI 5; D, V 5.2; VI 6 and E, II.

²⁸⁰ Hansen / Hirsch, p. 156.

of the first communication of the examiner in response to his arguments.²⁸¹ According to R 86 (3); no further amendments can be made to the description, patent claims and drawings without the consent of the Examining Division.²⁸²

If the patent claims have been amended before the termination of the technical preparations for publication of the application (up to 7 weeks before the expiry of 18 month period after the filing or priority date of the European patent application), the amended claim will be included in the publication (R 49(3)).

The boards of Appeal may also exercise their discretionary power in accordance with R 86 (3), second sentence in respect of requests made for amendments. It would be much better to request amendments as soon as possible during the appeal proceedings, e.g. in the statement of grounds of appeal. The amendment must be essential for the application and its admissibility must be obvious to a great extent.²⁸³

An amendment may relate to an amendment of addition, replacement or deletion. In many cases the purpose of making an amendment is to cut down the scope of what is claimed. As a result of such an amendment, the broadest claim may be deleted; or features of subsidiary claims may have to be added to it; or claims for different aspects of the invention may have to be united.²⁸⁴

Art. 123(2) EPC limits the amendments so that extension of the subject-matter beyond the content of the application is not allowed.

As prescribed in Art.123(2) EPC, an amendment shall be allowable as long as the amended application or the amended European patent do not contain subject-matter which extends beyond the content of the application as filed. The technical information existing in the originally filed application documents delimit the boundaries of the content. This principle applies both in pre-grant and in post-grant

²⁸¹ Visser,, p. 246.

²⁸² Singer / Stauder, EPC, Vol.2, p.474 “Pursuant to G 7/93, O.J.EPO 1994, 775, the Examining Division may permit amendments right up to the issue of the decision to grant”.

²⁸³ Singer / Stauder, EPC, Vol.2, p.477.

²⁸⁴ Cornish / Llewelyn, p.163.

(i.e. opposition) proceedings before the EPO. A possible extension of subject-matter must be assessed with respect to the content only of the application as filed.

In order to determine the allowability of an amendment, we have to check the components of the application as filed. In accordance with Art.80 EPC, the content of the application as filed (within the meaning of Art. 123(2) EPC) shall include;

- an indication that a European patent is sought;
- the designation of at least one Contracting State and information identifying the applicant;
- a description and one or more claims.

The description of the invention, the patent claims and the drawings are decisive for the disclosed content of the application. The content of the application as filed (within the meaning of Art. 123(2) EPC) does not include the abstract,²⁸⁵ the priority documents even filed together with the application²⁸⁶ and the contents of the documents to which reference is made in the description,²⁸⁷ i.e. cross-referenced documents.²⁸⁸

An amendment is not allowable if the resulting change in the content of the application is novel when compared with the content of the original application. No new subject matter must be generated by the amendment.²⁸⁹

An amendment may give rise to either claim broadening or claim narrowing:

- (i) Claim broadening (extension of patent claims by deletion of a feature) : An applicant may delete a technical feature from a claim in order not to

²⁸⁵ T 246/86, O.J. EPO 1989, 199.

²⁸⁶ T 260/85, O.J.EPO 1989, 105.

²⁸⁷ T 689/90, O.J. EPO 1993, 616.

²⁸⁸ Visser, p. 247 “By way of exception, features only described in a cross-referenced document can be introduced in an amendment if the description as filed leaves no doubt to the skilled reader that (a) protection may be sought for such features; (b) such features contribute to achieving the technical aim of the invention; (c) such features implicitly clearly belong to the description as filed; and (d) such features are precisely defined and identifiable in the reference document (T689/90).”

²⁸⁹ T 201/83 O.J. EPO 1984, 481.

exclude certain embodiments from the protection.²⁹⁰ Such a broadening of the claim by deleting a technical feature is allowable under Art. 123(2) EPC as long as the subject matter which is within the claims for the first time as a result of the amendment was already part of the content of the original application as filed.²⁹¹ It is not allowable to delete features from an independent claim that are presented as essential feature in the originally filed application. T 331 / 87, O.J.EPO 1991, 22 is considered as a landmark decision. It was held that the removal or replacement of a feature from a claim did not contravene Art.123/2 EPC when the skilled person can recognize that the feature is not explained as essential in the disclosure and is not indispensable for the functioning of the invention and the replacement or removal requires no real modification of other features to compensate for the change.²⁹²

In order to comply with Art. 123(2) EPC, such an amendment should have the same meaning as the unamended claim on its true construction in the context of the specification.²⁹³

- (ii) Claim narrowing : If an applicant adds a feature to a claim, he will narrow the protection sought. Such an addition is allowable under Article 123(2) EPC unless it causes the subject matter of the application to be extended beyond the content of the application as filed. According to established case law of the boards of appeal; incorporation of a feature into a patent claim is admissible, if it is seen as a part of the invention as originally filed.²⁹⁴

If the particular feature which is proposed to be added to a claim is a component which has only been disclosed in the application as filed in association with another component, and there is nothing in the application

²⁹⁰ Visser, p. 123 “The deletion of a feature in a claim is allowable and required, if it clarifies the claim and removes an inconsistency (T 172/82, O.J.EPO 1983, 493). A specific feature may not be replaced by a general expression, when such an expression introduces special features from an independent claim that are presented as essential in the description (T 260/85)”

²⁹¹ Paterson, A Concise Guide to European Patents, p.105.

²⁹² Singer / Stauder, EPC, Vol.2, p.488-489.

²⁹³ T 271/84, O.J. EPO 1987, 405.

²⁹⁴ Singer / Stauder, EPC, Vol.2, p.490, T 169/ 83, O.J.EPO 1985, 193.

as filed to indicate that the invention could consist of a device having the first such component but not the other component, the amendment will not be allowable.²⁹⁵ On the other hand even if the proposed additional feature is a component which has only been described in the application as filed in association with other components, the amendment will be allowable provided that it is evident to a skilled reader of the application as filed that the combination of features in the amended claim produces the result sought in the application, and is therefore a disclosed embodiment of the invention (T 17/86, O.J. EPO 1989, 297).²⁹⁶

Moreover the amended claims should still satisfy the basic rules that they must be clear and concise, be supported by the description and satisfy the requirement of unity of invention.

Examination Guidelines C, VI, 5.4 states that the amended European patent application may not contain anything that is not directly and unambiguously derivable from the originally filed application documents. The knowledge of the person skilled in the art is taken as basis while assessing what is disclosed directly and unambiguously disclosed in a European patent application.²⁹⁷

An amendment shall not be admitted if it generates subject-matter that is novel with regard to the originally filed application.²⁹⁸ Every amendment is to be subjected to similar factors as are involved in the examination of the novelty of a patent claim.²⁹⁹

It is allowable to correct a wrong calculation in a claim under Art.123(2) EPC if a skilled reader regards the amendment as clearly implied by the disclosure of the application as filed.

²⁹⁵ T 54/82, O.J. EPO 1983, 446.

²⁹⁶ Paterson, A Concise Guide to European Patents, p.106.

²⁹⁷ Singer / Stauder, EPC, Vol.1, p.482 "...who is the same as the skilled person involved in the assessment of an invention in accordance with Art.56."

²⁹⁸ T 201/83, O.J.EPO 1984, 481.

²⁹⁹ T 133/85, O.J.EPO 1988, 441.

Under Art. 123(1) EPC, amendments to the description are also allowable. The description must not be amended so as to introduce matter extending beyond that disclosed in the specification as filed . This applies whether the amendment is sought during the application or after. If such an amendment is improperly allowed after grant, this may constitute a ground for revocation of the patent in whole or in part.

Addition of reference to a prior art does not contravene Art. 123(2) EPC. On the other hand subsequent clarification or explanation in the description does not contravene Art. 123(2) EPC if a technical feature is disclosed in the application as filed, and its technical effect is not mentioned in the application as filed but can be deduced from such application using the common knowledge of the skilled person in the art.

According to Rule 57 a, the description, the patent claims and the drawings may be amended in the course of opposition proceedings provided that they are occasioned by the opposition grounds laid down in Art.100 EPC without having to be invoked by the opponent.

According to Rule 87, if amendments have to be made due to prior national rights in respect of one or more designated Contracting States, these shall be admissible in opposition proceedings although prior national right is not mentioned among the grounds of opposition in Art.100 EPC.³⁰⁰

R 57 a entered into force on 1 June 1995 and incorporated the case law of the board of appeal (T 127, 85, O.J.EPO 1989, 302; T 406/86, O.J.EPO 1989, 302; T 295/87, O.J.EPO 1990, 470).³⁰¹ R 57 a renders amendments admissible which actually set aside a ground of revocation which could be raised in revocation proceedings in designated Contracting States.

³⁰⁰ R 87 (Different claims, description and drawings for different States) If the European Patent Office notes that, in respect of one or more of the designated Contracting States, the content of an earlier European patent application forms part of the state of the art pursuant to Art.54, paragraphs 3 and 4 or if it is informed of the existence of a prior right under Article 139, paragraph 2, the European patent application may contain for such State or States claims, and, if the European Patent Office considers it necessary, a description and drawings which are different from those for the other designated states.

³⁰¹ Singer / Stauder, EPC Vol.2, p.475.

Art.123 (3) EPC provides that the claims of the European patent may not be amended during opposition proceedings in such a way as to extend the protection conferred.³⁰² In order to assess if an amendment extends the protection conferred, we have to consider the scope of protection conferred by the patent before the amendment. The scope of protection before the amendment is determined by the terms of the claims and the description and drawings that are used for interpreting the claims. (Art. 69(1) EPC).

If amendments after grant alter claims so as to extend the scope of protection, they may provide a cause for revocation.

A proposed amendment may involve a change of category, or a change in the technical features of the invention, or both.³⁰³ An amendment by way of change of category; e.g. “product” to “use”³⁰⁴ or “method of working” to “apparatus”³⁰⁵ for such a method, is only exceptionally allowable under Art.123(2) EPC.

An inconsistency can be clarified through amendment of a claim and such an amendment does not infringe Art. 123(3) as long as the amended claim has the same meaning as the unamended claim.³⁰⁶

European Patent Office has the authority to correct errors of translation, transcription, clerical errors and mistakes in all documents. In the case of specifications; R 88 allows the correction of linguistic errors, errors of transcription and mistakes in the description, claims or drawings provided that such a correction is

³⁰² Art. 138 EPC prescribes the grounds for revocation of a European patent under national laws. Art. 138(1)(c) and (d) correspond to the requirements of Art.123(2) and (3). Infringement of par. 2 and par.3 justify the revocation of the European patent by a national court.

³⁰³ The subject-matter of an invention involves the category of the claim and the technical features. “Category” is used to distinguish between a “compound” or “composition” claim (i.e. physical entity) and a “use” claim or a “process” claim (i.e. physical activity). Technical features contribute to technical subject-matter of an invention.

³⁰⁴ Paterson, A Concise Guide to European Patents p. 110, “...A claim to the use confers less protection than a claim to the product since a claim to a particular use of a product is a claim to the compound only when it is being used in the course of the particular physical activity.” Such an amendment is not open to objection under Art. 123(3) EPC (G 2/88, O.J. EPO 1990, 93).

³⁰⁵ In case T 378/86 O.J. EPO 1988, 386, such an amendment was allowed since it was held that a skilled person could deduce the apparatus suitable for carrying out the protected process from the technical teaching defined in the patent, and that the extent of protection conferred by the granted patent also encompassed the apparatus for carrying out the protected process.

³⁰⁶ T 271/84 O.J. EPO 1987, 405.

obvious in the sense that it is immediately evident that nothing else would have been intended than what is offered as the correction. R 88 allows corrections to any other document filed at the EPO. Corrections under R 88 have declaratory effect and do not contravene Art.123(2) EPC as long as they are within the limits what a skilled person would derive from these documents as filed by using his common knowledge. The mistake may relate to an incorrect statement or it may result from an omission. The mistake and its correction must be obvious to the skilled person using his common general knowledge.

3.10. Patentable Subject-Matter

Art. 52(1) EPC prescribes that patentable inventions must be capable of industrial application, new and involve an inventive step. Each of these positive requirements are defined in the subsequent articles of the Convention one by one. Most of the Contracting States to the European Patent Convention have incorporated the basic requirements stated in Art.52 EPC into their national legislation.³⁰⁷

Art.52 (2-4) and 53 EPC describe unpatentable subject-matter, either by way of exclusion (Art.52) or by way of exception (Art.53).

As a general principle , a European patent is to be granted for any invention assessing above mentioned positive requirements.³⁰⁸ Exceptions to this general rule should be interpreted narrowly. Although the TRIPS Agreement is not directly applicable to the EPC, the principle in Art. 27(1) of TRIPS stating that inventions from all fields of technology should be patentable without exception, applies.

European patent protection can be conferred upon all fields of technology in its broadest meaning such as chemical products, pharmaceuticals, foodstuffs, inventions in the field of biology, electronics, recent developments in biochemistry,

³⁰⁷ The Swiss legislature did not adopt the negative catalogue set in Art. 52(2)-(4).

³⁰⁸ Exceptions to this general principle should be interpreted narrowly (see G 1/83, G 5/83, G 6/83, OJ 1985, 60, 64 and 67 – Second medical indication-point 22 with reference to the identical view of the German Federal Court of Justice)

gene technology and computer science unless they are expressly excluded from protection by EPC provisions.

The EPC does not give a full definition of an invention as a concept. It only includes a negative non-exhaustive catalogue set in Art.52(2)-(4) EPC stating what cannot be considered as an invention.³⁰⁹ Important indications relating to the concept of invention can be found in various articles of the EPC such as Art.54(1) and Art.56³¹⁰ and the implementing regulations such as R 27(1)(a),(c) and R 29(1).

In order to be patentable, the invention must have a technical character and solve a technical problem. The claimed invention may consist of both technical and non-technical elements. The existence of non-technical elements does not affect the patentability of the invention adversely since a claimed invention must be considered as a whole. An invention lacking technical features is not patentable, e.g. a claim defining essentially a business operation is not patentable although it includes steps which include a technical component.³¹¹

An invention does not have to be a technical advance or useful to be patentable. Technical advance and utility do not count as requirements for patentability.

Art. 52(2)-(4) includes a non-exhaustive list excluding certain objects from patentability. These exceptions should be interpreted narrowly. There is a difference in the wording between paragraphs (2) and (4).

- The subject matters set out in paragraph (2) (a) to (d) are excluded because they have been regarded as more in the nature of ideas and activities which do not aim at any direct technical results. They lack technical character and industrial applicability and therefore they do not provide a technical contribution to the art. For example the discovery of X-rays can not be protected by patents since it is not regarded as an invention. If other

³⁰⁹ Ali Necip Ortan, Avrupa Patent Sistemi, Cilt I, Avrupa Patenti Antlaşması (Münih Antlaşması), Banka ve Ticaret Hukuku Araştırma Enstitüsü, Ankara, 1991p.68.

³¹⁰ Singer / Stauder, EPC, Vol.1 p.69 "... the state of art that forms the basis for the assessment of an invention."

³¹¹ Paterson, A Concise Guide to European Patents p.117.

requirements for patentability are fulfilled, the production and application of X-rays can be patentable.³¹² The exclusion in paragraph (2) may be generalised as subject-matter which is essentially abstract in character, non-physical and can not be characterised by technical features in the sense of Rule 29(1) EPC.³¹³ The wording of Art.52 (2) “in particular”, signifies that the subject-matter which is similar in nature to the defined categories can also be excluded.

- The methods set out in paragraph (4) are excluded from patentability because they lack industrial application. Even if they would have been capable of being applied industrially, they may not be considered patentable as a matter of policy. The policy behind this exclusion is to ensure that physicians who carry out such methods in treating humans and animals should not be impeded by patent monopoly.

Even though agricultural methods are susceptible of industrial application under Art.57 EPC, the particular methods defined in Art.52(4) EPC are excluded from patentability. For particular methods defined in Art.52(4) EPC, Art.52(4) EPC takes priority over Art.57 EPC.

3.10.1 Discoveries, Scientific Theories and Mathematical Methods (Art.52(2)(a) EPC)

Discoveries, scientific theories and mathematical methods do not fall within the scope of patentable subject-matter since they lack technical character. They usually constitute the basis for the patentable inventions.

A mathematical method is carried out on numbers and provides a result in numerical form. No direct technical result is produced by the method as such. A claim directed to a technical process in which a mathematical method is used can be patentable provided that the process is carried out on a physical entity.

³¹² Ortan, p. 68.

³¹³ T 163/85 O.J. EPO 1990, 379.

It is only the discovery of a technical application of the discovery, theory or method that can be patented as an invention. This principle is restricted in the case of newly discovered substances whose existence were unknown previously and whose structures and parameters are described for the first time.

Finding a substance freely occurring in nature is a mere discovery. If a process is used for isolating for such a substance from its surrounding, this process is patentable.³¹⁴

3.10.2 Aesthetic Creations (Art.52(2)(b) EPC)

The aesthetic effect of a creation is an intellectual property right. Such an aesthetic effect contributes nothing technical. Aesthetic creations fall within the scope of copyright or industrial design protection.

Technical solutions can have aesthetic effects. If the effects address the sense of shape and colour, they can not be capable of establishing a patent since they do not result in a technical advantage.

A process for producing an aesthetic creation may be patentable if it comprises a technical innovation.³¹⁵

3.10.3 Schemes, Rules and Methods for Performing Mental Acts, Games and Doing Business (Art.52(2)(c) EPC)

These instructions are not patentable due to lack of technical character. The decisive factor is whether an invention makes a contribution to the field of technology.

³¹⁴ Visser, p.44 “Moreover if the substance can be characterised by either its structure, by the process by which it is obtained or by other parameters and it is new in the absolute sense of having no previously recognised existence, then the substance per se may be patentable.”

³¹⁵ Visser, p.44 “Under the new practice a claim containing at least one technical feature will not be excluded under Art.52 (2); in the examination of inventive step any non-technical features will be disregarded.”

Instructions to users are not patentable. In one of his decisions, the Technical Board of Appeal regarded an instruction to bank customers to use their identification cards in a certain manner in a known automatic teller machine as a method for doing business since it does not have a technical character.³¹⁶

Methods of doing business which relate to technical means such as computer networks for carrying out a method or inventions which solve a technical program are regarded as patentable.

An invention related to the designing of chips was denied patent protection.³¹⁷ A patent was granted for the physical manufacture of chips.

An apparatus for carrying out a method of doing business is not excluded from patentability.

The solution to linguistic problems using a computer is not patentable since the automation of word processing does not make a contribution to the field of technology.³¹⁸

Summarizing of a document, the storing of the summary and the retrieval by means of a search query fell within the scope of Art.52(2)(c) EPC.³¹⁹

3.10.4 Computer programs / Computer-related Inventions (Art.52(2)(c) EPC)

The electronic hardware of computing technology is a natural subject for patentable invention. However, software poses considerable problems. Computer programs are excluded from European patent protection under EPC.³²⁰

³¹⁶ T 854/90, O.J.EPO 1993, 669.

³¹⁷ T 453 /91 of 31 May 1994.

³¹⁸ T 38/86, O.J.EPO 1990, 384.

³¹⁹ T 22/85, O.J.EPO 1990, 12.

Computer programs are only patentable if they have a technical effect, which in itself must involve an inventive step.³²⁰ A claimed process including a computer program is not patentable if it does not amount to any effect on the physical or technical functioning of a device and solve a technical problem.

The first milestone case in this field was VICOM and X-ray apparatus.³²² The Board of Appeal decided for the patentability of a method for the digital processing of images in the form of a two-dimensional data field with elements arranged in lines and columns, and a device to execute this method. The idea of the invention was based on a mathematical method that was used to execute a computer program. In this leading case the Board of Appeal assured that a claim to a known computer is admissible and capable of protection if the computer is prepared in such a way that it controls or executes a new technical method according to a specific program.³²³

A subsequent decision in case T 769/92 has extended the patentability of software beyond the line drawn by Vicom. In this case no technical means are required but only technical considerations which lend a technical feature to the invention in that they imply a technical problem to be solved by the implicit technical features.³²⁴

In most of the subsequent cases, the technical nature of the problem is regarded as sufficient to establish patentability.³²⁵

Decision T 1173/97 changed the interpretation of Art.52(c) EPC. The wording of Art.52(2) and (3) EPC together imply that not all computer programs are excluded from patent protection but 'only computer programs as such'. A computer program as

³²⁰ The term "computer program" describes basic algorithms capable of application in an indefinite number of more specific uses and also detailed instructions for the solution of particular problems.

³²¹ Visser, p. 44, T 38/86.

³²² T 208/84, OJ 1987, 14.

³²³ Singer / Stauder, EPC, Vol.1 p.73-74.

³²⁴ Visser, p.45.

³²⁵ T 26/86, O.J.EPO 1988, 19; T 115/85, O.J.EPO 1990, 30.

such is regarded as an abstract creation, lacking in technical character. A computer program having a technical effect shall be patentable.³²⁶

In T 395/94 of 15 July 1996, a method for analysing the data of the cyclical behaviour of a chart has been denied patent protection since it revealed no technical effect.

A claim directed to a technical process which is carried out under the control of a program (whether by means of hardware or software) can not be regarded as relating to a computer program as such.³²⁷

National differences in patentability of computer software give rise to inconsistencies. US approach to patentability of computer software is broader when compared to European approach. Mathematical algorithms that are applied to produce useful results are patentable in US.³²⁸ Japan has also changed his attitude in recent years. Art. 52 (2)(c) should be amended and processes implemented by software should be granted patent protection in a wider sense.³²⁹

ICC Roadmap 2004³³⁰ has emphasized that the European Commission's proposed Directive³³¹ on the patentability of computer implemented inventions should be clearer and specify the patentability of the computer programs unequivocally. It

³²⁶ Visser, p.45 "Examples of such a further technical effect are the control of an industrial process, the processing of data that present physical entities, or the control of internal functioning of a computer."

³²⁷ T 208/84 O.J. EPO 1987, 14.

³²⁸ State Street Bank v. Signature Financial Group and AT&T Corp. v. Excel Communications.

³²⁹ The Diplomatic Conference which convened to revise the EPC in 2000 objected to the removal of computer programs from the list of unpatentable subject-matter.

³³⁰ www.iccwbo.org/IP_Roadmap/, retrieved on 03.6.2005. International Chamber of Commerce-The world business organization. Intellectual Property Roadmap 2004, a guide for business and policy makers."patentability of computer implemented inventions, including business methods-Business action".

³³¹ www.europa.eu.int/comm/internal_market/en/indprop/comp/com02-97en.pdf, retrieved on 03.6.2005. Proposal for a Directive of the European Parliament and of the Council on patentability of computer-implemented inventions 2002/0047 (COD)-Explanatory Memorandum-International Competition : The Legal Situation in U.S. and Japan."...In Europe there has to be a technical contribution provided by the invention. In the U.S., the invention must simply be within the technological arts and no technological contribution is needed. The mere fact that the invention uses a computer of software makes it become part of the technological arts if it also provides a useful, concrete and tangible result. That the U.S does not require the invention to provide a technical contribution means that the restrictions on patenting of business methods (apart from requirements of novelty and inventive step) are negligible".

should overcome the conflicts over the granting of patents for computer-implemented inventions, software and business methods.³³²

3.10.5 Presentations of information (Art.52(2)(d) EPC)

The mere reproduction of information based on the performance of mental non-technical acts is not patentable. For example the colour of diskette sleeves to facilitate organisation is considered as having an aesthetic nature and as a presentation of information and it was denied patent protection.³³³

If the manner in which the information is presented includes new technical features, the method or the device for the presentation of the information may fall within the scope of patentable subject-matter. The Board of Appeal decided for the patentability of a colour television signal characterized by a technical feature since this television system was not merely the reproduction of information as such.³³⁴

3.10.6 Exclusion of Subject-matter 'As Such'

Art. 52 (3) EPC sets out an important qualification in respect of paragraph (2). Accordingly subject matters stated in paragraph (2) are excluded from patentability only to the extent to which a European patent application or patent relates to such subject matter or activities as such.

If an application consists of a subject-matter which is not regarded as an invention according to Art.52(2), it shall be unpatentable. An application relating to both technical and non-technical subject-matter is not excluded from patentability since such a mix of subject-matter involving means to solve a technical problem is regarded as an invention in the sense of EPC.

³³² For opposite view see Vincent Chiappetta, TRIP-ping Over Business Method Patents, Vanderbilt Journal of Transnational Law, Volume 37, January 2004, Number 1, p. 181, "... the current effort to expand substantive international patent law harmonization to include business method patenting is ill-conceived and unsupportable. They are not part of the existing TRIPS Agreement, and under present circumstances they should not be added."

³³³ Paterson, A Concise Guide to European Patents p. 119, T 119/8 OJ EPO 395.

³³⁴ T 163/85, O.J.EPO 1999/379.

3.10.7 Medical Treatment (Art.52(4) EPC)

Methods of treatment on the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as patentable inventions since they lack industrial application. Exclusion of medical treatment is mainly based on socio-ethical and public health considerations and it is aimed at protecting patients.³³⁵

This provision does not apply to products, substances and compositions for use in any of these methods. A new substance or composition –one that has had no previously known use- can be granted patent protection. This also applies to the selection of a specific substance or composition from a generally known class since the discovery of a specific quality justifies a claim to that thing.³³⁶

A medical treatment method can be either curative or non-curative. A curative treatment is directed to restoring or maintaining the health of the body while a non-curative treatment may include cosmetic treatment, castration, sterilisation, artificial insemination, removal of organs, embryo transplants.

The exclusion from patentability under Art.52(4) EPC applies to three types of method, irrespective of the person carrying out the method. In this sense, there should be no distinction between a therapeutic treatment of an animal carried out by a farmer or a veterinarian.

On the other hand decision T 24/91 has put emphasis on the person carrying out the treatment and made the nature of the person a decisive factor for determining exclusion. In this sense; a cosmetic treatment carried out by a doctor would also be excluded from patentability. In decision T 385/86, steps of a diagnostic method which

³³⁵ Visser, p.48 “In the not yet ratified version of the EPC of November 2000 it was decided not to uphold the (legal) fiction of lack of industrial applicability but to exclude methods in the interests of public health. It therefore moved the exclusion of medical treatment to Art.53, in which provision the methods are simply regarded as excluded from patentability.”

³³⁶ Cornish / Llewelyn, p.215-216.

could be carried out by a technician without specialist medical knowledge was not regarded as a medical treatment.³³⁷

a. Methods for Treatment by Surgery

Surgical treatment methods can be described as operations or non-bloody methods that are aimed at eliminating and curing illnesses or physical defects. Modern methods using laser³³⁸ or pressure waves are also considered as surgical treatment methods.³³⁹

Non-curative treatment methods which do not serve therapeutic purposes such as cosmetic treatment, the removal of an organ or artificial insemination are also of a surgical nature.³⁴⁰

b. Methods for Treatment by Therapy

Therapeutic treatment is a non-surgical treatment. It aims at returning a pathological condition to a healthy condition or preventing the occurrence of a pathological condition. Both prophylactic and curative treatments of disease (internal or external; temporary or permanent) constitute therapeutic treatment within the meaning of Art.52(4) EPC. Relief of pain or complaints and the reestablishment of physical performance must be regarded as therapeutic treatment.³⁴¹ Prophylactic measures used for the prevention of illnesses and disorders such as injections and vaccinations are not also patentable.³⁴² On the other hand a new application of a known vaccine can be patentable as a further medical indication.³⁴³

³³⁷ Visser, p.49.

³³⁸ Treatment of human eye with a laser is not patentable even it involves an artificial lens being placed on the cornea. (see T 24/91, O.J.EPO 1995, 512 and T 655/92, O.J.EPO 1998, 17)

³³⁹ T 182/90, O.J.EPO 1994, 641, point 2.2-2.4 explains the concept of surgical treatment in detail.

³⁴⁰ As a general rule, it is accepted that a surgical stage in the process gives a multi-stage medical treatment method a surgical character and excludes it from patentability. (see T 820/92, O.J.EPO 1995, 113, point 5.5; T 35/99, O.J.EPO 2000, 447)

³⁴¹ T 81/84, O.J.EPO 1988, 207.

³⁴² T 19/86, O.J.EPO 1989, 24. The wording of Art.52(4)EPC does not refer to prophylactic treatment. According to the established case law ; prophylactic treatment is therapeutic in nature since prophylactic and curative treatments are both aimed at the maintenance or restoration of health.

³⁴³ Singer / Stauder, EPC, Vol.1 p.80

If the non-therapeutic effect and the therapeutic effect of a step in a method of treatment are linked, a claim including the non-therapeutic effect would necessarily include the therapeutic effect and would fall under the prohibition of Art.52(4) EPC.

Cosmetic effects and medically beneficial effects of a compound may overlap . If the compound per se is already known, then in the case of a cosmetic effect, the method of treatment or use may be claimed as such. In the case of a medical effect, the further medical use may only be claimed in the form of use of a substance for the manufacture of a medicament for a specified therapeutic application. If a known substance is used both for the therapeutic treatment and the cosmetic purposes, than the cosmetic treatment can be patentable provided that in the wording of the claim, protection is sought for the cosmetic treatment but not for the therapeutic treatment as such.³⁴⁴ For example an appetite suppressant was held to be patentable due to its cosmetic effect.³⁴⁵ “Cleaning plaque/ICI” was later differentiated from this decision.³⁴⁶ EPO denied to grant patent protection to the removal of plaque from teeth since it was a way of preventing dental decay and a therapeutic effect was inevitably involved.³⁴⁷

Inventions involving physical activities carried out on a human or animal body for purposes other than therapy are patentable. A good example for such non-therapeutic methods is a method for the measurement and control of the flow of a drug-containing liquid passing through a device implemented in a human body.

c. Diagnostic Methods

A diagnosis is a determination of the nature of a diseased condition.

Diagnostic methods are also excluded from patentability under Art. 52(4). We should first of all determine whether a method has a diagnostic character or not.

³⁴⁴ Hansen/Hirsch, p.253 T 36/83, Appetite suppressant/Du Pont, O.J.EPO 1986, 195.”The fact that a chemical has both a cosmetic and therapeutic effect when used to treat the human or animal body does not render the cosmetic treatment unpatentable”.

³⁴⁵ T 144/83, O.J.EPO 1986, 301.

³⁴⁶ T 290/86 of 13.11.1990, O.J.EPO 1992, 414.

³⁴⁷ Such a treatment was directed to both improvement of appearance of the teeth and also to preventing caries. The two effects were inseparably linked and therefore the method is excluded under Art.52(4) EPC.

Methods consisting of major steps which should be carried out by medical experts, have a diagnostic character and fall within the scope of Art.52(4). Methods that do not contain any steps which require a doctor for its implementation or lead to a medical diagnosis activity or medical treatment are patentable.³⁴⁸

If a claim relates to a technical method for the function of a specific measuring device, this is not a diagnostic method intended to obtain a result from the investigation. Such investigation methods that only provide the basis for the diagnosis without establishing a relationship to the results are not considered as diagnostic methods. This means that only diagnostic methods whose results immediately make it possible to decide on a particular course of medical treatment are excluded from patent protection.³⁴⁹ Methods providing only interim measures , e.g. preliminary tests are not excluded, even if they can be utilised in making a diagnosis.³⁵⁰

If the method can be shown not to constitute surgery, therapy or diagnosis it will not be caught by this exclusion.

3.10.8 Products, Substances and Compositions used in a method Excluded from Patent Protection (Art.52(4) second sentence EPC)

Exclusion of medical treatment does not extend to products used in this treatment. Art.52 (4) second sentence states that products, substances and compositions used in excluded methods can be granted patent protection. Products used in medical methods can be defined as medicines for use in methods of therapy, tools for use in methods of surgery and devices for performing measurements in diagnostic methods. An invention consisting of a substance or composition for use in an excluded method of medical treatment remains novel, despite the fact that

³⁴⁸ Singer/Stauder, EPC, Vol.1, p.81-82 “T 655/92, OJ 1998, 17, No.5.2. last sentence. : A method is not a diagnostic method if it can be implemented by engineers themselves in order to create a basis for the doctor’s subsequent diagnostic activity.”

³⁴⁹ e.g. blood sampling.

³⁵⁰ T 384/86, OJ EPO 1988, 308.

substance or composition is known, provided that its use in any such method is not comprised in the state of the art.

There is a link between Art.52(4) second sentence and Art.54(5) EPC. According to the explicit wording of Art.52(4) second sentence, medicines are granted patent protection. If a therapeutic use of a known substance is discovered, the substance can be patented for use as a medicament. The substance derives its novelty from the new use according to Art.54(5) EPC.³⁵¹ If an inventor discovers that a substance has a quite specific field of effect, this substance qualifies for patent protection as a pharmaceutical for the first medical indication of a known substance.³⁵²

According to established case law of the Enlarged Board of Appeal; a patent can be granted for a substance already known as a pharmaceutical for all second and further medical indications.³⁵³ When deciding on various applications concerning second and subsequent discoveries of medical use, the Enlarged Board of Appeal confined the medical treatment exclusion strictly to what it described as “non-commercial and non-industrial medical and veterinary activities”³⁵⁴

Medical instruments and devices such as such as syringes and apparatus such as pacemakers³⁵⁵, heart-lung machines are patentable.

A claim relating to a method of operating a device may be excluded from patentability if a step of the method could be considered as a treatment by therapy or surgery or as a diagnostic method.³⁵⁶

³⁵¹ Visser, 55.

³⁵² T 128/82, O.J.EPO 1984, 164, points 12-14 for the first medical indication of a known substance.

³⁵³ G 1/83, G 5/83 and G 6/83-Second medical indication- OJ 1985, 60, 64 and 67.

³⁵⁴ Cornish / Llewelyn, p. 216-217 “EPC 2000, when it is implemented, will allow claims for substances for their subsequent medical use without the need to restore to the Swiss form”.

³⁵⁵ T 426/89, O.J.EPO 1992, 172.

³⁵⁶ Visser, 55-56 “For example, a claim relating to a method of controlling pulse energy in a pacemaker to prolong battery life is allowable if none of the steps of the computer program controlling the pulse has a therapeutic effect (T 789/96).”.

3.10.9 Art. 53 EPC Exceptions to Patentability

a. Ordre Public and Morality

Art.53 (a) EPC excepts from patentability inventions the publication or exploitation of which would be contrary to ordre public or morality. The concepts “ordre public” and “morality” are quite flexible terms which have to be construed narrowly.

The term ‘ordre public’ encompasses the protection of public security and the physical integrity of individuals as part of society. Inventions, the exploitation of which would breach public or social order shall be excluded from patentability.

Inventions which contradict the conventionally accepted standards of conduct are to be excluded from patentability as being contrary to morality.

Inventions which contradict the basic principles of legal order are deemed to be contrary to ordre public.³⁵⁷ This exception can be applied to all European patent applications but especially to the ones in the field of biotechnology. The EPC excludes the patentability of processes for cloning and modifying the genetic identity of human beings, genetic modification of animals and commercial use of human embryos.

The assessment of whether or not particular subject-matter is to be considered contrary to ordre public or morality is not dependent upon any national laws or regulations.

b. Plants and Animals

Art.53 (b) EPC excepts plant or animal varieties from patentability; essentially biological processes for the production of plants or animals. However microbiological

³⁵⁷ Ortan, p. 69.

processes and their products are not excluded from patentability under Art.53 (b) EPC. Methods for treating plants are also patentable.

Patents can be also granted for those uses of chemical substances in the production of plants and animals for commercial purposes.

The recent developments in biotechnology has made the determination of the scope of Art.53(b) EPC quite critical.

Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions recognizes in Art. 4(2) that patents shall be available for inventions which concern plants and animals, provided that the claims are not technically confined to a single plant or animal variety.

We must distinguish the term “plant varieties” from plants. Only plant varieties are excluded from patentability. “Plants” have been granted patent protection by the EPO in several cases.³⁵⁸ According to a definition reflected in the UPOV Convention; “plant varieties” mean a multiplicity of plants which are the same in their characteristics (i.e. homogeneous) and remain the same within specific tolerances after every propagation or propagation cycle (i.e. stable).³⁵⁹ Plants that are not stable cannot be classified as plant varieties and therefore are patentable. New plant varieties are produced by standard methods such as cross-pollination, hybridisation and grafting. These methods are not patentable under EPC since biological features take precedence over technical features

The Convention for the protection of New Varieties of Plants (UPOV) recognizes monopoly rights for new plant varieties, as provided under appropriate national rights.³⁶⁰ The protection available under the UPOV Convention is limited to

³⁵⁸ Cornish / Llewelyn, 221 “...Ciba-Geigy/propagating material: a claim to seed of any kind dressed with a defined chemical in order to make it resistant to certain weedkillers. OJ EPO 1984/112.”

³⁵⁹ Paterson, A Concise Guide to European Patents, 124 “...Plant varieties in this sense are all cultivated varieties, clones, lines, strains and hybrids which can be grown in such a way that they are clearly distinguishable from other varieties.”

³⁶⁰ The “UPOV” Convention was signed in 1961, (International Union for the Protection of New Varieties of Plants).

plant varieties, i.e. the specific products which are used in farming and gardening.³⁶¹ According to Art. 2(1) of the UPOV Convention, double protection is prohibited in respect of the rights recognised by the Convention: either a special "plant breeders right" may be granted, or patent protection, but not both.

Unlike plant varieties there is no alternative form of legal protection available for animal varieties. The patentability of animal life under EPC has to be decided on each individual case by means of interpreting sub-paragraphs (a) and (b) of Art.53 EPC and the inter-relation of these sub-paragraphs.

The existence of big national differences in patentability of biological materials is a sensitive matter. While the US allows organisms of all kinds (humans excepted) to be patented, Europe excludes patents on plant and animal varieties as a result of ethical concerns.

c. Microbiological Processes and Products

Art.53(b) EPC does not apply to micro-biological processes or the products thereof. Microbiological processes and products other than a plant or animal variety are patentable (R.23 c(c)). A microbiological process is involved or performed upon or results in microbiological material.³⁶²

A biotechnological invention is patentable if it concerns biological material isolated from its natural environment or produced by a technical process, even if it previously occurred in nature (R.23 c (a)). Such material is new because it was previously not technically available to the public.

A living matter is patentable at least at microbe level. European patents are granted for micro-organisms whether merely isolated from nature or when genetically changes, as well as for their components, i.e. specific DNA sequences, plasmids, etc.

³⁶¹ Visser, 57

³⁶² Visser, 58 "T 356/93 r.34 and 35 defines 'microbiological' as relating to technical activities in which direct use is made of micro-organisms and 'micro-organisms' as generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory."

3.11. Priority

The right of priority has the effect that the date of filing of an application will be replaced by the date of filing of an earlier application.³⁶³

A European patent applicant is entitled to claim priority for his application from the filing date of an earlier application in an individual country, party to the Paris Convention³⁶⁴ filed within the previous 12 months. An applicant should comply rigidly with the 12-month priority period. If this period is exceeded even by one day, priority will be lost. Restitutio in integrum is precluded in the event of failure to observe this period (Art.122(5) EPC). If the Convention year ends on a Saturday, Sunday or public holiday, the application may be filed on the next working day (Art.4.C(3) Paris Convention).

Priority right plays a vital role especially in respect of chemical inventions. During the 12-month priority period further compounds will be made and tested. New formulations or new process conditions shall be tried. An applicant can use all this material in subsequent patent applications to be filed abroad or in home country. The advantage would be that the new developments will then have an earlier priority date.³⁶⁵

The EPC constitutes a special agreement within the meaning of Article 19 of the Paris Convention. According to Art.19 of the Paris Convention; the Union countries may make special agreements between themselves for the protection of industrial property. Priority rights are governed by Articles 87 to 89 EPC and Rule 38.³⁶⁶ The EPC substantially adopts the provisions of the Paris Convention but it does not make a direct reference to the Paris Convention.³⁶⁷ The practice of the

³⁶³ Visser, p.140.

³⁶⁴ Convention for the Protection of Industrial Property, signed in Paris 1883, amended in Stockholm, 1967.

³⁶⁵ Grubb, 77.

³⁶⁶ The priority rules of the EPC only apply to Euro-direct applications, not to Euro-PCT applications. The priority rules of the PCT apply to Euro-PCT applications since the provisions of the PCT prevail of those of the EPC (Art.150(2)EPC).

³⁶⁷ Unlike the EPC, Art.8 PCT prescribes priority with a direct reference to Art.4 of the Paris Convention.

States party to the Paris Convention is taken into account in the interpretation of the EPC.³⁶⁸

Any first application in or for a State party to the Paris Convention confers on the applicant or his successor in title the right of priority for a subsequent European patent application. The first application may be either a national application filed within the national authorities (“filed in a State”) or an international or a regional application in which the State is designated (“filed for a State”) such as a national application, a PCT application or a European patent application.³⁶⁹ A European first patent application confers priority right for a European second application. This priority can also be claimed for subsequent national applications in the States party to the Paris Convention to which all EPC Contracting States acceded to.

Art.88 EPC and Rule 38 “Declaration of priority and priority documents” set out the details for claiming priority right

A person who has filed an application for a patent, a utility model (e.g. in Germany, Italy, Spain, Brazil or Japan), a utility certificate (e.g. in France) or an inventor’s certificate (e.g. in Cuba) in a State party to the Paris Convention; may claim a priority right during a period of twelve months in accordance with Art.87(1) EPC. This is an exhaustive list. A priority claim based on the deposit of an industrial design is not recognised.³⁷⁰ In contrast to the ambiguous wording of the Paris Convention, it has been clarified in Art.87(1) EPC that a patent application can not claim the priority of an industrial design or a trademark.³⁷¹

Art.87(3) EPC provides that a withdrawal, abandonment or refusal of the earlier application after its filing does not affect the right to priority.

The EPO may recognize the priority from a first filing in a State which is not a party to the Paris Convention but e.g. a member of the WTO-TRIPS Agreement.

³⁶⁸ G 3/93, O.J.EPO 1995, 18 No.4; G 2/98 No.3, O.J.EPO 2001, 413.

³⁶⁹ Ortan, p.112.

³⁷⁰ Visser, p.140, J 15/80.

³⁷¹ A few countries established their national legal systems to allow the priority of other industrial property rights, e.g. an industrial design in Germany.

Related Article (Art.87(5) EPC) has been amended to comply with Art.2 of the TRIPS Agreement.

To take advantage of the priority of a previous application; an applicant should file a declaration of priority stating the date of the previous application and indicating the state of first filing and the file number (R38(1)), a copy of the previous application (the priority document) and if the languages of the previous application is not one of the official languages of the EPO, a translation of it in one of such official languages. (Art.88(1) EPC).³⁷²

An applicant may take advantage of the first application as a basis for priority for several subsequent both European and national applications, provided that the states concerned recognize the first filing as giving rise to a right of priority.

Multiple priorities arise in cases where the subsequent application claims priorities from different prior applications for individual parts.³⁷³ Art.88(2) EPC provides that multiple priorities may be claimed in respect of a European patent application based on different earlier applications, notwithstanding the fact that they originated in different countries. Where multiple priorities are claimed, time limits which run from the date of priority shall run from the earliest date of priority.³⁷⁴

Partial priority arises in cases where priority is claimed in a subsequent application for a part of the invention only.

Under Art. 76 EPC, in case of divisional application based on the principle of the unity of the invention, the application date that is accorded to the parent application shall constitute an application date for the divisional (subsequent) application and it will constitute a priority document for the divisional application.³⁷⁵

³⁷² Ortan, p.112.

³⁷³ Multiple priorities exist where the invention disclosed in the subsequent application has been disclosed step by step in a number of prior applications.

³⁷⁴ Hüseyin Uludağ, "Patent Başvurularında Rüçhan Hakkı", Türk Patent Enstitüsü, 2003 İlkbahar Bülteni, pp.9-10.

³⁷⁵ Ortan, p.113

An applicant for a European patent is only entitled to claim priority from an earlier filed application if the European application is “in respect of the same invention” (Art.87(1) EPC). The Enlarged Board of Appeal has held that the wording “in respect of the same invention” must be interpreted narrowly.³⁷⁶ In Decision G 2/98, the Enlarged Board of Appeal has clarified the question in respect of the concept “the same invention” as follows;³⁷⁷

“The requirement for claiming priority of ‘the same invention’, referred to in article 87(1) EPC, means that priority of a previous application in respect of a claim in a European patent application in accordance with article 88 EPC is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole.”

The essential features of the invention must have been specifically disclosed in the priority document as a whole either explicitly or implicitly.

A general disclosure in the priority document does not establish priority for a later claim to an undisclosed specific example with such general disclosure.³⁷⁸ For example in case T 85/87, the priority of an Australian prior application was claimed for a specific compound in the European patent application. The prior application contained a generic disclosure which included this compound. The Board of Appeal came to the conclusion that the disclosure in the prior application did not subsume the specific disclosure in the relevant claim of the European patent application.³⁷⁹ In Xanthines/Draco and Spiro Compounds/Ciba-Geigy cases, the EPO did not recognise the priority for a specific compound because only a general formula was mentioned in the prior application.³⁸⁰

³⁷⁶ Visser, p.141 G 2/98.

³⁷⁷ Singer/Stauder, EPC, Vol.2, 411.

³⁷⁸ Paterson, A Concise Guide to European Patents p.129 “... For example, a claim defining a specific chemical compound is not entitled to priority from an earlier application containing a generic disclosure covering the specific compound.” (Anthropocidal compounds/Commonwealth Scientific, T 85/87 of 21.7.1988, [1989] EPOR 24)

³⁷⁹ Singer / Stauder, EPC Vol.2, 413-414.

³⁸⁰ Hansen / Hirsch, 187, Xanthines/Draco-T 7/86 of 16.9.1987, O.J.EPO 1988, 381, Spiro compounds/Ciba-Geigy-T 181/82 of 28.2.1984, O.J.EPO 1984, 401.

We must distinguish between the disclosure of essential and unessential features in the claims for the purpose of priority. If a particular feature in the claims of the European application is not specifically disclosed in the priority document, it has to be considered whether the presence of that feature changed the character and the nature of the claimed invention as such in comparison with what is disclosed in the priority document.

The specific disclosure in Art.88(4) EPC requires that the subject matter of a claim, i.e. all its features, must be derivable directly and unambiguously from the disclosure of the invention in the priority document. If certain elements of the invention for which priority is claimed do not appear among the claims formulated in the previous application, priority may nonetheless be granted, provided that the documents of the previous application as a whole specifically disclose such elements. (Art.88(4)EPC). It suffices if, on a reasonable assessment, there is in substance a disclosure of all the features of the claim. A priority document should contain a sufficient disclosure which enables the claimed invention to be carried out by a person skilled in the art if it is to support a claim to the priority.

An application can not serve as a basis for claiming a right of priority under Art.87(1) EPC if the subsequent application is distinguished from the previous application only by a limitation of the scope of protection which does not change the nature of the invention.

Art.89 EPC provides that the right of priority shall have the effect that the date of priority shall count as the date of filing of the subsequent application for the purpose of establishing the prior art relevant for the application and for the right to the patent. This means the priority date is crucial for determining the state of the art and for determining which of two applications from independent persons for the same invention is to proceed to grant. In other words; the “priority date” of a patent is the date on which it is tested against “the state of the art”; and it is the date on which it becomes part of the art, when assessing the novelty (but not the obviousness) of later applications.³⁸¹ The priority date also determines the expiry of certain time

³⁸¹ Cornish / Llewelyn, p. 150

limits, such as the designation of the inventor (16 months, Art.91(5)) and the publication of the application (18 months, Art.93(1)). An applicant may abandon the right of priority to meet a certain time limit running from the date of priority. Such an abandonment does not affect the time limits that have already lapsed.

The Enlarged Board of Appeal held that the disclosure of the subject matter contained in the priority document during the priority period does not constitute prior art which is citable against a European application claiming priority from the priority document, to the extent that the claims of the European application are not entitled to the claimed priority.³⁸²

Following the filing of an initial application for an invention in a Convention country, during the subsequent priority year to the filing of a European application, an applicant must take care not to disclose such invention, except in confidence. Any disclosure of the invention to the public may endanger the validity of claims which are included in a subsequent European application in respect of developments in the original subject matter.

An applicant may assign the right of priority to a successor in title, independently of the right to the grant of the patent.³⁸³ Such an assignment must have been effected after the first application and before filing of a subsequent application by the successor in title. The validity of an assignment of a priority right is determined according to the provisions of the national law of the country where the first application is a national application. If the first application is a European application, the assignment should comply with Art.71 and 72 where such an assignment should be made in writing and bear the signature of the parties to the contract.

³⁸² G 2/93 O.J. EPO(P).

³⁸³ Visser, p.141 "...If a subsequent application claims priority from only part of the subject matter of a first application, the applicant may transfer the priority right for other parts of the subject matter to another person. "

3.12. Novelty

In all modern systems patents are granted only for inventions that are unknown. An invention which does not form a state of the art is new.

3.12.1 State of the Art

Art. 54(1) EPC states that an invention shall be considered to be new if it does not form part of the state of the art. The purpose of Art.54(1) EPC is to prevent what is part of the state of the art from being patented.³⁸⁴

Several steps have to be carried out for the examination of the novelty of a claim. Firstly the effective date of the claim has to be determined. Secondly the state of the art, i.e. subject matter published before the effective date has to be selected and the contents of the state of the art must be established. Thirdly the features of the claim must be compared with the contents of the state of the art in order to find out if the claimed invention is new over the state of the art.

A claimed invention lacks novelty unless it includes at least one essential technical feature which distinguishes it from the state of the art.³⁸⁵ During such a comparison between the content of the state of the art and the claimed invention, it is important to determine whether what has been “made available to the public” includes all of the claimed technical features. The word “available” carries with it the idea that, for lack of novelty to be found, all the technical features of the claimed invention in combination must have been communicated to the public, or laid open for inspection.

These above mentioned basic steps are also applied in assessing the requests for the amendment of the claims.³⁸⁶

³⁸⁴ T 12/81 O.J. EPO 1982, 296; T 124/87 O.J. EPO 1989, 491.

³⁸⁵ G 2/88 O.J. EPO 1990, 93.

³⁸⁶ Ortan, p.75; Singer / Stauder, EPC Vol.1, p.104.

The examiner should prove the lack of novelty by citing reference to documents, he can not rest on his personal knowledge.

Art.54(2) EPC deals with the question what constitutes the state of the art. According to this article; the state of the art shall be held to comprise everything (whether a product, a process, information about either, or anything else) made available to the public (whether in Contracting States or elsewhere) by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application. This information can be published by the inventor and by someone unconnected with him.³⁸⁷ EPC involves two separate stages: availability of the means of disclosure and availability of information which is accessible and derivable from such means.³⁸⁸

The “state of the art” at the filing date of an application falls into two categories:

- The first category is published prior art which has been made available to the public such as prior published documents, prior used products (Art 54(2) EPC).
- The second category is prior rights, the content of European patent applications as filed, which have been filed but not published (Article 54(3) EPC).

The EPC system has adopted the “absolute state of the art” (absolute novelty) criterion. This criterion reflects that the EPC system contains no restrictions as to the means of disclosure, no restriction of time, no geographical restriction and no restriction as to the public.³⁸⁹ Everything that has been made available to the public

³⁸⁷ W. R. Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, London, Sweet & Maxwell, 1996, p.148.

³⁸⁸ T 952/92 O.J. EPO (P)

³⁸⁹ Grubb, p.54-55 “Under the 1949 Patents Act in Britain, ‘local novelty’ was the rule. Patents were granted for inventions that were brought into the kingdom for the first time by the patentee although known abroad. ‘Mixed novelty’ system is still the law in the USA where a later patent application is rendered invalid by written publication anywhere in the world but by use of the invention only in the home country; that is, prior use in a foreign country would not invalidate if there was no written description. Under the ‘absolute novelty’ system which is now the law in the UK and under the EPC, prior use of an invention anywhere in the world would invalidate a British or a European patent application, if that use made the invention available to the public.”

in any way before the date of filing, anywhere in the world is no longer regarded as new. This approach was adopted from Art.4 of the Strasbourg Convention (Convention on the Unification of Certain Points of Substantive Law on Patents for Invention of 27 November 1963).³⁹⁰ For example information which is made public anywhere in the world forms part of the state of the art and is therefore part of the published prior art for the purpose of Art.54 EPC. Information may become part of the published prior art for the purpose of Article 54 EPC at any point in time before the filing date.

The scale on which the information has been made available to the public is irrelevant. A single copy of a document or a single sale of an apparatus³⁹¹ is sufficient.

3.12.2. Availability of Information to Public

Availability of information is the possibility to access the information; it is not necessary that a person has actually accessed it. Subject matter is deemed to be available to public if one person could have gained the knowledge of it without infringing the secrecy.³⁹² This principle is valid for all forms of disclosure specified in Art.54 (2) EPC.

If a device is sold unconditionally, its contents are disclosed from the time of availability, even though it requires destruction or a time consuming investigation. A mailed document is available to the public not at the time of posting it, but at the time of delivery. If the document is in a place to which members of the public had access than the document is deemed to be admissible prior art. For example a document is available in a library if a member of the public could have looked into the document, it does not have to be entered in a catalogue. If one can ask for the latest edition of a periodical which has not yet been entered in a catalogue, the document shall be

³⁹⁰ Singer / Stauder, EPC Vol.1, p.103-104 “All the EPC Contracting States have adopted their national concept of novelty to that contained in the EPC, at least to the extent required by Art.4 of the Strasbourg Convention”.

³⁹¹ T 381/87 O.J. EPO 1990, 213; T 482/89, O.J. EPO 1992, 646.

³⁹² Examination Guidelines C-IV, 5.2; T 482/89, O.J.EPO 1992, 646.

deemed to be available to the public.³⁹³ A doctoral thesis is not public if not entered in a catalogue.

Art.54(2) EPC envisages that the state of the art comprises everything made available before the date of filing of the European patent application. Pursuant to Art.89 EPC; the date of filing for determining the state of the art is replaced by the priority date when priority has been claimed.³⁹⁴

Art.54(2) EPC requires that the information must have been made available to public. The article stresses the term “the public”. Relevant for availability is that a member of the public who does not have to have a certain knowledge could have had access to the information. In this sense the sale of an article unconditionally to a person amounts to the disclosure of its contents and makes it available to the public. But in some decisions, contrary to the wording of Art.54(2) EPC, “the public” has been interpreted as a skilled person who can understand the information and distribute it further.³⁹⁵

3.12.3. Confidential Information

Availability of information implies the absence of secrecy. Information that has been made available to one or more third parties, in confidence, is secret and has not been made available to the public in the sense of Art.54(2) EPC.³⁹⁶

Inventions which have not been the subject matter of a patent application can be introduced and displayed during licensing negotiations only within the framework of confidentiality. The contents of an EPO file of a patent application are secret before publication of the application and public thereafter according to

³⁹³ Ortan, p. 77 (T 381/87 Document in library, 10.11.1988)

³⁹⁴ Singer / Stauder, EPC Vol.1, p.105 “On the other hand, what was made available to the public on the same day, even if still before the filing of the European patent application, is not part of the state of the art and does not prevent the grant of a European patent (cf. T 123/82 of 30 March 1985).

³⁹⁵ Visser, p.64, T 877/90

³⁹⁶ Visser, p.64 “...The content of a meeting understood by the parties to be secret, even tacit and without a written contract, is not publicly disclosed . (T 830/90) ”

Art.128(4)EPC. Articles or goods demonstrated on factory premises do not become automatically public.

Secrecy can also be assumed if a clinical institute is entrusted with testing a new pharmaceutical which has not obtained market approval yet. In this case, experiments and test results are excluded from public domain.³⁹⁷

3.12.4. Means of Disclosure and Time of Availability

Technical information can be disclosed in written documents, drawings, oral statements, through display or by public use. A distinction has to be made between the availability of the means of disclosure itself and the availability of the information that can be derived from the means of disclosure (T 952/92, O.J.EPO 1995, 755, Headnote I).³⁹⁸

- Written disclosure of technical information is in the form of patent documents (patent specification) and articles in scientific or technical papers. If the claimed invention could be derived directly and unmistakably from the prior written document by a skilled person, such a document is a part of the state of the art.³⁹⁹ The general knowledge of the person skilled in the art is the decisive factor for the understanding of the technical teaching. For example if a photograph in a journal is clear enough to reveal the invention to an informed person, the patent shall be held to have been anticipated. Documents prepared by companies or correspondence between companies must be scrutinized whether they are confidential, secret or available to public.
- If a skilled person can derive a teaching from features shown solely in a drawing even without a description, in this case a feature shown in a drawing shall be a part of the state of the art.⁴⁰⁰

³⁹⁷ Hansen/Hirsch, p. 85.

³⁹⁸ Singer / Stauder, EPC Vol.1, p.108.

³⁹⁹ T 204/83 O.J. EPO 1985, 310; T 56/87 O.J. EPO 1990, 188.

⁴⁰⁰ Visser, p. 64 (T 857/91 r.3.2)

- The same principles concerning availability are applied to oral disclosure, such as a lecture. In the absence of a record of an oral description, difficulties may often arise in determining what was made available to the public. If an oral disclosure is followed by a written disclosure, the date of the oral disclosure shall be taken into consideration unless there is no doubt about the extent of the oral disclosure.
- The visible features of an object can be demonstrated in a display such as an exhibition and the non-visible features of the same object can be disclosed by written or oral statements provided during the exhibition.
- Public prior use is the availability or accessibility of an actual product or method to the public before the date of filing of the application. The use must take place before the filing or priority date of the patent in question and the subject-matter of the use must correspond to the content of the patent in question.⁴⁰¹ Use shall be prejudicial if it effects a public release equivalent to publication. The issue is whether a skilled worker, by observation or analysis, could discover and reproduce the invention. One should submit extensive evidence to prove the existence of public prior use. When compared with disclosure by public prior use, it is much easier to prove the existence of written disclosure.⁴⁰²
- The composition and internal structure of a product, whether chemical or other, is the state of the art when the product as such is available to the public and can be analysed and reproduced by the skilled person.⁴⁰³ The claim is

⁴⁰¹ Hansen/Hirsch, p.84.

⁴⁰² Visser, p.65 "...A product or method disclosed by the prior public use is regarded as part of the state of the art if the following items are clarified and proved: When, What, How, Where and Whom...A single sale is sufficient to render the article sold available to the public, provided the buyer is not bound by an obligation to maintain secrecy (T 428/89). The Opposition Division may claim a list of clients and dates of sale to prove availability of the product"

⁴⁰³ Visser, p.66 "...The possibility of a complete analysis of a prior sold product so as to enable an exact reproduction of such product is not required for destroying the novelty of a claimed product (T952/92r.2.3 last par. contrary to the requirement of complete analysis following from G1/92 r.1.4). Information as to the composition and internal structure of a prior sold product is made available if direct and unambiguous access to such information is possible by means of known analytical techniques where available for use by a skilled person before the relevant filing date (T 952/92 r.4.3)."

therefore anticipated.⁴⁰⁴ For example, a document does not effectively disclose a chemical compound, even though it states the structure and the steps by which it is produced, if the skilled person is unable to find out from the document or from common general knowledge how to obtain the required starting materials or intermediates.⁴⁰⁵ In a later case, it was held that even if the commercial product could not be analysed, it would destroy novelty if the analysis enable the production of anything falling within the claim.⁴⁰⁶

A document cited under Art.54(2) and (3) EPC shall be sufficient to destroy novelty only if it discloses the invention in a manner sufficiently clear and complete to be carried out by a person skilled in the art.⁴⁰⁷

Especially in chemical cases, the subject matter of a claim (e.g. a particular compound) is embraced by a general disclosure covering a large area than the specific claimed subject matter (e.g. a class of compounds of which the particular compound is a member). In such situations, when determining novelty, a distinction should be drawn between an extensive general disclosure and a narrow sub-disclosure within it which has not been individualised. In general terms, a generic disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure, but a specific disclosure does take away the novelty of a generic claim embracing that disclosure.

3.12.5. Novelty in respect of Product-by-process Claims, Analogy Processes and Selection Inventions

A new process for making a known product is protected by a process claim in which the result of carrying out the process steps is the production of the known product. Art.64(2) EPC provides that if the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process. Product-by-processes claims (claims for products defined

⁴⁰⁴ Cornish / Llewelyn, p.175 see footnote 19 Enlarged Board of Appeal [1993] O.J. EPO 277.

⁴⁰⁵ Paterson, A Concise Guide to European Patents p.143 see footnote 33 T 206/83 O.J. EPO 1987, 5.

⁴⁰⁶ Grubb, p.55 T 952/92, O.J.EPO 1995, 755, Fisans/Prior use.

⁴⁰⁷ Paterson, A Concise Guide to European Patents p.143 see footnote 34 T 81/87 O.J. EPO 1990, 250.

in terms of processes for their preparation) are admissible only if the products themselves fulfil the requirements for patentability. If the product of a new process is in all respects identical with the product of a known process, there is no novelty either in a claim to the product per se of the new process, or in a claim to the product-by-new process.

A known process for making a new product (analogy process) may be protected by a claim which defines the known process steps, the final step being the production of the new product.⁴⁰⁸ Analogy processes are also called as non-novel processes. In some countries the patentability of analogy processes is permitted if the resulting chemical is novel and displays unexpected properties.

Analogy processes for the manufacture of a new and inventive chemical product is considered to be patentable in the European law.⁴⁰⁹ In the EPO it has been always recognized that if a group of compounds is new and inventive, then not only are claims to the compounds per se patentable, but also are claims to the process for the preparation of the compounds, even if the starting materials are known and the process itself is known as a method for making similar compounds. When a patent is granted for a non-novel process, the novelty is derived from its previously unknown capability for producing a specific product and the inventive step lies in the unexpected characteristics of the final product.

An Appeal Board of the European Patent Office characterised an analogy process as a “problem invention”.⁴¹⁰ Analogy processes are deemed to be patentable insofar as they provide a novel and inventive product. This is because all the features of the analogy process can only be derived from an effect which is as yet unknown and unsuspected.

With the introduction of protection for products, the protection of analogy processes has lost its significance to a certain extent. Analogy processes had been of outmost importance in the past in the absence of chemical substance protection.

⁴⁰⁸ T 119/82 O.J. EPO 1984, 217.

⁴⁰⁹ Singer / Stauder, EPC-Vol.1, p. 158, T 119/82, O.J.EPO 1984, 217.

⁴¹⁰ Hansen / Hirsch, p.221, “Gelation/Exxon” – T 119/82 of 12.12.1983, O.J.EPO 1984, 217.

In selection inventions, an earlier publication discloses a broad class where the invention is characterized by a narrower sub-class. Selection inventions usually occur in the field of chemistry, where a narrow group of compounds is selected from a known broad group. As long as none of the members of the narrow subgroup are specifically disclosed in the publication (regarding the known broad group), a narrow group of compounds shall be considered novel even if they may have been described in general terms.⁴¹¹ For an invention to be patentable, there must be also an inventive step in choosing that particular sub-group from all these generally disclosed.

3.12.6. Decisive Date for the Determination of the Disclosed Contents and the Whole Content Approach

The contents of a document are what a skilled person would have read in it at the time of its publication or, where Art.54(3) EPC applies, the date of filing or priority, where appropriate.

The disclosure should enable a skilled person to practice the teaching, taking into account the general knowledge in the field. The disclosure of a document includes explicitly disclaimed subject matter with the exception of disclaimers for unworkable embodiments. Erroneous disclosures which do not represent the intended technical results should not be considered as a part of the state of the art.

According to Art.54(3), the content of European patent applications as filed, of which the dates of filing are prior to the date referred to in paragraph 2 and which were published under Art.93 on or after that date, shall be considered as comprised in the state of the art. A first European patent application which has a filing date earlier than the filing date of a second European application, but which has been published after the filing date of the second European application, is not a part of the published prior art under Art.54(2) EPC in respect of the second application. But the

⁴¹¹ Grubb, p. 55-56.

whole content of the first application as filed is comprised in the state of the art and may constitute a ground for an objection to grant of a European patent on the ground of lack of novelty. The earlier application is often referred to as a prior right. Double patenting is avoided by taking the earlier application into account when assessing the patentability of the later application.⁴¹²

The extent to which the earlier application is taken into account depends on the patent system. The EPC has adopted the “whole contents” approach where the whole content of an earlier unpublished application, i.e. not only the claimed subject-matter, is regarded as the state of the art for the later application.⁴¹³ In the EPO, an earlier unpublished European application is prior art against a later filed application provided that it is not withdrawn before the publication and to the extent that it validly designates the same countries. In the EPO, earlier unpublished national applications are not considered as prior art against European applications.⁴¹⁴

The entire disclosure of the prior right becomes part of the state of the art from the filing or, where applicable, priority date of the prior right (Art.54(3) and Art.89 EPC).

The harsh effects of the whole content approach are mitigated by confining its application to novelty and disregarding prior rights in deciding on inventive step (Art.56 EPC, last sentence). The existence of an earlier unpublished application can destroy the novelty of an invention but can not give rise to the lack of inventive step.

The whole content approach does not only apply to patent applications of rival applicants but also to successive applications by the same person to prevent self collision particularly in the case of mechanical inventions.⁴¹⁵

⁴¹² Grubb, p.56.

⁴¹³ The British Patents Act 1977 has also adopted ‘the whole content’ approach. In contrast to EPC, Switzerland has chosen the “prior claim” approach for national applications to avoid double patenting where the claims of the later application may not overlap the granted claims of the earlier application.

⁴¹⁴ Grubb, p.57

⁴¹⁵ In the field of mechanical inventions, one piece of research may produce a succession of broadly interrelated inventions, each of which calls for a separate application either as a matter of tactics or because of the requirement of “unity of invention”.

On the other hand Art.54(4) EPC limits the application of Art.54(3) EPC to situations where the same Contracting States are designated in both first and second European patent applications.

3.12.7. Individual Comparison

It is general rule that when assessing novelty, the disclosure of a particular prior art document must be considered in isolation . It is not allowed to combine separate items of prior art together.⁴¹⁶ As an exception to this general rule, if there is a specific reference in one prior document to a second document, it may be necessary to consider the part or all of the disclosure of the second document as part of disclosure of the primary document.⁴¹⁷

The prior art document must be assessed in its entirety without isolating parts of such document from their context in order to derive a technical teaching which would contradict the integral teaching of the document.⁴¹⁸ It depends upon the circumstances of each particular case.⁴¹⁹

The prior art document should be interpreted in the framework of the common general knowledge of the person skilled in the art in the relevant field as at the date of publication of the document.

3.12.8. Disclaimers

Particular subject-matter can be explicitly removed from the protective scope of the claims by means of a disclaimer. A disclaimer can be formulated in a negative way such as “with the exception of...”, as well as in a positive way such as a

⁴¹⁶ T 153/85, O.J. EPO 1988, 1; T 77/87 O.J. EPO 1990, 280.

⁴¹⁷ T 153/85 O.J. EPO 1988, 1; Grubb, p.58, T 305/87 (O.J.EPO 1991, 429) Grehal/Shear.

⁴¹⁸ T 56/87 O.J. EPO 1990, 188.

⁴¹⁹ Paterson, A Concise Guide to European Patents p.140-141.

limitation or deletion of features.⁴²⁰ A disclaimer results from the necessity of removal of non-patentable subject-matter from the invention on whatever grounds.

Disclaimers are often used in the system of EPC, to distinguish the subject-matter of the invention from a citation which is damaging to novelty or to exclude variants of a claim that are not inventive or industrially applicable. A disclaimer can only be used to give novelty and it can never contribute to the inventive step of the claimed subject-matter.⁴²¹ The EPO does not allow a claim to be amended by a disclaimer if the purpose is to establish inventive step rather than novelty.⁴²²

An examination as to inventive step shall be carried out in any case as if the disclaimer would not exist (T 871/96 of 8 October 1998).

In accordance with R 29(1) first sentence, a disclaimer should define that area which is not intended to be covered by the claim. In various decisions of the Boards of Appeal, disclaimers are admitted to establish novelty.⁴²³

It is necessary to admit disclaimers because an applicant may not be able to be aware of the conflicting applications at the time of drafting his application, which may only be taken into account when assessing novelty. If the situation is known before the filing of the patent application, the claims can be drafted so as to take account of the prior art. If the prior art is discovered during the examination proceedings, it is appropriate to insert into the claim a disclaimer to the prior art compound.

A disclaimer should not lead to an unallowable broadening. In case T 170/87, the Board of Appeal regarded a disclaimer in the form of a limitation as an unallowable broadening.⁴²⁴ The invention was a hot gas cooler but it was not differentiated from the state of the art in the description. The applicant wanted to use the limitation “with no internal fittings” in the main claim. The Board of Appeal did not

⁴²⁰ Hansen / Hirsch, p.177.

⁴²¹ Singer / Stauder, EPC-Vol.1, p.382 - T 597/92, O.J.EPO 1996, 135.

⁴²² Grubb, p.201 T 170/87 (O.J.EPO 1989, 441), SULZER/hot-gas cooler; T 597/92 (O.J.EPO 1996, 135), BLASCHIM/Rearrangement reactions.

⁴²³ Singer / Stauder, EPC-Vol.1, p.381 T 4/80, OJ 1982, 149; T 170/87, OJ 1989, 441.

⁴²⁴ T 170/87 of 5.7.1988, O.J.EPO 1989, 441.

consider this amendment allowable since it could not be derived in passing from a figure and not from the description. According to the decision of the Board, at least something inventive must be present in the original documents, which can be differentiated from that which is not inventive by a disclaimer.⁴²⁵

Further requirements for allowable disclaimers are specified in the “Polyether polyols/Bayer” case. Accordingly, originally disclosed subject-matter can be excluded from a wider claim by a disclaimer, if the subject-matter remaining in the claim cannot technically be defined directly more clearly and precisely. The scope of protection sought in the claims must be presented by means of positive technical features. However, disclaimers are allowed if such a formulation of claims is the most precise definition possible (Examination Guidelines C-III, 4.12). If the disclaimer concerns the subject-matter of an earlier, not previously published national application or corresponding patent, this does not constitute any hindrance to such a formulation.⁴²⁶ In this sense, disclaimers are particularly useful in the EPC system when the prior art is not a prior publication but an unpublished application of earlier priority date under Art.54(3) EPC. In this case, the prior art can be used to attack novelty and inventive step shall not be considered.⁴²⁷

According to the opinion of the Board of Appeal, the requirement for clarity is not fulfilled, if a further patent must be studied for determining the content of the disclaimer. The claims should also make it clear which technical features differentiate that which is claimed, from the excluded subject-matter. A disclaimer must refer either to a feature disclosed in the application, or word for word to the overlapping state of the art.⁴²⁸

⁴²⁵ Hansen / Hirsch, p.178.

⁴²⁶ Hansen/Hirsch, p.179, “Polyether polyols/Bayer” – T 4/80 of 7.9.1981, O.J.EPO 1982, 149.

⁴²⁷ Grubb, p.201.

⁴²⁸ Hansen/Hirsch, p.179, T 43/82 of 16.4.1984.

3.12.9 Collision Between European and National Patent Applications/Patents

Only prior filed European patent applications form part of the state of the art under Art.54(3) EPC. A prior national patent application is not a European patent application within the meaning of Art.54(3) EPC and it is not within the state of the art, for the purpose of Art.54(1) EPC.⁴²⁹ The prior right effect of national patent applications is a matter for individual national laws, and is governed by Art.139(1) and (2) EPC.

In case of “collision” between a European patent application or patent and a national patent application or patent having the same filing date, the matter is again left to the individual national laws of the Contracting States, under Article 139(3) EPC.

3.12.10. Special Cases regarding the State of the Art for Medicaments

The existence of novelty has to be scrutinised carefully regarding cases in further uses of a known product:

a. First Medical Use of a Known Product

Art.52(4) EPC excludes methods of treatment of the human or animal body from patentability. Art.54(5) EPC provides that a substance or composition for use in such a medical or veterinary method does not lack novelty, even when the substance or composition is itself part of the state of the art, provided that its use for any such medical or veterinary method is not comprised in the state of the art.

⁴²⁹ T 550/88 O.J. EPO 1992, 117.

b. Second and Further Medical Uses of a Product having a Known Medical Use

The patentability of a second and further medical use was considered by the Enlarged Board of Appeal. Since Art.54(5) EPC states that a first medical use is novel, implicitly because of the presence in the claim of the newly discovered medical use, the Enlarged Board of Appeal held that second or further medical uses were also novel on the same basis. In its decision, it was held that :

- Claims directed to the second or subsequent medical use of a product for the treatment of an illness in a human or animal body were equivalent to claims for a method of treatment of the human or animal body and therefore excluded from patentability by Article 52(4) EPC.
- Claims directed to the use of a substance for the manufacture of a medicament for a specified new therapeutic use were not lacking in novelty for the purpose of Art.54 EPC.⁴³⁰

In connection with non-medical inventions, there is obviously no potential difficulty in claiming new methods of using a known product where the methods steps themselves are new, i.e. where there is a novelty in the physical activity by the claim.

3.12.11. Non-prejudicial Disclosures

Art.55 EPC provides that an abusive disclosure or a disclosure at a recognized exhibition as non-prejudicial disclosures which will not be regarded as state of the art. This article is intended to protect an applicant against prior disclosure of his invention caused either by abuse or by display at an international exhibition provided that the applicant files the application with the EPO within 6 months from the disclosure. A later filing will make the disclosure prejudicial.

⁴³⁰ G 5/83 O.J. EPO 1985, 64.

In case of an exhibition, the applicant should additionally comply with Art.55(1)(b) and (2). According to Art.55(1)(b), the invention should be displayed by the applicant or his legal predecessor at an official, or officially recognised, international exhibition falling within the terms of the Convention on international exhibitions signed at Paris on 22 November 1928 and last revised on 30 November 1972.⁴³¹ According to Art.55(2), the applicant should state that the invention has been displayed while filing the European patent application and also submit a supporting certificate of exhibition (R.23) and identification within the period and under the conditions laid down in the Implementing Regulations. The statement must be filed on the filing date of the European patent application. The certificate of exhibition and identification must be filed within four months of the filing date (R.23). An invalid certificate or identification means that the disclosure at the exhibition is prejudicial to the application and this amounts to loss of novelty and consequently withdrawal of the application.

For the calculation of the six-month period, the date of filing of the European patent application shall be considered. The date of priority is not taken into account.

If a national first filing is made, the subsequent priority claiming European application must be filed within six months from the disclosure.

A decision of the Technical Board of Appeal holds that “abuse” does not require the intention to harm; a disclosure due to negligence or mistake is regarded as abuse. Important point is that the applicant experiences damages.⁴³² The disclosure is not only non-prejudicial when the applicant told the invention himself to the discloser, but also a third person is involved who happens to get to know the invention.

⁴³¹ Few exhibitions to which this rule applies are listed each year in OJ issue 4 under International Treaties.

⁴³² Visser, p.73, T 173/83 r.6

3.13 Inventive Step

An invention must be based on an inventive step to be patentable. Art.56 EPC states that an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. The Contracting States to the EPC had adopted an approach parallel to the definition in Art. 56 EPC while they were developing their case law concerning inventive step. This definition of inventive step in Art. 56 EPC is both binding on proceedings for the grant of a European patent and on national revocation proceedings against a European patent.⁴³³

3.13.1. Interpretation of the “Inventive Step”

Inventive step is to be assessed objectively.⁴³⁴ It should be based on the objective state of the art, not on the inventor's subjective achievement. When assessing the inventive step, all features which contribute to the technical character of the claim as a whole must be taken into consideration. Improvements lying in the non-technical features of the invention must be excluded since they do not contribute to the state of the art. The invention must present a new teaching that has an objective advance over the state of the art. It is of utmost importance to decide who is the skilled person and what would he have done. In assessing the state of the art for the inventive step, the general knowledge of the skilled person and the general technical knowledge of the specialist have to be considered.⁴³⁵

3.13.2. Different Criteria is Applied for Assessing Novelty and Inventive Step

Novelty and inventive step are different conditions for patentability. Novelty exists if there is any difference between the invention and the prior art. The question

⁴³³ Singer / Stauder, EPC, Vol.1, p.142.

⁴³⁴ T 1/80, O.J.EPO 1981, 206; T 24/81, O.J.EPO 1983,133.

⁴³⁵ T 195/84, O.J.EPO 1986, 121; T 171/84, O.J.EPO 1986, 95.

“is there inventive step ?” can be asked only if there is novelty. The expression “inventive step” conveys the idea that it is not enough that the claimed invention is new, that is, different from what exists in the state of art, but that this difference must have two characteristics. Firstly, it must be “inventive”, that is, the result of a creative idea, and it must be a step, that is, it must be noticeable. There must be a clearly identifiable difference between the state of the art and the claimed invention. Secondly, it is required that this advance or progress be significant and essential to the invention.

The state of art shall be assessed in a different approach for novelty and inventive step which can be summarised as below :

- The state of the art comprises prior rights for the assessment of novelty (Art.54(3) EPC). Prior rights are not considered for assessing inventive step (Art. 56, last sentence EPC).⁴³⁶
- Only one document can be taken into account at a time of novelty.⁴³⁷ Each document that is part of the state of the art is only compared individually with the invention to be examined in respect of novelty.⁴³⁸ For the examination of inventive step the common general knowledge that is represented by basic handbooks and textbooks on the subject, in the technical field of patent application is taken into account. The teaching of several non-conflicting documents such as a prior art document with another document containing common general knowledge may be combined for the assessment of inventive step. This is called “mosaic approach”. Cited documents do not have to be treated in isolation, they may be read in the light of one another.
- For novelty each document is assessed with the eyes of a skilled person at the time of publication of the document. For inventive step a document is assessed with the eyes of a skilled person at the time of filing date of the application. The filing date of an application is either the actual filing date, or if

⁴³⁶ Singer / Stauder, EPC, Vol.1 p.144 “...The prior rights in the European patenting process are the European patent applications with older priority not published by the date of application of the invention to be examined.

⁴³⁷ For details see subsection 3.12.7 Individual Comparison.

⁴³⁸ T 153/85, O.J.EPO 1988, 1 .

the application is entitled to a right of priority then the date of priority counts as the filing date.

The European patents' standard of inventiveness should not be below the standards applied by the Contracting States.⁴³⁹ Otherwise, they may be declared invalid by the national courts when their validity is contested.

The invention must not obviously result from the state of the art. Obviousness can be described as something that does not go beyond the normal progress of technology, but merely following logically from the prior art. It does not require a faculty beyond that of a skilled person.⁴⁴⁰ It is of the utmost importance to know what is obvious for determining inventive step in each individual case. The European patent application, the state of the art and the parties' submissions in the granting and opposition proceedings are the basis for this determination. According to the case law established by the Boards of Appeal; elimination of disadvantages, optimisation of parameters, saving energy and time, known equivalents to the skilled person are non-inventive.⁴⁴¹ If the closest state of the art leads in another direction away from the teaching in the invention, this is an indication in favour of the inventive step which means that the invention is non-obvious to the skilled person.⁴⁴²

Although technical progress is not a requirement for inventiveness and patentability under the EPC, lack of technical progress may indicate a lack of inventive step.⁴⁴³ If the solution of the problem does not require any technical ingenuity, but e.g. merely administrative or financial skills, the invention does not meet the requirement of inventive step.

In the field of chemistry, inventive step in the substitution of analogous substances depends on how well known the structures and characteristics in the field in question are.⁴⁴⁴ The mere replacement of a component with undesirable

⁴³⁹ T 1/81 O.J. EPO 1981, 439.

⁴⁴⁰ Visser, p.78.

⁴⁴¹ Hansen / Hirsch, p208.

⁴⁴² T 292/85, O.J.EPO 1989, 275.

⁴⁴³ T 22/82 O.J. EPO 1982, 341; T 119/82 O.J. EPO 1984, 217.

⁴⁴⁴ T 623/91 of 1 February 1994.

characteristics by another that is known not to have these characteristics is not inventive unless an unexpected effect is achieved.⁴⁴⁵

In the field of genetic technology, there is no inventive step if on the date of priority the skilled person can assume that the cloning and expression of a gene, even if very labour-intensive, poses no particular problems for the skilled person such as to call into doubt the success; the solution is obvious and not inventive.⁴⁴⁶

3.13.3. “Problem-and-Solution” Approach

In assessment of inventive step, “problem-and-solution” approach is usually applied by the European Patent Office. The EPC does not stipulate that this approach should be applied for assessing inventive step.⁴⁴⁷ Although the Board of Appeal held in one of its decisions that the use of the problem-and-solution approach is not a sine qua non, this method is widely used.⁴⁴⁸ In this approach, in which the examiners having identified the closest prior art, formulate the objective technical problem to be solved in reaching the claimed invention and then judge whether that solution is obvious in regard to further prior art and general technical knowledge. The view point must be forwarded from the prior art, not backward from the invention, otherwise the judgement will be infected by hindsight.⁴⁴⁹ This procedure is supposed to make the evaluation of the inventive step more objective and to rule out ex post facto analysis.⁴⁵⁰

⁴⁴⁵ T 213/87 of 8 July 1990, citing T 130/89, OJ 1991, 514 and T 192/82, OJ 1984, 415.

⁴⁴⁶ Singer / Stauder, EPC, Vol.1 p.150.

⁴⁴⁷ Grubb, p.59-60; Hansen/Hirsch, p.195 Problem and solution approach is derived from R 27(1)(c), which states that the invention is to be disclosed in such a way that the technical problem (even if not expressly stated as such) and its solution can be understood, and state any advantageous effect of the invention with reference to the background art.

⁴⁴⁸ Hansen / Hirsch, p.194-“Alluminium alloys/Alcan” – T 465/92 of 14.10.1994, O.J.EPO 1996, 32.

⁴⁴⁹ Cornish / LLewelyn, p.198; Hansen/Hirsch, p.245 “In the examination of inventive step, knowledge derived from the application to be examined can not be included in the state of the art (prohibition on ex post consideration).”

⁴⁵⁰ Grubb, p.60 - If it turns out that the technical problem disclosed has not in fact been solved, or that an incorrect state of the art was used to define the problem, the problem set out in the description may be amended provided that the rewording is not excessively general; the reworded problem is covered by the original disclosure and the amended technical problem does not lead to an alteration of the general purpose and essential character of the invention contained in the application.

If the problem underlying the solution in the patent was not known, its solution is not obvious from the state of the art.⁴⁵¹ The problem and the solution of the invention claimed must be stated in the description. The objectively closest state of the art should be first determined and used to identify the technical problem that is to be solved by the invention claimed. The patent specification is the starting point for the determination of the problem.⁴⁵² The problem is determined according to objective criteria and subjective elements are not taken into consideration.⁴⁵³ As a result of such objective assessment, the problem may actually differ from that documented in the application.

The starting point is objectively closest state of the art,⁴⁵⁴ irrespective of the inventor's knowledge. It is irrelevant whether the specific problem is expressly addressed in the closest state of the art; the decisive factor is what the skilled person objectively identifies as the problem in a comparison between the closest state of the art and the invention.⁴⁵⁵ Patentability requires the solution of the problem stated, although the problem-solution approach should not be interpreted as introducing an additional requirement for patentability that goes beyond Art.57 EPC. If a problem is obviously not solved, it cannot be taken into account in determining inventive step.⁴⁵⁶ The problem can contribute to or indeed be the sole decisive factor for establishing the inventive step if the problem on which the invention is based cannot be derived from the state of the art.

After the determination of the problem, consideration must be given to whether the solution found would have been obvious to the skilled person in the light of the state of the art.⁴⁵⁷ The invention is not obvious if the skilled person would have found the solution.

⁴⁵¹ T 59/90 of 12 March 1993.

⁴⁵² Hansen / Hirsch, p.197

⁴⁵³ T 13/84, O.J.EPO 1986, 253; T 1/80, O.J.EPO 1981, 206.

⁴⁵⁴ T 254/86, O.J.EPO 1989, 115, No.15

⁴⁵⁵ T 939/92, O.J.EPO 1996, 309, No.2.4.3

⁴⁵⁶ If the invention solves a number of individual problems, the question arises whether the technical relationship between these problems is so close that they can be taken into account jointly to determine inventive step

⁴⁵⁷ In its decision T 422/93, O.J.EPO 1997, 25, the Technical Board of Appeal reaffirmed that the starting point in selecting the competent person skilled in the art is the technical problem to be solved from the closest state of the art.

In the course of examination and opposition proceedings, even in appeal proceedings it may become necessary to reformulate the problem since further more relevant prior art becomes known in the meantime when compared with the prior art known to the inventor at the time that the invention was made. Art. 123 (2) EPC allows a new formulation if the skilled person regards the problem in the original application in the light of the nearest state of the art. Such a reformulation should not contradict earlier statements in the application about the general purpose and character of the invention.⁴⁵⁸ For example a result previously described as undesirable may not be made the new goal of the invention.

When following the problem-and –solution approach, hindsight must be avoided. This means that the knowledge of the claimed invention should not be taken into account when assessing inventive step. An ex post facto analysis is not allowed in examination. But the knowledge of the invention is used when determining the closest prior art and when defining the problem to be solved by the skilled person vis-a-vis such closest prior art.⁴⁵⁹

3.13.4. Closest Prior Art

The closest prior art forms the best starting point within the state of the art from which the claimed invention could have been made. The closest prior art has the most technical features in common with the claimed invention and is in the same technical field.⁴⁶⁰ In many cases, the prior art which is the most closely concerned with the problem underlying the claimed invention will be considered as the closest prior art. In identifying the closest prior art, commercial publications and products are to be treated equally with patent literature and other technical literature.

⁴⁵⁸ T 155/85, O.J. EPO 1988, 87.

⁴⁵⁹ Paterson, A Concise Guide to European Patents p.153.

⁴⁶⁰ Hansen / Hirsch, p.195 "... at the European Patent Office, the closest prior art in the area of chemical compound inventions is represented by the structurally closest compound in the same technical field of application, which belongs to the state of the art, i.e. which is disclosed in an enabling way so that the skilled in the art can obtain it (T 91/84 of 23.7.1984)".

3.13.5. Inventive Step in respect of Simple Inventions and Combination Inventions

In simple inventions; if a series of steps is necessary in order to arrive at the invention from the state of the art, and if the last decisive step, however simple it might appear at first sight, is not known or derivable from the prior art, this can be a significant indication of inventive step.⁴⁶¹

In combination inventions; if the combination as such or a single one of its elements cannot be obviously derived from the state of the art, this can establish an inventive step . If all the elements are anticipated by the state of the art but cause a synergetic effect when combined, the inventive step shall be deemed to be present due to such an overall effect. In other words the combination must have an unforeseen combinatorial effect, going beyond the sum of effects of each feature.⁴⁶² In the absence of such an overall effect, if all features are known, there is no inventive step since there is merely an aggregation of elements but not a combination invention. In such cases the invention is a “mere collocation” where two devices are to be placed side-by-side without any working inter-relationship and without making an advantageous contribution to the state of the art. There is no interactive or overall effect when these devices are placed together. The traditional example of such a case is the “sausage-machine patent” ; a claim to a known cutting-machine and a known filling-machine placed in juxtaposition.⁴⁶³ In this example there is no true combination but “mere juxtaposition of features” where there exists no functional relation between the features.⁴⁶⁴

If an independent claim is new and obvious, there is no need to investigate the obviousness of any dependent claims. If a claim for a product is new and non-obvious, there is no need to investigate the obviousness of any claims independent for a process or use of the product.

⁴⁶¹ T 113/82, O.J.EPO 1984, 10.

⁴⁶² Visser, p. 81

⁴⁶³ Cornish / LLewelyn, p.201-202.

⁴⁶⁴ Visser, p. 74. Notes from the guidelines chapter c-iv,9 and annex.

3.13.6. Inventive Step in respect of Analogy Processes, Chemical Intermediates and Problem Inventions

Analogy processes for the manufacture of a new and inventive chemical product are also patentable in European law, in so far as they lead to new products which display properties which are not expected. An analogy method is a method which is analogous to a known method and used for making a chemical substance. In this type of protection a patent is granted for a known process, the novelty of which is derived from its previously unknown capability for producing a specific substance and whose inventive step lies in the unexpected characteristics of the final product obtained by further processing. The method derives its patentability solely from the patentability of the end product. The character of the product, including its novelty and obviousness has a decisive role in the assessment of the inventive step since the effect of the process manifests itself in the product. This means that an analogy method for making a compound is patentable as far as the compound is new and inventive. An analogy process leading to a known or obvious product is normally regarded as not inventive. Analogy processes are used to be important for states without direct protection of chemical substances.⁴⁶⁵ With the introduction of patent protection for products, analogy process has actually lost its significance.

Intermediate products are the products which are only industrially applicable as starting materials in a chemical method for producing end products. The chemical intermediates are also patentable within the case law of EPO. Inventive step is deemed to be present for intermediates if the advantageous result obtained in the process is surprising and cannot be achieved without the intermediate.⁴⁶⁶ In one case, where the process was held to involve an inventive step, the intermediate was also held to involve an inventive step on the basis that it opened the way to the new and inventive chemical process for preparing the known and desired end product.⁴⁶⁷ Preparation of chemical substances and chemical intermediates must lead to a non-obvious advance of technology. This advance can occur in terms of an inventive

⁴⁶⁵ Visser, p. 75, 81.

⁴⁶⁶ Hansen / Hirsch, p. 237 "The preparation of an intermediate product was deemed fundamentally patentable if thereby the state of the art is enriched in a surprising way, either because of inventive further processing or of the inventive complete process leading to the end product". "Synthesis intermediate/Pierre Fabre – T61/86 of 2.12.1988.

⁴⁶⁷ T 22/82, O.J.EPO 1982, 341.

production method, an inventive further processing or the concept of an inventive overall process for the final product.

In problem inventions, the solution to the problem appears to be obvious but the problem itself is new and not anticipated by the state of the art. In other words; a problem invention is an invention based on the recognition of an unrecognised problem, it may give rise to patentable subject matter, even if the solution is trivial and obvious in hindsight.⁴⁶⁸ The problem itself contributes to the inventive step. Problem inventions can be found in chemical intermediates, which may be inventive if they make a new structural contribution to the products of the further processing.⁴⁶⁹

3.13.7. Novel Compounds

New compounds, new compositions, new manufacturing processes and new uses are categories of inventions in the field of chemistry. A novel compound must be also capable of industrial application in order to be patentable.

Many novel compounds of known structures are synthesized in search laboratories, but most of them are of theoretical interest and are not industrially applicable.

Compounds that are used only as intermediates in the preparation of other compounds are also patentable. If the endproducts are industrially applicable, then the intermediates shall be considered as industrially applicable. If such intermediates fulfil the criteria of novelty and non-obviousness, they shall be granted patent protection.

An invention does not consist of a single compound but a group of compounds having some structural features in common and the same end-use. A novel compound must also involve an inventive step to be patentable. In determining how close a compound is to a compound described in the prior art, one must consider not

⁴⁶⁸ Visser, p.79 (T2/83 hnI)

⁴⁶⁹ T 65/82, O.J.EPO 1983, 327.

only the structural formulae of the compounds, but the compounds themselves including their properties. It is difficult to patent compounds which, while new, are very closely structurally related to known compounds. If the structural similarities are less close, then the new compounds may be patentable and non-obvious irrespective of whether they have improved properties.

There is no general requirement that an invention must be better than what has gone beyond in order to be patentable. If the closeness of the prior art may cast doubt on it, a surprising improvement in properties may be evidence of the presence of an invention.

A compound which is structurally close to the prior art may have both predictable and unpredictable advantageous properties. Although the unpredictable advantages confer patentability in respect of non-obviousness, it can be argued that predictable advantages made it obvious to prepare the new compound and the determination of further advantages is only a discovery of properties of an unpatentable substance. The Technical Board of EPO took this view into consideration.⁴⁷⁰

In assessing patentability of a new compound, it is not only necessary to take into account the habitual methods of the field, but additionally it should also be taken into account whether the skilled man in expecting a certain advantage has a definite reason to apply these.⁴⁷¹

The burden of proof is with the party that relies on two compounds being different or the same especially, where no comparable parameters have been given for either compound.

⁴⁷⁰ Grubb, p.195 "...where an invention relating to sepulchrate complexes was held obvious over a publication by the inventor of similar complexes. The publication enabled the skilled man to arrive at the claimed complexes without inventive effort, and their predicted advantageous properties would give him an incentive to do so. The further unexpected property which was found was not relevant to the issue of patentability." (T 154/82, IPD 7031, Australian Nat. University/Metal complexes).

⁴⁷¹ Hansen / Hirsch, p.102.

3.13.8. Indicative Evidence

When deciding on inventive step, in addition to the criteria of examination, the European Patent Office has developed certain categories of indicative evidence (secondary indicia / secondary considerations) in the Examination Guidelines (C-IV 9.8); the commercial success, a surprising effect or an unexpected result, a long-felt need and overcoming prejudices in the art. The patent application should specify the advantageous effects of the invention. The evidence should compare the claimed invention with the closest state of the art not only with conventional products on the market.

The indicative evidence has a subsidiary character, it does not suffice to show inventive step alone. It can be only referred to, if an inventive step has not already been recognised on the basis of the problem-solution approach. They are useful in case of doubt about the inventive step. They may contribute to the positive assessment of inventive step but a qualitative assessment must be carried out in any case.

Detailed information regarding categories of indicative evidence is given below;

- The Boards of Appeal disagree on considering commercial success as an indicative evidence and do not base inventive step solely on commercial success.⁴⁷² Commercial success can act as an additional factor and support the conclusion of an inventive step drawn from a comparison of the invention with the state of the art. In some cases evidence of commercial success may play an important role in the assessment of inventive step if the special technical features of the invention can be shown to be casually related to the success.
- Unforeseeable advantageous results achieved from a combination of known features can also establish an inventive step provided that the unexpected solution of a sub-problem does not come easily to the skilled person when

⁴⁷² T 191/82, O.J.EPO 1985, 189.

applying obvious and scheduled measures. The additional advantage could only become the subject of a valid patent if it could be claimed as a new use or as a selection.⁴⁷³

- A long-felt need can be regarded as indicative evidence according to the indications revealed by the Boards of Appeal. A long-felt need occurs if the state of the art set out in the search report is relatively old and no development could have been made as compared with a long-standing state of the art in the field of the invention. An inventive step may be deemed to be involved if during that long period of time an urgent need for improvement has demonstrably existed. Evidence must be submitted showing that numerous unsuccessful attempts have been made in vain to solve the problem. A considerable number of publications must show that the invention would satisfy a long-felt need.⁴⁷⁴

- The existence of a prejudice in the art which might have diverted the skilled man away from the invention, may be an indication that an inventive step was required in order to overcome it.⁴⁷⁵

3.13.9. “Could” versus “Would” Approach

After having established the objective problem to be solved vis-a-vis the closest prior art, we have to consider if the claimed invention was obvious to a person skilled in the art.

In “could” versus “would” approach; the question of inventive step is often decided having regard to whether a skilled person would have arrived at the claimed

⁴⁷³ Cornish / LLewelyn, p.195-196 “... a patentee claimed a self-pulling type of corkscrew in which the screw element had a non-stick coating of the kind commonly found on saucepans. The coating produced a surprising improvement in extracting the cork. Because it was predictable that the coating would help to insert the screw, it was obvious to add it; whether there was any commercial merit in doing so was not relevant... A new use claim was not open in the “corkscrew” case; equally the patent had not been drafted as a selection: [1991] R.P.C. 195 at 217-218.

⁴⁷⁴ Singer / Stauder, EPC, Vol.1 p.165-166

⁴⁷⁵ T 18/81 O.J.EPO 1985, 166.

solution to a problem.⁴⁷⁶ In other words; the solution is obvious if the average skilled person with access to the total state of the art would have reached the same solution, not if he could have reached it. The “would” implies that the skilled person has an incentive to do it. For example; if there is no cross-reference to combine two documents, then a “could-would” argument can give the necessary incentive for the combination.⁴⁷⁷

3.13.10. The Average Skilled Person

The skilled person is a hypothetical person with average skill in the relevant technical area who himself has no inventive capability.⁴⁷⁸ The average skilled person is neither an expert in a field having a special knowledge above average, nor a basic person but a normally qualified practitioner. He is supposed to have access to all elements of this state of the art. He is informed about what is part of the common general technical knowledge in the field in question at the relevant time.⁴⁷⁹ For example, in respect of chemical patents, the person skilled in the art may be a qualified industrial chemist having an average knowledge in his field. A team of highly qualified scientists can be considered as the person skilled in the art in cases where biotechnological complex inventions have to be examined.

Handbooks and textbooks are considered as forming part of the common general knowledge. If the common general knowledge of a skilled person is not sufficient, it is assumed that he will collect information in international patent literature for the determination of relevant state of the art. When looking for a solution for a problem, he is presumed to study patent publications in the relevant patent classes. He had access to everything that forms the state of the art especially to the documents cited in the search report and he has at his disposal the normal means

⁴⁷⁶ Cornish / LLewelyn, p.194 “...it has been objected in the UK that “would” directs attention to commercial, rather than technical considerations and that can be important after grant, especially when searching for legal grounds that will justify an appeal”.

⁴⁷⁷ Visser, p. 80

⁴⁷⁸ T 39/93, OJ 1997, 134, No.7.8.4 .

⁴⁷⁹ The same level of knowledge is applicable when considering the questions of sufficient disclosure and inventive step. (T 60/89 O.J. EPO 1992, 268.

and skill for routine experiments.⁴⁸⁰ A skilled person is allowed to combine documents in assessing inventive step only if it would have been obvious for him to do so at the time of filing the patent application.⁴⁸¹

If the problem prompts the skilled person to seek a solution in another technical field, the specialist in that field is qualified to solve the problem.⁴⁸² He may consult colleagues in those fields of which the problem indicates that they are relevant. In this case a reference is usually made to the knowledge and ability of the specialist responsible for the field in question.⁴⁸³ In the case of complicated inventions such as computers or production of integrated circuits, the skilled person can be a team of skilled men. The place where the skilled person practices his trade does not play any significant role.⁴⁸⁴ There is no difference between a European and an American skilled person since knowledge is accessible everywhere.

If the technical fields of the problem and solution are different, the skilled person is the specialist having a technical knowledge in the field of the problem, not the one in the field of solution.

In the examination of inventive step, the skilled person should only consider his own or a close (neighbouring) technical field, even if the state of the art comprises all fields of technology. The technical field of an invention is the field in which the skilled person works; a neighbouring technical field is a field in which the skilled person will look for solutions. Only patent literature in closely related fields is relevant for inventive step. The skilled person should consider relevant developments within field of technology which are adjacent to his own but he does not have to know the patent literature of a remote field of technology. For example the filing of pharmaceutical preparations in hard or soft capsules have been regarded as neighbouring technical areas, although both processes are carried out by different skilled persons.⁴⁸⁵

⁴⁸⁰ Visser, p. 84.

⁴⁸¹ Grubb, p.60 T 552/89 (unpublished) Tetra Pak/Cold Cathode.

⁴⁸² Hansen/Hirsch, p.245 "Cleaning apparatus for conveyor belt/Fives-Cail Babcock"-T32/81 of 5.3.1982, O.J.EPO 1982, 225.

⁴⁸³ T 32/81 O.J. EPO 1982, 225.

⁴⁸⁴ T 426/88, O.J.EPO 1992, 427, No.6.3.

⁴⁸⁵ Visser, p.85, T 1/85 of 22 July 1986.

In addition to neighbouring fields, the superordinate general field can also be consulted for the state of the art if the same or similar problems as in the specialist field play a role and if the skilled person in the specialist field can be expected to know this.

3.14 Industrial Application

According to Art.57 EPC; an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture. This definition is particularly important for countries such as Great Britain and the Netherlands, which have previously excluded certain agricultural inventions from patent protection.⁴⁸⁶

In American system; an invention must be also useful to be patentable in addition to other requirements. For example a process leading to a particular aspect for tobacco leaves could not be patented in the USA due to lack of utility but such an invention can be patentable according to EPC.

“Industry” should be interpreted broadly. It defines an activity which is carried out continuously, independently and for financial gain. This broad definition complements the requirement that an invention must consist of technical elements. Activities for private use or for non-commercial purposes do not fall within the concept of industrial application.

Non-industrial activities such as manufacture of devices for religious acts or for the pursuit of arts are excluded from patentability on social and ethical grounds. These devices are manufactured industrially but not used commercially. Medical equipment used on humans and animals are also not patentable because the activity of a doctor is not regarded as a trade.

⁴⁸⁶ Singer/Stauder, Vol.1, p.176.

Industrial applicability requires that the invention can be manufactured and is sufficiently disclosed under Art.83 EPC.

Methods of treatment by therapy or surgery is excluded from patentability since they are considered to be incapable of industrial applicability but cosmetic treatment is not.⁴⁸⁷ If a chemical product has both a cosmetic and a therapeutic effect, the cosmetic treatment shall be granted patent protection.⁴⁸⁸

⁴⁸⁷ Visser, p. 86 “...(T 36/83, T144/83 r.5 appetite reducer, T 780/89) However if a surgeon is required for the cosmetic treatment, the treatment is excluded from industrial application (T24/91 r.2.4)”

⁴⁸⁸ T 144/83, O.J.EPO 1986, 301.

(IV) PATENT CO-OPERATION TREATY

4.1 Introduction

The Patent Co-operation Treaty, generally known as PCT can be defined as an arrangement for introducing a supra-national element into patent system. It is an agreement for international cooperation in the field of patents. When compared to EPC which is a supra-national arrangement of a regional character, the PCT is of worldwide character.⁴⁸⁹

The PCT does not establish a supranational patent Office or grant a world patent.⁴⁹⁰ It merely simplifies the process of filing a patent application in a number of countries. It is aimed at centralization of patent applications. The European Patent Convention has gone one step further and provided for the grant of a European Patent with validity in countries designated by the applicant..

The aim of filing an international PCT application is to obtain either a national patent (e.g. an Italian patent) or a regional patent (e.g. a European patent) for a series of designated countries.⁴⁹¹

The EPO may act as a designated office for Euro-PCT route as an international application. The requirements of the PCT are incorporated into EPC for the purposes of the processing of such international applications by the EPO.

PCT shall be applied in accordance with Articles 150-158 EPC⁴⁹² and R 104-112 EPC. In case of uncertainty, the provisions of PCT prevail over the provisions of

⁴⁸⁹ Reid, p. 180.

⁴⁹⁰ Grubb, p.29.

⁴⁹¹ Hansen / Hirsch, p.36 "Belgium, France, the Netherlands and Greece have excluded the possibility of obtaining national patents via the PCT route. Designation of these States is deemed an application for a European patent for these States."

the EPC for international applications whether in the international phase or later in the regional phase before the EPO.⁴⁹³

The PCT was concluded in 1970, amended in 1979 and modified in 1984 and 2001. The PCT is administered by the International Bureau (the Secretariat of WIPO or using the French initials, OMPI), a United Nations organisation with its headquarters in Geneva. Instruments of ratification and accession should be deposited with the Director General of WIPO. It is open to all countries that are members of the Paris Convention for the Protection of Industrial Property.

The PCT established a Union. The Union has an Assembly and every Contracting State to the PCT is a member of the Assembly. The Assembly is entrusted with the tasks of amending the Regulations issued under the PCT, the adoption of the biennial program and budget of the Union and the fixing of certain fees paid for the functioning of the PCT system.

The PCT includes all EPC States, USA, Japan, China and Russia amongst the Contracting States. The total number of PCT Contracting States is 124 as of December 31, 2004.

⁴⁹² Art. 150 EPC Application of the Patent Cooperation Treaty
Art. 151 EPC The European Patent Office as a receiving Office
Art. 152 EPC Filing and transmittal of the international application
Art. 153 EPC The European Patent Office as a designated Office
Art. 154 EPC The European Patent Office as an International Searching Authority
Art. 155 EPC The European Patent Office as an International Preliminary Examining Authority
Art. 156 EPC The European Patent Office as an elected Office
Art. 157 EPC International Search Report
Art. 158 EPC Publication of the international application and its supply to the European Patent Office

⁴⁹³ Singer / Stauder, EPC-Vol.2, p. 595-596.

4.2. The Functioning of the PCT System

4.2.1. Filing an International Application

PCT serves to eliminate unnecessary efforts when an applicant wished to designate a number of countries in his patent application. Under PCT, the applicant who is a national or resident of a Contracting State can file a single “International Patent Application” at a national or regional Patent Office which acts as an international authority for the purposes of the PCT and which carries out the initial and formal examination.⁴⁹⁴ International applications can only be filed with national offices, which will act as a PCT receiving Office.

An international application has the effect, as of the international filing date, of a national application in those PCT Contracting States which the applicant designates for a national patent in his application. It has the effect of a regional patent application in those PCT Contracting States which are party to a regional patent treaty, providing they are designated for a regional patent such as an ARIPO patent, a Eurasian patent, a European patent or an OAPI patent.

In an international application, an applicant can claim priority under the Paris Convention of an earlier application for the same invention for up to 12 months after the filing of that earlier application. An earlier application can be a national, a regional (e.g. European) or an international (PCT) application. If there is no priority claim from an earlier application under Paris Convention, the priority date will be the international filing date of the international application.⁴⁹⁵

The form and contents of international applications should comply with the standards set out in the PCT. According to Art.3 PCT in connection with Art.11 PCT,

⁴⁹⁴ <http://www.wipo.int/pct/en/treaty/about.htm> retrieved on 03.3.2005 “...If the applicant is a national or resident of a Contracting State which is party to the European Patent Convention, the Harare Convention on Patents and Industrial Designs (Harare Protocol), the revised Bangui Agreement Relating to the Creation of an African Intellectual Property Organization or the Eurasian Patent Convention, the international application may also be filed with the European Patent Office (EPO), the African Regional Industrial Property Organization (OAPI) or the Eurasian Patent Office (EAPO), respectively.

⁴⁹⁵ Grubb, p.29.

a patent application under PCT must include a request indicating that the application is to be handled as an international application under the PCT. The name of the applicant must be clear. At least one Contracting State has to be designated. Furthermore a description, at least one claim and an abstract must be included. If these minimum set of requirements are satisfied, the application shall be given an international application date under Art.11 PCT. No national law of a designated country may prescribe additional requirements.

A single set of fees including a transmittal fee to cover the work of the Receiving Office, a research fee to cover the work of the International Searching Authority and an international fee to cover the work of the International Bureau are to be paid to the PCT Receiving Office.

The language of an international application depends upon the requirements of the Receiving Office and the International Searching Authority.⁴⁹⁶ In international phase the proceedings are carried out in one language. Upon the entry into national phase, the particular Offices may demand the translations and payment of national fees.

After the filing of an application, the “Receiving Office” accords an international filing date and makes a formal check. Then the Receiving Office forwards a copy of the international application to the International Bureau of WIPO and another copy to an International Searching Authority which carries out the prior art search.⁴⁹⁷ The Receiving Office collects all the PCT fees and transfers the search fee to the International Searching Authority and the international fee to the International Bureau.

⁴⁹⁶ International applications may be filed in Chinese, English, French, German, Japanese, Russian and Spanish. Danish, Dutch, Finnish, Norwegian and Swedish are also accepted.

⁴⁹⁷ Major patent offices are appointed by the PCT Assembly as an International Searching Authority (ISA).

4.2.2. Obligatory International Search

Every international application is subjected to an international search which is carried out to determine the relevant state of the art (Art.51 PCT). International search is a high quality search of the patent documents and other technical literature in languages (English, German, French and in certain cases Chinese, Japanese, Russian and Spanish) in which most patent applications are filed.

Australian Patent Office, Austrian Patent Office, Chinese Patent Office, European Patent Office, Japanese Patent Office, Russian Patent Office, Spanish Patent and Trademark Office, the Swedish Patent Office and the United States Patent and Trademark Office are acting as International Searching Authorities (ISA). Each of them must have minimum patent documentation, as from 1920, of the major industrialized countries, together with agreed items of non-patent literature at his disposal. The obligation to consult at least the PCT minimum documentation guarantees a high level of international searching. For a given international patent application there may be one or more competent International Searching Authorities.

International Search Authority draws up an “international search report”, which is made available to the applicant by the fourth or fifth month after the application is filed. This search report cites the relevant prior art and lists citations of mainly such published patent documents relating to the previous inventions that might affect the patentability of the claimed invention. It doesn't contain any documents on the value of your invention.

International search report gives the applicant the opportunity to decide whether it is worthwhile to continue to seek protection for his invention in designated countries. If the search report is unfavourable, the applicant may amend the claims in his international application to better distinguish the invention from the state of the art. He may also withdraw the application before it is published and thereby he can save the costs involved in filing separate national applications under the traditional Paris Convention route.

If the International Search Authority concludes that the international application does not comply with the requirement of unity, the applicant shall be asked to pay further search fees (Art.17(3)(a) PCT). This procedure is similar to the one under the EPC.⁴⁹⁸

The International Search Authority sends the international search report to the applicant and to the International Bureau. The International Bureau includes the search report in the international publication of the international application and sends a copy to the designated Offices.

4.2.3. International Publication

If the applicant does not withdraw his application, the international patent application and the international search report are published by the International Office of the WIPO in Geneva, to disclose the invention to the public and to set out the scope of the protection. Normally, the search report is published together with the description, the claims, the drawings, the abstract and the details of the application.

If the claims have been amended by the applicant, the claims are published both as filed and as amended.

International publication occurs generally 18 months after the priority date of the international application. At the request of the applicant, the publication can be issued earlier. The applicant has two further months to prepare all necessary translations. The international phase ends on the expiry of 20 months from the priority date according to Art.22(1) PCT or of 30 months according to Art.39 (1) PCT when an examination request is filed before the expiry of 19 months from the priority date.⁴⁹⁹

⁴⁹⁸ For further details see Hansen/Hirsch, p.38-39.

⁴⁹⁹ Hansen / Hirsch, p.37 “ For the Euro-PCT Route (regional phase before the EPO) both of these terms have been extended by 1 month (Rule 104 b (1) EPC according to the Authorisation in Art.22(3) or Art.39(1)(b) PCT).”

Until the international publication, no third person is allowed access to an international patent application unless authorized by the applicant. If the applicant withdraws his international application then it won't be published and as a consequence the third parties shall gain no access.

International application together with the international search report are communicated by the International Bureau to each designated Office.

4.2.4. International Preliminary Examination

After the receipt of the search report, an applicant has the option to make a request for an international preliminary examination to obtain an opinion whether the patentability criteria in respect of novelty, inventive step and industrial applicability have been fulfilled in the sense of Art.33(1)-(4) PCT. The examination request must be filed within 19 months from the priority date. The applicant must indicate the Contracting States in which he wishes the international preliminary examination to be applied. International Search Report is transmitted to an International Preliminary Examining Authority (IPEA) which advises as to the patentability of the invention in question in the light of the prior art found. The major benefit of international preliminary examination is that the entry into the national/regional phase can be postponed for a further 10 months period and during this time an official opinion regarding the patentability of the invention can be obtained.

International Preliminary Examination authorities are appointed by the Assembly of the PCT. They have qualifications similar to those of international searching authorities. The same authorities are appointed which function as International Searching Authorities, with the exception of the Spanish Patent and Trademark Office.

International Preliminary Examination authority draws up a report and transmits it to the applicant and the local patent offices through the International Bureau. It provides a basis for the applicant to evaluate his chances of obtaining a

patent. Although it is not a binding report, the local patent offices usually pay attention to it when they are carrying out further prosecution.

Upon the publication of the international application latest by the end of the 19th month after the priority date, the International Bureau communicates the international application to the designated offices. The processing of an international application before the designated national Offices may not start prior to the expiration of 20 months from the priority date of the international application unless the applicant requests an earlier start.

4.2.5. National Phase

At the latest, with the expiry of 20, or 30 months if an international preliminary examination took place, the applicant must submit a copy international application and if necessary a translation of it to each designated Office, as well as pay the national fees (Art.22, Art.39 PCT).

The “national phase” describes the last part of the patent granting procedure which shall be carried out by the national patent offices of the designated countries. Within 20 months from the priority date; the application is transmitted to the individual Patent Offices of the Designated States and treated from then on as a national application in each designated country. Local patent offices have to deal with further prosecution in accordance with its normal procedure.

After having received the search report and where appropriate, an international preliminary examination report if the applicant decides to continue the procedure, he must pay the national fees and provide the translations of his international application to the national patent offices of the designated countries. These steps must be taken, in relation to the majority of PCT designated offices, before the end of the 30th month from the date of the priority.

Once the national processing starts, the normal national procedures apply, subject to specific exceptions arising out of the PCT procedure such as matters of

form and contents of the international application, and the provision of copies of the priority document.

Centralized procedures of the international phase (examination as to the form by the Receiving Office, search by the International Searching Authority and optional examination by an International Preliminary Examining Authority) reduce the workload of the national patent offices.

Although the examination of a patent application in designated countries is centralised to some extent under PCT, a bundle of national patents are granted at the end. The PCT does not provide for the grant of international patents since the national patent offices are exclusively responsible for granting patents.

4.3. Advantages of the PCT System

International search reports and preliminary examination reports have reduced the search and examination work of patent offices considerably. Patent Offices can handle more patent applications since applications coming via PCT are examined with regard to compliance with formal requirements during the international phase. They can save part of the publishing cost. The PCT does not affect the revenue of the designated offices on national fees. In several national offices, fees are fixed lower for international applications than direct national applications.

Examining patent offices benefit from drawing up international search reports and preliminary examination reports.

Publication of international application with an international search report gives third parties the opportunity to formulate a well-founded reasoning about the patentability of the claimed invention.

When approving licensing agreements, national authorities benefit from the great value of a patent granted on the basis of an international application.

An applicant can file a single international application within the priority year with effect in all States he has designated. That application may be filed until the last day of the priority year and may be identical both as to language and form with his own national application.

The applicant has up to 18 months more than he has in a procedure outside the PCT to express his intention of seeking protection in foreign countries, to appoint local patent agents in the designated countries, to prepare the translations and to pay the national fees. The applicant gains extra time (18 months after the search report and possibly a preliminary examination report have been received) for investigating commercial benefits of his invention abroad. At this point, an applicant has the opportunity to drop some or even all of the designated countries without wasting more money.⁵⁰⁰

Upon the receipt of an international search report and optional international preliminary examination report, the applicant can evaluate his chances of getting patent protection for his invention before incurring major costs.

The applicant may amend the international patent application during the international preliminary examination before processing by the designated patent offices.

Patents granted on the basis of international applications are usually more reliable for investment, licensing agreements and transfer of technologies since international standards are applied by the international searching authorities and international preliminary examining authorities when carrying out the international search and the international preliminary examination.

Many important inventions are subject to PCT applications and developing countries can accede to modern technological information earlier (within 18 months after the priority date) and easier through the international publication of these applications together with the search reports.

⁵⁰⁰ Grubb, p.29.

Due to the high quality of work performed by the international searching and preliminary examination authorities, any patent granted under the PCT is less likely to be successfully challenged. This fact renders international patents more reliable in respect of investment decisions.

(V) THE DEVELOPMENTS ON ESTABLISHING COMMUNITY PATENT

5.1. The Need for a Community Patent

Although the European Patent Convention is operating successfully, it does not create a unitary and autonomous patent protection throughout the Community.

The European patent is a bundle of national patents and subject to jurisdiction of national courts. In each Contracting State, a European patent has the same effect as a national patent granted by that state and can develop diversely in each Member State. Various decisions can be rendered concerning the same legal dispute by the national Courts of Contracting States, for example a European patent can be declared void in France, divided in Italy, lapse in the United Kingdom and be upheld in Germany. A European patent owner must enforce his European patent individually in each Member State. The scope of protection may differ from one Member State to another especially in respect of equivalence. The translation of a European patent application into the official languages of the designated states give rise to immense costs.⁵⁰¹

These weaknesses of the European Patent Convention have led to attempts for creating a unitary protection which can be guaranteed throughout the Community by a Community-wide patent.⁵⁰²

Attempts for the creation of a community-wide patent date back to 1960's due to the establishment of the EEC. The Community Patent Convention was signed on 15 December 1975.⁵⁰³ Conferences have been held in 1985 and 1989 in Luxembourg, in 1992 Lisbon and again in 1996 Luxembourg but the EC Member States could not resolve the deadlock.⁵⁰⁴

⁵⁰¹ Niels Hölder, "The Community Patent – Break-Through or Set Back ?", [2004] E.I.P.R. Issue 2, Sweet & Maxwell Limited [And Contributors] p.44. "Translation costs account for about 50 percent of the total costs for obtaining and maintaining an average European patent."

⁵⁰² Bainbridge, p.438.

⁵⁰³ Christopher Wadlow, *Enforcement of Intellectual Property in European and International Law*. Sweet & Maxwell. 1996, p. 214-215.

⁵⁰⁴ Özcan, p. 184-185.

The latest version of the Community Patent Agreement (the Luxembourg Convention on European Patents) was published in 1989.⁵⁰⁵ Its aim was to transform national stages of the European patent into a single community stage. It has gained significance in respect of eliminating trade barriers and creating a single market where goods and services can move freely. The Convention had never entered into force since it has been very difficult to obtain the consent of all participants. Especially Ireland and Denmark had met constitutional problems in the ratification process. They were reluctant to surrender a degree of their national sovereignty.

The European Patent Convention and the Eurasian Patent Convention can be both considered as important regional patenting arrangements which shall reduce costs and simplify obtaining patents on an international basis. Attempts for the completion of both arrangements must be encouraged by the Member States which will benefit from them in a short period of time, both within the financial and political meaning.

5.2. Council Regulation on the Community Patent

The Luxembourg Convention signed in 1975 and amended in 1989 had never entered into force because only seven States have ratified it. Following this failure, a Commission's Green Paper of 24 June 1997 on the Community Patent⁵⁰⁶ has led to the adoption of a proposal for a Council regulation on August 1, 2000 and presented by the Commission (COM 2000 (412) final).⁵⁰⁷ Since the publication of a proposal over three years ago, progress in the Council towards adoption of the Regulation has been slow but on March 3, 2003 the Council agreed unanimously on the Common Political Approach which is based on the Draft Patent Regulation for the Community Patent.

⁵⁰⁵ The Community Patent Convention and the Protocol on the Settlement of Litigation Concerning the Infringement and Validity of Community Patents, which both form the part of the Agreement relating to Community patents (89/695/EEC), published on 15 December 1989, OJ L401, 30.12.1989, p.1.

⁵⁰⁶ The Commission published a Green Paper on the Community patent and the patent system in Europe entitled "Promoting innovation through Patent" on June 24, 1997, (COM(97)) 314. It sought views on many aspects of the proposed system from industry, patent agents and individual inventors.

⁵⁰⁷ <http://www.chailot.com/En/circ/c72.html>, retrieved on March 8, 2005. Cabinet Chaillot, Industrial Property Attorneys in France.

All these difficulties that have been encountered in the process of adopting Community Patent Convention proved that the move to a Community Patent system should no longer be through an international Convention, but rather through the adoption of a Community Regulation.⁵⁰⁸ The adoption of a Community Regulation would offer three main advantages. First of all; the regulation shall be enforceable without the need of a ratification. Second, the date of entry into force of provisions would be known for certain, since the date would be fixed in the text of the regulation. The date of entry into force of a Convention is uncertain since it depends on the ratification speed and procedure of the signatory countries. A third advantage would be that the Regulation would automatically form a part of Community law when it came to future enlargements of the Community.

5.3. General Functioning of the Community Patent System

The Community patent shall not replace national patents and the European patent. It contains provisions to allow the Community and national systems to co-exist. But simultaneous protection is prohibited.⁵⁰⁹ Applicants wishing to be granted protection in one country only or designating three or more member states shall have the right to apply for national patents and European patents. A community patent which will also be administered by the EPO would be the best choice for the proprietors who want to obtain full protection throughout the Community.

The Regulation will supplement the Munich Convention. The European Patent Office shall use its expertise and issue Community patents, specifying the Community territory instead of designated individual Member States. The European Patent Office will alone be responsible for the examination of applications and the grant of Community patents. As a result of implementation of the Regulation, the

⁵⁰⁸ Prime / Booton, p.218.

⁵⁰⁹ Prime / Booton, p. 214 "... To achieve this the Convention provides that where a national patent granted in a Member State relates to an invention for which a Community patent has been granted to the same inventor or to his successor in title with the same date of filing, or, if priority has been claimed, with the same date of priority, that national patent is ineffective to the extent that it covers the same invention as the Community patent."

Community shall have to accede to the Munich Convention. The Convention shall be revised to enable the EPO to grant a Community patent.⁵¹⁰

5.4. General Characteristics of the Community Patent

In accordance with the articles of the proposal for a Council Regulation on the Community Patent, certain characteristics of a Community patent and rights conferred upon a Community patent owner can be described as follows:

The Community patent has a unitary and autonomous character. It can be only granted, transferred or declared invalid for the whole of the Community, not on a Member State by Member State basis. Such singularity is the basic idea of the Community patent (Art.2).

Community patent applications shall be filed either with the National Patent Office of a Member State or directly with the European Patent Office. Under partnership agreements which shall be concluded between the European Patent Office and National Patent Offices, the latter shall have competence to carry out novelty searches.

The inventor or a successor in title is entitled to apply for a patent for the claimed invention (Art.4/1).⁵¹¹

Conditions for patentability set out in the Munich Convention shall be applied to Community patent applications.⁵¹²

⁵¹⁰ <http://europa.eu.int/scadplus/leg/en/lvb/l26056.htm>, retrieved on March 8, 2005.

⁵¹¹ If the inventor is an employee, the right to patent is determined according to the law of the State in which the employee is mainly employed or, if that State cannot be determined, with that of the State in which the employer has his place of business (Art.4/2).

⁵¹² Hölder, p.46, "As a positive side effect of the accession of the European Community to the EPC, there is no need to create substantive law on patentability, The rules contained in the EPC (Arts 52 et seq.) will also apply to Community patents."

The European Patent Office shall examine the application and publish it. If a patent is granted, it will be published in the Register of Community Patents and/or the Community Patents Bulletin.

A community patent owner shall have the right to prohibit the direct and indirect use of the invention (Art.7-8) . He will be entitled to prevent third parties

- from making, offering, putting on the market or using a product which is the subject matter of the patent, or importing or stocking the product for these purposes,
- from using a process the subject matter of the patent or from offering the process for use within the community,
- from offering, putting on the market, using or importing or stocking for these purposes the product obtained directly by a process which is the subject matter of a patent,
- from supplying or offering to supply within the Community to a person other than one entitled to exploit the patented invention.(indirect use)

A patent proprietor or the beneficiary of a licence contract may bring infringement actions that must be based on a presumed infringement of the rights conferred by the patent.

A Community patent may be subject of an exclusive or non-exclusive license agreement in whole or in part for all or part of the Community (Art.19-20).

In the proposal for a Council Regulation on the Community Patent, it is stated that any negative effects of a monopoly created by a Community patent shall be prevented through a system of compulsory licences. The Commission and national authorities shall apply the Community Competition law.

In case of lack or insufficiency of exploitation of a Community patent or in case of dependent patents the Commission may grant compulsory licenses. In times of

crisis or extreme urgency or in a situation where it is necessary to remedy a practice deemed after a judicial or administrative process to be anti-competitive, the Commission may also authorise the use of a Community patent (Art.21).

The term of protection for a Community patent is twenty years, starting from the date of the application (Art.27(1)(a)). The renewal fees shall not exceed fees for an average European patent.

5.5. Establishment of Community Patent Courts (CPCs)

The Regulation provides for the creation of a centralised Community Intellectual Property Court which will comprise chambers of first instance and appeal. The main objective is to guarantee unity of law and consistent case law.

The centralised court shall deal with disputes between private parties and have exclusive jurisdiction in infringement and invalidation cases. It will be competent to render enforceable rulings and to impose sanctions and award claims for damages.

The national courts shall have jurisdiction in disputes which do not come within the jurisdiction of the Court of Justice and the Community Patent Court. National courts shall deal with cases such as where an employer and an employee are in dispute over the right to a patent.

On the other hand the establishment of Community patent courts shall amount to the generation of a large body of European case law in the field of patent protection. Infringement disputes in the field of intellectual property are civil matters and they are subject to the rules set out in the Council Regulation (EC) No.44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgements in civil and commercial matters.⁵¹³ According to Art.22 of the Regulation; decisions on revocation or cancellation of a registered patent may only be taken by

⁵¹³ OJ EC 12/2001 L, p.1 (Brussels Regulation)

the courts of the country for which the right has been granted. Cross-border competence is normally limited to the courts of the country where the defendant is resident or has his principal place of business and does not extend to the country where the infringing act has occurred. Due to the divergent approaches of the various national courts in Europe, the effectiveness of industrial property protection, especially in the field of patent law, will continue to depend on the quality of the national courts.⁵¹⁴

The European Commission has presented proposals for two Council Decisions for establishing a Community patent jurisdiction within the European Court of Justice. The first proposal would confer jurisdiction especially concerning infringement and validity disputes on the European Court of Justice.⁵¹⁵ The second proposal concerns the establishment of the Community Patent Court, whose judges would be appointed by the Council of Ministers, to exercise the Court of Justice's jurisdiction on its behalf. It also provides for the establishment of a specialised chamber within the Court of First Instance to hear appeals against the Community Patent Court's judgements. In exceptional cases, a decision of the Court of First Instance could be subject to review by the Court of Justice.⁵¹⁶ According to this judicial system, jurisdiction shall reside in the first instance in the Community Patent Court created by the decision taken pursuant to Art.225 a of the Treaty and, on appeal, in the Court of First Instance. The Court of Justice may take decision in the last resort.

According to the Proposal for a Council Regulation on the Community Patent, this system must be operational by January 2010 at the latest. Until that time, it is necessary to provide for a transitional period. During transitional period each Member State shall designate a limited number of national courts to have jurisdiction in disputes over the future actions and claims related to Community patents.

⁵¹⁴ Symposium on Effective Enforcement of Intellectual Property Rights in Turkey, April 2004-Istanbul, "Enforcing Industrial Property Rights: Patent Protection From A Comparative Viewpoint" Dieter Stauder.

⁵¹⁵ Proposal for a Council Decision Conferring jurisdiction on the Court of Justice in disputes relating to the Community Patent – COM (2003)827 final (23.12.2003).

⁵¹⁶ Proposal for a Council Decision establishing the Community Patent Court and concerning appeals before the Court of First Instance – COM (2003) 828 final (23.12.2003).

The seat of the Community Patent Court shall be at the Court of First Instance. The judges shall be appointed on the basis of their expertise and linguistic skills.

5.6. Invalidity of a Community Patent and Infringement Cases

Grounds for invalidity are set out in Art.28. The Community patent shall be declared invalid if

- the subject-matter of the patent is not patentable according to Articles 52 to 57 of the EPC;
- the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;
- the subject-matter of the patent extends beyond the content of the application as filed;
- the protection conferred by the patent has been extended;
- the proprietor of the patent is not entitled under Art 4(1) and (2) of this Regulation;
- the subject-matter of the patent is not new having regard to the content of a national patent application or of a national patent made public in a Member State on the date of filing or later or, where priority has been claimed, the date of priority of the Community patent, but with a filing date or priority date before that date.

A court's decision for the invalidation of a Community patent in whole or in part has a retroactive effect (Art.29(1)). There are exceptions to this general rule. In decisions on infringement which have acquired the *res judicata* effect and been enforced prior to the invalidity decision or where contracts are concluded and performed prior to the invalidity decision, the invalidation of a Community patent does not have any retroactive effect (Art.29(2)).

The Commission may refer an action for invalidity of a patent to the court and intervene in such proceedings if the Community's interests are at stake.

The national arbitration rules of the Member States will remain in force. A community patent may not be declared invalid in arbitration proceedings (Art.53).

In infringement cases, the Court may issue;

- an order prohibiting the defendant from continuing with the acts which infringed the patent;
- an order to seize the products resulting from the infringement;
- an order to seize goods, materials, etc., which enable the invention to be used;
- an order imposing other sanctions adapted to specific circumstances.

5.7. The Common Political Approach

The EU Council agreed on a common political approach on March 3, 2003.⁵¹⁷ It is based on the draft Community Patent Regulation, submitted on August 1, 2000 by the Commission. It covers vital issues which are aimed at compensating for the weaknesses of the European Patent System to a certain extent, especially in respect of exclusive jurisdiction in legal disputes and translation costs..

5.7.1. Principles and Features of the Jurisdictional System for the Community Patent

From 2010 onwards, the litigation of Community patents shall at first instance take place before a judicial panel established by a Council decision according to Art.225a of the EC Treaty, called the “Community Patent Court” (CPC).

The CPC will have exclusive jurisdiction over almost all kinds of actions that concern Community patents, including infringement actions, actions for declaration of non-infringement, claims of invalidity, nullity actions, requests for limitation, proceedings relating to the use of the patent or to the right based on prior use of the patent, counterclaims for invalidity or applications for declarations of a lapse and also

⁵¹⁷ International Treaties [OJ EPO 5/2003]

requests for provisional measures.⁵¹⁸ The CPC shall be competent to award damages and to grant interim injunctions. This judicial panel shall be attached to the Court of First Instance of the European Communities.

The proceedings before the CPC shall be conducted in the official language of the Member State where the defendant is domiciled. At the request of the parties and with the consent of the Community Patent Court, any official language can be chosen as language of the proceedings.

5.7.2. The Language Regime and Costs

A complete patent application shall be filed in one of the official languages of the EPO (English, German or French), which will be the working language. Once the patent has been granted, these claims shall be translated into all official Community languages (Art.24a) except if a Member State renounces the translation into its official language. The translations shall be filed with the European Patent Office and the costs shall be paid by the applicant who decides on the number and the length of claims to be included in the patent application. It is not necessary to translate a Community patent i.e. the entire specification into all the Community languages. The applicant has an option to deposit the translations of the patent into other official languages of the Member States which will be made available to public (Art.58).

The translation of the claims into all Community languages is being criticised since this would amount to a considerable amount of translation costs which shall be borne by the applicant.⁵¹⁹ Besides the costs, there are other two important issues on which the Member States have to reach a compromise. Who will decide on the legal

⁵¹⁸ Hölder, p. 46-47 "... The Council intends to establish the CPC by 2010, enough time to rethink the concept. A decentralised judicial system with national courts acting as Community courts and with a central court of appeal would be much faster, cheaper and closer to its users and would, at the same time, ensure the same type of harmonisation that a Community Patent Court would accomplish."

⁵¹⁹ Mario Franzosi, "A Community Patent: Three Suggestions for Two Difficulties", *International Review of Intellectual Property and Competition Law*, Published by the Max Planck Institute for Intellectual Property, Competition and Tax Law, Volume 35, No.4/2004 p.417-418 "...there is no need to translate all the claims. Only independent claims have to be translated. In fact, if the purpose of the translation is to make competitors aware that their actions may incur liabilities, translation of only the independent claims fulfils the purpose. Nobody can violate a dependent claim without also violating the main claim... limiting the translation to independent claims may reduce the cost of the translation to one-fifth (or one-tenth) of the figure anticipated."

validity of the translation and how shall be dealt with the effects of a mistranslation ? The length of period for filing translation of the claims within a reasonable time is another important issue. During this time the granted patent shall be valid irrespective of availability of translations of all claims into all official Community languages.⁵²⁰

5.7.3. The Role of the National Patent Offices and the Distribution of Fees

The national patent offices shall have an important role. They shall disseminate patent information, advise potential Community patent applicants and SMEs, receive applications and forward them to EPO. The applicants shall present their applications either to National Patent Office of a Member State in its working language or directly to the EPO. Through partnership agreements the National Patent Offices shall be able to carry out search work on behalf of the EPO.

National Patent Offices shall be compensated for their activities in respect of Community patents. The fees for the granting of patents should be split 50/50 between the European Patent Office and the national patent offices, in accordance with a distribution key, which will be decided by the Council.⁵²¹

⁵²⁰ http://www.european-patent-office.org/news/info/2003_04_30_e.htm retrieved on March 11, 2005. "...The council notes that the German delegation considers that a reasonable time would be within two years from the date of the grant of the patent".

⁵²¹ <http://europa.eu.int/scadplus/leg/en/lvb/126056.htm>, retrieved on March 8, 2005.

VI. PRIMARY ISSUES CONCERNING THE PATENTABILITY OF PHARMACEUTICAL INVENTIONS : LAW AND PRACTICE IN PHARMACEUTICALS

In the preceding sections, detailed information is given about the strict requirements and time-consuming procedures for obtaining patent protection for inventions. In this section, primary issues concerning the patentability of pharmaceutical inventions are scrutinized. Strong enforcement of patent rights is of utmost importance for the pharmaceutical industry because countries that adopt strong IP protection attract more investments than those that do not. On the other hand without adequate patent protection, patients would not have access to new medicines and technologies which enable them to live healthier and more productive lives.

It is a time-consuming and an expensive process to discover and develop new drugs. Only five in 5000 compounds that enter the preclinical testing make it to human testing. One of these five tested in people is approved.⁵²² It takes nearly eight to twelve years from the discovery of a new drug until the licensing stage. On average, it costs a company 350 to 500 million Dollars to get one new medicine from the laboratory to the pharmacist's shelf. Without recouping these huge amounts of costs, the pharmaceutical companies shall not be encouraged to carry on with further research and development activities. In 2000 these companies spent 44 billion Dollars on research. It is estimated that they will not undertake development of a new drug without anticipated sales of 1 billion Dollars a year.⁵²³

The earliest pharmaceutical patent is a German patent which was granted in 1903 for Barbitol. Aspirin was patented in 1956 and 1966.⁵²⁴

⁵²² Pınar Bulut, İlaç Endüstrisinde Patent Uygulamaları ile Türkiye'deki Mevcut Durum Üzerinde Araştırmalar, Hacettepe Üniversitesi Sağlık Bilimleri Enstitüsü Doktora Tezi, 1998-Ankara, p.62.

⁵²³ R.Davies Colin, "What Future for Altruism in the Pharmaceutical Industry?", [2004] E.I.P.R Issue 10, Sweet & Maxwell Limited, p.437.

⁵²⁴ Bulut, p.46.

New medicines are developed as follows:⁵²⁵

- Preclinical Testing : Screening tests, laboratory and animal studies are conducted to determine the pharmaceutical effect of a substance against the targeted disease. The compound is also assessed for its safety. These tests take three and one-half years.

After completing preclinical testing the company files an Investigational New Drug Application (IND) with FDA in USA to begin to test the drug in people.

- Clinical Trials, Phase I : These tests take about a year and they are carried out on 20 to 80 normal, healthy volunteers. The tests study a drug's safety profile, including safe dosage range, potential side effects and also determine how a drug is absorbed, distributed, metabolized and excreted and the duration of its action.

-Clinical Trials , Phase II : These studies take about two years and involve approximately 100 to 300 volunteer patients. Drug's effectiveness is assessed.

-Clinical Trials, Phase III : This phase takes about three years and involves 1,000 to 3,000 patients in clinics and hospitals. Physicians monitor patients closely to determine efficacy and identify adverse reactions.

Following the completion of all three phases of clinical trials if it is proved that the drug is effective and safe, a New Drug Application (NDA) is filed with FDA in USA. Once FDA approves the NDA, the new medicine becomes available for physicians to prescribe. For some medicines, FDA requires additional studies (Phase IV) to evaluate long-term effects.⁵²⁶

⁵²⁵ http://www.allp.com/drug_dev.htm Alliance Pharmaceutical Corp. A research and development company focused on transforming innovative scientific discoveries into novel therapeutic and diagnostic agents, retrieved on 22.05.2005.

⁵²⁶ www.fda.gov/OHRMS/DOCKETS/AC/99/slides/3506s4/tsldoo6.htm, retrieved on 22.5.2005.

As we know, patents are classified as “product patents” and “process patents” in respect of features of an invention. Pharmaceutical patents can be classified as follows :

- 1- Product patents which grant protection for pharmaceutical products can be divided into three subclasses;
 - (a) New active substance, or substance compositions : If an unexpected positive effect can be achieved in a treatment, the novelty and the inventive step are considered to be fulfilled per se.
 - (b) The use of a known substance or substances in therapeutic, surgical or diagnostic methods for the first time: If this substance has been used in one of these methods before, it shall not be protected by product patent even though, when it is used in one of the other methods for the first time.
 - (c) The formulation of a new or an already known substance as a medicine (e.g. new dosage of a novel or known substance): Such a formulation must be novel and involve an inventive step in order to be protected by a product patent. The invention should not be an easy solution for the skilled person.
- 2- Processes for the production of drugs are also protected by patents. Process patents in pharmaceutical field can be described as patents granted for a new synthesis method other than the method specified in the file of the patented active substance. An inventor produces the same active substance with another synthesis method. Simple crystalization and purification do not count as new processes. There are two possibilities in respect of drug production methods. If the process, namely the drug production method is new and involves an inventive step, the product does not have to be novel or have an inventive step. In the second possibility; the process is not new but the substance produced by using the process is new.⁵²⁷
- 3- Medical Use Patents : New indications of a known substance are patentable. According to the implementations of the FDA; “medical use patents” are

⁵²⁷ Ortan, p.81.

granted for “new indications” and “approved method of use ”.⁵²⁸ The legal basis for “first medical indication” is Art.54(5) in the European Patent Convention. If a compound is already known to have a certain pharmaceutical activity, a European patent may be granted for specific new and inventive therapeutic applications which are known as “second medical indication”.

An applicant must specify the classification of the invention in the patent application. According to the Strasbourg Agreement concerning the International Patent Classification, the main code for pharmaceuticals is “A 61K”.⁵²⁹

Twenty years term of patent protection is being criticised for being not long enough to make up for the effort and money spent until the new drug is brought onto the market. Effective patent protection is actually much shorter than twenty years. A drug can be brought onto the market after a long period of time following the grant of patent. The 12 to 16 years effective patent term in 1960’s decreased to 6 to 8 years in 1986 for drugs due to this patent erosion.⁵³⁰ The European Union tries to solve this problem by introducing Supplementary Patent Certificates.

Pipeline protection is granted by some countries when product protection is first introduced to allow protection for products already patented elsewhere. This type of protection is also called as retroactive patent protection. Bulgaria, Romania, New Zeland, Mexico, Brazil are some of the countries that have granted pipeline protection. Turkey did not accept to grant it since it has not been stipulated in the TRIPS Agreement.

⁵²⁸ Under the FDA rules, patents which may be listed in the Orange Book include those patents directed to the “drug substance” (active ingredient); “drug product” (formulation and composition); and the approved methods of use. In “method of use patents” ; where a party has already claimed the use of compound X for the treatment of hypertension, another party discovers that this compound re-grows hair. Than it is possible to claims this new use, i.e. a method of re-growing hair by application of compound X.

⁵²⁹ www.wipo.int/classifications/ipc/en “The IPC is a hierarchical system in which the whole area of technology is divided into a range of sections, classes, subclasses and groups. This system is indispensable for the retrieval of patent documents in the search for establishing the novelty of an invention or determining the state of the art in a particular area of technology. The Classification is periodically revised. The current, seventh edition of the IPC will be in force until December 31, 2005. The next, eight edition of IPC will enter into force on January 1, 2006.”

⁵³⁰ Bulut, p.65

In order to overcome above mentioned difficulties; international drug companies demand to obtain patent protection with certain advantages such as; grant of pipeline protection, restriction of compulsory licences, admission of importation of the patented drug as working the invention.

6.1. New Chemical Entities

Industrial applicability is one of the basic conditions for patentability. According to Art.52(4) EPC; an invention of a method of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body shall not be taken to be capable of industrial application. This article and the corresponding provisions in the national laws of Member States to EPC are the main source of problems arising in the field of pharmaceutical inventions. However this does not prevent a substance or composition from being capable of industrial application merely because it is invented for use in any such method.

Compounds which are novel and have a pharmaceutical utility are patentable in all countries which have implemented the TRIPS.

6.1.1 Patents for Prodrugs

A compound known to be pharmacologically active is regarded as a drug. A compound which itself is inactive but which is hydrolised or otherwise metabolized in the body to form the active drug is considered to be a prodrug.⁵³¹

Prodrugs are only metabolised to the actual therapeutically effective substances in the human or animal body. If the real active substance is invented first, a subsequently invented compound metabolized to it (prodrug) may have pharmacological advantage⁵³² or may be regarded as a way to evade the patent

⁵³¹ Grubb, p.211.

⁵³² Hansen / Hirsch, p.342. "...sometimes it is possible to improve the bioavailability of a tried and tested preparation by using a prodrug, e.g. with the valine ester ("Valtrex") of Acyclovir ("Zovirax").

protection for the drug. In such a case, the sale of a prodrug can be considered as an infringing act even though it literally falls outside the compound claims of the patent.

In *Beecham v. Bristol Laboratories Case*⁵³³, the court decided that the sale of antibiotic hetacillin, an acetone adduct of ampicillin which is hydrolysed in the body and breaks down again into ampicillin and acetone, infringed the ampicillin patent. The Court considered hetacillin as a “temporary mask” of ampicillin.⁵³⁴

Following the hetacillin case, Beechams obtained a patent in the UK (under the 1949 Act), a patent claiming a novel cephalosporin, its salts and ‘pharmaceutically acceptable bioprecursors thereof’. Such a broad claim may seem to lack sufficiency since it will amount to a demanding experimental work to determine whether a compound falls under the unclear definition of ‘bioprecursor’.⁵³⁵

Countries must determine whether the patent on the compound covers the prodrug, and the extent to which claims relating to certain compounds should also be allowed to include their prodrugs.⁵³⁶ Prodrugs are suitable for stretching the boundaries of the equivalent protective scope of pharmaceutical claims. If prodrugs are not covered by the equivalent protective scope of pharmaceutical claim, protective scope can not be stretched via indirect patent infringement because all infringing embodiments require the use of all of the features of the invention either identical or equivalent ways.

6.1.2. Patents for Active Metabolites

Sometimes patents may be accumulated on a compound and on the active metabolite that produces the desired effect in the body. If the active metabolite is novel and inventive, it can be patented separately.

⁵³³ *Beecham v. Bristol Laboratories* [1977] FSR 215 (HL).

⁵³⁴ Hansen / Hirsch, p.211.

⁵³⁵ Grubb, p. 212 ‘...it is nevertheless possible to draft allowable claims to drugs which literally cover prodrugs e.g. one can claim ‘physiologically hydrolysable and acceptable esters’ of alcohols or acids.’

⁵³⁶ <http://www.southcentre.org/publications/publichealth/publichealth-07.htm>, Special Cases in Pharmaceuticals, V.8 Prodrugs, retrieved on 04.4.2005.

Whether the sales of the original drug substance infringe the patent claiming the active metabolite was discussed in the Merrell Dow v. Norton Case.⁵³⁷ Merrell Dow attempted to patent the active metabolite of the drug terfenadine which had been sold as an antihistamine before the active metabolite had been patented. Terfenadine is an antihistamine which is modified in the body to the metabolite MDL 16455 which differs from Terfenadine in that a methyl group is replaced by a carboxyl group. When a generic firm began to sell the terfenadine upon the expiry of the term of patent protection, Merrell Dow sued the firm on the basis of a follow-up patent which covered the metabolite MDL 16455 alleging that the sales of terfenadine had infringed the metabolite patent. This was considered as an attempt to extend patent protection beyond the term of protection.

The House of Lords held that the patent for the active metabolite was invalid since the disclosure of the terfenadine patent specification itself, made available to the public the invention of the active metabolite. It enabled the public to work the invention by making the active metabolite in their livers by taking terfenadine. In that sense; patients had been making the active metabolite by swallowing the terfenadine before the date of the patent. The House of Lords decided that the metabolite was not longer new, in consideration of the disclosure of Terfenadine in the basic patent. The basic patent was held to disclose an antihistamine chemical reaction in the human body when Terfenadine was taken. A valid patent for the metabolite should have included a disclaimer to the substance when prepared by ingestion and metabolism of terfenadine.

6.1.3. Patents for Natural Products

Natural products from animal or plant sources having pharmacological properties can be also patentable if a claim to a newly discovered natural product is framed in such a way to distinguish the claimed product from the product as found in nature. This may be done by claiming the product in pure form. As long as the claim

⁵³⁷ Merrell Dow v. Norton [1996] RPC 76 (HK).

can be interpreted in such a way that it does not cover the product as found in the nature, it does not have to include any purity limitation.

Many patents have been granted which cover newly isolated hormones, cytokines and other substances occurring in the human body.⁵³⁸

Many antibiotics are also natural products that were originally isolated from cultures of naturally occurring fungi. Such antibiotics can be claimed as new compounds.

Natural products are patented without any problem by the EPO. According to the Guidelines for Examination in the European Patent Office (Part C – Chapter IV – discoveries) , finding a previously unrecognised substance occurring in nature is mere discovery and can not be patented. However if a substance found in nature can be shown to produce a technical effect, it may be patentable, e.g. a substance occurring in nature which is found to have an antibiotic effect.⁵³⁹ On the other hand if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. If the substance can be properly characterised either by its structure, by the process by which it is obtained or by other parameters and if the substance is new in the absolute sense of having no previously recognised existence, then the substance per se may be patentable. A new substance e.g. antibiotic which is discovered as being produced by a microorganism may be patentable. Similarly, a gene which is discovered to exist in nature may be patentable if a technical effect is revealed, e.g. its use in making a certain polypeptide or in gene therapy.

⁵³⁸ In the USA, a patent was granted for pure adrenalin isolated from adrenal gland tissues. *Parke-Davis v. H.K. Mulford*, 196 F.496 (2nd Cir.)

⁵³⁹ www.wipo.int/patent/agenda/en/meetings/2002/presentations/gallochat.pdf, retrieved on 20.5.2005, Alain Gallochat, Advisor-Ministry of Research Associate professor University Pantheon-Assas Paris II. “Natural compositions used in traditional medicine cannot be patented any longer since they have been known and used for a long time. On the other hand; EU Directive 98/44/CE on the Legal Protection of Biotechnological Inventions provides in Art.3(2) that biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature. This article shall play a vital role when it applies to genes or DNA sequences. Art.5.2 of the same Directive provides that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The novelty lies in the fact that such an element has been isolated while it was in its natural state in an environment which did not give the possibility of discerning it. “

Some natural compositions that are used in traditional medicine cannot be patented any longer since they have been known for a long time. However the active substance of those compositions can be patented if they are isolated and characterized since the existence of such active substance was not known before.⁵⁴⁰

6.2. Pharmaceutical Compositions

A pharmaceutical composition is a formulated product containing an active ingredient and appropriate additives. For instance, patents have been granted separately with regard to the injectable and oral forms of ofloxacin, a drug of relevance to the treatment of HIV patients.

Compositions may refer to combinations of previously known products.

If composition claims are accepted subsequent to a patent on the relevant active ingredient, the patent owner may be able to artificially extend the term of protection granted under the basic patent. Unless the composition includes additives that generate a truly new and inventive product, a pharmaceutical composition should generally be deemed anticipated by the effective ingredient that it contains and not patentable.

Another remedy would be to limit the scope of composition claims so that composition claim holders can not prevent commercialization of other compositions containing the same active ingredient or of the active ingredient in bulk after the basic patent has expired.⁵⁴¹

⁵⁴⁰ www.wipo.int/patent/agenda/en/meetings/2002/presentations/gallochat.pdf, Alain Gallochat, "The Criteria For Patentability: Where Are The Boundaries ?", retrieved on 06.4.2005.

⁵⁴¹ <http://www.southcentre.org/publications/publichealth/publichealth-07.htm>, retrieved on 04.04.2005.

6.2.1. Combination Preparations

Combination preparations is one of the types of pharmaceutical compositions comprising two or more known pharmaceutically active ingredients.

Simple mixtures of known compounds can be patented in many chemical fields provided that such mixtures are novel and involve an inventive step.

In the USA, claims to mixtures of two or more known pharmaceutically active ingredients are always considered as obvious and are refused unless synergism, or a 'superadditive effect' can be shown. On the other hand, national regulatory authorities shall not grant any marketing approval to the combination of two old drugs unless such combination shows a real advantage over the separate components.

Proving the existence of synergism is extremely difficult since it is impossible to predict what would be expected if there were no synergistic effect.⁵⁴² Synergism can be proved by comparing dose-versus-response curves for the two components separately as well as for the combination, which can be a difficult exercise.

If synergism can be demonstrated, combination preparations shall be patentable. It is also argued that even in the absence of synergism, the presence other advantageous or unobvious results should establish inventive step. For example A and B compounds at a dose of 100 mg, each have the same pharmaceutical effect but at this dosage each gives some undesirable side-effects. If a combination of 50 mg A and 50 mg B give the same desired effect but with reduced side-effects, such an advantage of reduced side-effects should be sufficient for patentability, assuming it was not predictable.⁵⁴³

⁵⁴² Grubb, p.216.

⁵⁴³ Grubb, p.216.

6.2.2. Drug Delivery Systems

In the recent years, attempts have been made to find ways of delivering existing drugs more effectively instead of developing new drugs which is becoming more time-consuming and expensive.

A new kind of tablet giving a controlled rate of release of drug when swallowed is a good example as a new drug delivery system. Adhesive patches from which a drug is absorbed slowly through the skin or depot injections which release a drug over a period of weeks or months are alternatives to the frequent swallowing of tablets at regular instances.

6.3. First Medical Use

It is possible to claim broadly pharmaceutical compositions containing the active ingredient. Such claims are not limited in respect of any specific pharmaceutical indications. They would equally cover the compound in a cough syrup or in a haemorrhoidal suppository.⁵⁴⁴

An alternative would be to claim the use of the compound as a pharmaceutical. Difficulties may arise since the use of a pharmaceutical is equivalent to a method of medical treatment which has been excluded in the EPC. However Art. 54(5) states that an invention consisting of a substance or composition comprised in the state of the art for use in a method of treatment human or animal body by surgery or by therapy shall be considered as novel provided that its use for any method referred to in Art.52(4) is not comprised in the state of the art.⁵⁴⁵ Although the substance or composition is already known, the invention shall be still considered as novel provided that no previous pharmaceutical use for surgical, therapeutic or diagnostic methods was known.

⁵⁴⁴ Grubb, p.217-218.

⁵⁴⁵ Art.54(5) EPC is identical to section 3(3) of the German Patent Act.

In other words Art.54(5) lays down a special rule for substances and compositions that are already part of the state of the art. If the use of such substances and compositions is new for one of the surgical and therapeutic or diagnostic methods, the product can be granted protection for a specific purpose, namely for use in one of such methods. The same substance or composition cannot subsequently be patented for any other use of that kind.

According to the Examination Guidelines December 2003, Part C, Chapter IV (4.2 Surgery, therapy and diagnostic methods); a claim to a known substance or composition for the first use in surgical, therapeutic and/or diagnostic methods should be in a form such as : “Substance or composition X” followed by the indication of the use, for instance “...for use as medicament”, “...as an antibacterial agent” or “...for curing disease Y”.⁵⁴⁶

In the case of the first new and inventive use of a known product in the therapeutic field, product protection is granted. In “Pyrrolidine-derivatives/Hoffmann-La Roche” case, the EPO held that in the case of a first indication, a very specific definition of the field of illness in the claim is not required, the phrase “for use as a pharmaceutical” (or diagnostic) was sufficient.⁵⁴⁷

Art.54(5) EPC provides for an exception from the general principle that product claims can only be obtained for novel products. However, products claims for the first medical use must fulfil the other patentability requirements, inventive step and industrial applicability.⁵⁴⁸

The discovery of a new specific therapeutic effect for a substance can also justify the grant of a patent claim for this substance as a medicament generally and not only a patent claim for the use for the treatment of a particular illness.⁵⁴⁹

⁵⁴⁶ A claim in the form of “Use of substance or composition X for the treatment of disease Y...” will be regarded as relating to a method for treatment explicitly excluded from patentability by Art.52(4) EPC and therefore will not be accepted.

⁵⁴⁷ Hansen / Hirsch, “Pyrrolidine-derivatives/Hoffmann-La Roche”-T 128/82 of 12.1.1984, OJ 1984, 164.

⁵⁴⁸ T 128/82, O.J.EPO 4/1984, 164.

⁵⁴⁹ Singer / Stauder, EPC Vol.1, p. 127-128, “T 128/82, OJ 1984, 164 for the first medical indication of a known substance; T 43/82 of 16 April 1984 for a substance whose biological properties, but not its therapeutical application, were known)

If the pharmaceutical effect of a known substance is unknown, a third party can obtain protection for this substance for the first medical indication as a pharmaceutical. The novelty of a claim of the form: 'the substance for use as a medicament' is also called the first medical indication.⁵⁵⁰

6.4. Second Medical Use

Patent protection can be granted for a substance or a substance compound already known to have a certain pharmaceutical effect for specific new and inventive therapeutic applications ("second and further medical indications").

EPO case law has developed a formula to claim a substance for a new second and further medical uses. Decisions G 1/83, G 5/83 and G 6/83 deal with the patentability of a second and further medical indications.⁵⁵¹ These decisions clarified whether and in what way a substance known for the treatment of a specific illness can be granted patent protection when used for the treatment of other illnesses. The use of an already known substance or composition for the manufacture of a pharmaceutical for a specific new therapeutic or diagnostic application is regarded as capable of patent protection. The novelty of the production of a known substance or composition is derived from the new therapeutic or diagnostic use.⁵⁵²

In the case of Bayer's 'Hydropridine' application, the invention was the use of a known cardiovascular agent to treat cerebral disorders. The application was refused by the German Patent Office, and an appeal to the Federal Patent Court was unsuccessful. The German Federal Supreme Court (DE Bundesgerichtshof) held that the German Law, which also excluded methods of medical treatment from patentability, did not preclude the patenting of new uses of known pharmaceuticals.⁵⁵³ A claim of the form 'use of substance or composition X for the treatment of disease Y' was accepted.

⁵⁵⁰ Visser, p.61

⁵⁵¹ O.J.EPO 1985, 60, 64 and 67.

⁵⁵² Singer / Stauder, EPC Vol.1, p.83 (G 1/83, G 5/83 and G 6/83, point 21; confirmed in T 143/94, OJ 1996, 430, points 3.1 and 3.2 for the first and second indications.)

⁵⁵³ Hydropridine X ZB 4/83 (BGH) [1984] 2 IIC 215.

Although the Enlarged Board of Appeal did not follow the above mentioned decision of the German Federal Supreme Court. The Enlarged Board of Appeal decided in the case concerning Bayer's 'Hydropyridine' application and other related cases, that the German form of claim was a claim to a method of medical treatment and was not allowed, but that the Swiss form of claim⁵⁵⁴ would be granted by the EPO.⁵⁵⁵ According to the Swiss claim wording; claims could be admitted for further medical indications concerning the use of a known substance or composition for the production of a medicament for a specific new and inventive use.⁵⁵⁶

In "Benzolsulfonylharnstoff" case, the German Federal Supreme Court acknowledged that a process which involves the use of a product for the purpose of treating a disease is patentable to the extent that in addition to the therapeutic utility for the doctor, the possibility for industrial application exists and allowed the claim 'use of the benzenesulphonyl urea according to claim 1 or its salts in the treatment of diabetes'. The Court stated further;

' The use of a product for treating an illness, in which the curative effect of the product is employed, is not achieved exclusively by the involvement of a doctor or the prescription of the medicine, but comprises as a rule a number of activities which are not outside the area of commercial use, unlike the activity of doctors, such as the formulation and the optimisation of the medicine, its dosing and packaging it in a ready-to-use fashion. All of these activities taking place before any use by a doctor are encompassed by the desired use claim. '⁵⁵⁷

It is irrelevant whether the diagnostic or therapeutic use is based on a first or a further medical indication. (T 143/94, point 3.2)

⁵⁵⁴ Hansen / Hirsch, p.220 'use of a substance or composition X for the preparation of an agent for the treatment of disease Y'; Examination Guidelines, Part C, Chapter IV, p.52 "Use of a substance or composition X for the manufacture of a medicament for therapeutic application Z" is allowable for either a first or subsequent (second or further) such application ("second medical use"-type of claim or "Swiss-type claim), if this application is new and inventive (G 5/83, OJ3/1985, 64). The same applies to claims in the form of "Method for manufacturing a medicament intended for therapeutic application Z, characterised in that the substance X is used" or the substantive equivalents thereof (see T 958/94, OJ 6/1997, 241).

⁵⁵⁵ Hansen / Hirsch, p. 220-221.

⁵⁵⁶ Singer / Stauder, EPC-Vol. 1, p.128.

⁵⁵⁷ Hansen/Hirsch, p.257, footnote 1416 "Benzolsulfonylharnstoff" (Benzenesulphonyl urea) – X ZR 13/75 of 20.1.1977, PMZ 1977, 198 (IIC 1978, 42)

T 19/86 developed the case law of the Enlarged Board of Appeal further. In this case sero-positive piglets were vaccinated against Aujeszki syndrome. A known medicament was used for the prophylactic treatment of the same illness in an animal population, i.e. sero-positive piglets, that is part of the same species but showing different immunological reaction. The assessment of the novelty of an invention concerning a further therapeutic use is to be based not only on the disease in question but also on for which subjects this treatment forms part of the state of the art. This was regarded as a new therapeutic use because the means in question was only known for the treatment of very specific animals such as sero-positive piglets.

The German Federal Supreme Court and the European Patent Office reached the same result although they followed different approaches and recognized the patentability of second and further medical indications. According to the German Federal Supreme Court, the use of a known substance fulfilling the criteria of novelty and inventive step shall be considered as a process for the treatment of an illness and granted patent protection even though the same substance had been used previously in another medical field and comprised in the state of the art. The Court stated that the use of a product for treating an illness should not only involve the activities of the doctors such as the formulation and optimisation of the medicine but also the commercial activities of drug producers such as dosing and packaging the drugs in order to meet the criterion of industrial application. According to Art.54(4) EPC, the European Patent Office considered that the use of an already known substance or composition for the manufacture of a pharmaceutical for a specific new therapeutic or diagnostic application is capable of patent protection.⁵⁵⁸

6.5. Selection Patents

A selection patent can be described as a patent under which a single element or a small segment within a large known group is selected and independently

⁵⁵⁸ Ortan, p.83-84.

claimed, based on a particular feature not mentioned in the large group. Selection inventions can be classified as “genuine” and “non-genuine” selection inventions.⁵⁵⁹

- A “genuine selection invention” is a selection invention in the narrower sense and it can be described as a claim under which a single element or a small segment within a large known group is selected and independently claimed, based on a particular feature not mentioned in the large known group. The German Federal Patent Court stated in one of its decisions that a new selection can only be deemed patentable when a particular new feature is chosen from a proportionately large area, which encompasses the feature, but does not mention it.⁵⁶⁰

- A “non-genuine selection invention” is a selection invention in the wider sense and can be defined as a claim to overlapping parameter ranges. The question of novelty is only raised in regard to the overlapping area. When determining the novelty of the overlapping area, one should determine what is disclosed in the state of the art.

If the selected elements possess a surprising advantage which is shared by all or nearly all of the large group, patent protection for selection patents shall be denied according to the national laws of some countries.⁵⁶¹ The TRIPS Agreement does not lay down any binding provisions concerning the patentability of selection inventions, it is at the discretion of Member States to enact the legislative provisions concerning this matter.

Patent protection for a selection invention may be denied in case where the earlier disclosure is a patent. It can be argued that a patent for a selection invention prolongs the monopoly unjustifiably since subject matter of a patented invention should be normally in the public domain after the expiry of term of protection. Nevertheless such an approach may lead to the invalidation of improvement patents in the field of chemicals. Some authors claim that if the earlier disclosure is broad and

⁵⁵⁹ Hansen/Hirsch, p.125.

⁵⁶⁰ Hansen/Hirsch, p.126, footnote 640 (16 W pat 66/75 of 14.12.1978, headnote PMZ 1980, 175)

⁵⁶¹ Germany has refused selection inventions by holding that disclosure of even a large group of elements is fully equivalent, for the purposes of inventive step, to the disclosure of each compound within the group.

general it may be a praiseworthy invention to find that a small sub-group has particularly good properties.⁵⁶²

A distinction should be made between selection inventions and normal prior art situations in case where the selection is a large class of compounds which overlaps with a class of compounds known in the prior art. Problems may arise even though no specific compound disclosed in the prior art falls within the claimed scope. The EPO held that the claimed invention was not novel, at least where the claimed compounds formed a major part of the previously disclosed class.⁵⁶³

The fundamental indications provided in the Examination Guidelines of December 2003 are helpful for the assessment of novelty where specific expressions and generic concepts are to be considered (C-IV, 7.4) . Accordingly, a generic disclosure does not take away the novelty of any specific example that falls within the terms of that disclosure, but a specific disclosure takes away the novelty of a generic claim. In other words; the novelty of subject matter claimed generically is destroyed by the disclosure of a specific term covered by the generic claim. For example, a disclosure of copper takes away the novelty of metal as a generic concept, but not the novelty of any metal other than copper.

The Examination Guidelines further assume that a publication describing a chemical composition does not also disclose the individual components it contains, but only those whose isolation from the composition is described. The case law of the Boards of Appeal has confirmed this rule by stipulating that such a description of the isolation must be in the form of a technical teaching of being carried out.⁵⁶⁴

In principle, a general concept is not deemed to destroy the novelty of a specific term.

⁵⁶² Grubb, p.199.

⁵⁶³ Grubb, T 124/87 (O.J.EPO 1989, 491), Du Pont / Copolymers.

⁵⁶⁴ T 296/87, O.J.EPO 1990, 195.

T 12/81 is a leading EPO case that provides fundamental guidelines for chemical selection inventions.⁵⁶⁵ There were two lists in the prior art; first list consisting of twenty specific starting materials and second list consisting of five different reaction conditions. Each of the starting material gave the same product whichever reaction conditions were used. Due to this fact, a selection of one starting material and one set of reaction conditions was not considered to be novel. It was further stated that if the prior art had given two different lists of two types of starting material which had to be combined to give the end-product, the selection of one or more specific end-product would be a novel selection invention.

In T 378/94 of March 1996, an opponent claimed that the subject matter of a contested patent was not novel since it fell within the scope of a granted patent which became part of the state of the art and it was not necessary for the state of the art to disclose specific technical features of the subject matter of the invention. The Board of Appeal has rejected this objection and stated that there is a significant distinction between the scope of the protection and the disclosure of a patent specification. The disclosure included concepts used for the definition of the invention. The scope of protection depended on what could be compromised under the definition of the invention of the patent claim. The Board of Appeal held that the invention was novel since the disclosed invention and the claimed scope of invention were not identical.⁵⁶⁶

6.6. Compounds of Unknown Structure

A compound can be still patentable even if its chemical structure is unknown either by defining the compound in terms of its properties and secondly by defining how the compound is made.

⁵⁶⁵ Grubb, T 12/81 (O.J.EPO 1982, 296), BAYER/Diastereomers; "... similar conditions apply to claims defining an invention in terms of one or more numerical parameters when the claimed range overlaps with a range disclosed in the prior art" T 666/89 (O.J.EPO 1993, 495), Unilever / Washing composition p. 197.

⁵⁶⁶ For detailed explanation about the decisions of EPO Board of Appeal concerning "selection from a range" and "compound selection", see Hansen/Hirsch, p127-147.

6.6.1. Fingerprint claims

An unknown compound which may be obtained in pure form can be claimed in terms of its properties in a so-called 'fingerprint claim'. For example a new antibiotic obtained from a mutant strain of a micro-organism can be defined in terms of its physical, physicochemical, chemical or biological properties.

The greater the number of such characterizing properties that can be found, the better.

It is more convenient claiming a compound in terms of its properties than making a guess at an uncertain structure, since if the guess is wrong the mistake cannot normally be corrected later. An applicant should mention only the reliable data in the claims. Otherwise questionable data may later turn out to be false and weaken the patent.⁵⁶⁷

6.6.2. 'Obtainable by' Claims

If it is not possible to define the product in terms of its properties or if it is desired to claim a group of compounds, the product may be defined as the product of reacting certain compounds together under certain conditions (product-by-process claim).⁵⁶⁸

A disadvantage may arise when the product is not obtained if made by a different process. National laws of some countries allow a inclusion of a definition such as a compound obtainable by reacting A with B, etc. It is ideal to add a dependent claim using the words 'obtained by' which should ensure that the 'obtainable by' claim is construed more broadly. Many patent offices simply refuse to accept claims drafted in 'obtainable by' form.⁵⁶⁹

⁵⁶⁷ Grubb, p.202.

⁵⁶⁸ defining a product through its method of production.

⁵⁶⁹ Grubb, p.203.

6.7. Conclusion

Special cases which are examined in the preceding paragraphs relate to a number of patents around a single product covering numerous aspects of the product.

So long as inventions such as basic composition including new compounds, drug delivery, prodrugs releasing active ingredient, substances resulting from metabolism in body or even devices for administering the drug fulfil the minimum criteria of patentability set by the TRIPS, they should be granted patent protection. A contrary approach shall give rise to discrimination of pharmaceutical inventions as compared to inventions in other fields of technology since Art.27.1 TRIPS provides patent protection for any inventions, whether product or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

In an environment where there is uniform and strong patent protection without discrimination in respect of pharmaceutical inventions, research-based pharmaceutical industry would be in a better and safer position to combat chronic and infectious diseases and carry on searches for the effective treatment of widespread, life threatening diseases such as cancer, AIDS and Alzheimer.

VII. GENERAL ASPECTS OF TURKISH LEGISLATION PERTAINING TO PATENT PROTECTION WITH SPECIAL REFERENCE TO PHARMACEUTICAL INVENTIONS IN TURKEY

7.1. Historical Background of Patent Legislation in Turkey

The legal basis for granting patent rights in Turkey dates back to the legal protection provided by the Patent Law of March 23, 1879 entitled as “İhtira Beratı Kanunu”, enacted at the time of the Ottoman Empire. This Law has been translated from the French Patent Law dated 1844, which favoured a patent system granted without examination.⁵⁷⁰ It remained in force until the enactment of the Decree Law No.551, until June 27, 1995.

The previous Law of 1879 “İhtira Beratı Kanunu” was regarded as insufficient in keeping up with the recent developments in the field of patent legislation enacted in a number of European countries. It used to provide for a system of mere registration of patents without prior examination as to substance.

Art.3 of the Letter Patent Law has excluded patent protection for pharmaceutical and veterinary processes and products for human beings and animals. Agrochemical processes and products and all other inventions were under protection. According to İhtira Beratı Kanunu, patent protection had been granted for pharmaceutical processes until a decision rendered by the Constitutional Assembly in 1961. This decision was approved by the Constitutional Court in 1967. In this way the grant of process patents was also hindered as well as the grant of product patents for pharmaceuticals.

⁵⁷⁰ www.apb.com.tr/patent/index.html, retrieved on 27.5.2005.

7.1.1. Establishment of the Turkish Patent Institute

Administration of industrial property legislation containing only trademark and patent protection was being conducted by the Head of Intellectual Property Division under the Ministry of Industry and Trade until June 24, 1994. With the Decree Law No:544 dated July 24th, 1994, Turkish Patent Institute (TPI) has been established. Law No.5000 pertaining to the Establishment and Functions of the TPI was adopted on 6.11.2003. The main responsibility of the TPI is to conduct all the administrative work related to the protection and proper functioning of the industrial property rights.

After the establishment of the TPI, Turkey has updated its whole intellectual property legislation through adopting a series of decree laws and regulations in a short period of time. Decree Law pertaining to the Protection of Patent Rights No 551 was published in Official Gazzete No.22326, on June 27, 1995. In the preparation of new patent legislation, not only the content of EPC and PCT but also the patent legislation of Germany, Japan, Switzerland, Belgium and Spain have been taken into consideration.⁵⁷¹

TPI should cooperate with other national and regional patent offices and benefit their organisational experience. As a result of such cooperation patent offices can reduce a major part of bureaucratic transactions especially through giving recognition to each other's examination, opposition and acceptance procedures.

7.1.2. International Agreements

In the meantime Turkey has become party to below mentioned international Agreements / Conventions / Treaties :⁵⁷²

⁵⁷¹ Uğur Yalçınar, "Update on Current Pharmaceutical Patent and IP Legislative Status, With Special Reference to Pharmaceutical Inventions in Turkey". An International Symposium concerning Pharmaceutical Patents and IP in EU Accession Countries. held on October 14-15, 1999 in Budapest.

⁵⁷² <http://www.turkpatent.gov.tr/uluslar1.htm>.

a. Conventions Concluded for General Purposes

- Paris Convention for the Protection of Industrial Property Stockholm Act,⁵⁷³
- Convention Establishing World Intellectual Property Organization (WIPO),⁵⁷⁴
- WTO - TRIPS Agreement,⁵⁷⁵

b. Agreements/Conventions Concerning International Registration of Industrial Property Rights

- Patent Cooperation Treaty (PCT),⁵⁷⁶
- European Patent Convention (EPC),⁵⁷⁷
- Protocol Relating to Madrid Agreement Concerning the International Registration of Trademarks ,⁵⁷⁸
- The Hague Agreement Concerning the International Deposit of Industrial Designs (The Geneva Act),⁵⁷⁹
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.⁵⁸⁰

c. Implementation Agreements

- Strasbourg Agreement Concerning the International Patent Classification (IPC),⁵⁸¹
- Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of Registration of Trademarks,⁵⁸²
- Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks,⁵⁸³

⁵⁷³ Turkey has become a party to the London Act in 1925 and to the Stockholm Act on February 1, 1995.

⁵⁷⁴ Turkey has become a party in 1976.

⁵⁷⁵ TRIPS entered into force on 01.01.1995.

⁵⁷⁶ Entered into force 1.1.1996 in Turkey.

⁵⁷⁷ Entered into force on 1.11.2000 in Turkey.

⁵⁷⁸ Entered into force on 1.1.1999 in Turkey.

⁵⁷⁹ Turkey has become a party to the Geneva Act in 2004. It shall be applied on 1.1.2005.

⁵⁸⁰ Entered into force on 30.10.1998 in Turkey.

⁵⁸¹ Entered into force on 1.10.1996 in Turkey.

⁵⁸² Entered into force on 1.10.1996 in Turkey.

⁵⁸³ Entered into force on 1.1.1996 in Turkey.

- Locarno Agreement Establishing an International Classification for Industrial Designs,⁵⁸⁴
- The Trademark Law Treaty (TLT),⁵⁸⁵

7.2. Implementation of the Provisions of TRIPS Agreement in Pharmaceutical Inventions in Turkey

Patent protection of pharmaceuticals has been excluded from patent protection by the transitional provision 4 of the Decree Law No . 551 up to January 1, 2000 for processes and January 1, 2005 for products. Although this provision was compatible with Article 65/1, 65/2 and 65/4 of the TRIPS Agreement, it has been amended by the new Decree Law No. 566 on September 22, 1995⁵⁸⁶ in order to fulfil the conditions prescribed by the Association Council Decision No:1/95.⁵⁸⁷ Amended Article has delayed patent protection for both pharmaceutical processes and products up to January 1, 1999.⁵⁸⁸

According to Art.1 of Annex 8 to the Association Council Decision No 1/95, Turkey undertook to implement the TRIPS Agreement no later than three years after the entry into force of this Decision. Art.6 stated clearly that no later than two years after the entry into force of this Decision, Turkey should adopt a legislation, or revise the existing one, in order to secure before 1 January 1999 the patentability of pharmaceutical products and processes.

In accordance with Article 70/8 and 70/9 of TRIPS Agreement; all patent applications related to the processes and products of the pharmaceuticals are being filed by the Turkish Patent Institute since January 1, 1995.⁵⁸⁹ This is called mailbox

⁵⁸⁴ Entered into force on 30.11.1998 in Turkey.

⁵⁸⁵ It has been signed but not entered into force yet.

⁵⁸⁶ Decree Law 566, dated September 22, 1995 for the Amendment of the Transition Period of Patent Protection of Pharmaceutical and Veterinary Products and Processes.

⁵⁸⁷ Association Council Decision No: 1/95 dated March 6th, 1995 completing the Customs Union terminated the transitional period and started the final stage of the Association as of January 1, 1996 on its entry into force.

⁵⁸⁸ Grubb, p.42.

⁵⁸⁹ Articles 70.7, 70.8 and 70.9 are intended to provide some protection for inventions made before the provisions in Articles 65 and 66 come into effect. WTO Agreement entered into force on January 1, 1995. Article 65 and 66 provide for transitional arrangements. In compliance with these transitional periods provided in Art.65(1), (2) and (4) , Turkey has delayed granting patent protection for pharmaceutical processes until 1

provision. It shall apply to these applications, as at the date of application of this Agreement the criteria for patentability set out in TRIPS as if these criteria were being applied on the date of the filing in that country.⁵⁹⁰ It shall provide patent protection as from grant for the remainder of the patent term (i.e. 20 years from the filing date) if the invention is patentable according to TRIPS criteria.

Although there was no patent protection granted for pharmaceutical products and processes before January 1, 1999, exclusive marketing right was given for a period of five years from the date of the marketing approval obtained from the Turkish authorities to the applicant of pharmaceutical product patents provided that he had obtained a patent certificate and marketing approval related to that product in another Contracting State to the WTO Agreement (TRIPS Art.70.9).⁵⁹¹ This exclusive marketing right may relate to the production or import of the pharmaceutical products. Exclusive marketing approval ceases to exist if the patent application is rejected even though the five year term of protection has not expired yet. If the applicant obtains patent protection for his pharmaceutical product, the exclusive marketing approval terminates.⁵⁹²

Turkey has started to grant patent protection for pharmaceutical products and processes from January 1, 1999. Patent applications have been filed since 1995. When we take into consideration the eight to twelve years period necessary for the market approval, the Decree Law will start to influence the pharmaceuticals market more significantly in the 2005-2007 time period.⁵⁹³

Research-based pharmaceutical companies are worried about the lack of protection from unfair commercial use for confidential test data in Turkey, which is required by the TRIPS Agreement. This proprietary data is submitted as part of registration and marketing authorisation process and it includes safety and efficacy

January 2000 and for pharmaceutical products until 1 January 2005. Art. 70(8)(a) prescribes that each Member State that does not make available, as at the date of entry into force of the Agreement establishing the WTO, patent protection of pharmaceutical and agricultural products, shall provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed.

⁵⁹⁰ Grubb, p.33 Black Box Applications.

⁵⁹¹ Kayacan, p.61.

⁵⁹² Ünal Tekinalp, *Fikri Mülkiyet Hukuku*, Beta, 2.Bası, Haziran 2002, s. 463-465.

⁵⁹³ Zeynep Ulusoy, "Present Situation of the Pharmaceuticals Industry in Turkey from the Perspective of Patent Law", Diploma Thesis, Eidgenössische Technische Hochschule, Zürich, 2003, p.18.

information gathered from lengthy and expensive clinical and human testing. Under TRIPS Agreement Art.39.3 “Protection of Undisclosed Information”, Turkey was obligated to have “data exclusivity” protection as of January 2000 under TRIPS Agreement.⁵⁹⁴ Due to this continued delay in implementation of data exclusivity, Turkey has been elevated to the Priority Watch List.⁵⁹⁵ Art.83 of the Decree-Law provides protection for proprietary data by prohibiting government disclosure, but only to a limited extend. It should also prohibit the use and/or disclosure by non-governmental parties who may have received such information.

Turkish patent legislation does not include pipeline protection (i.e. ‘early commercial benefits’)⁵⁹⁶ and supplementary protection certificate⁵⁹⁷ for medicinal products. There is no such obligation in the TRIPS Agreement or in the Association Council Decision for Customs Union between Turkey and EU. In the Turkish NPAA 2003 it has been stated that the implementation date for the Turkish legislation corresponding to the EU arrangements regarding supplementary protection certificates will be determined during the negotiation process, as the sector is not ready to absorb the potential consequences. The Patent Decree Law does not contain interim protection for pharmaceuticals in the research and development “pipeline”. Art.7 of the Decree-Law has been criticised for changing the standard definition of novelty in order to exclude any possibility of pharmaceutical pipeline protection.⁵⁹⁸

⁵⁹⁴ In accordance with the Association Council Decisions 1/95 and 2/97, Turkey should have implemented “Data Exclusivity” as of January 2001.

⁵⁹⁵ www.ustr.gov/Document_Library/Press_Releases/2005/April/Special_301_Rep..., retrieved on 16.03.2005, Office of the United States Trade Representatives. This year’s “Special 301” report on the adequacy and effectiveness of intellectual property rights lists fourteen trading partners on Priority Watch List. These countries are: Argentina, Brazil, China, Egypt, India, Indonesia, Israel; Kuwait, Lebanon, Pakistan, the Philippines, Russia, Turkey, and Venezuela. Turkey is included in this annual report especially due to lack of adequate protection against unfair commercial use for test data submitted by drug companies to health authorities.

⁵⁹⁶ This had the consequence that the applications filed for pharmaceutical products and processes before January 1, 1995 will never be granted patent protection in Turkey.

⁵⁹⁷ Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.

⁵⁹⁸ www.cptech.org/ip/health/pharma/nte-99/turkey.html, retrieved on 16.3.2005, Consumer Project on Technology.

A new paragraph is added to Art.75 of the Decree Law No.551 (Art.75(1)(f)) which resembles Roche Bolar Exemption.⁵⁹⁹ In accordance with that amendment, generic companies shall be allowed to work on a patented pharmaceutical product, that is to say, prepare samples, perform bio-equivalence studies that are necessary to get a market approval from the authorized drug agency. These acts shall remain outside the scope of rights conferred by a patent. Generic companies will be able to bring their generic products onto the market as of the first day on which patent protection for that pharmaceutical product expires.

In accordance with the provisions in Annex 8 to the Association Council Decision No:1 / 95; Turkey became a party to Patent Cooperation Treaty as of January 1, 1996, to Budapest Treaty as of October 30, 1998, to the Articles 1-12 of the Stockholm Act of the Paris Convention as of February 1, 1995, to the Strasbourg Agreement on International Patent Classification as of October 1, 1996.

7.3. Patent Protection Provided by the Turkish Decree Law No.551

As stated in the preceding paragraphs, the Decree Law pertaining to the Protection of Patent Rights No 551 entered into force on June 27, 1995. “First to file” system is implemented according to Turkish legislation.

Features that appeared for the first time in the field of patent protection in Turkey can be listed as below: ⁶⁰⁰

7.3.1. Patentability Criteria

The provisions concerning the patentability criteria of the inventions are defined in accordance with the requirements of the TRIPS Agreement. The new

⁵⁹⁹ European Union believes that clinical trials exemption-Bolar is contrary to Art.27(1) TRIPS since it discriminates against pharmaceuticals. EU initiated WTO dispute resolution proceedings against Canada for allowing such work, plus stock piling of product up to 6 months before patent expiry.

⁶⁰⁰ Selda Arkan, “Practical Problems of Enforcement of Pharmaceutical Patent and IP Legislation in Turkey”, Symposium on “Pharmaceutical Patents and IP in EU Accession Countries”, held on 14-15 October, 1999 in Budapest.

system in the Decree Law brought novelty, inventive step and industrial applicability as patentability criteria.

Art.5 states that inventions which are novel, which surpass the state-of-the-art and which are applicable in industry shall be protected by patents.

According to Art.6; methods of diagnosis, therapy and surgery applying to humans and animals are not within the patentable subject-matter. Patents shall not be granted for inventions whose subject matter is contrary to the public order or to morality. Plant and animal varieties or processes for breeding plant or animal varieties, based on biological grounds are also not patentable.

According to Article 7; an invention which is not comprised in the state of the art is new. The expression “state of the art” is defined in this article as any knowledge related to the subject matter of an invention which has been made public by written or oral presentation or usage or any other means accessible to the public anywhere in the world prior to the date of filing of a patent application.

According to Article 9; where the invention arose from an activity which could not be anticipated from the prior state of the art by a skilled person in the relevant field, the prior state of art will be deemed to have been surpassed.

According to Article 10; if the invention is capable of production or use in any branch of industry, including agriculture ,it will be considered industrially applicable.

7.3.2. Patent without Substantive Examination

According to Art.60 and 61; it is possible to grant patent protection (quasi patent right) without substantive examination upon the request of the applicant. Without considering the state of the art search report and if any, observations of third parties on the search report, the Turkish Patent Institute shall decide to issue a

patent without examination after the expiry of the term granted to the applicant to submit his observations against the search report.

It is possible to obtain patent protection for pharmaceutical products and processes without substantive examination.

Patents granted without examination shall be valid for seven years from the date of application and they shall be published in the relevant bulletin with the content defined in Art.61(1). The very existence and utility of the subject-matter of the patent without examination is not guaranteed by the Government.

The applicant and third parties may request the examination of the patented invention which has been granted without examination, within seven years from the date of patent application. In this case examination regarding conditions of patentability shall be undertaken by the TPI in accordance with the provisions set in Art.62. The request for patent examination will be announced in the relevant bulletin to enable third parties to raise their objections concerning the lack of patentability criteria under Art.62(2).

Where no request is made within seven years following the patent application, the patent right shall expire, after which no request for substantive examination may be filed.

If the results of the examination are in favour of the applicant, the applicant shall be granted patent with examination and the term of protection shall extend to twenty years commencing from the date of application. If the results of the examination show that the conditions of patentability have not been satisfied, the without examination shall terminate before the expiry of the seven year term of protection.⁶⁰¹

⁶⁰¹ Tekinalp, p. 493-494.

7.3.3. Patent with Substantive Examination

After the publication of the research report on the known state of the art, the third parties may, within three months, raise objections alleging non-compliance with the patentability criteria including the lack of novelty or the inventive step or inadequacy of the description, have not been met. These objections shall be communicated to the applicant so that he can reply to these objections within three months from the expiration of the term permitted for such objections, or if he so requests within an extension period of three additional months and he may amend the description, drawings and claims if necessary (Decree Law Art.62(4)).

Within six months from the publication of the research report on the state of the art, the inventor shall request the TPI to conduct examination and verify that the subject matter of the invention has been adequately defined, the invention is new and the known state of the art has been surpassed (Decree Law Art.62(3)).

The TPI shall commence the required examination regarding conditions of patentability after the expiry of the term set in Decree Law Art.62(4). It will issue a reasoned decision , limited by the extent of the claims whether the conditions of patentability have been met.

Upon completion of the examination, the Institute shall communicate its report to the applicant. The applicant shall then have six months to correct any deficiencies, change the claims and raise objections.

After the examination of such responses and changes, the TPI shall issue a final decision as to whether to grant a patent for the claims in whole or in part.

If no objections are raised and if there are no impediments, the TPI shall decide to grant the patent and notify the applicant.

The term of protection shall be twenty years starting from the date of the application.⁶⁰²

The grant of the patent with examination shall be announced in the relevant bulletin with the content defined in Decree Law Art. 63.

7.3.4. Utility Model Certificates

According to the Decree Law Art.154, an invention which is novel according to Art.156 and capable of industrial application under Art. 10 may be protected by grant of Utility Model Certificate.

A utility model certificate holder shall have the same protection as that granted to patent holder. The certificate shall be valid for a non-renewable term of ten years as from the date of filing of application. No certificates of addition, as provided for patents under Art.121, shall be granted for utility model certificates. (Art.164)

According to Art. 167; a utility model application can be converted to a patent application upon the request of the applicant prior to the decision of the Institute to grant the utility model certificate. There is no means of obtaining utility model and patent certificate for the same invention (Art.170).

The subject matter of a utility model certificate may also be registered as an industrial design, in which case the provisions of the Decree Law Concerning the Protection of Industrial Designs shall apply. (Art.169)

Utility models differ from patented inventions in two respects. First, the technological progress required is smaller than the technological progress (inventive step) required in the case of patentable inventions. Second, the term of protection for utility models (ten years) is shorter than the term of protection granted for patentable inventions.

⁶⁰² Tekinalp, p. 495-496

The owners of petty inventions are given the opportunity to obtain protection through the grant of utility model certificates. The procedure for obtaining utility model certificate is cheaper, faster and easier than the procedure carried out for obtaining patent protection. No search report shall be prepared for the determination of the state of the art.⁶⁰³ However upon the request of the applicant before the TPI, a search report on the state of the art shall be also drawn up for utility model certificates. (Art.160(4))

The invalidation of the utility model certificate may be requested, at any time, during its term of protection in situations specified in Art.165.

The State does not guarantee the usefulness and the very existence of the subject matter of the utility model certificate (Art.162(4)) .

No utility model certificate shall be granted for subject matters mentioned in Art.6 of the Decree-Law as well as for processes and products obtained by such processes, chemical products. (Art.155)

In the absence of provisions applicable to utility model certificates, the provisions pertaining to patents shall apply likewise, provided that they do not contradict the characteristic of utility model certificates. (Art.166)

7.3.5. Publication of the Applications.

According to Art.55 Decree Law; the patent application shall be published in accordance with the conditions as set forth in the Regulation Art. 27, after the expiry of eighteen months commencing from the filing date of the application or if priority has been claimed, from priority date. Publication can be performed after the completion of the examination as to form and the application to the TPI for a search on the state of the art.

⁶⁰³ Bahadır B. Erdem, Patent Hakkının Korunmasına ve Patent Hakkına İlişkin Sözleşmelere Uygulanacak Hukuk, Beta, 2002, p.22-23.

Applications shall be published in periodic bulletins as set forth in the Regulation Art.27.

Upon the request of the applicant, the patent application may be published earlier than the expiry of eighteen months, in conformity with conditions set forth in Art.55 Decree Law.

7.3.6. Opposition by Third Parties and Effect of the Objection to Formal Deficiencies

According to Art.70, third parties may raise objections after the grant of the patent, alleging the existence of formal deficiencies in the procedures contained in Articles 42 through 63. Art. 45 regarding the unity of the invention is excluded.

Such objection shall not require previous communication of observations against the state of the art search report or objections during processing of the patent application under system of granting patent with substantive examination.

Where patents are granted without substantive examination, the third parties may not raise objections on the grounds that the requirements concerning novelty and inventive step have not been fulfilled.

Upon such an opposition, if the TPI concludes that there has been some formal deficiency in the procedures contained in the said articles, the decision of the Institute to rectify such deficiency shall have the effect to annul the administrative actions pertaining the grant of the patent retrospectively to the stage of the procedure where the concerned deficiency occurred and to reengage the procedure from that stage onwards so as to perform anew all such actions (Art.71).

7.3.7. Employee Inventions

According to Art.17; employee inventions are classified as service inventions and free inventions.

Within the meaning of the Decree-Law; an employee is a person who is in the service of another person and responsible to carry out the work which he has been assigned to, with personal liability against the employer, within the framework of a private legal contract. Students and trainees who are not receiving any payment and are not bound to a specific working period are also considered as employees. (Art.16)

a. Service Inventions

According to Art.17(2); service inventions are defined as inventions which are made by the employee during the term of his employment while performing tasks which he has been assigned to or which are based to a great extent on the experience and activity of the private enterprise or a public authority.

Employee inventions that do not have the characteristics mentioned in the preceding paragraph shall qualify as free inventions and shall be subject to Articles 31 and 32.

The employee has to report to the employer that he has made a service invention without any delay. He must disclose the technical problem, its solution and how the service invention was realized. He must further specify the experience and activities of the enterprise from which he has benefited and if any, the contributions of other employees. Upon the receipt of the employee's report, the employer must inform the employee within two months about the corrections that he deems necessary to be made. Otherwise the report shall be deemed to be legally valid. (Art.18)

Upon the receipt of the employee's report, the employer may notify the employee in writing that he claims a right, in part or in whole, for a service invention,

within four months as from the date of the receipt of employee's report. (Art.19) If the partial use of the invention impedes employee's further exploitation of the invention, the employee may request that the employer takes over the invention as a whole within two months or releases it.

According to Art.21; a service invention becomes a free invention where the employer releases a service invention free in writing or where the employer makes a claim in part of the service invention or where the employer has not made a claim to the service invention within four months upon the receipt of employee's report or has not replied within two months to the proposal made according to Art.20(2).

If the employer claims the ownership of a service invention in whole or in part, the employee shall be entitled to receive a compensation. In assessing the amount of the compensation, commercial applicability of the service invention, the duties of the employee in the enterprise and the enterprise's contribution to the invention shall be considered (Art.22-23).

If the parties fail to determine the amount and the modality of the compensation within thirty days in compliance with the provisions of the Regulation, the dispute shall be settled by arbitration within sixty days.

An employer shall file a patent application for the service invention for which he has claimed ownership in whole. The employer must indicate the name of the employee as an inventor in the patent application according to Art.15. If an employer fails to file a patent application for the service invention within a reasonable period set by the employee, the employee may file such an application for patent in the name and on behalf of the employer. Where a utility model certificate appears to be more appropriate for the protection of the service invention, the employer shall file an application for a utility model certificate. (Art.26)

Where a service invention has become free, the employee shall be entitled to file an application in his own name.

For foreign countries in which the employer does not wish to obtain patent protection for the service invention, he should release the service invention free and enable the employee to apply for a patent in those countries (Art.27).

If the employer decides to discontinue prosecuting a patent application or to surrender the patent protection, he should inform the employee accordingly. At the employee's request, he must assign the patent right to him. If the employee fails to reply within three months, the employer shall be free to surrender his rights resulting from an application for patent or a patent.(Art.29)

Where the interests of the enterprise so require, the employer may refrain from filing an application for a service invention reported to him.(Art.30)

b. Free Inventions

An employee who has made a free invention, should inform the employer without delay as long as the invention is capable of being used in the employer's field of activity. He should also specify the characteristics of the invention so that the employer can assess whether it is in fact a free invention. If the employer does not contest that the invention notified to him is a free invention in writing within three months, he may not claim thereafter that the invention is a service invention. (Art. 31)

An employee should offer his employer on a non-exclusive basis to benefit from his invention on reasonable terms before exploiting his free invention in another way. But the invention should fall within the field of activity of employer's enterprise or the enterprise should be making serious attempts to become active in the field of the invention. If the employer fails to respond to this offer within three months of its receipt, he shall lose his right of precedence on the matter. (Art.32)

c. Technical Improvement Proposals

If an employer makes use of technical improvements proposals upon the written notification of his employee, he shall pay a reasonable amount of

compensation to the employee. Technical improvement proposals are not subject to utility model or patent protection. (Art.33)

d. Common Provisions Concerning Employee's Inventions

Provisions concerning employee's inventions are of a mandatory nature. These mandatory provisions may not be modified to the detriment of employees. Contracts concerning employee inventions are permissible, in case of service inventions after the patent application has been filed, or in case of free inventions and technical improvement proposals after their notification to the employer.⁶⁰⁴ It is forbidden to conclude such agreements beforehand which shall be otherwise null and void. (Art.34)

Terms of agreements concluded between the employer and employee concerning service inventions, free inventions and technical improvement proposals must comply with equity. Otherwise they will be declared null and void to the extent that they are manifestly inequitable. This rule is also applicable to the amount of compensation. Upon the termination of an employment contract, an employee should raise objections within six months as to the inequity of an agreement or the amount of compensation. (Art.35)

An employer is under obligation to respect the secrecy of the information concerning an employee's invention that has been notified to him. An employee must keep a service invention secret as long as it has not become free. (Art.36)

e. Inventions Made by Employees in Public Service, Armed Forces Personnel and University Staff

Provisions applying to inventions and technical improvement proposals of employees in private sector shall apply, likewise to inventions and technical proposals made by employees in public service and inventions of the armed forces personnel, without prejudice to the privately agreed dispositions. (Art.39-40)

⁶⁰⁴ Tekinalp, p.469

Inventions made by the teaching staff of the universities during their scientific studies at universities or higher schools shall be free inventions. Articles 31, 32 and 34 shall not be applied to such free inventions. If the educational body has made specific equipment and means available for the research work, the teaching staff has to notify the educational body. The educational body may demand a reasonable share of the proceeds from the invention within three months upon the receipt of the notification. (Art.41)

7.3.8. Compulsory License

Provisions concerning compulsory licences have gained legal certainty in Turkish law system for the first time with the enactment of the Decree Law No:551 Pertaining to the Protection of Patent Rights (Art. 99 –120).⁶⁰⁵.

Contrary to voluntary license; compulsory license is granted against the consent of the licensor.⁶⁰⁶ A right to monopoly can be abused by the rightholder in cases where he demands excessive prices for the sale of the patented products or he retains an important patented invention without working it for a long period of time.⁶⁰⁷ Such an abuse can only be overcome when the legislation allows the grant of the compulsory licenses and enables the other interested parties to work the patented invention and enhances its usefulness to a maximum extent.

The length and details of the section concerning compulsory licenses in the Turkish Decree Law has been criticised as facilitating the granting of compulsory licenses in violation of the patent owner's rights and for being far too broad. The term

⁶⁰⁵ Tahir Saraç, Patentten Doğan Hakka Tecavüz ve Hakkın Korunması, 2003, Seçkin, Ankara, p.119, see footnote 405.” Although provisions concerning compulsory licenses have not been laid out in the Turkish Letter Patent Law of 1879, the Turkish courts have referred to Art. 5 of the Paris Convention and decided in favour of the requests for compulsory licenses in a number of cases [TD. 15.3.1971, E. 1970/1922 K. 1971/1954 (Turkish Precedents Collected Works p..259-260)]. Contrary to this approach, the Council of State insisted that compulsory licenses should not be granted since there were no provisions in the Letter Patent Law (State of Council 11. Civil Chamber, 31.12.1970 E. 1969/1065 K. 1970/2936 (Council of State 12. Chamber Decisions, p.452)

⁶⁰⁶ Eren Fikret, Borçlar Hukuku, Genel Hükümler, Cilt 1, 5. Bası, İstanbul, 1994, s.370 -371

⁶⁰⁷ Saraç, p.117.

“public interest” is considered quite vague. There are no provisions for the termination of a compulsory license when the conditions leading to its grant cease to exist. Article 120 is also criticised since it provides publicity and financial incentives for applicants to seek compulsory licenses.⁶⁰⁸ Companies may reduce investment in inventing and developing new technologies if they feel that their interests are being threatened by compulsory licensing.

Articles 27 and 31 of the TRIPS Agreement lay down minimum standards for compulsory licences.

The “Motta Text” which has been prepared after the Doha Declaration⁶⁰⁹ lays down the principles for the grant of compulsory licenses. The necessary amendments shall be made in the TRIPS Agreement in accordance with the Doha Declaration⁶¹⁰ and the “Motta Text” and subsequently these amendments shall have to be transposed in Turkish Decree Law .

Grant of compulsory licenses is one of the legal instruments that restricts rights of a patent owner since it is granted without the consent of the patent owner, by a court’s decision or a decree issued by the Council of Ministers.

Compulsory licence can be exclusive and confer the right of exportation only in cases where it has been granted on grounds of public interest. Otherwise the rights of a patent holder arising from contractual licences that have been concluded for territories abroad, shall be in jeopardy if any compulsory license is granted the right to export the patented invention.

⁶⁰⁸ www.cptech.org/ip/health/phrma/nte-99/turkeychtml, retrieved on March 16, 2005. (Home Page of Consumer Project on Technology)

⁶⁰⁹ Davies, p.438 “...The Doha WTO Ministerial Declaration on TRIPS and Public Health was adopted on November 14, 2001. The Doha Declaration was a response to the needs of developing countries to have inexpensive access to certain patented drugs. Paragraph 4 provides that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO’s members’ right to protect public health and, in particular, to promote access to medicines to all. One of the mechanisms to be established achieve this is the use of compulsory licensing in these countries for the production of such drugs.”

⁶¹⁰ Larry A. DiMatteo, Kiren Dosanjh, Paul L. Frantz, Peter Bowal, Clyde Stoltenberg, “The Doha Declaration and Beyond: Giving Voice to Non-Trade Concerns Within the WTO Trade Regime”, *Vanderbilt Journal of Transnational Law*, January 2003, Volume 36, Number 1, p.95.

According to Art.119 of the Decree Law No:551, provisions related to compulsory licences under Art.88 shall also apply to contractual licences unless they contradict provisions foreseen under Articles 114 and 118.

Articles 114 and 118 of the Decree Law No:551 are considered as mandatory provisions in a way.

According to Art.96, compulsory license shall be granted in three cases.⁶¹¹ Compulsory license shall be granted by a court's decision, upon request, where no offer for licensing has been made and there is a failure to work the patented invention in accordance with Art.96 or in cases where there is a dependency of subject matter of patents as mentioned in Art.79. The Council of Ministers shall be competent to grant compulsory license on grounds of public interest as mentioned in Art. 103. (Art.99)⁶¹²

a. Compulsory License in Case of Failure to Work the Patented Invention

Under Art.100; any interested person may request the grant of a compulsory licence, if at the time of the request, the patent was not put to use or⁶¹³ that the delay in the use was not due to justifiable reasons or the use had been suspended during an uninterrupted period of three years without justifiable reasons.⁶¹⁴

Technical or economic or legal reasons of an objective nature which occur beyond the control and will⁶¹⁵ of the patentee shall be deemed to constitute justifiable reasons for the inability to put the patent to use (Art.100 (2)).⁶¹⁶

⁶¹¹ Saraç, p.120 “...This is a non-exhaustive list of conditions where compulsory license can be granted. For instance, it is foreseen in Art. 14 that compulsory license shall be granted under fair conditions to the former patent holder or the licensee if the patent owner changes as a consequence of termination of usurpation”.

⁶¹² Aslan Kaya, “551 Sayılı Patent Haklarının Korunması Hakkında Kanun Hükmünde Kararname ile Getirilen Zorunlu Lisans Sistemi” İstanbul Üniversitesi Hukuk Fakültesi Mecmuası, 1995-1996, C.LV, S.1-2, s.343

⁶¹³ Saraç, p 121 “... In this sentence there must be an “and” conjunction instead of an “or” conjunction. Otherwise, the failure to work the patented invention shall always constitute a ground for the grant of compulsory license without having to prove the existence of any legitimate reasons”.

⁶¹⁴ 11. Civil Chamber of Turkish Court of Appeal, 17.02.1998, 1998/367-943 (FMR, 2001/3, p.179.)

⁶¹⁵ Kaya, Zorunlu Lisans, p.348 “...Justifiable reasons can be considered as force majeure since the Decree Law defines them as reasons that occur beyond the control and the consent of the patent holder.”

⁶¹⁶ Saraç, p.122 “...justifiable reasons occur in cases where for instance the authorities do not permit the operation of the invention or prohibit the importation of the raw material necessary for the manufacture of the

The new Decree Law retains the obligation on a patentee to put to use the patented invention. The obligation to put to use the patented invention shall be interpreted in accordance with the provisions foreseen under Articles 96-98. This requirement can be met by manufacturing the patented product, applying the patented process, or by offering to license the patent ⁶¹⁷ within Turkey according to territoriality principle. A patent holder can not fulfil the requirement to work the patented invention by working it abroad or granting a license abroad.⁶¹⁸ It is being argued whether the working requirement can be met by importation of the patented product. Some allege that importation does not satisfy the working requirement since it does not contribute to the economic and technical development of the country through implementing the new technology in industry.⁶¹⁹ However, Art. 97 “Evidence of Use” implies that importation does not satisfy working conditions since inspection of the manufacturing facilities is a condition of patentability. On the other hand TRIPS Art.27.1 states clearly that patent rights shall be enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. Within the meaning of that article; importation should be admitted as meeting local working.⁶²⁰ It should be borne in mind that EC Member States amended their national patent laws to comply with the TRIPS Agreement. They recognised importation from WTO member countries as meeting the local working requirements.

Experimental use of the invention can not be considered as working the invention within the meaning of Article 96-98 due to its provisional nature.⁶²¹

According to Art.96; the obligation to put to use the work must be realized within three years as from the date of publication of the announcement related to the issue of the patent. This period is criticised for being too short for pharmaceuticals

patented invention due to various reasons temporarily. The lack of technical staff necessary for the use and maintenance of the invention can also be considered as a justifiable reason.”

⁶¹⁷ http://www.ladas.com/BULLETINS/1995/1195Bulletin/Turkey_IPLawsAmended.html, Ladas & Parry International Property Lawyers, retrieved on March 16, 2005.

⁶¹⁸ Kaya, Zorunlu Lisans, p.345

⁶¹⁹ Kaya, Zorunlu Lisans, p.346

⁶²⁰ Jacques Gorlin, ‘Improving Intellectual Property Protection’, Scrip Magazine, (a monthly magazine covering key issues and trends in the pharmaceutical industry), March 1993, p.36-38.

⁶²¹ Saraç, p.123; Kaya, Zorunlu Lisans, p.348

and agricultural chemicals since the marketing registration period typically takes far longer than three years after patent grant.

If the use is suspended, this suspension should last an uninterrupted period of three years. The patentee or the person authorised by him must in accordance with Art.97 submit an official certificate attesting the use of the patent to the Turkish Patent Institute to prove the use of the invention.

According to Art.102, the exportation of the patented invention shall not be accepted to constitute a ground for compulsory license. The patent holder enjoys a full freedom in choosing the right means for exploiting his invention commercially.

There is no provision in the Decree Law stating clearly whether the interested person should first apply to the patent holder for establishing a contractual license relation before requesting a compulsory license. According to the prevailing opinion in the doctrine, the interested person should have undertaken to conclude a license agreement with the patent holder before resorting to the court.⁶²²

b. Compulsory License in case of Dependency between Patents

In cases where there is dependency of subject matter of patents as mentioned in Art.79,⁶²³ interested parties may request the grant of a compulsory license. Such a request can be made before the court in three situations :

- If the patented invention can not be put to use without infringing the rights conferred by a prior patent, the right holder of the latter patent may request the court to grant license for using the patent of prior right by bringing evidence that his patent, with reference to the prior patent shall serve a different industrial purpose or⁶²⁴ achieve significant technical improvement.(Art.101(1))

⁶²² Saraç, p.123; Kaya, Zorunlu Lisans, p.347.

⁶²³ in other words where a patented invention can not be worked without using an invention, protected under a prior patent.

⁶²⁴ Saraç, p.123; Kaya, Zorunlu Lisans, p. 349 "... there should be an "and" conjunction instead of an "or" conjunction in the Decree Law."

- Where the patented inventions serve the same industrial purpose and where a compulsory license has been granted in favour of one of the dependent patents, the patentee of the dependent patent upon which compulsory license is granted may request from the court that a compulsory license be granted in his favour on the other dependent patent.
- Where the subject matter of a patent concerns a process aiming to obtain a patented chemical product or substance related to pharmacology, and where a latter process patent achieves a significant technical improvement, with respect to the patent of prior date, both the patentee of the process patent and the patentee of the product patent may request from the court the grant of compulsory license for using the patented invention of the other party.

In case, where there is dependency between the subject matter of the patents, the interested parties may request the grant of compulsory license at any time. There isn't any requirement concerning the lapse of a certain period of time.

In case, where one of the dependent patents is invalidated or expires, the decision on compulsory license shall remain without effect (Art.101 (4)).

c. Compulsory License on Grounds of Public Interest

The Decree Law does not give a precise definition of the term "public interest" but instead it categorizes the reasons in two groups which may qualify as grounds of public interest.

In the first group public health and national defence purposes are mentioned and putting the invention into use, increasing, spreading or improving its use are deemed to be of great importance in terms of public interest.(Art.103 (1)).

In the second group general reasons which relate to the economic and technical development of the country are specified. Situations where the non use of the invention or its insufficient use in terms of quality and quantity, causes serious

damage to country's economic or technical development, shall be deemed to involve public interest. (Art.103 (2)).

As a general rule, decisions concerning compulsory licenses can only be issued by competent courts. Where compulsory licenses on grounds of public interest are in question, the Council of Ministers has the authority to decide that the invention subject matter a patent or an application for patent to be put to use. Upon proposal of the concerned Ministry, the Council of Ministers issues a decree for the grant of compulsory license. In case, where the use of invention is important for national defence or public health, the proposal is prepared jointly by the concerned ministry, and the Ministry of National Defence or the Ministry of Health.⁶²⁵

The concerned Ministry may propose the grant of compulsory license of its own motion. The procedure for the grant of a compulsory license may also start upon the application of any interested person for mediation in the first instance to the TPI.

According to Art.103 (5); the decision to grant compulsory license, may, restrict the use of the invention to one or some enterprises on grounds of its importance for national defence. The term "enterprise" cited in Art.103 (5) has to be interpreted broadly as including both private law and public law legal entities.⁶²⁶

Under Art.103 (6), conditional compulsory license may also be granted by a court's decision in case, where the patent holder fails to put the invention to use or to spread and enhance the use of the invention in a manner sufficiently to satisfy the public interest within a certain period of time, not longer than one year. In this type of compulsory license, the patent holder is given the opportunity to enhance the use of his invention. After the decision of the Council of Ministers concerning the grant of conditional compulsory license, the court decides on the grant of compulsory license upon the request of any interested party. The court examines the situation after the lapse of the set period. If the patent holder fulfils the conditions stipulated in the court's decision, the court rejects the applicant's demand concerning the grant of

⁶²⁵ The proprietor of a patent has a right to file a lawsuit for the revocation of such a decree since all administrative acts are subject to judicial review. (Turkish Constitution Art.125(1))

⁶²⁶ Tekinalp, p.553

compulsory license. If the patent holder fails to meet the conditions, i.e. fails to satisfy the public interest, the applicant shall be granted compulsory license.

Since all administrative acts and transactions are subject to judicial review, any interested party may request the revocation of the decision of the Council of Ministers concerning compulsory license before the administrative courts.⁶²⁷

d. Mediation by the Turkish Patent Institute

In case, where the patentee refuses the applicant's request for the conclusion of a voluntary license contract, the applicant may in the first instance refer to the specialised court directly or resort to the TPI for asking its mediation with a view of obtaining a contractual license for the same patent .⁶²⁸

Mediation procedure has been set out in Articles 104-107 of the Decree Law No.551.

The Institute shall reach a decision on the request for mediation within one month as from the date of application. If the Institute is convinced that there is in fact a situation requiring the grant of a compulsory license, that the applicant is solvent and that has all the necessary means to put the invention to use, it shall accept to mediate. In this case, the Institute shall invite the parties to attend the contractual license negotiations which shall not last longer than two months. The Institute may extend this term upon joint request of the parties if it is convinced that the license agreement can indeed be concluded.

If the parties agree on the terms and conditions of a license agreement for the use of the invention during the negotiations in which the Institute has acted as a mediator, the licensee shall be given a term not exceeding one year to start putting the invention to use and the following conditions must be satisfied for the activity of mediation to come to an end:

⁶²⁷ Saraç, p.127.

⁶²⁸ Erdem, s.149.

- the license agreed upon by the parties shall be an exclusive one and shall not constitute an obstacle for being subject to compulsory license,
- documents should be submitted evidencing that the applicant possesses the equipment and materials necessary for putting the invention to use,
- a guarantee , in the amount set forth in the Regulation, should be supplied, to cover the liability if the applicant fails to start making use of the invention within the term foreseen,
- the fee set forth in the Regulation for this purpose should be paid.

The Institute finalizes the mediation procedure by entering the license granted, as a result of the mediation, in the Patent Register.

If the licensee fails to put the invention to use within the given term not exceeding one year, the Institute may decide for the payment of a fee by the licensee to the licensor. The amount of the fee shall be equal to the license fee, the licensee has to pay to the patent holder in a license agreement of a term equivalent to the term during which the invention was not used.

e. Request for Compulsory License

According to Art.108, upon expiry of a term of three months, as from the expiry of the term foreseen in Art.106 or as from the date of the Institute's decision refusing the request for mediation or when the parties fail to conclude a license agreement within term of the mediation activity, the applicant may file a lawsuit for the grant of a compulsory license. The applicant should prove that his attempt to establish a contractual license relation with the patentee, within the term of the mediation activity conducted by the Institute has failed. The applicant should further submit to the court the documents cited in Art.108 (3).

The patentee can raise an objection against applicant's request and the submitted documents before the court (Art.109)

The court shall notify patentee's objection to the applicant and afterwards render a decision within one month, either to reject the application or to grant

compulsory license (Art.110 (1)). If the court decides in favour of the applicant, the decisions shall include the scope, the fee, the term of the license, the guarantee produced by the licensee, the date when the use is to commence and measures for an effective and serious use of the patent. (Art.110 (3)).

It is not possible to raise an appeal against the decision of the first instance court, but the parties can request the rectification of the decision from the first instance court. There is no time limit foreseen for requesting rectification in the provisions of the Decree Law. It will be quite right to assume that the request for rectification should be made until the compulsory license is entered in the Patent Registry. Rectification shall neither suspend the finalization of the decision nor the execution of the finalized decision. If the court considers the evidence submitted by the patentee for suspending the execution of the decision adequate, the use of the invention shall be postponed until the decision on license is finalized.

f. Legal Nature of Compulsory License

A compulsory license can not be granted on an exclusive basis. Otherwise the patentee shall be deprived of exploiting his invention commercially if he is not allowed to grant voluntary license to others. The only exception to this rule is the compulsory license granted on grounds of public interest according to Art.103.⁶²⁹ In this case, exclusivity should not contradict the purpose of compulsory license and must be necessary for economically valorising the patented invention. (Art.114 (1))

The licensee has in principle no right to import the subject-matter of the patent, granted as a compulsory license. He must manufacture the patented invention instead of raising revenue through importing it . If the compulsory license has been granted on grounds of public interest and if the licensee has been specifically authorised to import, the subject matter of the patent may be imported. Such an authorization to import shall be issued on a temporary basis and shall be limited to meeting the demand.⁶³⁰

⁶²⁹ Saraç, p. 120

⁶³⁰ Tekinalp, p. 557 "... authorization to import shall be issue by a governmental decree signed by the Council of Ministers".

g. Scope of Compulsory License

A compulsory license covers the additions to the existing patent at the date of the acceptance of the license. If the additions newly issued after the grant of the compulsory license serve the same industrial purpose as the patent, subject of the license, the licensee may request from the court that the patent(s) of addition be also included within the scope of the compulsory license. (Art.116 (1)).

If the parties despite the mediation of the Institute, can not agree on the terms of the license including fees whose scope has been enlarged with the patents of addition, these shall be determined by the court. (Art.116 (2)).

h. Transfer of Compulsory License

A compulsory license may be validly transferred together with the business enterprise or the part of the business enterprise where it is being valorized. Where the compulsory license is granted for reasons of dependency between patents in accordance with Art.101, the license is transferred together with the dependent patent. (Art.117 (1))

The transfer of the compulsory license shall be entered in the register.

The beneficiary of a compulsory license may not grant sub-license. Such actions shall be deemed to be invalid. (Art.117 (2))

I. Request for Modifying the Terms of the Compulsory License.

The licensee or the patentee may demand the modification of the terms of compulsory license or the license fee from the court, on grounds of events occurring at a later date. Especially if a patentee subsequently concludes a contractual license under more favourable conditions, compared to those of compulsory license, each of the parties are entitled to request a modification under Art.118 (1).

If a licensee violates or continuously fails to fulfil his obligations arising from the compulsory license, that are cited in the court's decision or the governmental decree issued by the Council of Ministers, the patentee can request the cancellation of the license from the court. In this case, the patentee shall be entitled to compensation for damages.

7.3.9. Compensation of Damages Against Infringement.

Provisions laid down in the Decree Law No:551 cover three kinds of compensation; compensation for material damages, compensation for moral damages and compensation for the reputation of the invention.

Art. 137(1)(b) states manifestly that the proprietor of a patent whose rights are infringed may request compensation for material and moral damages incurred.

The illegal acts defined in Art. 136 constitute infringement of rights conferred by a patent and they lead to legal liability of the infringer. The acts that lead to the infringer's liability as compensating material and moral damages are defined in Art.138.

According to Art.138, a person who, without the consent of the proprietor of a patent, produces, sells, distributes or puts in commerce under any form or imports for these purposes or keeps in possession for commercial purposes, a product under patent protection or makes use of a process under patent protection shall be liable to remedy the unlawful situation and compensate the damages he has caused. The infringing acts defined in Art.136 (1)(c), (d), (e), (f) but not covered in Art.138 should also give rise to liability of compensation. A contrary approach would not contribute to the achievement of objectives of the Decree Law, such as encouraging the inventive activity. The statement "liability to remedy the unlawful situation" in Art.138(1) is used to signify the infringing acts defined in Art.136.⁶³¹

⁶³¹ Saraç, p.260.

In respect of compensation liability there is no difference between product patents and process patents.

The Decree Law No:551. distinguished the acts of a person who is using the patented invention from the acts of a person producing, selling, distributing, putting in commerce, importing or keeping in possession for commercial purposes without the consent of the patent holder. The proprietor of a patented invention should inform a person using the invention of the patent's existence and of the infringement of same and request him to stop the infringement. On the other hand the patent proprietor does not have to remind a person using the invention where such use constitutes a faulty behaviour. In this case the infringer shall be liable to compensate the damages he has caused.

The Justification of the Decree Law No:551 envisages that the Art.138(2) lays out the infringing act stated in Art.136(1)(f) . The persons keeping counterfeit goods in their possession and refraining from declaring where and how they obtained these products are deemed to be the persons using the invention within the meaning of Art.138(2). In other words, they are not the end/ final consumers.⁶³² Two conditions have to be fulfilled in order to demand compensation from the person using an invention. First, the patent proprietor must remind the person of the patent's existence and of the infringement and request him to stop such infringement. The person using the invention should continue with his infringing acts in spite of such a reminder. If the person using the invention under patent protection stops the infringement following the receipt of a reminder, the patent proprietor can not request compensation.⁶³³ Second, use should constitute a faulty behaviour. The acts of a person using the invention shall be deemed to constitute a faulty behaviour, in case where he continues using the invention following the receipt of a reminder from the patent proprietor or if he could have discovered the existence of counterfeit goods by making a small-scale research.

On the other hand Art.144 restricts the right of action in Art.138. Art.144 states that the patent proprietor may not institute proceedings against those persons using

⁶³² Saraç, p.267; Tekinalp, p.583.

⁶³³ Saraç, p.267

the products put on the market by the person who has paid compensation for damages to the patent proprietor.

The Decree Law referred to the concept of “damage” but did not define it. It should be interpreted broadly covering both material and moral damages. According to Art.137(1) (b) a patent proprietor whose rights are infringed can claim compensation for moral damages.

According to Art. 140, material damages which a patent owner can claim from the infringer is split into two parts as “effective loss” and “non-realized income”. In case of effective loss, there is a change in the amount and value of the patent proprietor’s property. There can be either a decrease in his assets or an increase in his liabilities.

7.3.10. Non-realized Income and Increasing the Non-realized Income

Art. 140 refers to non-realized income. Art.140(2) defines the optional evaluation methods for the calculation of the non-realized income. According to this provisions the non-realized income shall be calculated in accordance with one of the following methods;

- According to the income that the proprietor of the patent might have possibly generated if the competition of the infringing party did not exist (Art.140(2)(a));
- According to the income generated by the infringing party from the use of the patent (Art.140(2)(b));
- According to a license fee that would have been paid by the party, infringing the patent right, after utilizing the patent under a licensing contract (Art.140(2)(c)).

The patent proprietor has to choose one of these three methods. He may not combine two of them or all of them for calculating his non-realized income.

In calculating the non-realized income, circumstances such as the economic value of the patent, the term of protection remaining at the time of infringement, the nature and the number of licences granted in respect of the patent shall be taken into consideration.

Where the patent proprietor has selected the evaluation methods specified in Art.140(12)(a) and (b) for the calculation of the non-realized income, the Court may add a reasonable extra amount if the Court reaches a conclusion that the patent contributes substantially, from an economic aspect to the manufacturing of the product or to the use of the process (Art.141 (1)). If the patent constitutes the determining factor in creating the demand for the product, it shall be deemed to contribute to the economic value of the product. (Art.141(2)).

7.3.11. Documents Evidencing Infringement

The patent proprietor may request from the infringing party the documents related with the use for the evaluation of the damage. Commercial books of the infringing party are the primary documents. The infringing party must also submit other documents that form the basis of accounting records.

Although there is no period of time specified for the request of documents in the Decree Law, the patent proprietor should be able to request these documents from the infringing party before instituting any proceedings so that he will be in a better position to choose the most appropriate calculation method specified in Art. 140.

7.3.12. Reputation of the Invention

According to Art.142; the proprietor of a patent may request extra damages from the infringing party where the reputation of the invention is harmed by the manufacturing in a bad way or by the marketing of the patented invention in an improper manner.

7.3.13. Establishment of Specialized Courts

Art.146 (1) stipulates that specialized courts shall have jurisdiction for all of the actions and claims provisioned by the Decree-Law including interlocutory injunction and declaratory actions irrespective of the value of the matter in dispute. Specialized courts have jurisdiction both for civil and criminal proceedings.⁶³⁴

Upon the proposal of Ministry of Justice, the High Council of Judges and Prosecutors shall determine which of the Commercial Courts of First Instance and the Criminal Courts of the First Instance shall have competence as specialized courts and indicate their respective jurisdictions (Art.146(2)).

The parties to the dispute may resort to arbitration instead of instituting legal proceedings before the competent court .

For actions instituted against the decisions of the Turkish Patent Institute taken in respect of the provisions of the Decree-Law and for actions instituted against the TPI by third parties having been damaged from the decisions of the Institute, the specialized court in Ankara shall have competence. (Art.146(3))

7.3.14. Publication of the Court's Decision

According to Art.137(1)(f), a proprietor of a patent whose rights are infringed may request the communication of the court's judgement rendered against the infringing party to those related or its publication or its disclosure to the public by means of publication. The costs are to be met by the infringing party.

Art.147(1) states that the successful party in the proceedings having a legitimate ground or a interest may request the publication of the decision in full or in summary which has become res judicata. The provision does not confer the

⁶³⁴ Art.146 of the Decree-Law No:551 has been amended by the Law No.5194, adopted on 22.6.2004.

exercising of that right only on the patent proprietor, each litigant which proves his claims and wins the proceedings shall be able to request the publication of the court's judgement. The judgement is published in a daily paper or by similar means.

The court can not decide for the publication of the final judgement of its own motion unless the related party makes such a request.

The nature and the extent of the publication shall be determined in the judgement. The right of publication shall be void, if not exercised within three months after the judgement becomes *res judicata*. (Art.147(2))

7.4. Enforcement of the Legislation

Art.73/A pertaining to "Penalties and Fines" was added to the Decree-Law No.551 with the enactment of Law No. 4128 as from November 7, 1995.⁶³⁵ Moreover Act. No.3506 introduced a new system to raise the fines each year in connection with the raise of the civil servant salaries.

a. Those making false declaration with respect to the declaration prescribed in Art.44; or those removing, without authority the sign indicating a patent right rightfully placed on a product or on its packaging; or those falsely representing themselves as the right holder of an application for patent or of a patent shall be sentenced to an imprisonment term of between one and two years or to pay a fine of between 14.000 YTL and 27.000 YTL or to both of them.

The person who makes false declaration infringing Art.44 shall be sentenced to an imprisonment and to pay a fine. According to Art.44, the name of the inventor should be indicated in the patent application. If the applicant is not an inventor or where there are more inventors, the applicant should disclose by which means he obtained the right of filing patent application from the inventor/s. Otherwise the

⁶³⁵ Art.73/A has been amended by the enactment of Law No:5194 on 22.6.2004 to punish felonies committed in respect of inventions protected by utility model certificates. The amounts of pecuniary fines have also been increased.

Institute shall not commence patent examination. Patent Regulation Art.7 sets out the content of a patent application. According to Art.7(f), the identity of the inventor must be specified in the application. False declaration may relate to the identity of the inventor/s or to the disclosure of means by which the right of filing a patent application is obtained.⁶³⁶

The person who removes the sign indicating patent without authorization shall be sentenced to an imprisonment and to pay a fine. There is no general valid sign indicating a patent right placed on a product or its packaging. A patent number is usually used to indicate that a product is patented.⁶³⁷

The person who falsely represents himself as the rightholder of an application for patent or of a patent shall be sentenced to an imprisonment or to pay a fine or to both of them. According to Art.82, patent protection that is granted to the patent proprietor shall be also granted to the applicant as from the date of publication of the patent application in the related bulletin. According to Art.92 of the Decree Law and Art.46 of the Patent Regulation, the rights arising from a patent application and a patent can not be put forward against third parties unless they are entered in the patent register. The perpetrator deceives the others by introducing himself as the patent proprietor or applicant in the related market.

b. A person shall be sentenced to imprisonment between 2 and 3 years or a payment of a fine between 27.000 YTL and 46.000 YTL or to both of them.

- For having committed the acts unrightfully and without authority, transferring, or placing as security or undertaking any other such action for utilising any one of the rights of transfer, placing of security, execution of levy and other such rights as established under Art.86 and transferring to some other person the license pertaining to such right;

607 Serap Keskin, Fikri(Düşünsel) Mülkiyet Haklarında Patent ve Markanın Ceza Normları ile Korunması, Seçkin, Ankara, 2003, p. 55-56.

⁶³⁷ Tekinalp, p.593.

- For affixing signs on a product produced or put to sale by owner himself or by others, or on its packaging or on commercial documents or on advertising material in such a way that would convey the impression as if a relationship exists with a protected industrial property right;
- For using to the same effect similar writing and signs in the newspapers, advertisements and commercials without being the rightful proprietor of the IP right or after the expiry of the protection term or after the invalidation of the right or after the termination of the rights.

According to Art.86 of the Decree-Law, an application for a patent or a patent may be transferred to some other party, may be inherited or the right to use the patented invention may be subject to license. An application for patent or a patent may also be pledged. A person who transfers these rights or related licenses without authorization unrightfully shall be sentenced to above mentioned penalties. Only an authorized person may only transfer the invention, patent application and the patent.

Those affixing signs on products or packagings to convey the idea as if a relationship exists with a patent under protection shall be also sentenced to an imprisonment or to a fine payment or to both of them. In this case there is actually no patent that has ever existed or the patent right has terminated due to the expiry of term of protection, non-payment of renewal fees, surrender of right to patent or a court decision pertaining to the invalidation of the patent.

c. Those who have committed any one of the felonies specified under Art.136 shall be sentenced to an imprisonment term of between two and four years or to pay a fine of between 27.000 YTL and 46.000 YTL or to both of them, furthermore, judgement shall be ruled to close down the premises of their undertaking for a period not to be less than one year and to prevent them from practicing any commercial activity during the same period.

The acts specified in Art.136 are regarded as infringement of rights conferred by a patent and the patent holder is entitled to request compensation for material and moral damages. The same acts are considered as felonies according to Art.73/A (c).

These acts are :

- Imitating by producing in whole or in part of a patented product,
- Selling, distributing or commercializing in any other way, importing or keeping them in possession for commercial purposes,
- Using the patented process, selling, distributing or commercializing the products directly obtained through such patented process,
- Enlarging the scope of the rights granted on the basis of a contractual or compulsory license or transferring such rights to third persons,
- Participating in acts infringing patent rights,
- Refraining from declaring the source where and the manner the products unlawfully were obtained.

Where the felonies stated above are committed by those working in the undertaking, whether on their own initiative or under instructions, while carrying out their duties shall be punished in the same manner.

The employees and the owner or the manager of the undertaking or their representative and the person who manages the undertaking de facto under whatever title or authority and who have not prevented the committing of such felonies shall be punished. According to this provision, the owner of the undertaking or the person managing the undertaking de facto shall be jointly liable for the felonies that are committed by the employees .

Where the felonies specified under Art.136 have been committed during the execution of tasks related with a legal entity, the legal entity shall be jointly liable for expenses and the pecuniary fine.

Prosecution of above mentioned felonies are subject to complaint. The right of complaint belongs to the person whose patent rights has been infringed. The Turkish Patent Institute may also raise a complaint for all felonies, to the exception of those provisioned under Article 136. The Consumer Associations, the establishments under the jurisdiction of Laws No.5590 such as chamber of commerce, chamber of

commerce and industry, chamber of maritime, trade stock exchange, the establishments under the jurisdiction of Tradesman and Craftsman Law No.507 may also raise complaints for falsely making the declaration provisioned in Art.44, with respect to true identity of the patent holder, and for affixing signs on a product or on its packaging produced and put to sale, by own self or by others, or on commercial documents or on promotional material in such a way that would convey the impression as if a relationship exists with a patent under protection, or of using to the same effect writings, signs and expressions in the advertisements and commercials, at the published and visual media, without being the rightholder of the patent or after the expiry of the term of protection of the patent or after the invalidation or after the termination of the patent.

The complaint shall be made within two years from the date of being informed of the act and the identity of the infringer. The complaints shall be treated as of urgent matters in relation to Criminal Procedural Act.

7.5. Border Enforcement

(Seizure of infringing goods at the borders)

Art.152 lays out the precautionary measures which have to be exercised to secure the effectiveness of the judgement fully. Art. 152 (b) provides for the seizure of the goods produced or imported in infringement of rights conferred by the patent or means used in implementing the patented process, within the borders of Turkey, wherever they are found including the customs, free ports or free trade areas. Such goods do not have to be in the possession of a person or an infringer, they will be seized even if they are in the possession of a forwarding agent or in a warehouse.⁶³⁸ Such a precautionary measure can not be exercised for the goods which are in possession of final consumers since use without pursuing commercial purposes does not constitute an infringing act.

⁶³⁸ Saraç, p.226.

The above mentioned provision allowing the seizure of the goods within the free trade areas has been often criticized since free trade areas are not deemed to be within the customs frontier of a country.⁶³⁹

Seizure of the infringing goods at the borders is a special kind of precautionary measure which has been adopted in the Turkish Customs Law in accordance with the provisions of the TRIPS Agreement. In principle, courts have jurisdiction to render decisions for the exercise of precautionary measures. But upon the request of a rightholder infringing goods can be seized at the borders without any court decision. Furthermore customs administration may seize the infringing goods with its own motion without any request of a rightholder if there are clear evidences indicating that the goods are counterfeit. (Customs Law Art.57(1) (2)).

Following the notification of the decision concerning the seizure of goods at the customs, to the rightholder, unless an action is brought on the merit of the case, or an injunction decision is given by the court within ten days, the Customs Administration will release the goods. (Customs Law Art.57(4)).

For the lawful seizure of counterfeit goods at the Customs, the related goods should have been manufactured without the consent of the patent holder. Goods which have been manufactured with the consent of the patent holder but have been delivered to the Customs zone or exported without the consent of the patent holder or have been produced under conditions other than the ones approved by the patent holder, can not be seized.⁶⁴⁰

The court may render three kinds of decisions concerning the counterfeit and pirated products which have been seized at the Customs. If the court concludes that the products are counterfeit, the court may decide for the destruction of these products or their delivery to the owner after they have been modified in such a way that they won't be the same again or their abandonment to the State.

⁶³⁹ Saraç, p.226.

⁶⁴⁰ Saraç, p.228.

7.6. Conclusion

In the aftermath of the TRIPS Agreement negotiations and the Association Council Decision No: 1/95 starting the final stage of the Association, Turkey has enacted a whole new patent legislation to comply with the minimum standards set out in the TRIPS Agreement and also joined the EPC, PCT and Strasbourg Agreement to align the scope of patent protection and the patent grant procedure with the modern world.

The establishment of specialized courts that deal with both criminal and civil cases in the field of intellectual property rights is a further step taken towards strengthening effective protection of these rights. Due to increasing number of IP disputes, more specialized courts should be established throughout Turkey, not only in Istanbul, Izmir and Ankara.

Weak Intellectual Property protection in a country does not only affect the industry where protection measures are considered to be insufficient. As stated in the preceding paragraphs, Turkey is unfortunately elevated to Priority Watch List (Special 301) in 2005 due to lack of adequate protection against unfair commercial use for test data submitted by drug companies to health authorities. In the future this may give rise to imposition of trade sanctions not only in the pharmaceutical industry but also in other fields of industry having a great economical significance in Turkey such as textile and automotive.

A new patent law, which shall replace the existing Decree Law No:551, is now being drafted to align Turkish patent legislation with the *acquis communautaire* of the European Union. Effective implementation of harmonised patent legislation shall be considered a significant indication of Turkey's efforts towards achieving her goals in respect of global patent protection and enforcement.

VIII. CONCLUSION

The main aim of this study is to bring forward the primary issues concerning the patentability of inventions in detail and to emphasize the utmost importance of patent protection for the pharmaceutical industry. The sections of the thesis clarified the fields of intellectual property rights, E.C. Harmonisation measures, international agreements. The European Patent Convention is scrutinized in connection with the Patent Cooperation Treaty. The developments on establishing a community patent are discussed. Primary issues concerning the patentability of pharmaceutical inventions are examined. General aspects of Turkish patent legislation with special reference to pharmaceutical inventions are introduced.

The resulting study shows clearly that innovations should be encouraged by providing effective IP protection so that sustainable development can be maintained. Life-saving and cost-saving medicines would not have been developed if the inventors, whether they work for government or universities or business, had not benefited from adequate patent protection.

In the meantime interests of the drug consumers living in developing and least-developed countries and those of pharmaceutical research-based companies should be balanced through adequate measures. The Doha Declaration on the TRIPS Agreement and Public Health is an important attempt for ensuring such a balance by recognizing the gravity of the public health problems, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. It stressed the importance of interpreting and implementing the TRIPS Agreement in a way that supports public health. The WTO General Council adopted on 30 August 2003, the Decision on the Implementation of Paragraph 6 of the Doha Declaration, also referred to as Motta text. The Motta text allows countries to export patented medicines at lower prices to third countries with no manufacturing capacity in the pharmaceutical sector, by making use of compulsory licences.

Effective patent protection is beneficial both for economic development of a country and public health. Research-based pharmaceutical industry would not invest in any country where it faces with counterfeit medicines, dictated prices and insufficient IP protection measures.

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Office for U.S. Trade Representatives

<http://www.wipo.int>

World Intellectual Property Organization

<http://www.wto.org>

World Trade Organization

X. INTERNATIONAL AGREEMENTS

The Convention Establishing the World Intellectual Property Organization (WIPO)
http://www.wipo.org/treaties/en/convention/trtdocs_wo029.html - 79k

The Berne Convention for the Protection of Literary and Artistic Works
<http://www.wipo.org/treaties/en/ip/berne/> - 25k

Rome Convention 1961, International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations
http://www.wipo.org/treaties/en/ip/rome/trtdocs_wo024.html - 73k

The Paris Convention for the Protection of Industrial Property
<http://www.wipo.org/treaties/en/ip/paris/> - 26k

The Madrid Agreement concerning the International Registration of Marks
<http://www.wipo.org/treaties/en/registration/madrid/> - 27k

Protocol Relating to the Madrid Agreement concerning the International Registration of Marks
http://www.wipo.org/madrid/en/legal_texts/trtdocs_wo016.html - 90k

The Hague Agreement for the International Registration of Industrial Designs,
<http://www.wipo.org/treaties/en/registration/hague/> - 29k

The Treaty on Intellectual Property in Respect of Integrated Circuits (IPIC Treaty)
http://www.wipo.org/treaties/en/ip/washington/trtdocs_wo011.html - 65k

The Madrid Agreement for the Repression of False and Deceptive Indications of Source on Goods
http://www.wipo.org/treaties/en/ip/madrid/trtdocs_wo032.html - 39k

The Lisbon Agreement for the Protection of Appellations of Origin and their International Registration
http://www.wipo.org/lisbon/en/legal_texts/lisbon_agreement.htm - 60k

The Patent Law Treaty
<http://www.wipo.org/treaties/en/ip/plt/> - 26k

The Substantive Patent Law Treaty
http://www.wipo.org/scp/en/documents/session_5/ - 26k

Patent Cooperation Treaty
<http://www.wipo.int/pct/en/>

European Patent Convention
<http://www.european-patent-office.org/legal/epc/>

Protocol on Jurisdiction and the Recognition of Decisions in respect of the Right to the Grant of a European Patent (Protocol on Recognition) of 5 October 1973. The Protocol is an integral part of the EPC (Article 164(1) EPC)
<http://www.european-patent-office.org/legal/epc/e/ma4.html>

The Strasbourg Agreement Concerning the International Patent Classification
<http://www.wipo.int/treaties/en/classification/strasbourg/>

The Agreement on Trade-Related Aspects of Intellectual Property Rights
http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

The General Agreement for Tariffs and Trade
http://www.wto.org/english/docs_e/legal_e/legal_e.htm

The Agreement establishing the World Trade Organization
http://www.wto.org/english/docs_e/legal_e/final_e.htm

European Patent Litigation Agreement
http://www.european-patent-office.org/epo/epla/pdf/agreement_draft.pdf

Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of Registration of Trademarks
<http://www.wipo.int/treaties/en/classification/nice/index.html>

Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks
http://www.wipo.org/treaties/en/classification/vienna/pdf/trtdocs_wo031.pdf

Locarno Agreement Establishing an International Classification for Industrial Designs
<http://www.wipo.int/treaties/en/classification/locarno/>

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure
<http://www.wipo.int/about-ip/en/budapest/guide/>

Vienna Convention on the Law of Treaties
<http://www.un.org/law/ilc/texts/treaties.htm>

UPOV International Convention for the Protection of New Varieties of Plants
<http://www.upov.int/en/publications/conventions/>

XI. EC LEGISLATION

Treaty establishing the European Community, OJ C 325 of 24 December 2002

Treaty on the European Union, OJ, C 325 of 24 December 2002

Treaty on Amsterdam, OJ C 340 of 10 November 1997

EC Brussels Convention on jurisdiction and the enforcement of judgments in civil and commercial matters of 27 September 1968, OJ C 189 of 28 July 1990

Council Directive 93/98 of October 29, 1993 harmonizing the term of protection of copyright and certain related rights, [1993] O.J.L290/9

Council Directive 91/250 of 14 May 1991 on the legal protection of computer programs ([1991]OJ.L 122/42)

Council Directive of 11 March 1996 on the legal protection of databases (96/9/EC) OJ L 77/20

Council Directive 92/100 of November 1992 on rental right and lending right and on certain rights related to copyright in the field of intellectual property ([1992] OJ L 346/61)

Council Directive 93/83 of 27 September 1993 on the co-ordination of certain rules concerning copyright and rights related to copyright applicable to satellite broadcasting and cable retransmission ([1993] OJ L248/15)

Proposal for a European Parliament and Council Directive on the resale right for the benefit of an author of an original work of art COM(96) 97 final.

Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society.

Council Regulation 40/94 on the Community Trademark [1994] O.J.L 11/1, as amended by Regulation 3288/94[1994] O.J.L 349

Council Regulation No 3288/94 of 22 December 1994 amending Regulation (EC) No 40/94 on the Community Trademark for the Implementation of the Agreements Concluded in the Framework of the Uruguay Round, OJL 349, 31/12/1994 P.0083-0084

Commission Regulation No EC/2868/95 of 13 December 1995 Implementing Council Regulation (EC) No EC/40/94 on the Community Trademark, OJ L 303, 15/12/1995 P 0001-0032

First Council Directive 89/104 of December 21, 1988 to approximate the laws of the Member States relating to trademarks [1989] O.J.L40/1 (See also Council Decision 92/10 December 19, 1991 postponing the date on which the national provisions applying Directive 89/104 to approximate the laws of the Member States relating to trademarks are to be put into effect [1992] O.J.L6/35)

The Commission's Green Paper on the Legal Protection of Industrial Designs which forms the basis for the current proposals for a Council Regulation on the Community Design, and a Council Directive on the approximation of national design law [1993] O.J.C345/14 (proposal directive); [1994] O.J.C29/20 (proposal regulation)

Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998 on the Legal Protection of Designs.

Council Regulation (EC) No.6/2002 of 12 December 2001 on Community Designs OJL 3, 5.01.2002

Council Directive 87/54/EEC of 16 December 1986 on the Legal Protection of Semiconductor Products.

EC Council Regulation No.2081/92 of July 14, 1992, on the Protection of Geographical Indications and Designations of Origin for Agricultural Products and Foodstuffs amended by Council Regulation (EC) No 535/97 of 17 March 1997 [Official Journal L 83, 25.03.1997]

Directive 2004/48/EC, of the European Parliament and of the Council of 29 April 2004 on the Enforcement of Intellectual Property Rights (Official Journal of the EU L 157 of 30 April 2004).

Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing intellectual property rights and the measures to be taken against goods found to have infringed such rights. (Official Journal of the EU L 196 of 02.8.2003)

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the Creation of a Supplementary Protection Certificate for Medicinal Products (OJ EC L 182/1992, 1) ; Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the Creation of a Supplementary Protection Certificate for Plant Protection Products (agro-chemicals) .

Proposal for a Directive of the European Parliament and of the Council on patentability of computer-implemented inventions 2002/0047 (COD)