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PATENT PROTECTION
IN THE PHARMACEUTICAL INDUSTRY
IN THE EUROPEAN COMMUNITY

M.A.THESIS

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1. INTRODUCTION

Patent protection is a controversial topic with respect to its monopolistic nature. I believe that a general evaluation can not and should not be made with respect to the patent protection as 'absolutely beneficial' or 'absolutely harmful'. This is mainly because any legal concept is embedded with in a social system which is, in turn, shaped by the specific social and economic conditions of that society. Therefore, being a legal concept, an assessment with respect to patent protection has to be made within a specific context.

Within the context of pharmaceutical industry where the issue at stake is the development of healthcare, questions arise as to the legitimacy of pharmaceutical patents. Given the specific characteristics of the pharmaceutical industry, the nature of the industry may show variations depending on whether the country in which the industry is situated is a developed or a developing country. It is generally known that developed countries have a research-oriented pharmaceutical industry and that developing countries display a completely different picture mainly because they have completely differing social and economic conditions. Thus it becomes especially important to make an evaluation of patent protection in these two types of countries within their specific context. Therefore, I believe that it is necessary to narrow the scope of this thesis down to the pharmaceutical industry in the developed countries.

As a result, this thesis is mainly concerned with pointing out the developments with respect to patent protection and the present trends in the pharmaceutical sector of

the developed countries and see how these confirm the necessity for protection of pharmaceutical patents in the European Community.

The thesis consists of four chapters designed to lead to the conclusion. The first of these chapters tries to give an understanding of the concept of patent right together with arguments for and against this right. Second chapter aims at establishing the legal basis for patent protection in EC after reviewing the different approaches toward internationalization of such protection. In the third chapter, characteristics unique to the pharmaceutical industry in general are explained. Recent developments affecting the industry and the significance of patents to the pharmaceutical industry in developed countries are also topics dealt with under this chapter. Next chapter concentrates on the pharmaceutical industry in EC and narrows down to the confirmation of the necessity for EC pharmaceutical patents.

As a final word, I would like to express my gratitude for Prof. Halûk Kabaalioglu and Ateş Akıncı for their help.

2. CONCEPT OF PATENT RIGHT

A patent is a right, either granted by the state or by a public authority representing the state, which gives the holder exclusive rights in respect of a product that is novel, involving an inventive step and industrially applicable. This exclusivity is mainly concerned with the legal protection of the invention against the infringing actions taken by the third persons.

The above mentioned invention is considered an object of property from the legal point of view(1). Therefore, its owner, in this case the patent holder, has the same rights to his inventions as a person with respect to his immovable property. Specifically, these exclusive rights, creating a certain kind of monopoly, relate to the manufacturing, using and selling of the invention as well as to taking actions against the breaching of these rights. Thus, manufacturing, using and selling a patented invention is legally possible only with the permission of the patent holder. The patent holder can apply these rights only within the territory of the state granting the patent and for a limited period of time. In general, this period is a term of 20 years.

Since patents are exclusive, they are of a monopolistic nature. This is why, if not limited in certain respects, the practice of patent rights may violate the competition rules. The exercise of rights arising out of a patent may either be limited by rules and regulations, procedural requirements or by the existence of other patents. Having to avoid the breaching of already existing patents constitutes a limitation. One other obvious limit is in the pharmaceutical field. The market regulations impose upon the patent holder the necessity to obtain permission from the

responsible health authorities in order to exercise his rights concerning a drug patent(2).

The patent is a system that can be taken into consideration from three different point of views; namely the technical point of view, the economic point of view and the legal point of view. It can be viewed technically because the subject matter of a patent is a technological invention. On the other hand it can also be viewed economically both because the exclusive right with respect to using the patented invention has an economic aspect to it and also because patents can be used as instruments of economic policy. Finally it can be viewed legally because the patent right that consists the core of the patent system is a legal concept.

It is important also to note that since every legal system is a reflection of a certain existing legal mechanism, it is necessary that the legal concepts and approaches must be in accordance with the social life mechanism they regulate. This is why each legal concept no matter how well they are formulated cannot be considered as absolute(3). Each should be evaluated within the legal framework valid for a specific social system. The social and legal system are in constant interaction. The social flux is usually the determining factor for the changes in the legal concepts as well as the emergence of new ones. This is why it is difficult to formulate a universal definition of the concept patent.

2.1. Transfer of Patent Right

Now the different ways a patent holder can make use of his rights needs to be discussed. As above mentioned since the patent is of monopolistic character, first of all, it is

the legal right of the patent holder to manufacture, use and sell his invention. A third person can use these rights only with the permission of the patent holder. The alternative way of giving license to third persons are as follows; - either to give a third person a license which contracts the patent owner completely out, or - to retain the same rights together with the licensee.

Regulated by the agreements concluded between the parties, the license is given in return for a royalty and valid for a period of time. These two points, namely, the clauses included in the patent licensing agreements and the determination of the royalty, need some elaboration.

The first point is closely related to the fact that the patent holder and the licensee becomes competitors with respect to the patented invention in the second alternative mentioned above(4). Thus, it is common practice that the patent holder includes in the licensing agreement certain clauses which are restrictive of the activities of the licensee with respect to the invention in question. In this way, the patent holder tries to make the licensee less of a threat to himself in terms of competition.

As for the second point, that is, the determination of the royalty the licensee is to pay, the patent holder is in a position to charge as much as he wants. However, he is bound by the profit he would obtain if he does not consent to give a licence. This is because the patent holder would not want to give up his monopoly profit in return for a royalty to be paid by the licensee. Therefore, it is unrealistic to think that he would want to charge less than that amount as a royalty fee. On the other hand, it is not in the interest of the licensee to pay a greater amount than the monopoly profit of the patent holder.

Consequently, it follows that the royalty, which the licensee is to pay is set somewhere around the monopoly profit that the patent holder hoped to obtain.

2.2. Justification for Granting of Patent Right and Counter-arguments

Gaining an insight into what a patent is and what kind of rights it confers on the patent holder, it is now necessary to discuss how the granting of this exclusive right is justified and on what grounds the counter arguments are based. Since patent right constitutes one aspect of the patent system, it is better to approach the issue from a general viewpoint; that is, of the patent system.

The patent system is a complex and controversial issue both as to the different aspects of the system and also to its value as perceived by different interest groups. There exist certain conflictual elements embedded in the system which makes it rather impossible to come to the conclusion whether or not the patent system is beneficial. Together with this complexity, the fact that many groups have their differing and, most of the time, conflicting interests in relation to the system. The inventors, industrialists, consumers, licensees and governments can be counted among those groups, not to mention the legislators and economists. Each having a different area of interest with respect to the patent system, the debate over the positive and negative aspects of granting patents yet continue.

The paradox of the system is that while the ultimate aim of granting patent monopolies to certain individuals is the good of the public at large, exercise of these monopolistic rights may in some respects prove to be contradictory to the aim(5). Those effects of the exercise of

patent rights which fulfill the objective of being beneficial to the public and which are considered the most important are used as justifications for the maintenance of the patent system.

Summing up, therefore, it can be said that there are mainly three reasons which make the existence of the patent system mandatory for those in favor of the system.

First of all, granting of patents and the legal protection afforded against third parties encourage people to make inventions with the belief that they will be protected against infringements by third parties. In this way, a contribution is made to the technological progress. Second, through patents, developments and commercialization of the inventions in question are encouraged. Before explaining why this is so, one thing has to be mentioned; in the modern industrial world, the activities for inventing and developing are carried by different organizations and it is the developmental activities which constitute most of the R & D expenditures(6). Having this in mind, it seems more clear why patents promote the development and commercialization of inventions. The large amounts of R & D expenditure needed to develop an invention can only be made under the protection of a patent which provides that the inventor gets monopolistic profits for a certain period of time and recover the R & D expenditure he has made. The result is again for the public good since new inventions contribute to the life standards and speed up the commercial activities. Finally the fact that granting of a patent is conditional upon the disclosure of the invention obviously is a benefit to the society since in this way inventions can be learned and progress made quickly unlike the old times when patents didn't exist and therefore people kept their inventions a secret for others not to imitate.

Besides these main justifications, granting of a patent prevents the duplication of R & D expenditures and causes to make savings on resources which would otherwise be directed for R & D in the same field.

Up until now, arguments in favour of the patent system has been reviewed. There are naturally counter-arguments closely related to the value attributed to the system. These counter-arguments are mainly centered around the points mentioned in the arguments justifying patents. In general arguments against patents suggest that the monopolistic profits attributed to inventors through granting of patents in return for their spending more on R & D is not the incentive for the pursuit of new products and R & D expenditures.

Arguments favoring considered them as a shield against imitators who, by copying the new product which is put on the markets prevent its inventor from recovering his R & D expenditures as a result of the competition by these imitated products.

Counter-arguments, on the other hand, come up with a number of factors related to the imitation process which are claimed to act as a shield retarding imitation naturally. These factors can be summarized as the time gap, the experience gap and the advantage of being the first on the market(7).

First of these factors is the natural imitation lag . It's argued that a long period of time is needed to learn about a new and complex invention. Secondly, in most of the cases, examining the specifications disclosed for the patent grant is not an adequate basis to imitate successfully. Much of the know-how is achieved through the R & D process of an

invention anyhow. Finally the advantage of being the first producer of a certain invention on the market is so great compared to other competitors lagging behind that the necessary development expenditures can easily be obtained without the gains from the shield of a patent.

3. PATENT PROTECTION IN EUROPE

Patent protection is an aspect of the patent system just like the patent right. Actually, protection follows from the definition of a patent right and is granted to the patent holder by the state or by a public authority. Before going on to the patent protection in EEC, it is important to give a historical development of the concept until it took its modern form.

It is known that legal protection had been provided for material property even in the earliest legal systems. However, it took centuries of social and economic developments before the social and economic realities necessitated that legal protection afforded to the products of the mind; that is the intellectual property. A few more centuries had to pass before such protection took its present form.

3.1. Historical Background

It is recorded that patent had been granted as early as 1470 in Venice when Venice was at the height of its powers as an international commercial, political and cultural force(8). At that time in Venice, patents were granted for a limited period of exclusivity for the innovator in return for immediate disclosure of his invention. By 1594 when Galileo was granted a patent for an irrigation machine, the patent system in Venice seems to have made progress. For a patent to be granted for a 20 year term, the system required "that the machine be constructed within one year and that the machine had not previously been thought of by others; in modern terminology, compulsory working and novelty requirements"(9). As Venice lost its power and importance in the world, this highly developed patent system could not keep

up with the changes occurred in the technological sphere.

Britain, on the other hand, where the first patent in the modern sense was granted in 1565 for a new type of furnace, was successful always in updating its patent system(10). In the early times, one can talk of monopolies granted for the importation, making and selling of common products by letters patent. "Letter patent means a document issued by or in the name of the sovereign, addressed to all subjects and with the Great seal pendant at the bottom of the document so that it can be read without breaking the seal"(11). The Statute of Monopolies enacted by the Parliament in 1624, formed the core of patent law in England. This statute prohibited the grant of the above mentioned monopolies. However patents for new inventions were excepted from the general rule. This legislation conferred on the inventor no automatic right to a patent for the invention. The grant of a patent was still an act of royal prerogative which had to be sought by petition and which could be refused at will(12). Moreover, within the context of this statute, the term inventor also covered persons who bring something new into the country for the first time.

First patents granted for inventions in England only required the title. There was no need for the description of the invention. This way due to the fact that technological progress was slow and that few inventions were being made. With an increase in the number of inventions as a result of technological developments, patent applications for inventions with subtle differences showed an increase also. Therefore, it became necessary, by the early 18th century, that patents be granted on the condition that a detailed description is provided within a certain period after the grant(13).

There were also patent laws in other countries. The

first modern patent on the continent of Europe is found in France in the era after the French Revolution(14). This is good proof of the interaction between the social changes and the legal systems.

Each country had its own patent law. The territorial nature of protection afforded by a patent proved to be an obstacle for the development of international trade in that the same product could be protected by the laws of more than one country. Every one of these patent laws protected the rights of their nationals against the nationals of other states. Therefore, patent laws, in a way, constituted the legal basis for discrimination against non-nationals. This situation made it difficult for the technological inventions to move around the countries and thus impeded the industrialization process which took place through the transfer of technology. Discrimination based on nationality slowed down the development of international trade to a great extent.

3.2. Developments in Terms of Patent Protection

Among the interested circles, the industry suffered the most from the developments in the international context. They began making pressure for the creation of a uniform patent system. There was indeed an urgent need for some attempts towards uniformity and centralization of patent protection in the international arena.

The first of such attempts was The Paris Convention for the Protection of Industrial Property of 1883, now considered as 'the basic instrument in the field of international patent protection.'(15). Certain fundamental rules have been established within the framework of this Convention. First of these rules provides for 'national treatment!'. That is, as Art.2 of the Paris Convention states.

"Each Member State must apply to nationals of other Member States the same treatment as it gives to its own nationals."

Second rule, expressed in the words of Art.4C(1), gives an applicant, who has filed an application for a patent in any (MS) Member States, a 'right of priority' for the purpose of, filing in other Member State during a period of twelve months. In the meantime, it is immune to any act which may be used to invalidate it. Finally, Art.19 of This Convention provides for 'special agreements' to be concluded amongst the contracting states provided that these agreements do not contravene the provisions of the Paris Convention. It is a provision of vital importance for the internationalization of patent protection because it forms the basis for further developments within the context of such special agreements. Amongst them are The Hague Agreement of 1947 establishing the International Patent Institute, the Strasbourg Convention of 1963 on the Unification of Certain Points of Substantive Law on the Patents for Invention, the Patent Cooperation Treaty of 1970 and the European Patent Convention of 1973.

In the course of the developments following The Paris Convention, different approaches have come up with respect to the uniformity wanted to be achieved in the patent system within the international framework. Each of these approaches were different in that they attempted to make uniform a different aspect or stage of the patent system.

The first step resulted from the fact that there were two different patent granting systems; the registration system and the examining system(16). The attitudes underlying these systems created different standards. In order to prevent complexity, a proposal was made to concentrate the

centralization efforts on "the sole element of patent proceedings which is indeed common to all patent systems: the search of the state of the art, with which the invention concerned is to be compared"(17). In this proposal, the idea that only this aspect should be brought into the international context.

Such thinking formed the basis of the next attempt, The Hague Agreement signed on 6 June 1947(18). This agreement provided for the establishment of the International Patent Institute whose task was to prepare documentary search reports on the state of the art with regard to patents to be granted or granted in MS. What came out of this went even further in that it treated the search activities as distinct from the granting procedures and emphasized that aspect of patent granting for further progress.

In the meantime, the Council of Europe took an interest in the matter, with the hope of achieving, more with respect to the internationalization of patent systems. The first of such efforts was the plan prepared by Longchambon and submitted to the Consultative Assembly of the Council of Europe in 1949. Though this plan was not approved, it is an important beginning point for the discussions within the Council of Europe framework. Many plans were submitted to the relevant organ of the Council but were rejected. The ultimate aim of every one of them was the creation of the European patent. These plans were mainly variations on the two approaches presented in the form of plans in this era(19). Therefore, in order to have an overall understanding of the ideas which identified the era of Council of Europe, it is necessary to see what the above mentioned plans were about.

One of them proposed that it was necessary to achieve uniformity in the post-grant stage(20). It was suggested that

the existing national examining Patent Offices be given the authority to grant patents that would be valid in all the Member States (MS) and that the MS apply their own national provisions. Moreover, the need for a European Court which would have "The jurisdiction for revocation and infringement procedures relating to these European Patents" was stressed(21).

Saying that such a practice would go for beyond the national sovereignty of MS, the second plan objected to the former one and instead put the emphasis on the pre-granting procedures. Accordingly, a European Patent Office was to be established. This office would grant the European patent, which would in fact be a bundle of national patents, in accordance with the autonomous criteria and procedure as stated in the relevant convention. These patents would be subject to the national law in the country concerned as to its scope and effect.

Although no consensus has been reached on any of these plans proposing to centralize either the pre or post-grant procedures, one can mention two successes in the same years. One of these is the European Convention Relating to the Formalities required for Patent Applications signed in 1953 in Paris. Its function was to set the formal requirements to be met by the patent applications during the granting procedures.

The second 'success' is the European Convention on the International Classification of Patents for Inventions which was signed in 1954 in Paris. This was a success because the classification of patents carries an importance for documentation and research. Since there exist different national systems in this respect, this convention provided for an important progress towards uniformity at least on one

aspect of the patent system. It was also for this reason that a lot of countries adopted it, even the non-members of the Council of Europe. This fact, however, caused a certain problem since the Convention was carried on within the Council framework. The non-members would not be allowed representation in The Committee of experts which made the necessary adaptations and the modifications. By providing a new institutional framework outside the scope of The Council of Europe, the same subject matter was to be dealt with through the provisions of Strasbourg Agreement Concerning the International Patent classification signed in 1971(22).

At this point, it is important to mention the signing of the Convention on the Unification of Certain Points of Substantive Law on Patents for Invention in 1963 in Strasbourg(23). This can be considered as the last attempt within The Council framework. It was carried under the effect of the efforts made within the EEC framework. This Convention aimed to bring closer the national patent laws. It aims at the harmonization of the patentability requirements. The extent of the protection conferred by patents has also been discussed. The ultimate aim was declared as the creation of an international patent. Indeed, provisions of this convention was taken into account during the preparatory stage of the EPC.

Whereas none of the plans with the Ultimate aim of creating the European patent within the Council framework was adopted, reaching a consensus on both the formalities and the classification matters was interesting. Such an outcome is the result of the fact that both of the Conventions had as their subject matter the technical details of the patent granting procedure. It is easier to come to an agreement on the technical matters. The non-approved plans, however, required a change of economic policy and at times a different

legal set-up enabling certain countries to ratify the plans. Consequently, a general conclusion was reached: it was not possible to make further developments without extensive legal harmonization. In the meantime, the recently established EEC was looking for ways to achieve 'the Unity of the Common Market'. EEC had the extensive legal harmonization necessary to make progress towards unification of patent laws; moreover such an achievement would suit the purpose of EEC to create a non-fragmented Common Market. Indeed it would help a lot because the territoriality effect of each of the national patent laws could easily constitute barriers to intra-community trade and thus conflict with the objectives of the Common Market. The need for change in this area is supported by Art.100 of the EEC Treaty which provides the legal basis for harmonization among the laws of MS.

Even harmonization would not be a solution for the case of patents because different national patents would continue to exist. Therefore, The Common Market actually needed "the creation of a unitary and autonomous European Patent ... governed by Community law proper and dealt with by Community Institutions"(24). Such a plan didn't involve the abolition of national patents; instead it provided that such a patent should coexist with the national patents.

Since the main concern within the EEC framework was the Common Market, it was logical to extend these activities to trademarks and designs as well. With this reasoning, three Working groups were given the task of preparing three Draft Conventions for each of the above mentioned industrial property. According to the plan, these conventions would be covered by another convention dealing with the institutional framework(25). General principles would be set by the Coordination Committee whose task was to coordinate the activities of the Three Working Groups proved to be develop-

ments in the subject.

In summary, one of these principles provided that the new Convention would not contravene the obligations of MS, especially those created by the Paris Convention. This was similar to the provision in Art.19 of The Paris Convention. Second principle concerned the coexistence of European patents and the national patents. Third principle was of great significance: It stated that "The European property rights should be conceived as autonomous and unitary and not as a bundle of national rights. Accordingly it was thought that independent administrative and judiciary authorities at the Community level should be provided for(26). The fourth principle provided for 'the maximum guarantee' to the owners of these European Property rights as long as these don't prove to be obstacles to free trade.

The 1962 Draft for Patents, which was based on these principles, was not approved although it received criticisms praising it as "the most important piece of European law-making" in case it was adopted in this form(27). The weakness of This Draft originated from the fact that no agreement had been reached as to whether and to what extent non-members of EEC could participate in this Convention and whether this proposed system should be solely reserved to nationals of EEC countries while nationals of non-EEC members used the old, traditional way.

Some defended the idea that since EEC approach was concerned mainly with The Common Market, this Convention should be limited to EEC Members only. Others, on the other hand, were still under the effect of the activities of The Council of Europe which stressed the "international" character of the future patent system.

Another proposal was made; it involved two conventions complementing each other for The Ultimate aim of 'European' and 'Community' patents respectively(28).

Participation to the first Convention would be open to a large number of European countries and would have effect only with reference to the granting procedure and result in a bundle of national patents.

The other convention would be exclusively open to the member states of The Community and would serve The Community purposes. It would be different from the first convention in that it would treat the patents granted by the first convention as having a unitary and autonomous character even after the granting procedure.

The political situation in 1965 within the EEC, especially the negative attitude of France towards UK which then was a Third state was a factor together with the fact that no agreement could be reached on the fundamental aspects once more caused the failure of this plan.

Next in the chronological order is the Patent Cooperation Treaty which was signed in 1970 but which did not enter into force till 1978. It aimed to reduce the duplication of efforts for both the applicants and the national patent offices(29). Also adopting the tendency for distinguishing the search activities from the granting procedure as the Hague Agreement establishing the International Patent Institute, this Treaty (PCT) provides for an 'international application'. In this way, it gives the applicant the opportunity to designate simultaneously all the states in which he seeks patent protection. The first 20 months after the filing of the application are reserved for an 'International Searching Authority' to make a search for the state of the

art. Under PCT, also it is possible that certain national Patent Offices may act as 'International Searching Authorities'. The search reports prepared by the above-mentioned authorities will have to meet the standards set by this Treaty.

Apart from the 'International Search Reports', the PCT also provides for the 'International Preliminary Examination'. This examination helps to understand whether the claimed invention is novel, involves an inventive step and is industrially applicable. In fact, it is an optional stage.

Actually, the PCT has made it a principle that it shall not require States to change their national laws(30). The PCT even goes further by stating that final decisions as to the substance of the patent application should be made on the national level and not on the international level. Therefore, in the general sense, this Treaty facilitates cooperation in the filing, searching and examining of 'international applications'. The major costs of applying in a number of countries are not incurred for a year, during which time the applicant presumably has more information about his product's marketability, profitability and other..."(31). Providing for such facilities, 'international application' of the PCT is a most useful means for American applicants to file in Europe and Japan(32).

Such achievements within the PCT framework seemed attractive for France who was not an 'examining country'. Therefore, France took the initiative this time to start the negotiations for the European Patent. The main concern of France was the practice of 'prior examination' to be brought into the international patent system within the framework of this Treaty.

Along the lines parallel to the two-convention system, an Intergovernmental Conference for the Setting up of a European System for the Grant of Patents was organized and many European States participated to it(33). First and Second Drafts of the 'European Patent Convention' and the 'Community Patent Convention' were prepared parallelly and were submitted respectively in 1970 and 1971. 1972 Draft for the European Patent Convention was adopted by the Conference and it entered into force on Oct.5, 1973 in Munich(34). Within the framework of this convention, the European Patent Organization, its Administrative Council and the European Patent Office (EPO) is established in Munich with a branch at The Hague.

The EPC is more important than the others from the European point of view in the sense that it constitutes part of the European system of patent law which is valid in the EC countries today. It is part of the system because without the Community Patent Convention entering into force, one cannot speak of a complete and uniform system of patent law regulating the relevant matters within the community as a non-fragmented territory. The two conventions complement each other in the sense mentioned above. This is why it will be useful to go into more detail of the system created by the EPC. The provisions of EPC which govern the patent legislation in the contracting countries among which are all EC countries can be classified into three groups for the purposes of this thesis.

There are provisions which state the aim and legal basis of the Convention together with the nature of the patent provided in this system of patent law. Other provisions set up the institutional framework needed to maintain The European system. Finally, there are provisions which lay down certain standard rules governing patents so granted.

It is considered as a 'special agreement' within the framework of the Paris Convention, and a 'regional patent treaty within the framework of the PCT(34). Being a special agreement in this sense, "all obligations under the Paris Convention are recognized as applying also to the European system"(35).

The main purpose of the EPC is declared to provide the inventors seeking protection for their inventions in more than one country with the choice of applying to those countries through a single procedure for an international grant instead of filing separate applications for each and every one of them(36). The common, uniform procedure used to obtain the grant of a European Patent - a patent granted through an international application - is set in accordance with the principles of the EPC itself. The EPO is responsible for the administration of granting of European patents based on the uniform rules concerning the term of the patent as 20 years, patentability requirements with a view to the uniform opposition proceedings, if and when they come up, to declare the European patent invalid.

To carry out this task EPO is attributed, a legal personality, it enjoys certain privileges and immunities but also assumes contractual and noncontractual liability for acts within its competence. Moreover, it has administrative and financial autonomy(37). Thus granted, Art.2(2) provides that

"The European patent shall in each of the contracting states for which it's granted, have the effect of and be subject to the same conditions as a national patent by that state, unless otherwise provided in this convention"(38).

Giving the opportunity to designate as many countries

as an applicant wishes in the application for a European Patent, the Convention provides, just as the proposal of De Haan, that once granted, the European patent constitutes a bundle of national patents in the countries designated. This provision is similar to the "national treatment" rule laid down in the Paris Convention.

Consequently the rights under a European patent in each of the contracting states designated in the application and granted are the same as the rights conferred by a national patent in that state. As regards the infringement of such rights, again the procedures and remedies available under national law will apply.

Such a patent system created by the EPC contributed a great deal to the internationalization process of the patent system.

3.3. Legal Basis in EEC

Now that a general view of the field of patent protection has been presented through the conventions concluded in the international arena, it is in the specific interest of this thesis that the subject be discussed within the EEC legal system.

At the time of the establishment of the EEC based on the Rome Treaty, the so-called constitution of the EEC, the intellectual property rights of which patent protection is one form were not taken within the competence of the new supranational organization. As a result they were left within the competence of national authorities; that is, these rights were to be governed in accordance with the relevant national rules and regulations and with those of International Conventions for these MS who were signatories.

3.3.1. Reference to EEC Rome Treaty

It is for this reason that 1957 Rome Treaty includes no principles or rules directed specifically for the protection of intellectual property rights. However, there is one reference made to "The protection of industrial and commercial property"; that is under Art.36 which, in the general sense, constitutes a derogation from the fundamental principle of free movement of goods. As long as justified on grounds specified in this provision, Art.36, provides the basis for "prohibitions or restrictions on imports, exports or goods in transit" as long as "such prohibitions or restrictions shall not constitute a means of arbitrary discrimination or a disguised restriction on trade between MS". Under this article, the industrial and commercial property rights are referred to as one of the grounds for justifications for not conforming to the free movement of goods principle of the EEC.

In a more general sense Art.222 deals with the subject stating that "This Treaty shall in no way prejudice the rules in MS governing the system of property ownership". However, this provision was later interpreted by the ECJ as "not excluding any influence whatever of Community law on the exercise of national industrial property rights."(39). Later on, in the same case, Advocate General Roemer further explained the object of Art.222 as "solely to guarantee in a general manner the freedom of the MS to organize their own system of property but not to provide a guarantee that the Community Institutions may not in any way intervene in subjective rights of property"(40).

3.3.2.Conformity With Other EEC Principles

Two of the underlying reasons/objectives for the

establishment of the EEC as declared in the Preamble of the Treaty of Rome are "to ensure the economic and social progress of their countries by common action to eliminate the barriers which divide Europe and to "remove the existing obstacles through" concerted action in order to guarantee steady expansion, balanced trade and fair competition". These objectives are then transformed into principles of which only two are of relevance to this thesis; "the abolition as between MS, of obstacles to freedom of movement for goods persons, services and capital"(41) and "the institution of a system ensuring that competition in the common market is not distorted"(42). Each of the above mentioned principles are governed with a set of rules for implementation. These rules provide for the elimination of quantitative restrictions on trade between MS (Arts.30-36) and for fair competition of enterprises (Art.85-86). While the scope of applicability of these sets of rules differ in many respects their objectives are mutually complementary and interdependent(3). "By giving all products access to national markets free of state-controlled restrictions, Arts.30 et seq. provide the basis for a common market within which the system of undistorted competition (Art.3, lit.f, Arts.85 et seq.) may fully deploy its market integrating effects"(44).

The above mentioned territorial protection of these rights causes conflicts to arise with the community principles of free trade and fair competition. Bound with Art. 5 which states That Member States

"shall abstain from any measure which could jeopardize the attainment of the objectives of this treaty".

The national courts often referred such cases to the E.C.J under Art.177 for interpretation of Community law or for preliminary rulings. Since case law is considered as part of

community law, the rulings of the ECJ have gradually become a body of community law on the industrial and commercial property rights(45). Before going on to case law, application of each of these principles to industrial and commercial property rights will be dealt with briefly. Because of the interdependency of the rules on free movement of goods and the rules on competition, all the important cases will be dealt with following a time sequence. This will provide to see more easily the changes in the approaches taken by the Court and The Commission. Going through the cases except for those laying down fundamental principles, only the cases related to patents will be taken up.

3.3.2.1. Free Movement of Goods Principle

Rules governing the principle of free movement of goods are laid down in Arts.30-36. Arts 30-34 aim at the elimination of quantitative restrictions on import and export and all measures having equivalent effect on trade between MS. These provisions are addressed to MS and besides burdening them with eliminating all existing barriers, they put the MS under the obligation to refrain from introducing new restrictions on trade.

In order for any kind of restrictions or measures to be treated under Art.30 existence of any potential for impairing trade between MS is sufficient; it's not necessary that such measures reduce trade between MS(46). Addressed to MS, art.30-34 are laid down to eliminate measures resulting in protectionist effects on the national market and to provide free access to the market to all enterprises as well as to make MS refrain from introducing measures favoring some enterprises through channelling the flow of goods.

Some implementations by MS of the industrial and commercial property rights may put restrictions on imports and exports. Such implementation may have a protectionist impact on free trade between MS the resulting situation may have the equivalent effect of barriers to free trade as in the above mentioned provisions Art.30-34.

Actually the protectionist tendency referred to in the previous paragraph is a consequence of the territorial character of the industrial and commercial property rights. The territoriality principle governing such rights on the international sphere states that the rights in question are governed by the law of the state with respect to which protection is sought. In more detail, it can be said that the law of the territory granting the protection is always in control of "acquisition, transfer and termination of the protection of exclusive rights" as well as "the kind and scope of protection"(47).

Such protection which is national in character has two consequences when the issue in question is the effect of the exercise of these rights on the functioning of the EEC. First, protection being territorial, rights concerning industrial and commercial property does not "follow the extra-territorial movement of the covered products"; once on the international market, these products, therefore may be subject to different rights of protection. Such a situation would result in the prevention of both the buyer and user of the rights from crossing national borders. Another consequence follows from the fact that the right to protection determines the scope of the protection in accordance with the national rules. In this way, protection is granted on national terms even in an international context. Its significance for the Community comes from the practice that "imports are defined and prohibited in terms of their foreign origin

irrespective of whether the right abroad belongs to the same enterprise which claims protection"(48).

Both of these consequences which may be summarized respectively as having protectionist and market dividing effects are in contradiction with the free trade principles of the community.

As a result of conflicts, cases have been referred to the ECJ under Art.177. The decisions of the ECJ in this respect have shown that Arts.30-34 are not only addressed to MS in cases where they take measures which impair trade. But they are also interpreted by the Court to apply to "activities of private enterprises governed by national legislation" (49). Usually based on industrial and commercial property rights such activities, when applied Arts.30-34, end up, on the one hand with the erosion of such rights due to the wide interpretation of such provisions and on the other with the development of community industrial and commercial property law.

As explained Art.36 provides for derogation from the free movement of goods if an activity is justified on grounds specified in that article. The one ground of justification related to this thesis, is 'the protection of industrial and commercial property'. Second sentence of the some provision sets a limit to such grounds of justification; that they "shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between MS."

Many cases were referred to the Court. The Court taking into consideration the fact that intellectual property rights could be used under Art.36 interpreted this provision restrictively so that such justifications under Article 36

would be allowed as long as they are compatible with both free movement of goods and competition rules.

3.3.2.2. Competition Policy

Competition policy has been employed as one of the instruments to see to it that the Common Market works to its full effect. Now, it is also used to "speed up single market integration"(50). Both of these objectives have a common element; that all boundaries within the community should be eliminated so as to make it possible for all the territories of Community countries to be treated as one territory.

Competition policy is governed by a set of rules laid down in the Rome Treaty; Art.85-94. However, the provisions which are of relevance to the topic of intellectual property rights are only Articles 85 and 86.

Art.85 consists of three 'sections': art.85(1) states the activities which "shall be prohibited as incompatible with the common market". Art.85(2) provides that "any agreements or decisions prohibited pursuant to this Article shall be automatically void". Art.85(3) provides for exemption from the prohibition that Art.85(1) sets. Article 85(3) also expresses the qualifications for conditions of exemption.

In order for the prohibition in Art.85(1) to apply, there must be a concerted action between at least two undertakings; such action must actually or potentially restrict competition within the Common Market and as a result may affect trade between MS. The tendency of the Commission is to interpret the meanings of the terms used in this provision as widely as possible in order to broaden the scope of applicability of Art.85(1). When one looks at the decisions taken with respect to the relevant cases, an undertaking is

defined as "virtually every natural or legal person participating in the economic process";(51) that is, "covering any entity engaged in economic or commercial activities..."(52) with no limitations as to the type of activity carried on or as to the size of the 'entity'.

The Court also adopts the term 'economic entity' with respect to Art.85; The court ruled, in a case, which involved an agreement between the parent company and its subsidiary, that this provision doesn't apply to such a relationship since the subsidiary, though has a separate legal personality, enjoys no economic independence(53).

Will regard to 'effects on competition', the case law requires that the agreement in question should be evaluated within its economic content and then decide whether the influence on trade and competition is noticeable rather than deminimis(54).

Due to their relevance to the pharmaceutical industry, it is necessary to mention one final point on Art.85(1); that the prohibition stated there applies to restrictions of intra-brand competition as well as to those of inter-brand competition(55).

Art.85(3) provides for exemption from the prohibition in Art.85(1) provided that the agreement, decision or concerted practice which qualifies for such prohibition "contributes to improving the production or distribution of goods or to promoting technical or economic progress"; one of the several grounds for exemption. The agreements which qualify for this condition are given in the Preamble to the Regulation issued for a block exemption(56). These include exclusive dealing agreements, exclusive purchasing agreements patent licence agreements, specialization agreements,

selective distribution agreements for motor vehicles and research and development agreements. According to this guide, the positive aspects of patent license agreements which make them qualify for the exemption are that the "patentees are more willing to grant licenses", "licensees become more inclined to undertake the investment required to manufacture, use and put a new product on the market or to use a new process". Such agreements also provide "access to new technology" and cause an "increase in the number of production facilities and the quantity and quality of goods purchased in the Common Market".

As far as Commission is concerned, the nature of the agreement together with the position of the parties on the market play an important role in determining for the granting exemption or not(57).

Article 86 of the EEC Treaty is also worth going into detail. As the text of the provision suggests, there are two parts to it. The first part is concerned with the criteria applied in determining whether a certain activity falls within the scope of the prohibition laid down in this article. Second part attracts the attention to the particular activities to which this prohibition applies.

Whether or not a certain type of activity falls under Art.86 is determined according to whether the undertaking/s in question enjoy a dominant position. Unlike Art.85, this provision does not necessitate that there should be a concerted practice; that is the existence of more than one undertaking. A company acting on its own may equally fall under the scope of this provision. Actually, it is not the dominant position as it is which qualifies for the prohibition; there should be abuse of such a dominant position. In addition, this abuse of dominant position should be within

the common market or in a substantial part of the common market. Finally, in order for Art.86 to apply to any such activity it must affect trade between Member States. Unlike both Art.30 and Art.85 which are to be applied in the case of interaction of the exercise of the intellectual property rights with the community principles, Art.86 does not contain an exemption clause. This means that abuse of a dominant position has such a negative impact on competition within the common market that it has no exemption clauses.

In order to apply Art.86 to a situation, more has to be made clear with respect to the terms used in the wording of the provision. As is the case with any field of community law, The Court's jurisdiction in the cases that arise as well as the preliminary rulings it gives under Art.177 holds light to the interpretation of these terms.

In order to speak of a dominant position, the relevant market has to be defined since competition can be meaningful only in a context where products can be substituted to a certain extent. Relevant market can be perceived in one of two ways; relevant product market and relevant geographic market. Before going on to the explanations of these in more detail, it is necessary to state that market power is another term in close relation to a dominant position. Market power being "the ability to behave to a significant extent independently in the market or to prevent the maintenance of effective competition". The criterion for the market power of a company is the existence of this ability and to what extent it proves to be effective in the market.

Determination of the relevant product market is to a great extent dependent on the interchangeability of the products; that is, whether and to what extent certain products can be substituted. The Court made a distinction

between products which are 'only interchangeable to a limited extent' and therefore not part of the relevant market and products which are 'reasonably interchangeable' and therefore part of the relevant product market(58). The criteria for interchangeability are the nature of the products, their price and use, on the one hand, and the competitive conditions and the structure of supply and demand on the market on the other hand(59). As for "reasonableness" of interchangeability, it is necessary to examine the case law for the interpretation of the court as well as the commission decisions which show that they require products to be interchangeable to a great extent. One way to measure the interchangeability of products in terms of demand is the criterion of cross-elasticity which is said to exist when a small change in the price causes a shift in the demand in favor of cheaper products which may fulfill the same purpose. This in return, shows that such products are interchangeable and thus defines the relevant product market.

In terms of supply the interchangeability is measured with the capacity of the producer to adapt its production techniques and machinery for the production of other products both in terms of time and money. If the time and money required for such adaptation is not much. Then those products are accepted as substitutable and therefore belonging to the same product market.

In terms of consumers, the perception of a certain product as interchangeable with others or not is important for the definition of the relevant product market.

Concept of 'a relevant geographic market' also arises from the wording of the Art.86. Since the prohibition covers any abuse of dominant position either "within the common market or in a substantial part of it", then the criteria for

deciding first on the relevant area within the common market and second on the 'substantiality' of this area need to be laid down.

Geographically, a market which is considered to be relevant to that of a product in question is the area where the producer competes in terms of its product; in case of Art.86, this is the area in which the producer holds a dominant position and uses this position against other competitors in an abusive manner. Therefore, in order to define a relevant geographical market with respect to a product, the existence of equal competitive conditions for all producers or traders is necessary. The Court's approach to the determination of whether or not such a market constitutes a substantial part of the common market is by taking into consideration 'the pattern and volume of the production and consumption of the said product as well as the habits and economic opportunities of the vendors and purchasers'(60).

Now that the concept of relevance both with respect to the product and to the geographical area has been evaluated, it's suitable to go on to what a dominant position is and how it is determined. At this point, the case law suggests that a firm is considered to be holding a dominant position if its economic strength enables it to behave independently of its competitors and consumers and thus prevent effective competition. Here the concept of 'economic strength' needs elaboration in order to determine the economic strength of a firm, the market share it holds is firstly taken into account. However, most of the time this does not prove to be a sufficient criteria and it may even change in accordance with the interpretation of the relevant product market. If its narrowly interpreted in a specific case then it's most probable that a dominant or even a monopolistic position will come up. If, on the contrary, the relevant market is

interpreted broadly then the market share of a firm may seem as insignificant. In case the market share is seen as an insufficient indicator of a dominant position then certain structural factors are taken into consideration. However, these factors which are thought to be indicative of a dominant position in fact may coincide with the characteristics of leading firms in a given market. Therefore, at this point, market conduct must also be taken into account together with the overall competition.

One final point to be mentioned in relation to the application of art.86 is that prohibition under this provision should be based on the anti-competitive effect in the community of the dominant position. In accordance with this, the commissions approach to the issue is whether the company is situated in the EEC or outside the EEC, the decisive factor is whether the effect of the prohibited action takes place in the EEC or outside its territory.

Having reviewed the relevant aspects of the competition policy of the community, it is important to have a look at the outcome of the interaction between the industrial and commercial property rights.

It is stated before that the industrial and commercial property rights are governed by the national legislations of the MS and that they are territorially protected. This situation may cause conflicts in two areas. First; while the existence of such rights may in no way fall into contradiction with the Community principles, their exercise as distinguished by the Court and as will be discussed in more detail later, causes conflicts. Therefore, as is the case with the free movement of goods principle, the exercise of the industrial and commercial property rights will be allowed, with no intervention by the Community, as long as these

rights don't form obstacles to either free trade or free competition. To explain in more specific terms, the conflict arises due to the concern of the competition policy for parallel trading(61). It occurred many a times that because of the territorial protection granted to the industrial and commercial property rights, attempts were made to prevent parallel trading especially parallel imports. Here mention should be made of the importance of the competition policy as an instrument for speeding up the single market integration. In order to achieve this objective, competition rules and their application to conflicts that arise are used in favor of making the community into one, single territory. Therefore, the interest of the community lies in resolving such conflicts in a way to prevent the aim of compartmentalizing the common market along national boundaries(62). Both the Commission and the Court are in particular against "vertical agreements whereby a manufacturer would entrust the distribution of his products to a separate distributor or licensee in each of the MS and prohibit re-exports thereby preventing parallel imports"; the commission and the court are not particularly against "horizontal price cartels" which are considered as having greater damage on consumer welfare(63).

Second area of potential conflict in the field of competition in a way follows from the above sentence. The licenses which, as one of the methods of using the exclusive rights granted to the patent-holder, falls within the scope of Art.85 since it is a form of agreement concluded between the two parties. The problem here arises with respect to the provisions included in licence agreements and which may have a restrictive effect on competition.

3.4. Case Law

It is intended, under this subtitle, to give first an understanding of the development of community law of industrial and commercial property as a result of the actions and rulings of the commission and the court. The actions taken by the Commission as well as the rulings of the Court are the determining factors in the formation of this result. Moreover, events will be taken up in a time sequence in order to perceive the change of attitude on the side of both the Commission and the court. Second part will deal with the recent Council Regulation No.2349/84 granting block exemption for the patent licensing agreement which is of special interest to the thesis.

The first part includes the development of two kinds of approaches; one towards the applicability of the rules on competition and free movement of goods on the exercise of the industrial and commercial property rights and the other towards the patent licenses. The origin of both of these approaches lie in the same few cases which set the fundamental rules for community law in this field.

Before going on to the cases, it is important to look at the first of such action taken with regards to the industrial and commercial property rights. A reference to the patent licenses is made in 1962 Council Regulation No.17 which was issued for the implementation of the basic provisions of the competition policy; Arts.85 and 86(64). Here patent licenses which are concluded between two parties and which impose certain restrictions on the licensee are referred to as having "special features which may make them less prejudicial to the development of the Common Market"(65) Moreover, as stated in art.4(2) of the Regulation, formal notification of such licenses to the Commission was no longer

mode necessary as a precondition for the grant of exemption under Art.85(3).

Second move came from the Commission also in 1962 in the form of a 'Notice on Patent Licensing Agreements of 24 December 1962(66). Regarding territorial limitations "as justified under the 'limited grant' or 'the scope of the patent right'theory(67). This Notice had adopted an approach such that most provisions of patent licenses did not constitute infringements of Art.85(1) since restrictive provisions followed from the exclusive rights of the patent holder(68).

3.4.1. Establishing The Fundamental Principles

Case law in this field began with Consten and Grundig (69). It was a case concerned with trademark rights; Grundig's exclusive distributor in France, Consten, wanted to seek protection of its trademark license as registered in France to prevent the parallel importation of Grundig products from other MS. It was ruled by The ECJ that such exclusive distributorship contracts were contrary to Art.85(1). Moreover, a distinction was made between the existence and exercise of industrial and commercial property rights. The decision of this case proved to be a departure from the approach commission took in its Notice of 1962(70).

The same distinction was made in a case related to patents this time; Parke, Davis(71). It was about the importation into The Netherlands of pharmaceutical products which originated in Italy where such products were not granted patents. The Court came to decide that the existence of rights granted by a Member State to the holder of a patent is not affected by the prohibitions contained in Arts.85(1) and 86. Furthermore, even the exercise of such rights don't, of itself, fall within the scope of these provisions. They

can only be contrary when their exercise is incompatible with these Articles. The Court had also observed in this case that "the owner of an industrial and commercial property right does not enjoy a dominant position within the meaning of Art. 86 merely because he is in a position to prevent third parties from putting into circulation products that infringe upon his right"(72).

Next case which is of importance to the development of the attitude of the Court with respect to the interaction of competition rules with the exercise of industrial and commercial property rights is the case of Sirena which was concluded in 1971. It was about the action taken by owner of a trademark in Italy against importation into Italy of products bearing the same trademark by the unrelated German owner of this trademark who had indeed manufactured the products. Both owners had separately acquired those rights in 1937(37). The Court ruled that art.85 is applicable in such a case but stated that in case "The agreements in question were concluded before the entry into force of the Rome Treaty, it is both necessary and sufficient that they continue to produce their effects after that date"(74). The Court ruled that art.85 was applicable even if there was no evidence of concerted practice which went on(75). Such an extreme decision was reversed in EMIV CBS.

The ruling in Deutsche Grammophon V Metro is important in two ways. First, it is important because it shows a change of attitude on the part of the Court in that it began applying Arts 30-36 unlike in the previous cases in which decisions were based on arts.85 and 86. Second, it is important because another fundamental principle of the developing Community law has been laid down. It is also in a way the confirmation of

the existence-exercise principle for the copyrights. The case was about an attempt by Deutsche Grammophon to use its exclusive rights based on copyright protection under German law to prevent parallel importation by Metro into Germany of its products produced, manufactured by its own subsidiary in France, Polydor. The Court ruled that if the exercise of industrial and commercial property rights doesn't come within the scope of Art.85 in that there is not an agreement in question, it is necessary to see whether such exercise of rights is compatible with Art.36. It goes on to say that "...Art.36 only admits derogations from that freedom to the extent to which" the restrictions on the free movement of goods" are justified for the purpose of safeguarding rights which constitute the specific subject-matter of such property"(76). As important is the statement of the Court in the same case saying that "The prevention of the marketing in a Member State of products distributed by the holder of the right or with his consent on territory of another Member State on the sole ground that such distribution did not take place in that territory" would result in partitioning of the Common market along national markets contrary to the essential purpose of the Treaty which is to make one single market out of many national markets. This last point shows that the exercise of industrial and commercial property rights is considered contrary to the Community principles if such rights are enforced for the prevention of parallel imports(77). Different than the rulings of Parke Davis and Sirena, the judgment in Deutsche Grammophon declares that if the exercise of such rights is used to prevent the importation of products placed on the market in another Member State by the patent holder himself or with his consent(78). The exhaustion principle as accepted as such and developed in the following cases has some characteristics specific to the Community(79). Unlike the traditional concept of 'exhaustion' applied under some national legislation to the trademark

existence of patent rights. Fiamma also had an argument which amounted to saying that compulsory licenses should be granted under Arts.30-36. This was again rejected by the ECJ on the same basis.

The last case was about licenses of right; Allen and Hanbury V Generics(87). Generics of England applied for licenses as of right based on the Patents Act 1977 stating that "anyone who wishes to work the patent may do so on terms to be settled by the Comptroller General in default of agreement between parties"(88). Generics went on to declare his invention of importing the products from Italy. However, Allen and Hanbury who were the owners of an English patent endorsed licenses of right' from 1983 objected to this since the products in Italy were produced without their consent. The Court ruled that Allend and Hanbury could not prevent imports from italy since Generics had applied for a licence in England and since an injunction could not be granted a firm that had produced the goods in England.

3.4.2. With Respect to Licensing Agreements

Whereas the tendency of the court has been to apply the provisions on free movement of goods principle (Arts.30-36) in the cases arising in relation to the industrial and commercial property rights in general and patents in particular, the situation is quite different with respect to patent licenses. Since patent licenses are granted on the basis of "agreements whereby one undertaking, the holder of a patent (The licensor), permits another undertaking (the licensee) to exploit the patented invention by one or more of the means of exploitation afforded by patent law, in particular manufacture, use or putting on the market"(89). By giving the licensee to exploit his invention, the Patent holder and the Licensee become competitors with respect to the invention. Therefore, it is in the interest of the patent

holder to put restrictive clauses in the licensing agreement so as to ensure that the licensee does not constitute a threat neither to his profit nor to his position in the market.

Such restrictive clauses vary as to their nature and from the community point of view may fall within the scope of Art.85(1) in that they may result in the distortion of competition within the common market. The commission was given the power by the Council Regulation No.1965 of 2 March 1965 to apply art.85(3) to certain patent licensing agreements or concerted practices falling within Art.85(1). The 1970's can be characterized as an era when The Commission adopted a series of decisions in which it applied Art.85(1) to various clauses in such agreements while exempting some under Art.85(3)(90). Overall, it can be said that in this era, The Commission took a stand in some respects against that of the 1962 Commission Notice which can be characterized with its liberal attitude towards the restrictions in patent licensing agreements(91).

This era was followed by a Draft Regulation published in 1979; The group exemption intended to be granted to certain categories of patent licensing agreements were based on Regulation No.19/65. Though published in 1979, Regulation was not issued until 1984 due to the delay in the Court's judgment in the Maize Seed case which was the first case submitted to the Court concerning whether the exclusivity provisions are within the scope of Art.85(1) or not(92). The Court as will be discussed later, took a more liberal attitude than the Commission; actually, the judgment showed "some sensitivity to commercial and economic context of licensing agreements"(93). Finally Regulation No.2349/84 was issued in 1984 after a long consultation process with both national competition authorities and other interested parties and now

regulates patent licenses in the Community. It will be in force until 31 December 1994(94).

The Regulation covers patent licensing agreements and those agreements which involves both the licensing of patents and know-how to which only two undertakings are party and which fall within the scope of Art.85(1). The provisions of this Regulation will in general apply to the mentioned agreements whether or not these are exclusive but will not do so to sole know-how agreements. In order for the block exemption to be granted under this Regulation, the agreements in question have to contain obligations which relate to territories within the common market. Even if they contain obligations relating also to non-member countries, then the rules stated in this Regulation will also apply.

A classification of the clauses which may be included in patent licensing agreements which fall under the scope of this regulation is made and as a result there exists three lists.

One of these lists (Art.1) contain a number of clauses which is considered as falling under Art.85(1) but which can be granted an exemption under Art.85(3) and the regulation. Second list (Art.2) includes provisions which don't necessitate the application of Art.85 since they are considered as non-restrictive of competition. This list is referred to as 'the white list'. While Third list is 'the block list' since it contains provisions in Art.3 the existence of which in a patent licensing agreement will make it impossible for the Regulation to apply.

Exclusivity in patent licensing agreements can be either in the form of sole licenses which requires that the licensor does not grant licenses to any other person for the

licensed territory or exclusive licenses which requires that the licensor does not exploit the patented product within the licensed territory. The Commission's attitude towards such clauses was rather liberal at the time of 1962 Notice in that it considered them as not falling within the scope of Art. 85(1). The Commission justified this attitude by stating in respect of an exclusive licence that "... the undertaking not to exploit the patented invention oneself is closely akin to an assignment of right and accordingly does not seem to be open to objection."(95) In the decisions adopted by the Commission in 1970's with respect to cases relating to exclusivity, it accepted the fact that in some cases such clauses may restrict competition and fall under Art.85(1). The first time the Court took the issue of exclusivity was in the Maize Seed case and the judgment turned out to be an important one. In this case in which the main issue was a plant breeder's right licence and not a patent licence. The Court, accepting the argument that under some circumstances it may be necessary to give some protection from the intrabrand competition to the licensee in his territory so as to encourage him to take the risk and the expenses for producing the products in question(96). As a result, the ECJ distinguished, 'open exclusivity' from 'absolute territorial protection'; open exclusivity meaning that the licensor agrees not to grant other licences in the territory of the licensee in question. Since such a condition would not affect the activities of parallel importers and licensees for other territories, the ruling was in favor of the licensee suggesting, however, that it is only valid for products involving new technology and therefore high risk and expenses. It can be said that the commission has become more tolerant towards exclusivity clauses and allow some "protecting the licensee, for the life of the licensed patent, from the grant of licences to other licensees in the licensed territory or from any form of competition by the licensor, including selling

activities"(97). A licence limited to sales exclusively were left out of the scope of this regulation to be dealt with under Regulation 1983/83 on distribution agreements. Also the protection given against the sales of patented goods by the licensor or other licensees will be invalid for preventing parallel imports governed by Arts.30-36 of the Treaty(98).

Among the clauses which are allowed to take place in patent licensing agreements are tie-ins if necessary for a technically satisfactory exploitation of the licensed invention, minimum royalty and quantity clauses, clauses to keep know-how secret and to observe minimum quality standards.

On the other hand, no-challenge and non-competition clauses are prohibited together with provisions for charging royalties even after the expiry of the patent term, maximum quantity provisions, price fixing and customer restriction clauses.

The regulation contains a provision that whenever found necessary by the Commission "in particular where the goods in question face no or virtually no inter-brand competition at all" and "where an agreement exempted by this Regulation has been observed to have certain effects incompatible with the condition of Art.85(3)"(99).

Regulation No.2349/84 which has been mentioned above from a rather general view is indeed very comprehensive with respect to the clauses which may or may not be exempted under The regulation. For this reason, in a way dictates to the interested parties what to include and not include in patent licensing agreements and therefore, influences the licensing arrangements in the community to a large extent(100).

3.5. The Community Patent Convention

The Community Patent Convention was signed on December 15, 1975 in Luxembourg. Designed as a complementary body of law to the EPC but only valid for the Member States of the EEC, originally it was intended that this should enter into force just after the EPC. However, the requirement that all Member States should ratify the Convention made the situation even worse with the accession of new members; Greece, Spain and Portugal. By 1985, while one of the signatories, the Netherlands, had recently completed its internal procedure, Ireland and Denmark, two other signatories could not as yet succeed in fulfilling their national requirements for ratification of the EPC and the CPC(101). Of the new Member States, Greece reluctantly had to accept the CPC as part of Community law which it had to conform to; its objection originated from the fact that no reference was made to the CPC in its Act of Accession(102). Spain and Portugal had already put themselves under the obligation to ratify both the EPC and CPC after a transition period by 1992 in the negotiations.

Claiming that there is an urgent need for greater uniformity in patent law, to the benefit of the Community, EC Commission together with Germany has already started the activities for speeding up the ratification procedures.

Finally, the requirement of ratification by seven states instead of all MS was adopted in October, 1985. The Second Luxembourg Conference of December 4-18, 1985 was concluded by the signing of "a Final Act and the Introduction of three major new instruments"(103) One of them is the Community Patent Agreement; a revised version of the 1975 CPC. Though it has not entered into force yet, it is worth looking at it in some detail.

Since there are two versions of the Luxembourg Convention, it is better first to look at the original text and then see what changes have been made on it in the second version.

At the time of conclusion, 1975 CPC was designed to establish a uniform patent law "in the whole of the Common Market as one patent territory"(104). The underlying concern for such an attempt just after the EPC, was the attainment of the aims of the Treaty establishing the EEC as stated in the Preamble of the CPC. Among these objectives were to provide for free movement of (in this case) patented goods as well as to prevent "the distortion of competition which may result from the territorial aspect of national protection rights"(105).

Article 148 of EPC leaves EEC States the necessary freedom to agree on a specific regime for European application as an object of property.

The CPC is a special agreement within the meaning of article 19 of 1883 Paris Convention and of article 142 of EPC 1973 and a "Regional Patent Treaty" within the meaning of article 45(1) of PCT(106).

Community patents are unitary in that they may only be granted, transferred, revoked or allowed to lapse in respect of the entire territories of Community countries. Equally, they have the same effect for the whole of the Community.

Community patents are autonomous in that they are governed by rules (specific to) CPC and those of EPC because of the fact that all Community patents are granted through a European application. Designation of one or more of Community

countries in a European application will automatically result in a Community patent due to its unitary character. If an applicant doesn't want a Community patent, but only a European patent, article 86 of CPC requires that a declaration be made to say so.

Once granted the Community patent confers on the holder of the patent the right to prohibit direct and indirect use of the product and process subject to certain limitations.

Direct use constitutes "the manufacture of the product without his consent, the offering of the product for sale, lease or use, and finally the marketing of the infringing product subject to the exhaustion rule"(107).

Article 30 of CPC which prohibits indirect use of the invention is such that in this way "any third party in the territory of the contracting states to whom he had not given permission from offering for delivery and from delivering the means necessary for exploiting the invention concerned, providing that these means are related to an essential part of the invention"(108). Exhaustion rule applies to Community patents in the same way as it does to national patents. That is, once a product has been put on the market in any one of the MS by the patent holder or 'with his express consent', then the patent holder no longer be able to prohibit any acts done within the territories of MS concerning the product. Here a reservation is made with respect to a situation when extension of rights to such acts may be justified under Community law.

The resulting exhaustion principle valid for Community patents is due to the effect of the unitary character of the Community patent as well as to the free movement of goods principle.

With respect to national patents, it has been stated

that the same Exhaustion rule shall apply provided that there exist economic connections between the two patent owners.

There are also rules relating to licensing. The CPC text distinguished between three types of licenses, contractual licenses, licenses of right and compulsory licenses.

According to Article 43 contractual licensing with respect to patents are such that they may be licensed "for the whole or part of the territories in which they are effective". Such licensing may be exclusive or non-exclusive. If a licensee violates the rules of the contract by not conforming to the restrictions imposed by his license, the patent holder may invoke his rights against him before the relevant national law. When however, a conflict arises between national law and Community law then Community law shall prevail(109).

License of right is given by the patent holder in order to pay lesser amount of renewal fee as governed by Article 44 of CPC. It is required that the patent holder files a written statement with EPO saying that "he is prepared to allow any person to use the invention as a license in return for appropriate compensation".

As for compulsory licenses construed as "including official licenses and any right to use patented inventions in the public interest" for the purposes of this convention they are governed by the law of the state concerned with respect to its rules for granting compulsory licenses for national patents(110).

Article 47 of CPC applying only "to compulsory licenses granted because of insufficient use of lack of the patent, states that such licenses may only be granted in any contracting state if a product covered by the patent which has been manufactured in a different contracting state has not

been put on the national market of the first state in sufficient quantities to satisfy demand in its own national territory."

The effect of this rule is that "it prohibits treating sole fact the product is not manufactured in the national territory as constituting a reason for granting a compulsory license for insufficient use or lack of use. By virtue of Article 82 this rule applies also to national patents."

Providing for a uniform system with respect to granting as well as opposing patents, CPC refers the actions relating to enforcement of patent rights and infringement of such rights to national courts Article 69 makes a list of all the possibilities: an action for infringement may be heard and before the court of a contracting state in which the defendant has his residence or his place of establishment. If not, it is brought before the court in the plaintiff's country and if that is not possible then the case is heard before the German Courts. Also the case may be heard before the courts of a contracting state in which an act of infringement has been committed; however, in that case only with respect to that specific act committed within the territory of that state.

National courts may refer matters for interpretation on the convention or supplementary provisions for a preliminary ruling in accordance with Article 177 of EEC Treaty. In line with the Resolution(111) which the Contracting States passed as a result of the existing duality of the system to overcome such differences, the Second Luxembourg Conference which provided for a revised version of the 1975 Community Patent Convention also included proposals which aim to abolish the duality of the system. First of all, it is necessary to look at the Preamble of CPA;

"Convinced that a gradual implementation of the Community Patent System, characterized by the creation during a transitional period of a unitary patent with effects beyond national frontiers for a majority of the MS, will permit inventors and enterprises to evaluate the advantages of the system vis-à-vis the national and European patent system which will continue to be available to them; anxious to promote the completion of the internal market and the establishment of a European technological Community by means of such a patent"(112).

This paragraph together with Art.10 dealing with the number of ratifications required for entry into force of CPA have a provisional character since these are not agreed upon absolutely. Main topics discussed at the Conference were concerned with the rapid entry into force of the CPC as amended, a new approach to patent litigation and revocations proceedings, and a new approach to defining the role of the Court of Justice of the EC within the framework of the Community patent system.

Although the Member States were not ready to adopt any decisions concerning the rapid entry into force of the CPC. The Netherlands and Greece, Spain and Portugal were not of the same opinion as the other MS. However, it seems possible from the meeting of the Internal Market Council of February 4, 1986 that an agreement can be reached on a solution for nine MS including the seven and Greece and Spain(113). In line with this, Spain and Greece ratified the EPC in July 1986.

As for the new approach to patent litigation agreed upon, it provides for a counterclaim for revocation by the dependant in infringement proceedings. Proceedings of first instance are to be carried by specialized national courts called Community Patent Courts which will have the authority to revoke a Community patent on the grounds of revocation as

indicated in the CPC. The second instance proceedings are either decided by a Common Court of Appeal (COPAC) to be established and by national Community Patent Courts of second instance depending on the issue. Questions of validity and infringement will be dealt with by the former and issues relating to national law by the latter. The solution reached as to the role of the ECJ within the new context of this Conference and its Protocols was a compromise between different approaches. This solution provided that COPAC will refer to ECJ for a preliminary ruling in accordance with Article 177 in case an interpretation of the CPA was needed. This development reflects the need for specialized European courts and to reduce the burden of ECJ.

The importance of ratifying the CPC lies in the fact that "industrial property has always been the vanguard of international harmonization and unification of the legal environment"(114). Although EPC was an attempt of considerable significance in this respect and turned out to be successful in its own sphere, the completion of the internal market requires more. This is in order to eliminate the potential barriers of the principle of territoriality of protective rights. Therefore, it can be said that CPC works as an instrument to fulfill Community obligations.

4. PATENTS IN PHARMACEUTICAL INDUSTRY

Having already discussed the legal aspect of patents; the concept, the course of development of international legislation on patents and finally patent protection within the legal context of the EC, it is now necessary to examine patents from the economic aspect.

One of the requirements for being granted a patent is the 'industrial applicability' of the invention. The meaning of this term is expressed in the wording of Art.57 of the European Patent Convention, the most widely ratified international convention on patents:

"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 requirement brings forth the economic aspect of patents. Yet the term 'industrial applicability' is very general and the conditions for 'applicability' show great variations from one industrial sector to the other. Therefore, patents should be examined individually for the different sectors of industry, if a conclusion is to be arrived at as to its value. It is for this reason that this chapter will examine the specific characteristics and conditions of the pharmaceutical industry before going on to discuss whether patents are of any value for this specific sector of industry.

4.1. Historical Development of the Industry

In order for the pharmaceutical industry to take its modern form based on scientific research and development, it had to go through three stages.

In the period before the World War I, the drugs then existed were very few in number and not very effective in treating diseases. They were mostly taken from nature.

It was not until after a certain kind of dark-red dyestuff was found to be effective in treating a certain type of infection (streptococcal) that the therapeutic revolution began. There were mainly three reasons for the rush to developing new derivatives of sulfanilamide, which was patented as a dyestuff raw material. First of all, because of the fact that its molecular structure was simple, it was possible for the chemists to easily modify the structure and make a synthesis. Secondly, there occurred a sudden rise in the world demand for this anti-bacterial drug. Finally, pharmaceutical companies realized that if they succeeded in developing new and more effective derivatives of this drug and patent them there would occur an increase in their sales volume. As a result, many sulfa-based drugs were invented one after the other and put on the market in 1935.

With the outburst of the Second World War, there emerged an urgent need for new drugs in large quantities. This need provided the necessary incentive for making investments to develop a new drug effective against wound Penicillin was the outcome. It was only after 1939 when certain therapeutic characteristics of this drug was found out that research concentrated on finding methods for mass-production of Penicillin. The fact that the US government had also participated in the research activities of this drug enabled

every interested person to obtain a patent; Penicillin was being produced in large quantities and therefore, there occurred a fall in its price. This development in the pharmaceutical industry not only provided for a stimulus to research and development activities for finding new production methods of antibiotics, but also directed the pharmaceutical companies to invest on activities for the development of machines producing capsules and tablets.

Third stage began in 1949 with the invention of Terramycine by Pfizer. Until this date, the pharmaceutical companies preferred to sell their products in bulk quantities to packaging firms which then turned these drugs into finished products. In the beginnings of '50s, Pfizer decided that it would sell its products under its own brandname with the help of a number of sales and marketing personnel by means of drug presentations directed to doctors. With this aim, Pfizer established a distribution network. This method proved to be very effective in increasing the sales by large quantities. Another result was that brand names instead of generic names began to be used widely. In this way, advertising and marketing became two important aspects of the pharmaceutical industry.

In the next period, pharmaceutical companies gathered all the R+D production, distribution and marketing activities within their capacity. This in turn gave rise to product competition which resulted in an increase in the number of new products. However, a decline is observed since 1960's. This may be due to two reasons. First in the earlier stages of the therapeutic revolution 'relatively easy' therapeutic fields had been exhausted. What is left behind are the 'relatively difficult' therapeutic fields which don't offer high probabilities of making inventions. Second reason is the heavy R+D expenditures due to government control mechanisms.

Such a historical background helps one to gain an insight into the operations of the pharmaceutical industry but it is not enough to understand the nature of the modern pharmaceutical industry.

4.2. Nature of Pharmaceutical Industry

The modern pharmaceutical industry is "an entrepreneurial high-tech industry, a social service, a vehicle of government policy"(115).

This is a very brief but all-encompassing summary of what the pharmaceutical industry is about. A closer look at the summary reveals a lot about the peculiarities of this sector when compared to other branches of the manufacturing industry(116). First of all, it is important to note that success or failure of the industry is almost exclusively dependent on the outcome of the R+D activities. Success of the R & D process, in turn, depends on the production of new drugs. This is why the industry spends huge amounts of money on R & D investments. Secondly, the industry serves a social purpose; that of safeguarding people's health through efforts for finding the most efficient drugs in the treatment of human diseases. Finally, comes the governments' interest in the healthcare of their people and as a result in designing policies to protect public health is to be noted.

The fact that the industry spends a considerable amount of its sales on research and development, a sum which is higher than that spent in the other high-tech industries, together with the high risk related to the outcome of the R+D activities are the reasons underlying the high profitability of this sector. Patent protection granted to the pharmaceutical products is an important means to obtain high profits mainly due to the monopoly-like effects of the patents. The high prices that the industry charges its consumers for drugs

is one field of tension between the industry and the governments. This is mainly due to the fact that in the more developed western world, the governments are the main purchasers of pharmaceuticals. As a result, it is in the interest of the governments to push down drug prices through pricing policies they implement.

Second field where the industry and the governments come face to face is the experimentation stage which is identified by the control mechanisms introduced by the governments to ensure the safety and efficacy of drugs before marketing. This stage takes a long period and contributes high amounts to the expenditures of the industry. This long period works to the disadvantage of the industry by causing a reduction in the effective life of a patent in countries where the patent term begins at the time of filing an application.

Third point relates to the interaction between the national governments and the foreign pharmaceutical companies which may cause tension. It is an often encountered practice that national governments take measures and implement certain mechanisms favoring their domestic industries in order to increase their national wealth.

All these factors add up to the operational uniqueness of the pharmaceutical industry operations. There are other specific features with respect to the structure of the industry, the nature of demand and the operations of the industry. These will be discussed below in detail.

4.2.1. Structure of Industry

An overall view of the pharmaceutical industry today shows that it is one of the few sectors of industry which has internationalized its activities to such a great extent.

Due to the developments stated in Section 4.1, the world pharmaceutical production began increasing in the '50s and gained an impetus in the '60s. This, in turn, resulted in an increase in trade activities, in particular after the '70s.

Parallel to the increase in production and trade, the emergence of the multinational organizations showed up in the industry(117). At the beginning of the century, German, Swiss and US pharmaceutical companies began to establish networks of local subsidiaries throughout Europe. Until after the Second World War when local manufacturing became widespread, these subsidiaries operated only as marketing organizations. Local production developed as a response to restrictions on pharmaceutical imports which were being put also by the developed countries right after the Second World War.

It can be said that the result of escaping import restrictions ended up in the multinational character of pharmaceutical industry. Thus, the leading pharmaceutical companies are multinationals carrying their activities on an international level in different countries. Japanese pharmaceutical companies are exceptions in that they operate mainly in their domestic market.

Closely related to the multinational nature of the companies is the other feature of the structure of pharmaceutical industry. It can easily be observed that there is

a concentration. With respect to total sales, 1982 figures show that the top 25 firms in the world accounted for 51 per cent of total sales, the top 50 for 68 per cent, and the top 100 for 80 per cent(118). There is also concentration in the sense that these multinationals originate from a few developed countries(119).

At this point it is necessary to go over the factors which underlied the internationalization of the activities of this industry. These are that R+D process constitutes the main part of the competition strategy in this sector and that high costs and risks are involved in these R+D activities.

Since as mentioned before, competition takes place through the introduction of new products, the main purpose of the companies is to gain monopoly profits until a second product is introduced to the market by others. However, there is no guarantee in the pharmaceutical research process that a new chemical entity (NCE), which will have a commercial value, would be discovered at the end of each research. Therefore, the companies file an application for a patent as soon as they come up with a NCE. Yet the development process is more important, time consuming and even more expensive than the research process. What is more, by filing an application it is necessary that the NCE is described. In this way competitors can have easy access to information about the NCE as soon as an application is filed. The fact that imitation is rather easy in this sector is vital at this point. Thus by the time the inventor company develops the NCE and examines it in accordance with the regulations before putting it on the market, others proceed along the way to imitating it. Not long after the inventor company gets the necessary licence to market the finished drug, the patent term which begins at the date of filing is over. In the meantime, competitors come up on the market with a new product which is a slight variation of

the original product. Once competitors bring similar products on the market, the profitability of the inventor companies falls. All this process repeats itself each time a NCE is discovered. As a result, the pharmaceutical companies came up with the solution that in order not to lose the profits, which will then be recycled into the R+D activities for a new entity, they should operate on a bigger market so that they can enjoy the monopoly profits till imitation occurs. Consequently, they began to establish subsidiaries in different countries throughout the world.

The fact that R+D activities necessitate heavy expenditures and involve high risk factors also contributed to the internationalization of the industry. While R+D in a specific therapeutic field costs a lot, to carry out R+D in more than one such field is even more expensive. Therefore, what happened was that the pharmaceutical companies preferred to concentrate their R+D activities in a limited number of therapeutic fields which would turn out to be more profitable in the end. However, this caused a decrease in the number of new drugs produced. The result is that again the companies preferred to operate on the international market in order not to be limited to their national markets for profits.

Reiterating what has been stated, the modern pharmaceutical companies are vertically integrated in that they gather the R+D, production, distribution and marketing activities under their roof. They are organized on a multinational basis and carry out their different activities in different countries. Due to the size of the market to which they respond and also due to the monopoly profits which they enjoy, even though for a gradually lessening period of time, they are highly profitable.

Besides this type of companies, however, there are

also others which take part in pharmaceutical production by producing either drugs which have not been patented or out-of-patent drugs(120). These are the generic drug producing companies. The erosion of the effective patent life is in the interest of these companies whose activities are not research oriented at all. Mostly they concentrate on copying drugs of other companies once they are out-of-patent. These companies are relatively small and produce those products at cheaper prices than those of the branded originals produced by the multinationals(121).

4.2.2. Nature of Demand

Before passing on to the nature of demand, it's best to describe the kinds of pharmaceutical products which are available on the market.

Pharmaceutical products can either be for animal or for human use. This thesis is interested in the pharmaceutical products effective in treating human diseases. Two different distinctions are made with respect to such products; that of between prescription and over-the-counter (OTC) drugs and that of branded and generic drugs. Prescription drugs cover those products which can only be obtained on a doctor's prescription whereas OTC drugs can be obtained freely from any retail pharmacy shops or, in some countries like the US, even from the supermarkets. Branded products carry the brand name of the company by which it is produced, whereas generic drugs are sold under their chemical names. Prescription drugs carrying a brandname are called ethical drugs, whereas OTC drugs under a brandname are called proprietary drugs. Ethical drug sales cover about four-fifths of all drug sales and as a matter of fact one can also talk of concentration on this issue.

The nature of demand for pharmaceuticals is rather different from the demand in other industries and this mainly is responsible for the almost unique characteristics of this industry when compared to other sectors in the manufacturing field.

Since pharmaceutical products are concerned with treating diseases, at least in the case of ethical drugs, the demand comes from the doctors who prescribe the drugs and not from the patients themselves. Of course, it is a different case with OTC drugs; however, thinking that up until the recent times, sales of ethical drugs cover as much as four-fifths of all the drug sales, it should not be wrong to state that the choice of drugs is, to a large extent, made by the doctors(122).

Since specific drugs are used in the treatment of specific diseases, it can easily be stated that the pharmaceutical market is subdivided into different markets which contain drugs for those specific therapeutic fields(123). It is known that individuals' reactions to drugs may vary to a great extent(124). Therefore, it is desirable that there exists a range of products in the same therapeutic field so that the doctors can choose among those the one which suits best that specific patient's physiology.

One other point which makes demand different in this sector of industry with respect to other sectors is that demand for drugs is inelastic to price differences unlike many consumer goods. This is mainly due to the fact that it is the physician's domain to prescribe any drug which he sees will serve his goal of best treating the illness.

Demand for drugs is also dependent on a number of other factors. Among these are the national wealth and the

existence or efficiency of the health care institutions. Drugs are rather different from ethical drugs. Up until recently they did not constitute the most important market within the pharmaceutical industry. The recent developments in OTC production will be dealt with in section 4.2.4. All these characteristics of the demand for pharmaceutical products affect the market structure of the industry and accordingly determine the competition strategy to be followed.

4.2.3. Operation of the Industry

It has been explained before, that the industry has a global character; that is, it operates on an international level through the subsidiaries and licencees of multinational companies around the world.

In order to gain an insight into how it operates as a manufacturing industry, one has to go into details of the stages involved in the development of a drug.

There are mainly three stages involved. The first stage corresponds to the R&D activities. It is the most important stage in the development of a new drug. This process begins with an enormous number of chemical molecules being tested until an individual chemical entity is found out to have the desired effect for a specific disease. Although the success of this research process was dependent on luck to a great extent until recently now it is carried out more consciously with the use of biotechnology as a basic research tool. Biotechnology describes a range of scientific procedures concerned with altering genetic material in living organisms either to develop new biological entities or to make existing natural processes more efficient(125). Therefore, the use of biotechnology makes it possible for the scientists to understand beforehand, the way genes influence the course

of specific diseases and then design a new drug for that purpose to interfere with this process, to stop the disease or prevent its advance.

Having found a new chemical entity (NCE), scientists try to develop it into a marketable drug. The NCE, in the development stage subjected to safety trials and clinical, testing first on animals then on humans. The results demonstrate "the efficiency of a company's research philosophy and skills"(126). After this, the NCE is put into a form and applied a method which enable it to be produced in large quantities. In the meantime, the product whose safety and efficiency has been proven is tested against competitor drugs also. The overall R&D process requires high amounts of investment; around \$ 100 million is needed for the production of a new drug(127). Heavy expenditure on R&D activities are mainly due to a few factors among which are the high costs of establishing a laboratory, the need for highly qualified personnel and the tests to be carried out. These tests involve those carried out during the R&D activities as well as those to be applied to drugs in accordance with the government rules and regulations before a marketing licence is granted by the public authority. The need for such as extensive testing and government intervention is the result of the fact that the industry's field of operation is concerned with public healthare. This necessitates that the products fulfill certain requirements and are made up to the standards set by state health authorities.

The next two stages are concerned with the manufacturing of a drug; first, the production of active ingredients and raw material to be used for making up the drug and second, the formulation of these into finished products.

Chemical production of active ingredients and raw

material is a rather complex process and requires high technology. It follows from this that a high amount of money has to be invested. Since it is found out by the pharmaceutical companies that costs are at the lowest when production of this type is centralized, only a small number of companies are involved in this stage both on a national basis and world basis(128). Therefore one can mention high concentration in this sense.

After the active ingredients and raw materials are produced by using high technology, the product is to be formulated so that it can be put on the market. This process, in contrast to the others, can be carried out by the use of simple and already known technology and this makes it possible for production to be carried out at different places. It can be stated that as a result of the relative mobility of this stage, the international activities of the pharmaceutical industry became more widespread. Internationalization mainly took place through the establishment of subsidiaries by the use of direct foreign investment, especially in the Third World countries. Consequently, the companies involved in the formulation of pharmaceutical products are, in general, of small and medium size.

Once a pharmaceutical product develops into a marketable drug of commercial value it needs to be marketed, the second most important stage which has an impact on the success of a certain drug.

In order to understand the market strategies used by the pharmaceutical companies, it is necessary to stress the fact that the pharmaceutical is subdivided into different therapeutic fields. Drugs are then considered within the therapeutic field to which they belong. This is important

with respect to competition because drugs belonging to different therapeutic fields don't compete with each other since they are not substitutable. One can only speak of competition between drugs belonging to the same therapeutic group. The drugs can be divided into two main categories; prescription drugs and OTC drugs. Both types can be sold under brand names or generic names. Drugs with generic names have price competition to a certain extent. However, competition among branded products is mainly based on non-price competition; that is, it is based on differentiation of products. Branded product differentiation within the same therapeutic field reinforces inelasticity of demand on the part of the consumer by eliminating substitutability through creating brand loyalty. Since OTC drugs are freely available to the consumers, the market structure of these drugs are, to a great extent, similar to those of any other consumer goods. Consumers' preferences are the determining criteria in the sales of proprietary drugs and, therefore, the marketing strategy is designed to affect the consumers directly.

The situation is quite different with ethical drugs which are only available on a doctor's prescription. Since, in this case, physicians' choices play an important role in the sales of ethical drugs, marketing strategy is directed towards persuading the doctors as to the safety, efficiency and superiority of a new drug. Due to the fact that the only information the physician gets concerning the drug is from the manufacturer until he tries it on the patients, it is vital that the sales representatives are highly qualified and well-informed. The most efficient marketing technique is found out to be direct marketing where the physician and the sales representative gets into a one-to-one relationship. Organization of conferences and advertising in medicine magazines may also be employed as marketing techniques. The substantial economies of scale involved in this stage results

from the fact that the same sales representatives are used to promote a range of drugs in the case of multinational companies. In the case of smaller companies, the sales force turns out to cost more since range drugs to be marketed is less. The substantial economies of scale leads to a better frequency of visits to the physicians and a concentration of marketing possibilities.

At this point, price controls emerge at the national level mainly due to the fact that governments are, in Western countries, the almost exclusive buyers of drugs due to extensive social security schemes. Therefore, the drug pricing policy is, to a great extent, determined by the health policy of that specific government. Pricing policy is important since it affects the level of drug company profits and, therefore, the return that companies are able to receive on their pharmaceutical patents.

4.2.4. Recent Developments in the Industry

The recent years have witnessed certain developments which may affect the pharmaceutical industry positively as well as others which may affect the industry negatively.

While the steady growth and the advances in biotechnology had positive impacts, the cost-cutting efforts of the governments to reduce their drug expenditure has a negative impact on the pharmaceutical industry. This is mainly because the governments, in relation to their cost-cutting policy, encourage the production of the generic drugs; thus disfavoring patented products. Moreover, the industry is under pressure as a result of the increased period of time and cost of the R&D process mainly due to the clinical testing and safety trials that the governments require for granting a marketing licence. In the meantime, the fact that some of the

highly profitable drugs is almost coming to the end of their patent lives causes an anxiety for the pharmaceutical drug manufacturers.

In relation to these negative impacts, the pharmaceutical companies undertook certain activities which, if become more widespread, may amount to the all-over restructuring of the industry. One such activity is the creation of mergers between the leading pharmaceutical companies of the world(129). At the same time, others engage in joint ventures or conclude agreements among themselves in order to increase collaboration(130).

There exist two different attitudes towards these changes. According to one view, these mergers took place mainly on a defensive basis. It is a fact that mergers were between companies involved in the production of patented and prescription drugs. The operations of these companies are research-intensive and they spend around 10% of their total revenues on R&D activities(131). This view suggests that these companies engaged in mergers in order to deal with the increasing R&D costs which lie at the basis of their operations as well as the threat of the cost-cutting policy of governments. In this way, they can achieve the economies of scale in research and marketing and hope to overcome the hardtimes. The other view suggests that these changes are occurring as a natural response to the movements in technology and changes in the consumer preferences. According to this view, the reorganization activities through mergers are the reorganization ways to make the most of these changes preferences rather than evading their loss of profits.

The developments made in biotechnology have become the source of research ideas for the leading pharmaceutical companies. In spite of the difficulty in the patentability

of biotech products, the big companies try to get into collaboration agreements with the increasing number of biotech companies(132). Others have already become important shareholders in these biotech companies.

One more development that took place and is of capable of changing the structure of the industry is the change in the consumer preferences with respect to drug use. Self-medication has appeared as an alternative to the visits to the physicians(133). This change in consumer preferences in favor of OTC drugs is relatively more seen in the US rather than in Europe. However, the overall trend is that there is a growing demand for OTC and this couples with certain activities in the OTC sector(134).

Information on the nature of the pharmaceutical industry provides evidence for stating that this sector of industry is different from the other sectors of the manufacturing industry. To an extent, such information also sheds light on the issue as to why pharmaceutical patents should be considered in a different context than patents in other industries. However, support is needed from the present situation of the pharmaceutical industry to make the argument in favor of pharmaceutical patents stronger. An overall review of the present situation with reference to the developments in specific areas of the sector explained in 4.2.4. will serve this purpose.

Though an advanced high-technology industrial sector, the pharmaceutical industry has yet to reach its maximum level both in terms of development and in terms of achieving one of its main objectives; the protection of the health of world population. There are two reasons for this. One reason is that the innovative sciences which direct development in this sector are still in a phase of rapid evolution and are

f r from having reached maturity. The other reason is that a there are still many diseases which are not satisfactorily treated with currently available therapy. Among these are the numerous 'orphan diseases' of which there are so few patients that they have largely been neglected by the medical research activities which were mainly devoted to wider scale needs. This recalls the many specialized health problems and local diseases of the third world which have also been neglected. All of this demonstrates that there is major growth potential for the pharmaceutical industry worldwide in the near future. Consequently, it is necessary to take into consideration these factors in relation to the research process vital to the industry while making an assessment of the pharmaceutical patents.

4.3. Pharmaceutical Patents

Before going on to discuss the situation of patents in the pharmaceutical industry, it is necessary to go into some detail as to what may be covered by a pharmaceutical patent. In a patent application, a claim is made in order to define both the invention and the scope of the forbidden area.

It is possible to make four kinds of claims in the pharmaceutical field; product per se claims, claims for pharmaceutical formulations, process and product by process claims and second indication claims. Claims for biotech products and for methods of treatment can also be mentioned; however, they are of less importance at this point(135).

A product or substance per se claim covers active chemical ingredients and provides for the widest scope of protection. The first draft of the claim generally covers an enormous number of molecules. As the R&D activities proceed,

these molecules fall in number and the final claim is made for a few individual chemical entities which are seen to be promising in terms of commercial value. These chemical entities will then be claimed by their full systematic name.

Such a claim is not always made for new compounds. It is also possible to claim for protection of an already known compound which is later discovered to have a different effect or to a greater degree as to its known effect. This kind of a claim results in the granting of a selection patent which requires that it has not been disclosed in the earlier patent.

Infringement of a product patent occurs due to any commercial production or use of the substance in question, no matter what it is used or sold for. Such absolute protection enables the patents to be enforced more easily.

Claims for pharmaceutical compositions or formulations can be one of three types. The first is made with respect to an active ingredient already known; but not as a useful medicine. This is similar to claims for a product and has the effect of limiting the monopoly to what actually had been invented. Second type is for the combinations of two or more known active ingredients which, when come together, has an increased effect. Third type specifies not only the active ingredients but also the other components or characteristics of the composition in detail. Such patents result from detailed research and are applied for several years after the patent for the active ingredient itself. This type gains importance as formulations and delivery systems become more sophisticated and is of high commercial value.

Process and product by process claims, however, are of limited commercial value. These claims become important in countries which have not allowed medicinal products to be

patented but do allow patents for processes for their preparation. Here the claim is made with respect to the precise process by which a new invention was first synthesized. Although the techniques used are probably standard, that is already known, this type can be granted as to the novelty of the process. Countries which allow only processes to be patented do not, however, allow such claims to go very far in making up for the lack of patents for products. Such a limitation may create problems as to the enforcement of patent rights against infringing actions. This is because there are almost infinite ways to synthesize a given organic molecule, because it can be very hard to prove that the production of a given molecule infringes that of the patented one and finally, because the burden to prove that he did not use the patented process is put on the defendant. As for its commercial value, it can be said that sometimes it may prove to be useful to patent a better process. It follows that claims can be made for products which are produced by the patented process and they are called product by process patents.

Finally, claims for second indications are made for new medical indications of the already known medicines. This is a new development and such patents have only been recently granted in Europe and will not expire for some time. It is important for products whose patents are about to expire; by finding a new medical use of that product, it can again be patented. Under the protection of such a patent, the patent holder can prevent competitors advertising the product in question, for the use declared in the second indication patent. It would, however, be invalid in cases where the product is used and sold for the original purpose or in cases where doctors and patients use the product for the new purpose. The most important application for second medical indication will occur where the original medical use was

disclosed but never practiced. It is necessary to note here that most of Europe and the USA allow second medical indications to be patented.

Biotech product patents create problems for the company trying to patent it since a chemical is the natural product of a micro-organism; claims for these are legitimate if it is claimed in a form which does not occur in nature. Methods of treatment, on the other hand, are not patentable in Europe.

This background information on what may be covered by a pharmaceutical patent is vital in order to be able to understand the significance of patents for the industry in one aspect. Especially the product per se patents and patents for pharmaceutical compositions are good examples for showing the necessity of patent protection even in the very early stages of the invention. This is mainly due to the extensive research activities being carried in the whole industry. For this reason, the companies feel the need to patent a chemical molecule if it seems to be promising in the least sense of the word. It follows from this that competition is based on launching new drugs on the market; rapidity and abundance of new drugs are two crucial factors in the competitiveness of the pharmaceutical companies. Assuming that competition lies at the basis of development, a reward is needed for encouraging inventions and "patents are a device for ensuring that such a reward is made possible" (136).

The fact that pharmaceutical products can easily be copied once they are put on the market also necessitates the protection of such products. It is common practice that new patented drugs are analyzed by a competent company which is able to rapidly determine their composition. The next step

is to make the necessary minor molecular modifications so as to avoid infringing the patent protection granted to the initial innovation(137). Referred to as 'imitative innovation', this practice is considered to neutralize the impact of the existence of pharmaceutical patents which amounts to a barrier to entry(138).

Referring to a study carried by Taylor and Silberston in 1973, it was found that, in general, the impact of the patent system was not so important to innovation, and also to prices and profits. The main exception was in pharmaceuticals, where the impact was held to be very important such that "without patent protection, research, development and innovation were considered by the authors likely to suffer severely."(139)

One more point to be made is that the patent system benefits the society by encouraging early disclosure of inventions. However, in return for his contribution to the society, the inventor is granted a monopoly for a certain period of time during which the society is denied free exploitation of the invention, a new drug in this case. The fact that such a situation leads to higher prices for the new drug than would otherwise be the case is used as a counter argument to pharmaceutical patents since concerned with vital issues. However, "the monopoly element in the patent system is generally held to be a price worth paying since the alternative is either industrial secrecy or a reduction in the R&D investments crucial to the pharmaceutical industry"(140).

The present situation with respect to the industry is such that certain elements detrimental to the pharmaceutical patents have developed over time.

R&D activities have increasingly become costly in terms of both time and money. This situation is the consequence of the government policies concerning public health and drug pricing. Governments' concern over public health together with the negative image created by the adverse effects of certain drugs in the '60s caused the governments to impose on pharmaceutical companies lengthy, extensive and costly clinical testing and safety trials. This resulted in an increase in R&D costs and in the erosion of effective patent life.

It has already been mentioned a few times that the governments' role in the implementation of the policy on public health results in the fact that they become the main buyers of pharmaceutical products in West European countries.

This, in turn, results in the interest of the governments to cut down the prices being spent on drugs and also to encourage the production of generic drugs which are available at cheaper prices. In this way, the pharmaceutical companies can not, anyhow, obtain the profits arising out of patents for the whole of the patent term. The erosion of the effective patent term when coupled with the emergence of generic drugs, as soon as that short-term comes to an end, have a negative impact on the profits of pharmaceutical companies. Thus it may lower the innovative capacity of these companies.

Difficulty in finding new drugs also contributes to negative impacts on inventions. This is mainly due to the fact that the inventions made up until today have been in the 'easy' therapeutic fields. The 'difficult' therapeutic fields have been discovered to an extent but there are yet specific areas to be discovered. However, as the name recalls, it is difficult to find new drugs which are effective in these specialized fields. As a result of the large number of drugs which are produced in the earlier periods and which are effective for broad therapeutic fields, the companies now try to discover the narrow fields in between. Such a situation causes further segmentation in the pharmaceutical product market and reduces the interchangeability of such products almost to a non-existing level. The monopolistic character becomes even more preeminent. However, there is a problem of demand. As this segmentation divides the whole market into smaller therapeutic markets, the demand for such specific drugs also shows a decrease mainly because these drugs are effective in the treatment of relatively rare diseases, the so-called orphan diseases. Thus a balance is established.

Finally, it will be appropriate to mention a study on "The term of Patents" carried out in 1986 as evidence for showing that pharmaceutical patents are different than other patents in any other industry(141). As a result of the questionnaires and interviews carried out in relation to companies operating in chemical and pharmaceutical, electrical, oil and engineering industries, it turned out that all companies except those engaged in the pharmaceutical sector were content with a patent life of twenty years. Such a finding shows two things; first, that pharmaceutical patents are different than patents in other industries, and second, that the effective patent life, as it is, currently is not

sufficient for fulfilling the objectives of this industry.

Taking into consideration all the above arguments in favor of pharmaceutical patents and the factors affecting them negatively leads into the conclusion that attempts are needed to increase the effective patent life.

At this point, mention should be made of the recent developments with respect to moves to give longer periods of protection for new drugs.

The USA, in which patent protection is 17 years from the date of grant, is the leading country in taking such an action; the Waxman-Hatch Act has been passed by the US Congress in 1984. It is a kind of a compromise between the manufacturers of the branded drugs and of the generic drugs. The legislation extends the patent term for branded drugs for up to five years to compensate for the lost time. Such an extension may be granted for a drug product, or process of manufacture of a product, provided that the term of the patent has not expired and that the product has been subject to a regulatory procedure before being marketed or used. As regards generic drugs, the Act provides for the filing of an abbreviated application for the approval of a new drug. However, reference should be made to a previously approved drug which had the same ingredients and conditions of use and which is out of patent.

Japan who grants 15 years of protection after the grant of the patent as of 1976 has made a similar attempt. A revision has been made to the effect that a six year period of exclusive marketing was given in 1980. As from 1988, the Japanese patent law was revised to give a maximum of five year patent term restoration for pharmaceuticals(142).

5. PATENT PROTECTION IN EC PHARMACEUTICAL INDUSTRY

Just as patents in pharmaceutical industry need to be considered in a different context than patents in other industries, EC pharmaceutical patents require further consideration than the pharmaceutical patents in other countries. This is due to three reasons. Firstly, the pharmaceutical industry in EC experiences hard times mainly due to: the high degree of fragmentation of the market, the varying levels of economic and cultural development across the Community and the diversity of cultural and scientific traditions. Secondly, patents, which by their nature necessitates territorial protection, experience a quite different legal status within the EC framework as explained before. This situation is also reflected in the situation of pharmaceutical patents in EC. Finally, the significance of patents in EC pharmaceutical industry requires special attention because of the role of the EC pharmaceutical industry in the development of pharmaceutical industry on a world basis as a consequence of its being one of the three leading figures with respect to operations in this sector.

5.1. EC Pharmaceutical Industry

The pharmaceutical industry in the European Community shows a high degree of similarities to that of the pharmaceutical industry in general in terms of the basic characteristics which distinguish it from the other sectors of industry. However, it is different from any other national pharmaceutical industry because of the high degree of fragmentation with respect to the existence of 12 different territories within the boundaries of the European Community. This is followed by the fact that there exists different attitudes to the use of medicine as well as wide variations in national wealth(143).

Different attitudes to the use of medicine is the result of differences in the training and behavior of physicians as well as the expectations of patients. Such differences, in turn, are the result of social and psychological factors fundamental to different societies.

These differences are reflected in the EC pharmaceutical industry in a number of ways. The industry in EC is also dominated by research-oriented multinationals originating both from within and outside the Community mainly because the costs of innovation are too high to allow any other strategy to be followed(144). However, there also exists quite a number of independent companies of more limited capacity both in terms of innovation and supply. These companies have annual sales of ECU 5-75 million and they are successful in keeping as high as 20-30% of the retail market in France, Germany, Italy and Spain(145). The existence of these independent the relatively small companies is proof of fragmentation of the pharmaceutical market in the EC; mainly because they concentrate on national markets and, therefore, move along national boundaries.

Supply is to a large degree internationalized; such that in France and Germany, local companies have a share of the market more than 50%. Supply from companies based within the community accounts for 23% of the total whereas supply from outside the Community amounts to 34% of the total 23% of which is by us based companies(146).

The impact of fragmentation of the EC pharmaceutical market can best be seen in terms of demand. Demand shows variations from one country to the other. These variations can be explained in terms of the differences in attitudes towards medicines and in institutional arrangements by which they are delivered to patients. There can be observed

three traditions in this respect throughout the Community. Denmark, Ireland, Netherlands and the UK display a kind of negative attitude towards taking drugs. The situation in the Mediterranean countries is quite the opposite in that they are positive about taking drugs. Germany is a case in itself; it shows elements of both traditions and also of its own(147). Existence of these different attitudes to the use of medicine is reinforced by the role of physicians especially of those practising outside the hospitals since they influence the scale and nature of consumption(148).

With respect to the operations of the industry, it can be said that research activities are centralized; UK is the country in which such activities are carried out to a great extent. Clinical and development activities, on the other hand, are decentralized mainly due to the differing rules and regulations in each MS. Manufacturing of active ingredients takes place in a small number of places among which Ireland is one where such activity is concentrated. Since dosage and formulation stage is relatively mobile and requires simple technology and not much rules and regulations to conform to, these activities can be carried out anywhere in the Community(149).

As a result of the existence of differences in culture as well as in social and psychological factors, the consumer preferences as well as the choices of the physicians show variations. This results in the fact that marketing is carried out on a national basis rather than on Community basis(150).

Price levels throughout the Community differ to a great extent. Besides the variations in exchange and VAT rates, variations in the reimbursement schemes and government controls are factors which cause differences in drug prices.

This, in turn, caused the emergence of a new trade practice within the Community; that of parallel imports. The practice of parallel imports infringes the exercise of national intellectual property rights and yet it is allowed according to the jurisdiction of the Court who bases its decisions on the free movement of goods principle. Such rulings of the Court are not in the interest of the owners of the pharmaceutical patents in EC and, therefore, the issue of parallel imports needs to be further elaborated.

There are also variations among the Community countries with respect to the rules and regulations that the national governments impose concerning pharmaceutical products. These variations result from the different attitudes of the Member States with respect to: the safety and efficiency of the pharmaceutical products, the reimbursement systems and policies on drug expenditure and the local pharmaceutical industries(151).

5.2. Harmonization Activities in EC Pharmaceutical Industry

Emergence of different national approaches on the safety and efficiency of pharmaceutical products corresponds to the creation of EEC in 1957(152). Such multiplicity of rules and regulations governing the pharmaceutical marketing authorizations throughout the Community is not desirable from the industry point of view. It is not desirable mainly because it increases the risks and expenditures involved in the operation of the industry on a Community basis. The situation is also not desirable from the Community point of view since it has a negative impact on the efficient working of the common market based on free trade.

Mainly based on the above mentioned evaluations, the Commission undertook the task of preparing a package of

proposals aimed at the approximation of the national administrative procedures for evaluating product safety(153). Presented to the Council in 1962, the package of proposals opened the discussion between the then six Member States as to the system to be adopted by the Community. The choice was to be made between harmonization of decentralized controls based on the mutual recognition of national authorizations and a centralized registration procedure to be implemented by the creation of a European registration office. The outcome of the discussion favored the harmonization of administrative procedures for the evaluation of applications for marketing licences in the short-run. However, it set the ultimate aim of the standardization of scientific and medical principles and criteria on which these licences were based(154).

To serve this purpose, a series of Council Directives on pharmaceuticals for human use have been gradually adopted. The first of these is Directive 65/5/EEC of 26 January 1965. Giving a definition of a 'proprietary medicinal product' in Article 1.1, it declares in Article 3 that

"No proprietary medicinal product may be placed on the market in a Member State unless an authorization has been issued by the competent authority of that Member State".

The criteria on which the marketing approval mentioned above is assessed are safety, quality and efficacy.

While the next Directive 75/318 of 20 May 1975 laid down the basis for general standards and protocols relating to the required clinical tests and trials to be carried out prior to marketing approval(155), Directive 75/319 provided the basis for the establishment of the Committee on Proprietary Medicinal Products (CPMP)(156). This Committee comprised of

experts who were to assess the clinical tests as specified in Directive 75/318. The main purpose for establishing such a Committee was to enable rapid mutual recognition of a licence granted by one Member State by some or all of the Member States.

The 1985 White Paper, the main concern of which is the completion of the Internal Market, provided a new stimulus for the elimination of technical barriers. This development was also reflected in the pharmaceutical field through the adoption of a number of Directives serving this purpose. Directive 87/22 of 22 December 1986, also called the EEC High-Tech Directive, introduced a set of rules to aid the development of European biotechnology industry in particular. However, it applied to other advanced technological techniques also. In practice, certain aspects of the Directive applies to any new drug which involves a significant technical advance(157). According to this Directive, when a licensing application for a biotechnology product (or a high-tech product) is made to the relevant authority of any Member State referring to this Directive, the matter must be brought by that authority before the CPMP for an opinion. If the outcome is in favor of the product in question, then extensions of exclusivity are granted by the provisions of Directive 87/21. This Directive gives a period of ten years' marketing exclusivity to the innovator. The market protection period starts from the date of the first authorization of the product in the EC(158). A shorter period may be granted to products not subject to biotechnology or high-technology rules. This procedure provides for more centralized opinion formation by the CPMP.

The Commission prepared a report in 1988 stating that the multi-state procedure based on mutual recognition did not work well in practice due to the fact that national licensing

authorities had little confidence in each others, system. Final situation is that most of the Member States have stated their preference for reinforcement of the CPMP; both in terms of its tasks and the possibility of making binding decisions(159). The proposals for the "future system" in line with the preferences of the Member States involve: a decentralized procedure which would probably apply to about 90% of product applications; a centralized procedure-mandatory for biotechnology products and optional for NCES; and national procedures for purely local products. A new development provides for a two-three year transitional period after 1992 so that companies will still be able to apply for registration in several Member States at once, not just one, as will be required under the decentralized procedure(160).

The diversity of drug prices throughout the Community as well as the diversity of national marketing authorization procedures create distortions in the Community pharmaceutical market and industry(161). One result is the emergence of parallel importing as a trade practice within the Community. It is a trade practice which involves the reimportation of products which are put on the market in another Member State where a lower price is charged for that product than the price in the country of origin and selling, in the country of origin, that product in parallel with the some product. Rulings of the Court of Justice allow parallel imports under Article 30 of the free movement of goods principle "even when the differences in price arise from official regulation"(162). However, this situation is contrary to the interests of the multinational pharmaceutical companies since this will result in constant downward pressure on prices which, in turn, cause a decrease in the revenues of companies. Consequently, financial source for research will not be sufficient to make innovations in the long run. Therefore, the countries which are the destination points of parallel imports and in which

products thus imported are significant, attempted to control the admission of parallel imports into their country. Price regulations are common practice so as to make parallel imports unattractive.

However, price regulations, in turn are sometimes used "to influence decisions about the location of industry facilities"(163). Authority to control prices constitutes an instrument for putting pressure on multinationals so as to force them to create or expand local facilities in return for the price they require for a certain product. Such expansion may burden the multinational companies with extra costs so that they can not enjoy the benefits arising out of economies of scale.

With respect to the differences in price levels, the price transparency Directive has been adopted. The Directive "seeks only to effect the transparency of pricing and reimbursement systems in the EC Member States, not to harmonize them or instruct national governments in how to run their pricing policies"(164). It is expected that, in the long run, this Directive will have an effect as to the approximation of national prices. One of the most important aims of the Directive is stated as avoiding all discrimination in favor of certain products in terms of the free movement of goods within the Single European market(165).

5.3. EC Pharmaceutical Patents

As it is seen, the EC has developed a Community legislation by adopting Council Directives governing certain aspects of the pharmaceutical industry where harmonization was required. However, there exists no such action taken on the part of the Council or the Commission as regards pharmaceutical patents which are the crucial instrument for the development of the industry.

Indeed, the legal status of pharmaceutical patents in the Community should be considered in reference to the Community law on industrial and commercial property rights explained in section 3-4. Actually, it is important to note, at this point, that there occurred a shift as to the legal basis on which the Court based its decisions concerning the industrial and commercial property rights. The Court's rulings in the first few cases in this field were based on Articles 85 and 86 of the competition policy. Beginning with the case of *Deutsche Grammophon*, it began applying Arts. 30-36 of the principle of free movement of goods in cases regarding industrial and commercial property rights. It can be said that the shift of the legal basis can be attributed to the frequency of cases on industrial and commercial property rights. Which come up in relation to the practice of parallel importing.

There are mainly two cases related to pharmaceutical patents: *Centrafarm v. Sterling Drug*(166) and *Merck v. Stephar*(167). The former was explained in Section 3.4 before, but it is necessary to mention it under this section also. The case was concerned with parallel imports arising out of the differences in pharmaceutical prices in the Netherlands and the UK. Referring to a question as to whether it was possible for the patent holder to exercise the patent to prevent such imports, the court ruled that free movement of goods can only be prevented under Art. 36 for safeguarding rights which constitute the specific subject-matter of this property. The Court's definition of the specific subject-matter of a patent included: that the patent was given to reward the creative efforts of the inventor; that the patent guaranteed to its holder an exclusive right; that this exclusive right was limited to the use of this right for the manufacturing of such products and putting them into circulation for the first time; that the exclusive right

could be exercised either by the patent holder or by the third parties having licences; that this right also involved opposing infringements. The Court came to the conclusion that Article 36 could be used to stop free movement of goods between MS on the grounds of protection of industrial and commercial property rights, if the product in question was not patentable in the country of exportation where that product had been put on the market by third parties and without the consent of the patent holder. However, if the country of exportation allowed the product to be patented and that the product was put on the market by the patent holder or with his consent, then Article 36 could not be applied to prevent free movement.

Second case, Merck v. Stephar, involved the parallel importation of the pharmaceutical product from a MS where it was not possible to patent such products. The Court ruled, in relation to this case, that even if the products were not covered by national industrial property rights in a given MS, the fact that such products have been put on the market by the patent holder or with his consent provides sufficient ground for the exhaustion of such rights.

The jurisdiction of the European Court of Justice on cases involving industrial and commercial property rights had two important consequences: erosion of exclusive rights arising out of national industrial and commercial property rights and emergence of a Community law of such rights. These consequences, in turn, reduced the negative impact of the differences between national laws concerning industrial and commercial property rights on market integration in the Community.

Attempts were made to support the case law in shaping a better harmonized law of industrial and commercial property

rights. The first of the two complementary Conventions, which provided the basis for further progress in this field, is the European Patent Convention. As explained in more detail in Section 3.2, this Convention also applied to countries other than the Member States of the Community. It was concerned with the patent granting procedures and left the patents in the field of competence of national authorities once they were granted. The European Patent Convention Article 167(2) enables the signatory states to make a reservation with respect to "chemical, pharmaceutical and food products"(168). This reservation only concerns European patents in so far as they confer protection on such products. Since this Convention is concerned mainly with the granting procedures, it only declares that a reservation is possible with respect to pharmaceuticals. The rest is left within the field of competence of the signatory states. What is of concern for the EC pharmaceuticals with respect to the above-mentioned reservation is not applicable in the Member States of the Community Patent Convention since there is no specific provision to this effect. Such a consequence results from the unitary character of the Community patent(169).

"The system under the European Patent Convention is quite favorable to pharmaceutical patentees"(170). Claims to new chemical entities are allowed except in Greece, Portugal and Spain where patent protection for pharmaceuticals is not available at all(171). Italy was included in this group until 1978. It is now possible to apply for pharmaceutical patents but most of the commercially important medicines of today were invented before the change in the law so that they are still not protected in Italy.

European Patent Office does not allow method of treatment patents but allow patents for second medical indications. In theory, the fact that the European Patent

Office decides to grant a patent in particular form does not mean that the courts in any particular country will uphold it, but second indication claims have been allowed under national law in Germany, and the UK(172). On the other hand, the Community Patent Convention, not ratified as yet, was designed to complement the European Patent Convention to reach the ultimate aim of a unified Community Patent System. For this reason, the former showed variations from the latter. First of all, Community Patent Convention is designed to apply exclusively in the Member States of the European Community. It has a wider scope than the other in that the former aims to regulate all stages of a patent system. Its provisions are, to a large extent, based on the Court's judgments. This Convention provides for a unitary patent which would not prejudice the operation of the single market.

Relevance of the Community Patent Convention to the pharmaceutical patents can be found in its provisions governing licences and exhaustion of rights opening the way to parallel imports. The Convention distinguishes between three types of licences which are contractual licences, licences of right and compulsory licences. Since no Court precedents existed concerning the exhaustion of rights arising out of a product put on the market under a compulsory licence, this Convention provides under Article 81(3) to the effect that exhaustion of rights principle does not apply with respect to such licences within the meaning of Article 81(1) and (2)(173). Article 81(1) stresses the need for 'express consent' of the patent holder in order for the exhaustion principle to apply to rights conferred by national patents. Article 81(2) provides for the exhaustion principle to apply whenever it can be shown that economic connections exist between the two patent holders involved in parallel imports.

Another issue to be discussed about EC pharmaceutical

patents is the erosion of their effective life of patents. It is a problem which, indeed, threatens the pharmaceutical industry all over the world.

This situation arises mainly due to two factors. First, pharmaceutical companies seek patents as soon as they feel that a patentable invention has been made. Therefore, the development activities still take considerable time. Second, increasingly more complex regulatory procedures have been adopted before granting a licence for the marketing of new drug.

The result is that the pharmaceutical companies can not enjoy the exclusive rights arising out of a patent to the fullest. This, in turn, results in a fall in the profits which are invested in further R&D activities. The measures encouraging generic drug production cause them to come up on the market soon after the patent expires and worsens the situation for the research-oriented pharmaceutical companies.

The EC Commission acknowledged the situation in 1984. Furthermore, in 1987, it noted that the protection conferred by patent law, and in particular, the European Patent Convention, is sometimes insufficient because the maximum period of 20 years is frequently reduced by the time taken to complete testing and obtain authorization(174).

The 10-year marketing exclusivity period, provided for in Directive 87/21 has helped, but it is not an answer to the problem. In Denmark, Ireland and Luxembourg, the period of exclusivity is six years and Spain and Portugal do not need to implement the Directives until 1992.

Attempt to approach the problem by making an amendment to the patent term stated in the European Patent Convention

was prevented since the German government opposed the idea and also since the British government preferred that an initiative is taken on a European basis not on a national basis(175).

The inspiration for the Commission's proposal for patent restoration certificates came from the similar French proposal made by the body representing the French pharmaceutical industry. A draft Directive was prepared by the European Federation of Pharmaceutical Industries' Associations (EFPIA) and presented to the Commission in May 1989. The scheme was that the holder of a marketing authorization pursuant to Directive 65/65 would apply to his national patent office for the certificate within six months of the first such approval and before the expiry of the patent. The draft Directive provided for a maximum of 30 years' protection from the date of filing(176). It was designed in a manner to avoid conflicts with the EPC. Belgium also submitted a draft law in May 1987 to introduce a 20 year patent term from the date of marketing authorization for pharmaceuticals.

However, the Commission's initiative to extend pharmaceutical patent terms by means of a complementary certificate was not welcomed by the European Patent Convention. A working party has been established to consider the compatibility of the EC initiative with the Convention and whether the contracting states would be willing to make a special provision for pharmaceutical extension or rather restoration(177).

Following this, the Commission submitted a proposal for a Council Regulation on "the creation of a supplementary certificate for the protection of medicinal products"(178). The proposal aims at improving the protection of the innovation in the pharmaceutical sector and patents are regarded as the best tool for achieving this. In this way,

it is intended that the pharmaceutical industry will be provided with necessary conditions for the discovery of NCEs which will in turn guarantee therapeutic and scientific progress in European health care.

The fall in the number of European originated NCEs compared to those of the USA and Japan, and the need to compensate long experimenting and authorization periods and to provide harmonization of national developments in this respect have been the additional major forces behind this proposal.

Basic requirements and the duration of supplementary certificate will be uniform for the whole Community. The overall protection will be 16 years and the duration given by the certificate will not exceed 10 years. The proposal also refers to the fact that a similar legislative action has gone into force in the USA in 1984 and in Japan in 1988.

In the achievement of the above mentioned respects, the proposal creates a supplementary protection certificate which will be granted by each Member State at the request of the holder of the basic patent. The request is made with respect to a pharmaceutical product with authorization for marketing.

"The proposed system, which is linked to both the marketing authorizations system and the patents system, has specific characteristics and particular features, as a result of which the certificate is a national certificate harmonized at the Community level and essentially different from the basic patent"(179).

It is commented on the proposed patent certificates that "they would be granted on the basis of a specific EC instrument and not on the basis of the European Patent Convention. The conditions under which they would be granted

would be different from the EPC conditions, in that the patent certificate would not be protecting a pharmaceutical invention but a marketing approval. This means that "the patent certificate would be a specific form of industrial property protection giving the product the same rights as would a national patent for a specific period of time... The certificate would use the existence of a patent only as a condition for the granting of a new form of industrial property protection right. As a result, ... it's probably incorrect to talk about an extension of patent life, although economically this might well be the effect"(180).

It follows that such an action taken by the Commission suggests an intention of the Community to proceed along the path towards the creation of an industrial property system of its own.

6. CONCLUSION

In this thesis, an attempt has been made to show that it is vital for patent protection to be granted to pharmaceutical products in the EC. The outline is designed to arrive at this conclusion through dealing with the topics of internationalization of patent protection, pharmaceutical patents and EC pharmaceutical patents individually. The conclusions arrived at each chapter forms the basis of the next chapter; thus in the end showing the necessity for EC pharmaceutical patents. Therefore, the concluding remarks on each of these topics will be given in order.

It can easily be observed that attempts to unify the national patent laws on a Convention level proved successful only so far as the granting procedure is concerned. It can be concluded that further unification requires a greater degree of integration on social and economic as well as legal aspects.

With respect to the necessity of patent protection in pharmaceutical patents, it can be stated that such a claim may be made mainly on the basis of the characteristics unique to the pharmaceutical industry.

- The importance of R&D for competition and development in the industry,

- The necessity for patent protection in the early stages of invention against imitators because of the easily-copied nature of the NCEs, and

- The early disclosure of inventions providing for the society to benefit from the innovations in a rapid and widespread manner are the most important features of the industry which make patents for pharmaceutical products a 'must'.

Besides these, recent developments with respect to social, political and economic concerns over the pharmaceutical industry are also important in that these caused the emergence of new trends which, in turn, led to the destabilization of the traditional pharmaceutical industry. New developments in the industry point to the need for more R&D which can only be reinforced by the patent protection granted to the pharmaceutical products.

The increase in R&D and operating costs, the encouragement of the production of generic drugs by the governments as well as the pressure on the industry for price-cutting constitute severe threats to the pharmaceutical industry in its existing form. Other problems faced by the industry are the drop in the number of NCEs as a result of the above developments, the shift in the consumer preferences towards self-medication and, one of the most important, the difficulty in finding NCEs. The last point is closely related to the fact that all the easy therapeutic fields have been discovered before. The only remaining therapeutic fields are difficult in the sense that inventions are not possible at the end of each research process. This situation threatens the health-care of the world population since there are as yet diseases for which no remedies have been found.

All these factors necessitate the restructuring of the pharmaceutical industry. The main trend is the formation of mergers and acquisitions to build a greater mass in R&D and a globalized market force. Emphasis being put on R&D bring together with it the emphasis on pharmaceutical patents.

In addition to all these, the fact that EC pharmaceutical industry risks being left behind the USA and Japan as a result of the final measures taken with respect to patent terms in their countries. The fact that attempts for similar measures

have been initiated by some of the Member States gives rise to an urgent need for the unification of the national patent systems, the divergences with respect to which already hinders the operation of the common market. Consequently it can be concluded, on the whole, that on the way to single Market, it is inevitable for progress to be undertaken in this respect.

NOTES

- (1) Philip W.Grubb, "The Nature and Origins of Patent Monopolies", Ch. 1; Patents in Chemistry and Biotechnology, Oxford, Clarendon Press, 1986, p.5.
- (2) Grubb, p.5.
- (3) Dr.iur Ernst E.Hirsch, Hukuki Bakımdan Fikrî Sâı, trans. by V.Çernis 1, İstanbul, Kenan Basımevi ve Klişe Fab., 1942, p.2.
- (4) Ateş Akıncı, "Mukayeseli Hukuk Açısından Amerikan ve Avrupa Toplu-luğu Hukuklarında Rekabetin Yatay Kısıtlanması", basılmamış doktora tezi, İstanbul, 1985.
- (5) F.M.Scherer, Industrial Market Structure and Economic Performance, 2nd ed., the USA, Houghton Mifflin Co., 1980, p.442.
- (6) Scherer, p.440.
- (7) Scherer, p.444.
- (8) European Federation of Pharmaceutical Industrias' Associations, "Memorandum on the Need of the European Pharmaceutical Industry For Restoration of Effective Patent Term for Pharmaceuticals", 1989, p.3.
- (9) Grubb, p.11.
- (10) Grubb, p.12.
- (11) Grubb, p.3.
- (12) Grubb, p.11.
- (13) Grubb, p.12.
- (14) Virginia Brown, Intellectual Property, Lecture 1, Spring 1989, p.3.
- (15) M.Van Empel, The Granting of European Patents, p.347.
- (16) Van Empel, p.4.
- (17) The stage of the art is held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filling of the European patent application.
- (18) It was revised on Feb. 16, 1961 and the revised version entered in-to force as from Dec.30, 1971.

- (19) The Reimer and De Haan Plans, see Van Empel, p.14.
- (20) The Reimer plan, see Van Empel, p.15.
- (21) Van Empel, p.15.
- (22) This was indeed the new international WIPO Convention.
- (23)
- (24) Van Empel, p.20.
- (25) Van Empel, p.21.
- (26) The term European property rights' used here refers to patents, trademarks and designs.
- (27) E.Stein, "Assimilation of national laws as a function of European integration, Am J Int L 1964, p.26, quoted in M.Van Empel, The Granting of European Patents, p.23.
- (28) The fact that a two-convention system has also been agreed upon at the same time within the EFTA framework was an interesting development to take into account.
- (29) Van Empel, p.9.
- (30) Van Empel, p.365.
- (31) Brown, Lecture 2, p.4.
- (32) Brown, Lecture 2, p.4.
- (33) In the first meeting of this Conference which took place on May 21, 1969, 17 states were represented.
- (34) The Community Patent Convention has not entered into force as yet.
- (35) Van Empel, p.347.
- (36) D.Lasok, The Law of the Economy in the European Communities, London, Butterworths, 1980, p.269.
- (37) Lasok, p.270.
- (38) Van Empel, p.33.
- (39) Cases 56 and 58/64: Consten and Grundig EEC Commission (1966) ECR 299 at 366, Lasok, p.255.
- (40) Lasok, p.256.
- (41) Article 3(c).

- (42) Article 3(f).
- (43) Hanns Ullrich, "Intellectual Property in the EEC", EEC Commentary, Suppl.7, Dec.1977, p.501.
- (44) Ullrich, p.501.
- (45) The terms 'intellectual property rights' and 'industrial and commercial property rights' are used interchangeably.
- (46) Ulrich, p.503.
- (47) Ullrich, p.518.
- (48) Ullrich, p.519.
- (49) Lasok, p.72.
- (50) Ivo Van Bael and Jean-François Bellis, Competition Law of the EEC, Oxford, CCH Editions Limited, 1987, p.11.
- (51) Van Bael and Bellis, p.22.
- (52) Van Bael and Bellis, p.21.
- (53) Van Bael and Bellis, p.24.
- (54) Van Bael and Bellis, p.32.
- (55) Van Bael and Bellis, p.33.
- (56) Van Bael and Bellis, p.40.
- (57) Van Bael and Bellis, p.45.
- (58) Van Bael and Bellis, p.51.
- (59) Van Bael and Bellis, p.51.
- (60) Van Bael and Bellis, p.55.
- (61) Van Bael and Bellis, p.153.
- (62) Richard Whish, Competition Law, London, 1985; p.358.
- (63) Van Bael and Bellis, pp.11,12.
- (64) George Wright, "Patent and Know-How Licensing", in EEC Competition Law: an Analysis of Recent Decisions and Developments, ed. by Barlo Beckerleg, Oxford, ESC Publishing Limited, 1978, p.2.
- (65) Wright, p.2.

- (66) It was also called 'the Christmas Message' since it contained good news.
- (67) Wright, p.2.
- (68) Whish, p.359.
- (69) Cases 56 and 58/64.
- (70) Whish, p.359.
- (71) Case 24/67 (1968) ECR 55 (1968) CMLR 47.
- (72) Van Bael and Bellis, p.154.
- (73) Whis, p.358.
- (74) Van Bael and Bellis, p.154.
- (75) Whish, p.358.
- (76) Peter Oliver, Free Movement of Goods in the EEC: under Articles 30 to 36 of Rome Treaty, London, European Law Centre Limited, 1982, p.158.
- (77) Van Bael and Bellis, p.155.
- (78) Van Bael and Bellis, p.155.
- (79) Van Bael and Bellis, p.156.
- (80) Oliver, p.159 and also D.Lasok, Intellectual Property, p.683.
- (81) Case 15/74 (1974) ECR 1147 (1974) 2 CMLR 480.
- (82) Oliver, p.160.
- (83) Lasok, Intellectual Property, p.681.
- (84) Lasok, Intellectual Property, p.682.
- (85) Case 35/87 (1988) 3 CMLR 549, in Lasok, Intellectual Property, p.683.
- (86) Lasok, Intellectual Property, p.683
- (87) Case 434/85 (1988) 1 CMLR 701, in Lasok, Intellectual Property, p.684.
- (88) Lasok, Intellectual Property, p.684.
- (89) Council Regulation No.2349/84 of 23 July 1984, Recital (2).

- (90) Whish, p.359.
- (91) Van Bael and Bellis, p.158.
- (92) Case 258/78 (1982) LC Nungesser KG v EC Commission ECR 2015, (1983) 1 CMLR 278. in Whish, p.365.
- (93) Whish, p.363.
- (94) Van Bael and Bellis, p.159.
- (95) Van Bael and Bellis, p.164.
- (96) Whish, p.363.
- (97) Van Bael and Bellis, p.165.
- (98) Whish, p.366.
- (99) Van Bael and Bellis, p.162.
- (100) Whish, p.368.
- (101) Alfons Schäfers, "The Luxembourg Patent Convention, the Best Option for the Internal Market", Journal of Common Market Studies, Vol. 125, No.3 (March 1987), p.197.
- (102) Schäfers, p.197.
- (103) Schäfers, p.198.
- (104) Lasok, The Law of Economy, p.269.
- (105) Preamble of the Community Patent Convention.
- (106) Preamble of the Community Patent Convention.
- (107) Lasok, The Law of Economy, p.274.
- (108) Prof.F.Savignon, "Report on the Results of the Luxembourg Convention", in European Patents at the Crossroads, ed. by Robert R. Pennington, London, Oyez Publishing and New York, Matthew Bender & Co. Inc., 1976, p.14.
- (109) Lasok, The Law of Economy, p.277.
- (110) CPC Article 46(4).
- (111) Lasok, The Law of Economy, p.279.
- (112) Schäfers, p.198,199.
- (113) Schäfers, p.200.

- (114) Schäfers, p.204.
- (115) Peter Marsh, "Pharmaceuticals", Financial Times, 8 Nov.1988, p.35.
- (116) Arman Kırım, "Uluslararası İlaç Endüstrisinin Ekonomisi", ODTÜ Ge-
lişme Dergisi, 14(2) (1987), p.147.
- (117) M.L.Burstall and Ian Senior Economists Advisory Group, The Commu-
nity's Pharmaceutical Industry, London, 1985, p.22.
- (118) Economists Advisory Group Ltd., 1992 The "Cost of Non-Europe" in
the Pharmaceutical Industry, p.9.
- (119) Burstall, p.19.
- (120) Burstall, p.19.
- (121) Prof. Aubrey Silberston, Patent policy: Is the Pharmaceutical
Industry A Special Case?, by The International Pharma Policy Unit,
PJB Publications Ltd., Feb.1989, p.35.
- (122) Peter March "Woorries over the future", Financial Times, 6 Nov.1989
p.28.
- (1237) Kırım, Uluslararası, p.155.
- (124) Burstall, p.8.
- (125) Peter March, "Buzz-word to research tool", Financial Times, 8 Nov.
1988, p.36.
- (126) Daniel Green, "No guarantees of Success", Financial Times, 8 Nov.
1988, p.36.
- (127) Only one-third of R&D expenditures are spent on research, the rest
is for the development process.
- (128) Burstall, p.13 and also Kırım, Uluslararası, p.164.
- (129) Smith Kline Beckman of the US decided to merge with Beecham of the
UK. Merrel Dow and Marion, both of the USA, also agreed to join
forces just like Squibb and bristo Myers, again both of the US. All
took place in July 1989.
- (130) Merck and Johnson & Johnson decided on a joint venture over the OTC
drugs in March 1989 while Merck and Du Pont decided to collaborate
to draw Du Pont more into drugs market.
- (131) Silberston, p.37.
- (132) See section 4.3.
- (133) Daniel Green, "Preventive measures", Financial Times, 6 Nov. 1989,
p.30.

- (134) Joint ventures have been formed between Procter & Gamble and Syntex and Johnson & Johnson and Merck in the OTC sector.
- (135) Kevin Mooney, "Pharmaceutical Patents", 1989, p.103.
- (136) Silberston, p.6.
- (137) Silberston, p.9.
- (138) Arman S.Kırım, "Reconsidering Patents and Economic Development: A Case Study of the Turkish Pharmaceutical Industry", World Development, Vol.13, No.2 (1985), p.222.
- (139) Silberston, p.7.
- (140) Silberston, p.6.
- (141) Evidence related to this subject was collected by CLIP (The Common Law Institute of Intellectual Property) for the mentioned study carried out for the Commission of the European Economic Community. Silberston, p.59.
- (142) Silberston, p.54.
- (143) Economists Advisory Group Ltd., p.27.
- (144) Econ.Adv.Grp.Ltd., 1992, p.93.
- (145) Econ.Adv.Grp.Ltd., 1992, p.39.
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- (147) Econ.Adv.Grp.Ltd., 1992, p.27.
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- (149) Econ.Adv.Grp.Ltd., 1992, p.39.
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- (151) Econ.Adv.Grp.Ltd., 1992, p.42,44.
- (152) Leigh Hancher, "The European Pharmaceutical Market: Problems of Partial Harmonization", European Law Review, (Feb.1990), p.11.
- (153) Hancher, p.12.
- (154) Hancher, p.12.
- (155) Commission of the European Communities, The Rules Governing Medicaments for Human Use in the European Community, July 1987, O.J. 1975 L 147, p.13.

- (156) Commission, The Rules, O.J. 1975 L 147, p.29.
- (157) Silberston, p.55.
- (158) Scrip No.1299, 13 april 1988, p.4.
- (159) Prof.Dr.A.G.Hildebrandt, "Proposal Concerning the Future Authorization System of the Committee for Proprietary Medicinal Products of the European Community", Pharmazeutische Industrie, 52, No.1, (1990), p.75.
- (160) Scrip No.1485, 2 Feb.1990, p.1.
- (161) Econ.Adv.Grp.Ltd., 1992, p.84.
- (162) The differences in price may result from low production costs government controls on prices and exchange rate movements.
- (163) Econ.Adv.Grp.Ltd., 1992, p.85.
- (164) Scrip No.1492, 28 Feb.1990, p.1.
- (165) Scrip No.1492, 28 Feb.1990, p.1.
- (166) Case 15/74 (1974) ECR 1147, (1974) 2 CMLR 480.
- (167) Case 187/80 (1981) ECR 2063, (1981) 3 CMLR 463.
- (168) Van Empel, p.96.
- (169) Van Empel, p.97.
- (170) Mooney, p.103.
- (171) The Only existing patents are process patents which are easily circumvented.
- (172) Mooney, p.103.
- (173) Oliver, p.161.
- (174) "Memorandum", p.5.
- (175) Mooney, p.109.
- (176) Scrip No.1490, 21 Feb.1990, p.1.
- (177) Scrip No.1490, 21 Feb.1990, p.1.
- (178) COM(90) 101/2 O.J.1005 - 28 March 1990.
- (179) COM(90) 101/2 O.J.1005, p.4.
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