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PHARMACEUTICAL BUSINESS STRATEGIES: COMPETITION BETWEEN ORIGINATOR AND GENERIC COMPANIES IN EUROPEAN UNION AND ITS RELATIVE IMPACT ON INDIA.

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Abstract:

The historical paradigm of unified patent system in Europe is traced back from 1949 where it was realized that harmony in patent laws is important for establishing refined relations amongst the European masses. Incentives are necessary to have better technical innovations and fragmented legal framework would not suffice in incentivizing the rational economic behavior. The filing of separate application in different countries indicated the unreasonableness of the process and difficulties faced by innovators in the according compliance to the process. Not just a separate application was required to be filed rather there were no uniform standards over which different patent offices were examining the patent and the practiced procedures were also different. The system lacked coherence in terms of standard patentability requirements & standards. To address this coherence in the patent system Council of Europe sought to introduce some changes which in turn will make the process easy for the innovators and less hectic for the patent office to examine the same patent in different country with different procedures and standards. This European Idea of Patent system lead to adoption of two conventions, one conforming consistency in certain patent application formalities and other stepping ahead towards an International classification system.

Key words: Conventions, Innovators, Incentivizing, Standard Patentability, Unified Patent System.

PATENT LINKAGE SYSTEM IN EU

EU Pharmaceutical policy focuses primarily on the harmonization of drug regulations across all Member States. It's targeted at creativity, economic integration, market access and public health, among other issues. There have been various multinational branded drug companies located in the EU. It is significant to observe that while it is home to different branded companies, the viewpoint of the EU is that the patent connection system inhibits generic entry, which in turn will have an effect on drug accessibility.

The European Medicines Agency (EMA) is the agency for the approval of drugs according to EU law. It doesn't allow marketing authorization to be associated to the patent position of the optimized formulations of reference drugs with that of the originator. Article 81 of the EC Regulation and Article 126 of the EC Directive stipulate that the approval to manufacture a medicinal product must therefore not be denied temporarily suspended or permanently revoked except for the reasons set out during the Regulation and the Directive, where market approval is not connected to the designation of a patent.

Nevertheless, by providing long-term data exclusivity, EU incentivizes the involvement and attention of the originators. For a novel chemical entity the EU has the longest data exclusivity period in the world. The new EU Directive adopted in 2004 developed an integrated EU data exclusivity provision for eight years with an additional two-year market exclusivity requirement. This successful market exclusivity of 10 years may be expanded by an extended one year (maximum), if there is substantial progress in new drugs in just the first eight years of those ten years. This pattern of exclusivity for 8 + 2 + 1 years refers to new chemical entities in all EU member states.

As a result of data exclusivity, the generic market authorization application can only be submitted after 8 years, and the drug can only be sold after 10th or 11th year. In each Member State there is a national drug approval procedure, as well as the EC Directive. Unlike the EU, the US model provides for a shorter data exclusivity period with patent connection. As a result, some European firms choose US as their principal place of operations. Nonetheless, several EU countries used the Patent Linking scheme. In Hungary, Article 7(9) of the Ministry of Health Decree necessitates generic companies seeking marketing authorization to claim that they do not infringe any patent right and therefore will not promote the product until the patent has expired. Portugal and Slovak Republic have also enforce patent linkage.

Similarly, a drug promotion agency in Italy needs a generic product assurance that the promotion authorization does not encroach upon any patent. Originator companies will pursue legal action for marketing authorisation towards generic companies. In Portugal, originator firms will sue generic firms to get marketing authorisation. For Slovak marketing authorisation comes into the equation only after patent expiration.

In EU even if there is no express recognition of Patent Linkage System to make the Pharmaceutical Environment slightly pro-innovator still the balance is maintained by incentivizing the innovators through extensive data exclusivity of 10 to 11 years and Supplementary protection certificate and letting the generics obtain marketing approval once the data exclusivity period is over to compete in the market along with brand drug manufacturers. But this non-approval of Patent Linkage system lead to innovators indulging in strategic patenting for increasing the age of their patented drug and impeding the generics in their entry to the market which ultimately hampers competition leading to an interface between the two laws.

EUROPEAN PATENT SYSTEM: REQUIREMENTS FOR PATENTABILITY

One of the prime elements of new European Patent system is that by virtue of the Convention on grant of European Patents, filing of one application for grant of patent in all regimes and a uniform patent granting procedure has come into place. This does not mean that all the contracting states are patent bound in the new system but there still exist limitation to the extent of the designated states in the patent application. This means that the entire European Community is not bound by that uniformly granted patent.

The underlying limitation of this system is the core operating base to be national laws of different countries due to which their lies a perpetual discordance in the national patent laws which inventor has to go through with varied treatment of the same subject matter. Hence, even the revocation and infringement cases will be dealt applying varied procedures which lead to distinct outcomes. This implies that for getting the remedy for infringement one might necessarily do that country's visit which is an expensive task thus discouraging the practice of obtaining protection in EU regime by smaller innovation firms and also not disputing the fact of infringement of their patent due to inherent difficulties in the procedure. The base of European Patent system lies on the two treaties i.e. the Paris Convention for the Protection of Industrial Property (ParC), the Patent

Cooperation Treaty (PCT). This research work is confined to the Patent Cooperation treaty only.

EUROPEAN PATENT CONVENTION

It is seen that EPC by far has regulated only few stages of patent grant application i.e. pre-requisites and rules regarding the application, examination of that patent and final grant of patent protection whereas in order to obtain a European Patent there are two phases of evaluation of application. The first phase commences when the application is filed by fulfilling all the requirements and is hence granted by European Patent Organisation (EPO). In this application it is important for the applicant to designate the states he wants protection to be granted in. Then according to the states designation, a designation fee is payable in accordance with the states in which he is seeking protection.

Second phase of the application has a different prospect of supervision. It is the authority of the designated country's which preside over the application in process. This is important for granting of validation to the patent in the designated country as per their requirements. This point establishes the fact that the process of granting validation is not only restricted to validation given by EPO but by the authorities of other designated countries as well as per their requirements for the patent application. This is an open for all convention which gives right to all the individuals to seek European patent.

The regulatory framework of EPC as given in Art 2(2) articulates that the patent granted shall have the same effect and would be subject to the same conditions as a regular national patent in the contracting states as well, if nothing contrary is provided in the EPC. This provision makes the point clear that though EPC and the respective national laws do not share the same domain but still the convention extends to provide a minimum protection which shall not be subject to the national patent provisions. For instance- protection conferred to the act of patent infringement are the basic minimum which shall be constant as per 64(3) EPC.

While recognizing the effects of the European patent, EPC sets its requirements from the national laws as; firstly dealing with Art 63 EPC which talks about the term of the patent which is given to be 20 years from the very date of filing but provides an extra hand to contracting states as they can go on extending this term provided statutorily or may also grant protection which shall follow corresponding to the expiry of the patent, thus the extent of protection is not limited. Secondly, it

talks about Art 138 EPC which deals with revocation of European patents and lists the specific grounds on which revocation can be done. Lastly Art 69 is taken herein which asserts that the determination of extent of protection is analogous to the claims and for claims shall be further determined being in correspondence with tools and drawings.

To determine the patentability of an invention, there are few requirements to be fulfilled. Substantive examination is carried on of the patent application to examine whether the patent applications fulfils the basic requirements of granting procedure. When the application moves to examination procedure it lays down four criteria's to be complied with.

PATENTABILITY REQUIREMENTS

The basic patentability requirements are highlighted in Art 52 of EPC

"European patents shall be granted for any invention, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application."

Thus the requirements highlighted herein constitute the basis of whether the patent application is contributing something novel and is innovative enough to grant betterment in human life and experience. These are commonly accepted requirements by virtue of Art 27(1) of TRIPS but the difference from country to country lies in its interpretation.

TECHNICAL CHARACTER

Its the very first requirement provided in the definition that the invention shall have a technical nature. EPC Rules on technical nature are additive to Art 52 EPC and thus the rules ascertain that in order to determine whether an invention has technical character or not it should have some technical contribution to a technical problem and this solution to the problem is easily got through by the use of that invention.⁴⁶ But here we are dealing in the realm of Pharmaceutical Patents where what shall constitute as technical character is the very therapeutic nature of that drug which shall give technical solution to a technical problem. What constitutes an invention here is the property that the drug possesses and the therapeutic effect it has on the patient. The derivation of desired technical effect would be established by the clinical testing of the drug and if this testing establishes that the drug offers the biological solution to the desired problem its said to have the technical character.

NOVELTY

Novelty of the patent establishes its uniqueness and gives a reason for letting something new have a monopoly for certain period which might encourage others to move on the similar lines. Art 52(1) establishes the concept of novelty as a patentability requirement whereas Art 54 tells that what constitutes a novel invention that which stands alone from the state of the art, this article also explains further as to what all shall constitute state of the art. Everything which is already known and is there in public domain is labelled as state of the art. For an invention to qualify the criteria of novelty it shall have at least one technical novel feature which distinguishes it from the rest. In pharmaceuticals whether the new compound or the New Chemical Entity (NCE) qualifies for the test of novelty is seen on the basis what addition is done by it in the already present state of art. What is novel about it, the drug formulation, the way of administering it etc.

INVENTIVE STEP

This stage comes following the establishment of novelty test. An invention necessarily needs to have an inventive step involved which is discussed in Art 56 EPO. This article asserts that the invention shall be in variation with the obviousness to any person skilled in the art. It is the non-obviousness of that invention which clarifies it having an inventive step. Inventive step requirement helps in the taking up the development process further. For Instance- Mere following up for what is existing in the state of art has no value. Patent values the new biological effect of any drug through its R & D, not a mere follow up by no improvement in the therapeutic results and the pharmaceutical technology innovation.

INDUSTRIAL APPLICABILITY

Art 57 EPC discusses about the issue of Industrial Applicability where it looks upon the invention and analyses if the invention is actually able to be applicable in the industry. Any addition it would do in the practical arts would lead it to be capable of industrial applicability.

SUPPLEMENTARY PROTECTION CERTIFICATE

This certificate basically deals with the patent term and provides an opportunity to the originators in stretching the patent term of their medical products in the market but it operates as an impediment to the launch of generics as due to the extension of the term none can copy the original

drug. This certificate grant is an express step to incentivize R & D as the original drug formulation costs a decent amount of time & expenses. One more reason to justify the reasonableness of this certificate is the time elapsed from the stage of filing of application to the grant of patent. This certificate is specifically granted for one state which grants patent, so it shall be taken from each member state while the patent grant and thus is not uniformly available in all nations.

Its important to address that SPC rewards the similar benefits during the extension period as are given by the patent protection but the pre-requisite for the grant of SPC is that a drug shall have been authorized to be in the market. There is a time duration of six months given from the authorization of drug to be in the market in which an originator shall apply for SPC. This certificate has the effect from the day when patent expires and there is a loss of exclusivity. There is a formula provided for the calculation of duration of SPC that is the duration elapsed from the date of filing of patent application to the first marketing authorization in the community, minus five years. Although the maximum duration of SPC is already fixed for five years from the patent expiry. After expiry of the exclusivity granted by SPC, generics are free to compete with the original products.

COMPETITION LAW IN EU

The Competition law advocates for the prevalence of healthy competition in the relevant market which is beneficial for the consumers security and for enhancing efficiency of other competing agencies as well from combination which might take up the whole economic power in their hand. European Union exercises its complete control in its dealing with European Competition law. The major competitive policies covered by the European Union Competition law i.e. agreements between the companies that are anti-competitive in nature and that tend to impede competition, cartels or agreements that might turn up making market as one single unit and leaving little room for competitive activities ,abuse of dominant position, combinations leading to monopolistic practices and state aid. In Pharmaceutical market the practice of extending the market position by few players in the market or increasing the market share shall amount to the deprivation in the competition by price setting agreements.

The very object of this thesis would revolve around Art 102 TFEU. This article expressly prohibits the abuse of dominant position by few undertakings and lists what constitutes abuse i.e. unfair trading conditions, applying dissimilar conditions to equivalent transactions etc. The essence of

this article prohibits merely the abuse by the undertaking gaining the control of market power and not the monopoly per se.

THE CONCEPT OF ABUSE OF DOMINANT & MONOPOLY POSITION

Art 102 only talks about the undertaking that obtains the dominant position in the relevant market prohibits only the behavioral abuse the undertaking having monopoly. Though the abusive practices are listed in the article but that does not form an exhaustive list rather only specifies certain examples of abuse.

The article does not within its meaning specify as to what constitutes dominance but its interpretation is done by the market control taken over by the undertakings and thus prevent effective competition due to the occupation of economic strength. In the case of Hoffman La Roche, It was asserted by ECJ that relevant product market is having a very wide interpretation as to include within its ambit interchange ability between the products belonging to the same market. The products can be substituted by the consumers in the product market on the basis of demand substitutability and by the potential suppliers on the basis of supply substitutability. European commission has established a test for analysing demand substitutability and its effect upon the competition in the market. SSNIP test focuses on the effect of cartelization or monopoly on the increase in the price of the product up to some percentage with no improvement upon the product and keeping up with conditions of sale. This test concluded that if due to availability of better versions of competitive product in the market and product switching is done by the sufficient amount of consumers then the increased price by the dominant undertaking would not invite for Competition scrutiny.

The most crucial attempt to define the relevant product market was done in the case of United Brands Continental v Commission case where United Brands Continental was aggrieved by the fine imposed upon the undertaking by the commission and brought the matter before ECJ seeking for the revocation of the decision. In the appeal the point brought forth was that commission's definition of product market and how undertaking interpreted it was too narrow for the cause. UBC undertook the market share of 35 percent of world's banana exports and thus constituted the definition of relevant product market as the market is specifically for bananas and including all the soft fruits within it would be to generalize the notion. It was held by ECJ that, since the

consumers associated with the banana market are relatively large and the demand of banana is comparatively higher than other fruits hence the substitution of banana market cannot be done with the other fruit market.

Now in dealing with Art 102 TFEU we need to have a clear idea of geographical market as the dominant position of an undertaking and then abuse of that dominance would be restricted to that geography per se as the article suggests that substantial part of the common market needs to be considered. For considering the relevant areas under the geography they shall be possessing similar conditions of market and not the result of the competition.

DOMINANCE OF AN UNDERTAKING WITHIN THE SUBSTANTIAL PART OF THE MARKET

In order to attract Art 102 TFEU its important that the market economic dominance of the undertaking shall be within substantial part of the common market. This analysis of whether its a substantial part of the common market or not has to be done in the light of the specific market of product and not the geographical area concerned with the market.

This point of determination of substantial part was done extensively in the case of Suiker Unie. The fact scenario herein is quite complicated as it involves 16 applicants who were aggrieved by the decision of the commission by imposition of fines and ceasing the order taken up by the undertaking. It was alleged by the plaintiffs that plaintiffs were in a dominant position by virtue of their sugar production in Luxembourg and Belgium, which was in the eye of commission constituting a substantial part of the Common Market. To this court held that since what is important to take into consideration herein is he specific market of the product. Sugar production and consumption in the specified areas and sale and purchase dealing of the product in that area constituted 15 percent of the total market and hence considering the volume and pattern of sugar production it was held that such significant market share necessarily constitutes a substantial part of the common market.

WHAT CONSTITUTES ABUSE OF DOMINANCE

Since its clear that the basic tenet of abuse lies not in sole dominance of the undertaking in the market rather the behavior of the undertaking in the economy after acquiring the dominant position and its effects on other competing partners and consumers is where abuse is brought home. When the market structure in particular is hindered or put in jeopardy due to an undertaking acquiring dominance and weakening the degree or further growth of competition.

Here the emphasis also lies upon the special responsibility which Dominant undertaking withholds by virtue of being in dominant position as that not prohibited per se. So the undertaking acquiring dominance has to maintain its conduct of such sort that competition in no way shall be hindered or distorted. The undertaking can surely take care of its interest but a conduct beyond that would be deemed to unfair due to its position in the market.

Though abuse can take various forms and can be done in various way. In this paragraph only few practices are highlighted to clear the context. If the dominant undertaking involves in practices where the entry of new product is being hindered by its conduct where there is potential consumer demand for that product would amount to abuse. Another such practice to eliminate or jeopardize the competition is Predatory pricing by the dominant undertaking to do away with the competitors offering their products on fair competitive prices by selling their products at the minimum price or the lowest possible price at the cost of short term loss-making to attract the customers. But the prime objective involved here is to suddenly raise the prices above competitive levels when no player in that relevant product market is left and that ultimately harms the customers. Seeking such an advantage of dominant position leads to abuse.

APPLIED PATENT STRATEGIES DURING THE DRUG LIFE CYCLE BY THE INNOVATORS & COMPETITION INTERFACE

The competition in pharmaceutical sector began to be regulated and investigated in 2008-2009 when the European commission indulged in Pharmaceutical sector inquiry. It lead a step towards conducting inspections of various innovator and generic companies and inspections directed towards focusing upon the barriers in entering the market by generics. Here the applied conduct of innovators were under the scrutiny of European Competition Law by acknowledging the fact

that legality of such behaviors to impede the generic entry might be challenged.

During the drug life cycle there are multiple phases involved before the original innovation drug reaches the market. The primary division can be done into three phases wherein the first phase involves R & D of the drug before its launch and the regulatory approvals attached thereby. Secondly, the period of exclusivity enjoyed by the originators by virtue of patent protection of their drug and putting the drug into marketing and sales phase. Third phase comes up when the particular original drug loses its exclusivity and the generics start to enter the competitive market due to the patent expiry. The initial two phases are of extremely great importance to the innovator company, as they seek the maximum profit in these two phases from their patented product which in turn helps them to finance the expenses incurred in R & D and NCE which had failed during the test process. In all these phases different strategies are adopted by the innovator companies with respect to generic entry in the relevant drug market. Its possible for originators to turn up to these strategies by the backing provided to them by the patent law system. These strategies weigh too much for the originators for the retaining their market position which can sometimes be dominant.

Measures vary in their form according to the phase in which they have their original product such as taking precautions of the time and scope of filing by strategic patenting, patent litigations and putting their submissions before National regulatory authority. Product switching by laying emphasis upon the follow on product or enhancing product loyalty. Now the strategies also seek the possibility of generics entering the product market even before patent expiry by finding loopholes in the protection granted to the drug or challenging the validity of the patent and if they succeed then the generics can successfully enter the market before the patent term expires.

SECOND GENERATION OR FOLLOW ON DRUGS & INFLUENCING MEDICAL FRATERNITY

Follow on drugs are such which are developed upon the original product but are structurally distinct enough to get patented. These are strategically made by improving structural formulations in order to extend the patent protection term which is nearing expiry. These are introduced some few years before the patent expiration sothat the switch which is done over the product takes place well to market it amongst the consumers. The idea to capture the relevant drug market by a follow on drug can only be accomplished if the drug offers sufficient clinical

advantage.

Innovators also indulge in practices where they earn the trust and loyalty of doctors and pharmacies for prescribing their drugs as the consumer in the pharmaceutical domain does not have a direct choice rather blindly goes upon the prescriptions of doctors and pharmacies. Hence conquering the support of these two bulwarks can lead to enough marketing of the innovator's drug by default and it also becomes one of the reliable choice for consumer due to which they gain implied monopoly in the relevant drug market.

PATENT CLUSTERS

The clustering of patent happens when numerous number of applications are filed for seeking the patent protection due to the different patent claims. The variation in claims might be there on the basis of the dosage of a particular drug, the process of its production or different pharmaceutical formulations. But the essence of this whole process lies in it possessing the same NCE. If one of the patent is challenged by the generic company and it succeeds in the suit then also it cannot enter the market due to several other patents obtained on various other claims of the same drug, This practice by the originators is called 'multilayered defense'. This is one of the biggest barriers for entry of generics as when several additional patents happen to be there on the same drug in the course of the base patent protection, there is a certain increase in patent protection term and the following SPC term. Its for the commission to be cognizant of all the additional applications filed due to different claims over the base patent for a given NCE.

DIVISIONAL PATENT APPLICATION

This strategy brings in the confusion and uncertainty among generics because they are unsure of the what patents have been granted or revoked and which patent claims are still pending over the same NCE. In a divisional patent application, the 'parent application' and 'divisionals' are separated by the applicant from the main patent application. It can only be done when the scrutiny of parent application is still unresolved. Once the divisionals are culled out from the main patent applications, then they operate as a separate application altogether having no nexus whether the parent application have been granted patent or is revoked. This is merely to put the generic entry on hold for quite long period of time. Divisional applications give the originators more time while they are pending and there is a period of legal uncertainty as to which part of the patent claims

have been granted patent protections and what all claims are pending as each of the divisional application needs individual assessment. Hence this invites a lot of uncertainty among generics as to use of what part of the drug would constitute infringement and what not and hence their entry into the market is delayed by default.

PATENT LITIGATION

In this case the generics tend to make AT RISK ENTRY into the market by producing the generic versions of original drug. In such cases the originators take a different path by taking up the procedural enforcement strategies which step up to the path of patent settlements or patent litigation further. Why patent litigation is looked upon as one of the efficient strategies is due to the fact that during the litigation period the originator can seek for temporary injunction which in turn will restraint the generics to enter the market and sell the drug until there is a final decision given on merits. But for the issuance of injunction the originator needs to appraise the court with the grounds for its claim of the Enforcement Directive.

DEVELOPMENT OF PATENT PORTFOLIO

The patent portfolio is made stronger by taking up the patent on follow on drugs, which is an applied strategy to extend the patent protection term beyond the pure patent strategy which is inclusive of various other aspects like marketing and production. Herein the main focus is just on the improvement over or developing upon the already existing drug which might be called as a follow on product of the original drug but are seen as important improvements to satisfy the needs as the invention need not necessarily be a NCE. For instance the applicability of a follow on drug can be seen as useful and enhanced if the development upon it makes its administration process easier like from being an inject able fluid to a drug which can be swallowed, then there will be a switch of the product from original NCE to the follow on drug.

All these five strategies adopted by the innovators lead to the situation where patent law is providing a backing to such acts but when these acts are applied in pharmaceutical market they are directly coming into interface with EU Competition law.

THE ASTRAZENECA CASE

FACTS-

AstraZeneca AB of Sweden & AstraZeneca Plc (hereinafter AZ) of the UK were imposed heavy fines by the European Commission in its decision for abusing the dominant position over the blockbuster drug Losec basically meant for treating the acid related gastro-intestinal diseases. This drug was one of the best selling drugs in the constituting a turnover of 63 billion dollar. The superseding drug which was of second generation was named as Esomeprazole which was claimed to have improved efficacy and therapeutic benefits over the original drug so it was intended by AZ that the patents shall be switched to the new product. This follow on product was developed but the switch was a time taking process and the patent term of the original product was about to expire and it was likely that generics gets launched and if the product switching happened after the launch of generics then AZ would no more have market dominance with its switched patent and there will be huge prize difference between the secondary product of AZ and generics. Now this time gap had to be resorted between the patent expiry and secondary product launch , so for this 'bridging strategy' was applied the originators. This involved drawing out of the marketing authorization of the active ingredient Omeprazole, which in turn would have the effect of eliminating the reference drug so what shall constitute the substitution for generics which they were needful of while procuring market authorization for themselves.

The administration technique of the original drug Losec was changed due to which a follow-on product was developed in place of it named as Losec MUPS tablets, this swifter development upon the original drug also resulted in delaying the generic entry for some time. Above all of these strategies, AZ applied for SPC which will grant more addition exclusive period to it and more time to switch. The Commission while holding AZ responsible for unfair conduct and abuse its conduct by being in dominant position is due to taking into consideration all these strategic applications for extending the exclusivity period. The Commission gave two bases for coming to te adoption of such a decision which are-

- (i) There was a misuse done by AZ of the patent protection provision by seeking for SPC to extend the protection for some additional period.
- (ii) By playing strategically with the market authorization criteria for generics AZ misemployed the withdrawal of its own original product and also embezzled with the

pharmaceutical regulatory system.

FIRST ABUSE:

The first abuse determined by the general court was regarding the misrepresentations made by AZ for seeking SPC certificate to the patent offices of various member states. The misstatement was regarding the date of the market authorization which was one of the core rounds for calculating the term for which the SPC certificate has to be granted.⁸² This extended exclusivity is granted from the date of the grant of marketing authorization for the patented drug. Since the dates were misstated in different member states as there are divided into three dates; '1982-states', '1985- states' and '1988-states' and then the determination would be done on the basis of first date of marketing authorization. So, in order to obtain SPC AZ misrepresented that the first authorization date was in 1998 Luxembourg whereas commission found it to be in France 1987. This implied that for seeking addition patent term protection for Losec AZ has wronged the whole patent system of the Union and deliberately excluded the generic competition. The court therefore held that employment of such strategies hindered the competition and no submission on the part of AZ could be entertained as it was truly a deliberate conduct to mislead various member states to obtain SPC protection.

SECOND ABUSE

The second listed abuse was misemploying the rules of national regulatory authority for the purpose of misdealing with grant marketing authorization regulations. The generics have been given the leverage of not getting into clinical trials for the bio equivalents of the original drug hence are given allowance for using the clinical information from the test of the original product and do not need to conduct these tests by themselves. Due to this reason, for generics the already available data of tests conducted for the original drug is the major reliance for obtainment of marketing authorization for their products. It is due to this reason that that it was found out by the court that deregistering was a step not required for the introduction of Losec Tablets in the market. Also the undertaking acquiring the dominant position in the market has some special responsibility and has to take care of its conduct necessarily. Its conduct should not hamper the competition in the market but here in this case the undertaking made use of the whole regulatory process itself to delay the generics thus this act is no way objectively justified. Thus it was concluded by the general court that the conduct of AZ here itself was condemnable as it withdrew the data so that generics have no reference medical product which was essentially seen as not competing on merits.

CONCLUSIVE ANALYSIS OF JUDGMENT

This judgment shows a very detailed interface of European Union Competition Law & IPRs in context of Pharmaceutical framework. This ruling also holds significance since in this judgment all the applied strategies by AZ were critically looked upon by the commission and it was held that any strategy which hampers the potential and effective competition in the market would be faced by strict measures to overcome such impediments upon the competition.

This judgment has challenged the very legality of these applied strategies by originators and has brought them on the ground that any imposition or implied constraints on generic market due to the application of these strategies would not be appreciated. It is stated specifically in the judgments that it is legitimate for the originators to protect their legitimate interest in the commercial market when they see and impending danger from generics but strategically doing away with that danger by mend ling with the regulatory framework and withdrawing the data available to not let generics pass the stage of marketing authorization even has no objective justification.

Since the provisions of data exclusivity are already available so protecting any data which is a result of extensive R & D beyond the exclusivity period does not fall in the legitimate conduct.

CONCLUSION OF STRATEGIES LEGALITY

The reason why it is important to determine the legality of the of these strategies is the fact that these applied strategies being well within the contours of IP law still are seemed to be infringing the competition law. So, when these applied strategies are applied by the innovator companies, a vacuum is formed where there occurs no correspondence between IP Law & EU Competition law, hence it becomes primary to determine the threshold of application of these strategies as to when can they be applied without attracting penalty.

The object of this study is to decide the legitimacy of the strategies applied by the originators, and it can be described in simple terms; the legality of the strategies is currently ambiguous and unclear.

The originators' applied practices are legally, quite often, under patent law but, illegitimately, far too away from EU competition law. How so? For what? The rationale for this deformity is due to

the two legal disciplines not being in connecting correspondence.

The techniques are applied to shield their products from generic competition by the originators. Different types of strategies are applied, for example where the originators build patent clusters which mean that one product is covered by multiple layers of patent protection they deprive the market of potential competition and the consumers of their rights to have variation in the relevant drug market by practicing the formation of such patent clusters. Some other illustration is to build up a follow-up product of the original drug with a view to prolonging the first drug's lifetime. The strategies can, however, constitute violation of EU competition law, and are therefore unlawful. The difficulty in deciding whether or not a technique constitutes competition law violation is indicative of the fact that it's legal under IP law. The IP law grants the originators legal protection for their innovations.

Yet, at around the same time, as they exercise certain rights, the originators will infringe the rule. In the AZ case, the European Court asserted that any behaviour that 'may' just stifle competition, irrespective of its validity under other laws, entails a violation of the antitrust law.

The word "may" is one aspect of the nature of the issue, because the courts do not offer sufficiently specific explanations why IPR practice conditions constitute an infringement of competition law. The declarations in the rulings result in the originators' ambiguity about the level to which they can protect their drug.

To sum up, competition between drug firms must be fostered so that generics can reach the market during the prescribed timeframe, resulting in costs being reduced for the benefit of consumers and public wellbeing in general. Competition law must be applied to keep that effect as far as probable. However, careful consideration should be given to the originators of their huge R&D costs, and even the time-consuming aspect. Therefore, the inventions of originators must be sufficiently covered under the law to make R&D feasible and productive.

As discussed earlier in this thread, there are developments that the creators suggest relocating their facilities outside of Europe. The expectations of the European Court when reviewing the patent policy are to encourage competition and guarantee that the conduct of the originators does not result in a limitation of trade or in a hindrance to generic entry. There is therefore no independent corroboration on the healthcare market of the long-term effects that this implementation of the

law would have. If the originators believe they are not utilizing their protection, they will want to relocate their business outside the European Union. For this reason, it is currently important for EU legal bodies to carefully examine the potential dangers of their application of the law. The aim can not be to promote competition at all costs, at the detriment of intellectual property protection to new innovative products. Furthermore, while they may have believed themselves to do so in previous decisions, the courts must have explicit judgments where the criteria for what constitutes abuse of dominant position are evident. This implies that both the originators and the generics are more willing to adjust their business effectively to the laws and regulation.

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