INTERFACE OF IPR AND COMPETITION LAW: IMPACT ON ACCESS TO MEDICINE

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INTRODUCTION

Competition issues in pharmaceuticals largely pertain to the area of prescription medicines. It must be noted that there is an inherent development dimension in the application of competition law and policy to economic activity and its application to the p harmaceutical industry is more so important. The pharmaceutical industry is an important source of health care for billions of people globally. Hence, it is a highly regulated sector. The pharmaceutical industry is influenced by a host of practices which may primarily relate to price regulations, insurance and reimbursements, drug procurement by government agencies, patent laws, innovation polices, biotechnology and safety policies, drug regulation, data protection, trademarks and use of international non-proprietary names, drug promotion regulation, drug advertising regulation etc. Hence competition law has to work in tandem with all such diverse set of laws, polices and regulations governing the pharmaceutical sector. The legal and policy issues raised by intellectual property have attracted increasing attention from policymakers around the world. Modern advances in technology have created classes of products and processes that present new challenges for patent and competition authorities. The Intellectual Property Rights (hereinafter IPR) awarded under patent law gives exclusive rights to an innovation which are limited in scope and duration and attempt to strike the appropriate balance between these competing concerns. Competition law impacts on the exerc ise of those rights, and therefore on the innovator‘s reward, by restricting certain practices involving the IPR. The IP grant seeks to protect property rights, and, in so doing, limits competition. In contrast, competition law generally has reflected the premise that consumer welfare is best served by removing impediments to competition. However, this previous short–run view of competition authorities has been replaced by a long–run view, which acknowledges that technological progress contributes at least as much to social welfare as does the elimination of inefficiencies from non-competitive prices. There is, therefore, a growing willingness to restrict competition today in order to promote competition in new products and processes

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tomorrow. Thus, IPRs and competition policy are now seen as complementary ways of achieving efficiency in a market economy. In this literature two patent instruments are considered, the length of the patent grant and the scope (or breadth) of the patent. While patent length establishes the extent to which firms have exclusive rights over their own inventions, patent scope establishes the extent to which a pioneer has property rights over related inventions. That is, patent scope dictates how similar imitations can be to the original innovation without infringing the patent grant. If patent scope is narrow, then firms may develop a close substitute, for example, through small chemical changes in a drug‘s composition. For patented innovations, patent law ensures the existence of property rights, while antitrust policy restricts the exercise of those rights. While the rules or guidelines for competition policy explicitly acknowledge the rights provided by patents and the benefits from diffusion from particular licensing restrictions as well as the possible adverse effects on prices, they are silent on whether competition policy should evaluate the impact that the licensing restriction may have on incentives to innovate. The role that competition policy should take in promoting research and development is more contentious. The belief is that competition is the best approach for innovation and to save consumers money. In the pharmaceutical industry, the first generic competitor typically enters the market at a price that is 20% to 30% of the brand name counterpart and then gains a substantial market share in a short time. After six months other generic companies can enter, meaning a discounted price of about 80% of the price of a brand name drug, with generic sellers capturing 50-90% of the market. In a typical pay for delay settlement, the branded manufacturer will pay the potential generic entrant an amount of money, in exchange for the generic company delaying its entry into the market. In the absence of an exclusionary reverse payment or a pay for delay settlement, the generic companies could be expected to enter at an earlier date. In effect, these agreements allow the brand name company and the generic firm to share the excess profit that should have gone to consumers. Competition authorities should focus on the behaviour after patents have been granted, rather than questioning the granting of monopoly rights through allowing the patent in the first place. A less competitively distortive means of incentivizing innovation could be the use of innovation prizes, where large sums of money are offered for certain types of discoveries, e.g. a cure for neglected diseases.

The innovation should not be inexorably tied to IP rights, and a significant amount of valuable innovation is never patented. There are other means of incentivizing innovation, e.g. through the trade secret regime or contractual protections, and in some cases technology

moves too quickly for patenting to be worthwhile. However, in terms of prizes or government funding, research suggests that these methods are not as effective as IP rights. Given the substantial amount of investment necessary in pharmaceuticals, the prize fund would have to match this. The prizes would also become distortive and drive innovation towards the prize regime, rather than more valuable goals. An example from Italy will explain the impact of patent policy on competition. Patent coverage is more extensive in Italy, resulting in a distortive effect on competition. Legislative intervention gradually reduced this supplementary patent coverage by six months every two years until the Italian legislation aligned itself with other European legislation. Incentives are distorted as pharmacy distribution margins are fixed by law as a percentage of the price of the product, and as a consequence pharmacists have an incentive to sell higher priced drugs. Suggestions for rectifying this include moving to a fee for service remuneration system or requiring doctors to write the active ingredient on the prescription and not the name of the branded drug. Competition Authority should judge the negative impact of patent related trade practices more seriously and should intervene accordingly to minimize the anti-competitive effects on the market.

WHETHER IPR AND COMPETITION LAW ARE IN AGREEMENT OR DISAGREEMENT?

The premise of intellectual property rights is to recognize and reward the innovators and creators of intellectual work, encourage industrial and technical progress as it spurs invention and innovation. It also infuses efficiency and stimulates competition in new products, new markets and new technologies which is the life-breath of market driven economies; the consequential positive impact of which is felt by the consumers as well. On the other hand, competition law and policy also have a vital role to play in market based economies, as they usher an environment of free and fair play of market forces. They carve space for new entrants in the market by putting restraints on monopolistic anti-competitive behaviour of dominant enterprises and by checking collusive tendencies. They function on the touchstone of consumer welfare and economic efficiency. The ability of IPR owners to charge above marginal cost derives from the exclusivity/monopoly which they are granted. This is not necessarily a monopoly in an antitrust sense, but it does limit competition to a great extent. The effect on competition depends on the nature and extent of IPRs granted and the extent to which close substitutes are, or are likely to be, available. For example, patent rights provide exclusive rights over ideas, whereas copyright only provides protection against copying

particular expressions of ideas; so, patents are likely to have a much greater impact on competition than copyright. Hence, it is likely to be much more difficult, and require considerably more sunk costs, to produce a substitute pharmaceutical product without breaching existing patent. The nature of competition problems arising from IPRs include excessive prices, price discrimination and raising barriers to entry in both the immediate and downstream markets through licensing arrangements, brand loyalty, pre-emptive patenting and restrictions on access.

At the highest level of analysis IPR and competition policies are complementary because they share a concern to promote technical progress to the ultimate benefit of consumers. Firms are more likely to innovate if they are at least somewhat protected against free-riding. They are also more likely to innovate if they face strong competition. The problem is that even completely legitimate use of IPR can restrict competition at least in the short run, thus producing a trade-off between the benefits of increased competition and the gains from further innovation. Such a trade-off probably lies outside patent office mandates, and is inherently difficult for competition agencies to address. This problem could be aggravated by competition agencies taking a strictly short run view of competition. Such agencies, however, are increasingly adopting a dynamic view especially in the high-technology industries where IPR can play a very important role in the competitive process. A common thread runs through competition policy and intellectual property law as they intersect at the point of fostering innovation, efficiency, consumer welfare and economic growth. Yet, an inevitable gap exists in the sphere of ―monopoly rights‖ which is the essence of IPR. While an individual IPR may have several substitutes and not pose competition problems, the aggregation of IP may create market power. This is particularly likely to occur in a country where the original IPR are located overseas and ownership may be dispersed, but a single company acquires the licenses to manufacture and distribute a range of competing products. Another area of concern regarding the aggregation of IPR occurs where rights are collectively administered. Concomitantly, the abusive exercise of these very monopoly rights is antilogous with the undisputable views of competition policy. The monopoly rights as granted by IPR could lead to substantial market power (though not necessarily) which may be used to annihilate competition in the market by ―exclusionary conduct‖ such as refusal to deal by dominant enterprises. Likewise, anti-competitive behaviour could be in the form of ―collusive activities‖ of a combination of IPR holders. IPR also afford an opportunity to the right holders to maneuver the prices in a manner which enable them not only to recoup the R&D

costs but also secure unprecedented profits. These are only a few examples of how IPR propelled market power could trample competition; these activities are discussed in depth in next sections. There are quite a few practices in the market trend which can be considered as anti-competitive. Merger and acquisition is the most important of them, but there are other trends also which are also discussed here. The impact on intellectual property rights will be discussed later on.

SIGNIFICANCE OF MERGER AND ACQUISITION

The pharmaceutical industry is witnessing increasing consolidation, which is likely to continue in the following years. Like the pre-1970's situation, it appears that the multinational drug companies are all set to repeat its success in capturing a larger pie of Indian markets. In 2009, India has seen few public offers for acquisitions. Experts believe that a crash in the stock market over the year before that had helped the MNC's to increase their acquisition activities. In the recent past there has been an increase in number of public offers by the MNC's like Abbott India, Novartis India and Pfizer Ltd. to raise their equity stakes. For e.g. it is reported that Pfizer Inc, a US pharmaceutical giant, has decided to raise its equity stake in its Indian arm from 41.23% to 75%. This may work to an investment of Rs. 680 crore for Pfizer. In June 2008, Japanese firm Daiichi Sankyo Co. Ltd. had acquired 51% stake of Ranbaxy, one of India's leading generic firm. Daiichi primarily looked at Ranbaxy's marketing network in 60 countries as opposed to its own network of 21 countries, so the market power for Daiichi had enormously increased by that deal. Again, Novartis AG had acquired an additional stake of up to 39% in its majority owned Indian subsidiary Novartis India Ltd. At present it has a controlling stake of 50.9% in its Indian arm. It was expected that this will increase the stake to over 90% with investment of Rs. 440 crore. During September 2008, Abbott India completed its buy-back offer. With this offer, the promoters have increased their stake from 65.14% to 68.94%. One of the major reasons identified by industry experts is the current economic crises. If news reports can to be relied upon, at least seven out of 10 foreign drug makers that have revenues of less than Rs. 500 crores each will find this number rising to around Rs. 1,000 crore plus. In a recent move, global pharmaceutical major, GlaxoSmithK line has signed an agreement with Dr. Reddy's to develop and market selected products across an extensive number of emerging markets, excluding India. While the full terms of agreement are not clear, news reports suggest that GSK will gain exclusive access to Dr. Reddy's diverse portfolio and future pipeline of more than 100 off-patented, branded

pharmaceuticals. These products and pipeline falls under the fast growing therapeutic segments such as cardiovascular, diabetes, oncology, gastroenterology and pain management. Under the terms of the agreement, revenues will be reported by GSK and shared with Dr. Reddy‘s as per the agreed terms. The products will be manufactured by Dr. Reddy‘s and licensed and supplied by GSK in various countries in Africa, Middle East, Asia Pacific and Latin America. In certain markets, products will be co-marketed by GSK and Dr. Reddy‘s. However, Dr. Reddy‘s ,one of the major Ind ian firm investing in R&D, surprised everyone when it decided to bury its prolific 15 year old R&D model. 15 years ago, Dr. Reddy‘s developed itself under the guidance of Mr. K. Anji Reddy (founder chairman), who was a scientist and whose visionary thoughts led to the experimentation of high risk and high capital intensive model of drug discovery among Indian generic firms. It is well acknowledged that any in new drug discovery, more molecules fail than succeed, and costs run into millions of dollars. Dr. Reddy‘s built well-equipped labs and put together a team of highly paid Indian scientists. It also created the Atlanta lab to research novel targets, but its continued focus on generics to capture the lucrative market, did reportedly put it on the R&D back front. Two major reasons have been manifested for Dr. Reddy‘s change in R&D strategy - first, R&D is a high risk business, specially without appropriate human resource and investor confidence and second, it is reported that Dr. Reddy‘s intended to save $10-15 million in fiscal 2011 from the renovation. In 2008-09, Dr. Reddy‘s spent Rs. 409 crores on R&D (including on generics), up 18% over the previous year, however, the future investment after the GSK tie- up is uncertain. During the period 2000-2006, the global generic industry witnessed around US$ 35000 million of M&A value, suggesting increasing trends in consolidation not just in research based pharmaceutical industry but in the generic industry. Most of the Indian domestic mergers are between medium sized firms and most of them are horizontal mergers. There are also high instances of cross-border acquisitions, and unlike in case of mergers they are acquisitions by foreign companies. Large number of acquisitions occurred among the foreign owned firms. It is noted that foreign firms are increasingly willing to raise their stakes in the Indian subsidiary, the reason being a favourable investment policy of the government and a conducive patent law regime for marketing new technology products. These acquisitions have occurred where firms already had some managerial tie- ups. Certain examples of firms that had such managerial tie- ups and subsequent acquisitions that occurred are: Solvay Healthcare acquired 44.52% of equities in Solvay Pharmaceutical India, the promoters of Syncom Formulations India have acquired 5.22% of equities; Abbott Laboratory, USA acquired 51% of equity holdings in Abbott Laboratory India Ltd. etc. In

many cases, firms have acquired a small portion of the assets and later on opted for merging with the same firms. Some of such cases are the mergers of Boehringer Mannheim with Nicholas Piramal India Ltd. (NPIL), Roche Products with NPIL, Sumitra Pharmaceuticals with NPIL, MJ Pharmaceuticals with Sun Pharmaceuticals, Vorin Laboratory with Ranbaxy Laboratory, Rhone Poulance with NPIL, Matrix Laboratory with Ranbaxy Laboratory etc.

An interesting suggestion about a possible effect of combining through merger patents of uncertain validity can be made. Suppose, prior to the merger, both the technology claimed by A's patents and the technology claimed by B's patents are required to produce a commercially marketable product. But each set of patents are also associated with a certain probability that either the other patent owner or a third party will be able to invent around the patent or have the necessary claims declared invalid. Thus, even without acquisition, pooling, or cross- licensing, the two parties are potentially horizontal competitors, and there is some possibility that a third party will be able to enter by obtaining a license from one and inventing around or challenging the patent claims of the other. The prices for licenses will reflect the perceived probabilities. After the acquisition or pooling, the probability of competition is greatly reduced. A potential entrant will have to invent around or declare invalid a much greater array of patents. This is potentially anticompetitive in the same way as a two- level entry problem is anticompetitive under competition law. [1] Application of such a theory would have to be limited by considerations such as the degree to which the transaction increases the need for multiple- level entry, the extent to which such entry is more difficult than single-level entry, and the degree to which the affected markets are susceptible to monopolization or collusion.

In rapidly changing, high-tech industries, the most important dimension of competition is often not the price of existing goods and services, but the price and, more importantly, the quality, of goods and services that may come into being in the future. The US Guidelines describe two ways of analyzing innovation effects: *"as a separate competitive effect in relevant goods or technology markets, or as a competitive effect in a separate innovation market."*[2] There has been considerable debate about the innovation market concept, [3] some of it revolving around whether the effects in question can be analyzed equally well under the

[1] *American Cyanamid Co.*, 72 F.T.C. 623, 684-85 (1967)
[2] U.S. Dept. of Justice & Fed. Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (April 6, 1995), Section 3.2.3.
[3] Roscoe B. Starek, III, Former Commissione, *Innovation Markets in Merger Review Analysis: The FTC Perspective,* Address before the Florida Bar (Feb. 23, 1996)

potential competition doctrine—with perhaps less risk of misunderstanding. [4] In Glaxoplc acquisition case, Glaxo, the acquiring firm, sold an existing product for the treatment of migraine attacks that was approved by the FDA in injectable form only. Both Glaxo and Wellcome, the acquired firm, had products in the FDA approval process that would treat migraine with an oral dosage. Hardly any other companies were involved in research and development for such drugs, and barriers to entry were high. The FTC challenged that aspect of the acquisition because it would have eliminated both the competition to develop those drugs and the competition between those drugs once developed and approved. The result was a consent order allowing the transaction as a whole to go through but restoring the competition in that class of drugs.

IMPACT OF HIGH TRADE MARGIN

A survey conducted on doctors, pharmaceutical industry, consumer organizations, hospitals and the pharmacists in India bring to light various facts about collusion along the pharmaceutical distribution chain at the ground level.

In the study, the majority of the pharmaceutical companies surveyed claimed awareness with respect to the existence of collusive practices in the pharmaceutical industry and a high 32.2% of respondents asserted that such practices prevail in the industry to a great extent. Some of these unethical practices were pertaining to irrational drug prescriptions by doctors motivated by kickbacks received from pharmaceutical companies. As a result they prescribe expensive drugs that may not be even necessary. What encourages such rent-seeking behaviour is the information asymmetry and low elasticity of demand to chang in price because here the doctors are the influencers and not the consumers. Collusion also takes place along the distribution between drug companies, stockiest, retailers, medical representatives which disproportionately inflates the cost of medicines & the overall treatment. Consumers have little or no choice in such a ‗rigged' market and have to buy what is prescribed by Doctors or what is sold by Chemists.

Table1. Exorbitant Trade Margin in India

Company	Brand	MRP (Rs)	Purchase Price of

[4]FTC Staff, *Anticipating the 21st Century: Competition Policy in the New High-Tech, Global Marketplace*ch. 7 (1996); Richard T. Rapp, *The Misapplication of the Innovation Market Approach to Merger Analysis*, 64 Antitrust L.J. 19, 37-46 (1995).

			Retailers (Rs)
Ranbaxy	Stannist	26	1.80
Cadila	Ceticad	26	1.60
Cipla	Ceticip	27.50	2.00
Lupin	Lupisulide	24	1.94
Wockhardt	Setride	25.20	1.70
Lyka Labs	Lycet	25	1.44
Ranbaxy	Pyrestat-100	25	1.50
Welcure Drugs	Omejel Cap	33	4.50
Wockhardt	Merizole-20	39	6.48

IMPORTANCEOF ANTI-COMPETITIVE AGREEMENTS

Collusive Activities are seen in India at different levels between manufacturer and health service providers; like (i) Manufacturer and Doctors – driven by incentives for prescribing, (ii) Irrational combinations, prescribing expensive brands and prescribing unnecessary medicines – driven by incentives for prescribing, (iii) Manufacturer and Pharmacist – colluding to clear a particular drug despite availability of cheaper variants, (iv) Tied Selling Practices between manufacturer – doctor – pharmacist, (v) Manufacturers and Hospitals by unethical manipulation. Affordable medicines are not produced – They are not stocked owing to collusive agreements. Reining in such activities will go a long way in preventing supernormal profits and allowing consumer access to affordable medications.

Over the last couple of years, Indian pharmaceutical companies have been increasingly targeted by multinationals for both collaborative agreements and acquisition. During the first half of 2011, Bayer and Zydus Cadila agreed to set up a joint venture called Bayer Zydus

Pharma (BZP), for the sales and marketing of pharmaceutical products in India. Other recent collaborations include Sun Pharma working with MSD (Merck & Co) to market and distribute Merck's Januvia (sitagliptin) and Janumat (sitagliptin+metformin) under different brand names in India. In May 2011, Par Pharmaceutical Companies entered into a definitive agreement to acquire privately- held Edict Pharmaceuticals, a Chennai-based developer and manufacturer of solid oral dosage generics, Hikma Pharmaceuticals announced in April 2011 that it had agreed to acquire a minority interest in Unimark Remedies, a privately- held Indian manufacturer of active pharmaceutical ingredients and API intermediaries. Abbott had a patent on Hytrin (Used to treat hypertension). In 1998, Abbott's sales of Hytrin amounted to $542 million (over 8 million prescriptions) in the United States. Abbotts patent on Hytrin was nearing its expiry. Abbott projected that Geneva's entry with a generic version of Hytrin would eliminate over $185 million ofHytrin sales in just six months. Abbott paid Geneva approximately $4.5 million per month to keep Geneva's generic version of Abbott's proprietary drug (Hytrin) off the U.S. market, potentially costing consumer s hundreds of millions of dollars a year. Geneva also agreed not to launch the generic version till another competitor in the market undertook to do so. Such an agreement was held anti-competitive as it prevented the entry of competitors.

Tie- up agreements are made for controlling supply of active ingredients also, like Agreements between FTC and Mylan Laboratories Inc. Complaint charged Mylan and other companies with monopolization, attempted monopolization, and conspiracy in connection with agreements to eliminate much of Mylan's competition. The alleged agreements were in the nature of tying up supplies of the key active ingredients for two widely-prescribed drugs - Lorazepam and Clorazepate; used by millions of patients to treat anxiety. The FTC's complaint charged that Mylan's agreements allowed it to impose enormous price increases - over 25-30 times the initial price level for the drugs. For example, in 1998, Mylan raised the wholesale price of Clorazepate from $11.36 to $377.00 (per bottle of 500 tab lets) and Lorazepam from $7.30 to$190.00 (per bottle of 500 tablets). The price increase resulting from Mylan's agreements allegedly cost American consumers more than $120 million in excess .Mylan agreed to pay $100 million for disbursement to qualified purchasers of Lorazepam and Clorazepate.

MAGNITUDE OF PATENT POOLING

Patent pooling is normally pro-competitive if it is strictly confined to share complementary patents. Competition agencies must be vigilant, however, against companies seeking to combine substitute technologies and thereby reduce horizontal competition. There is a particular danger that this could happen in the context of settling patent litigation.

Pooling and cross- licensing arrangements occur where two or more owners of different IPRs license their respective IPRs to each other. In a pooling arrangement, they typically do so by assigning or exclusively licensing their IPRs to a separately administered entity, which thereafter controls the licensing of the portfolio and its individual items to those who contributed the IPRs and, in many cases, to third parties. The terms of such arrangements may vary. The pool members may have the use of the IPRs royalty- free or at a positive price; they may split the proceeds according to various formulae; there may be different voting structures or veto rights. As indicated above, a critical issue in evaluating the competitive significance of such arrangements is whether the arrangement is horizontal or vertical.

If, for example, two IPR owners control b locking patents (a vertical relationship), they ought to be encouraged to combine their IPRs by licensing each other or forming a pool. Without such an arrangement, neither could use the technology, and society would be worse off. On the other hand, if neither IPR owner needs the other in order to compete at maximum efficiency (including as to creation of ―next-generation‖ products), then what is the legitimate purpose of the arrangement? In such a circumstance, the arrangement likely serves only to fix prices or divide markets. For example, if manufacturers X and Y form a pool, and the pool licenses X to use the technology only in North and South America and Y to use the technology only in Europe and Asia, the effect would be to set each of them up as monopolists in their respective territory, even though, without the pool, each could have competed world-wide. Similarly, if X and Y license form the pool at a very high per- use royalty, such an arrangement could ensure that their marginal costs will be so high that each will be forced to price at the joint monopoly profit- maximizing level.

More complex situations arise when the arrangement is partly vertical and partly horizontal. For example, if X and Y would have been able to compete with each other, but their products would not have been quite good, then a trivial improvement entitle parties that otherwise would be competitors to form a highly restrictive pool that fixes prices at the joint monopoly

profit-maximizing level. Conversely, the possibility would be that, the parties could have produced some product, even though greatly inferior, which would prevent them from forming a more efficient pooling arrangement. The issue also comes up in challenges to pooling and cross- licensing. The US Guidelines cite the Singer case for the proposition that settlement of infringement litigation by cross-licensing IPRs can be challenged if it eliminates competition among horizontal competitors. Such a challenge would typically have to show that the relationship among the pool members was horizontal. In other words, the antitrust challenge would, in effect, have to resolve the patent issues that were the subject of the infringement litigation. In the infringement litigation, each party typically is contending that the other was infringing, and that the other could not lawfully be in the market without a license. If that contention were true, the IPRs would stand in a blocking, and therefore vertical, position. For Singer to apply, the parties would have to be in a horizontal position, i.e. at least two pool members must have been in a position to compete without obtaining a license for the same IPRs being used by the other.

Three distinct but related issues often go under the terms –breadth‖ or –scope‖: (a) how easy it is to obtain the IPR in the first instance, (b) the breadth as such, i.e., how completely the IPR covers the field as opposed to allowing other competing ways of accomplishing the same objective or the same way of accomplishing other objectives, and (c) the duration of the IPR. Any particular resolution of each of these issues, in turn, can affect innovation in two conflicting ways: (i) it can increase or decrease the expected rewards to an innovator and thereby affect the incentive to undertake the innovation, and (ii) it can increase or decrease the difficulty, cost, and risk of innovation by making it more or less likely that someone else will later assert that the innovation infringes a prior IPR. The tension between these two effects is sometimes described as a trade-off between subsequent (or secondary) innovators and primary innovators, but this is something of an oversimplification. A firm that is about to undertake pioneering research still has to consider the risk that it will later turn out that some aspect of its research and development will infringe an IPR of some other firm, so that a patent system in which very broad patents are too easily obtained and enforced can inhibit pioneering research as well, particularly if it is difficult to identify the existence of such patents. Conversely, of course, secondary innovators also have an interest in reaping a reward for their contributions.

IMPLICATION OF ANTI-COMPETITIVE MEASURES – IMPACT ON HEALTH AND PRICE

IPR protection in some sectors (notably biotechnology) and in some countries may be so broad that it actually inhibits innovation. However, there remain valid reasons for competition agencies rejecting direct remedial measures while engaging in competition advocacy to ensure patent offices are aware of the anticompetitive effects of overbroad patents. Though broader patents will typically translate into greater rewards to primary innovators, they simultaneously tend to increase the costs and uncertainties facing secondary innovators. Empirical studies have yielded inconclusive results concerning the net effect of patent breadth on both types of innovation taken together. This might encourage competition offices to take action to reduce anticompetitive effects of what they might consider unnecessarily broad patents. Unfortunately, such ex post interference by competition agencies would tend to reduce innovation by introducing greater uncertainty about possible rewards. Moreover, there is already a certain degree of automatic fine-tuning being practiced by competition agencies. This arises through the positive correlation between patent breadth and likelihood of finding that an IPR holder enjoys a dominant position. In many countries, such a finding is pre-requisite to the competition agency taking some action against a competitive restraint, including one linked to IPR.

Both competition agency and patent office lack the knowledge required to determine optimal patent breadth, but of the two, the patent office seem to be in a better position to make trade-offs between incentives for primary as opposed to secondary innovation. At the same time, competition agencies enjoy a comparative advantage in discovering and appreciating the anticompetitive effects that overly broad patents might entail. Competition agencies s hould ensure that the patent office decisions about patent breadth are well informed concerning their possible anticompetitive effects.

CONSEQUENCES OF EFFECT ON SALE OF DRUG

The approach of focusing on the effect of competition in the sale of the drug, rather than the R&D competition to produce the drug, is the approach taken by the European Commission in some of the pharmaceutical mergers that were investigated on both sides of the Atlantic. In its 1996 report on the US/EC antitrust co-operation agreement, the Commission describes the differences in approach as follows:

–*In Glaxo/Wellcome case, both Glaxo and Wellcome had similar anti-migraine treatments at an advanced stage of development and it was considered that the time and cost involved for a*

competitor in reaching the same stage of development were such that it was essential to maintain both products in competition with each other. The approaches taken by the European Commission and the FTC to resolve this problem were different; the FTC considered a horizontal market for R&D for anti-migraine drugs on its own, while the Commission looked at the spill-over effects of R&D in the market for the sales of medicines. The Commission decision therefore provided for the merged company to license one of the two anti-migraine treatments in development and so retain a potential competitor, while the FTC required full divestiture of Wellcome"s R&D for this anti-migraine treatment.[5]

REPERCUSSION OF PRICERISE

Because of merger or patent pooling or cross licensing the companies acquire market monopoly, as is evident from the above cited examples. The negative impacts of enormously increased market power certainly affect the price of the pharmaceutical products. Medicines are essential commodity in terms of prevention and treatment of life threatening diseases, more so in current situation of spread of both communicable diseases like HIV/AIDS or tuberculosis, malaria or cardiac ailment. Dearth of supply of appropriate medicine at affordable prices makes the life of human being highly vulnerable and is exponentially tragic for the poorer and compromised sections of population. Competition agencies should keep this fact in mind and handle the anti-competitive practices as seriously as possible. With poverty, unemployment and other socio-economic challenges in developing and least developed countries of Asia, Africa and Latin America, situation becomes tougher if essential elements like medicines are not available in need. State has the obligation of procuring the drugs at affordable prices for the public health service centers, but sometimes even that becomes impossible in case of hugely costly medicines like anti-cancer drugs or anti-retroviral.

CONCLUSION AND SUGGESTIONS

The importance of both sets of policies for encouraging innovation would not attract such attention, much less cause the convening of a roundtable to address them together, were it not for the fact that the two policies are often seen to be in conflict. In the United States, for

[5] *Commission report to the Council and the European Parliament on the application of the Agreement between the European Communities and the Government of the United States of America regarding the application of their competition laws*, COM(96)479final, 8 October 1996, available at http://europa.-eu.int/en/-comm/dg04/lawenten/en/com479.htm

example, the Supreme Court's approach for many years was epitomized by its declaration that –since patents are privileges restrictive of a free economy, the rights which Congress has attached to them must be strictly construed....‖ Since the purpose of the antitrust laws was to prevent monopolies and constrain the exercise of monopoly power, whereas –the very object of the patent laws is monopoly,‖ it was thought that the two bodies of law were inherently in conflict.

United Nation Development Programme (UNDP) recently discussed the impact of interaction of IP law and competition law on the access to medicine, specifically for the developing and least developed countries. In the ideal situation of the policy implementation the tools of intellectual property and competition law must be in perfect balance. To enhance the consumer welfare, this balance may shift in one way or other according to the socio-economic status of the nation. Usually in developed countries the balance goes towards the intellectual property law, but in case of developing and least developed countries the balance may go more towards the competition policies. Even in a country the attitude towards the balance may change with the change in socio-economic conditions, like in USA during 1960s and 1970s competition policy (implementation of anti-trust law) was very aggressive but by late 1980s a swing in attitude had been seen with a relaxation to prevent in restrictive practices. Hence there are differences in the implementation of competition policies at national level, but requirement is felt for the international harmonization in the area of competition law. United Nations General Assembly adopted the _Set of Multilaterally Equitable Agreed Principles and Rules for the Control of Restrictive Business Practices' (UN RBP Principles) in December 1980. This was a non-binding instrument, later on low and middle- income countries endeavoured to alter the instrument as a binding one, but the efforts were in vain. WIPO General Assembly in 2007 had adopted the Development Agenda and recommended that measures need to be taken to deal with anti-competitive practices related to intellectual property and technical cooperation needs to be provided to developing and least developed countries to take such measures. WHO a lso recommended that necessary action be taken for promotion of competition to increase availability and affordability of medicine and other health products and also to prevent the restraint of international technology transfer as well as restrictive trade practices done under the ambit of intellectual property rights.

There are some suggestion to draw balance between IPR and Competition Law which are as follows:

1. The US approach as also adopted in Canada is that of treating IPRs at par with other property rights. This seems to be a viable option for India as well since it lends simplicity to the application of competition laws.

2. Most of the jurisdictions recognize that the existence of IPRs does not necessarily confer market power. This is a rational presumption and may be adopted by the Competition Commission of India in dealing with cases involving intellectual property rights. The legitimate interests of IPR holders must be taken into account since unbridled exercise of power by the competition authorities may thwart innovation.

3. The premise of IP guidelines could be that competition and IPRs are not at loggerheads. Rather they complement each other in encouraging innovation, efficiency and consumer welfare. Such an approach echoes the Schumpeterian view on ―competition on merits‖ and would augur well for dynamic efficiency.

4. The guidelines could list out the anti-competitive conduct of IP owners under a ―per se‖ category. This would enable the holders of IPRs to exercise their rights in a manner which is congruent with competition policy. If the conduct which is per se illegal and anti-competitive is listed out by the Commission in its guidelines, it may lead to reduction in the number of cases falling foul of the competition laws.

5. The exemption in favour of ―agreements in research and development‖, on lines of EU exemption may go a long way in encouraging innovation whilst maintaining healthy competition in the market. Combinations (mergers & amalgamations) usually have grave implications for ‗innovation markets', 'An innovation market consists of the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development'. They may pose a threat for subsequent entry of products by stifling competition at the R&D and product development stage.

6. The definition of market could be bifurcated into markets for goods, services and technology or innovation. This would reduce the complexity and enable the Commission to address situations in which IP is used to charge excessive prices for or prevent access to protected technologies.

7. Lastly, the impact of IPRs on the market substantially varies depending upon the legal and socio-economic contexts in which they apply. Thus, the static-dynamic efficiency rationale applicable to a developed country does not necessarily hold in low income countries. High levels of IPR protection may have significant negative distributive consequences in the latter without contributing to– or even impeding – their technological development. As a result, competition authorities may legitimately give static efficiency precedence over dynamic efficiency considerations and challenge, for instance, situations of excessive pricing emerging from the exercise of IPRs. Therefore, in case of India also it is necessary to identify as to whether static efficiency precedes dynamic efficiency or vice –versa. In my view, it may be analyzed and dealt with on a case to case basis. For example in case of competition in the pharmaceutical sector, both static and dynamic efficiency would matter. Static efficiency matters as the prices of essential drugs must not be manipulated by those having monopoly rights so as to reap unprecedented profits at the cost of public welfare. Thus, the scales may tilt in favour of competition policy. On the other hand, dynamic efficiency is equally relevant so as to encourage innovation in this sector and in such cases the tilt would be towards protection of exclusivity of IPRs so that there remains sufficient incentive to invest in R&D. The challenge in the end is to strike a balance.