THE PHARMACEUTICAL INDUSTRY AND PARALLEL TRADE

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1. Introduction

In all countries the production and sale of pharmaceuticals is heavily regulated. The nature of demand for drugs, the identity of drugs brought to market and the nature of competition in the drug market over time are all shaped by regulation. The combined effect of this regulation is that competition takes a different form than in other industries. On the supply side, competition is mainly for the market, while competition in the market is mainly provided by the introduction of generics. With respect to competition for the market, the risk of failure inherent in R&D investment and the substantial costs and delays of the drug authorisation process make new drug development a risky and costly business. But, successful drugs, protected from competition by intellectual property rights, can yield a substantial reward. On the demand side, the presence of health insurance partially insulates final consumers from the prices of the drugs they consume. In their place, public and private health insurers adopt a host of mechanisms for controlling the quantity and quality of drug consumption. In any case in most countries the price of pharmaceuticals is regulated in order to prevent the exercise of excessive market power.

This paper, after a brief discussion of intellectual property rights in pharmaceuticals and the way a fair return on capital is assured by different mechanisms of price control, describes the EU competition rules and practices and addresses, in particular the question of parallel imports and their impact on competition.

2. Intellectual Property Rights and Pharmaceuticals[1]

The protection of intellectual property rights lies at the foundations of R&D investment in the pharmaceutical industry. There is some evidence that intellectual property rights, in the form of patents and trademarks, are relatively more important in the pharmaceutical industry than in other sectors. This may be due to the fact that patents on prescription drugs are a more effective means of raising imitation costs than patents on other products. The value of patent protection depends upon the length of the period of exclusivity. Although patent life is fixed by international agreement at 20 years from the date on which the patent application is filed, in practice, due to the delay between patenting and obtaining marketing approval, the "effective life" of a patent is much less than 20 years. As a consequence, both the US and the EU have adopted special legislative provisions extending the life of pharmaceutical patents. In the case of the US, the Waxman-Hatch Act extended patent protection on name-brand drugs for up to five years, but also limits the total period of exclusivity following marketing approval to 14 years. Within the EU, patent life can be extended by up to five years by means of a so-called "supplementary protection certificate".

Patents play a very important role in stimulating and rewarding research and innovation in the pharmaceutical industry. However, it is useful to recall that patent protection of pharmaceuticals (like patent protection of other products) has both advantages and disadvantages. The primary disadvantages of patent protection are its rigidity as a policy

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1. Paragraphs 2, 3 and 4 of this paper reproduce parts of the background paper of the OECD Secretariat to the Round Table discussion on "Competition and Regulation in the Pharmaceutical Industry" organised in February 2000 by the working party "Competition and Regulation" of the Competition Law and Policy Committee of the OECD.

instrument and the resulting market power which it generates. The primary advantages are that patents provide the right incentive for R&D investment and, in the process, they make new innovations public information. Patents, and the related licenses, have a geographically limited validity. In particular most countries maintain a national exhaustion regime as opposed to an international one, which implies that parallel trading and absolute territorial restrictions are absolutely legal according to the legislation on intellectual property rights. As a consequence national market segmentation is a fully accepted principle in the protection of intellectual property rights.

Patents are a rigid system for assuring the rewards to innovation and they are not necessarily the outcome of an efficient R&D competitive race. In particular, the protection offered by a patent may be disproportionate to the cost of the innovation when there is inadequate competition in R&D. For example, in the absence of effective competition in R&D, a company may be able, without any competitor be allowed to step in, to choose the timing of the granting of a new patent in such a way as to extend the protection over an existing drug. Recently SmithKline Beecham was granted a new US patent on its brand-name antibiotic Augmentin. Just before the end of the original patent period, SmithKline filed an additional patent covering other elements of the drug, including an acid that stops the active ingredient in Augmentin from degrading. The new patent ensures a substantial new period of exclusivity with very little or no new research.[2] Similarly, new techniques have allowed drug manufacturers to separate out non-active and possibly harmful components of existing drugs, increasing potency and reducing side-effects. By patenting the new forms of the drugs, the original period of exclusivity can be extended. The drugs affected by these new techniques include Prozac Jr, a version of the anti-depressant Prozac (estimated 2000 sales $2.5 billion), Desloratadine, a version of Claritin, a hay-fever medication ($2.2 billion) and Nexium, a version of Losec, an ulcer medicine ($six billion) made by Astra Zeneca.[3] In addition, patent protection enables price to be above marginal cost, introducing the conventional economic distortion due to market power. The economic effects of this distortion can be significant.

With such a system of widespread patent protection the problem for developing countries is that if they accept the 20 years from filing rule, as they have to by joining the TRIPS agreement, they might introduce a period of effective patent protection much longer on average than that available in developed countries. The request for a patent is usually filed at the very early development of a new drug in the country where the drug is being first tested. The drug is patented in third (consuming) markets only when the marketing in the home producing country has been already assured and the drug is already in use. Indeed developing countries strongly rely on the testing already performed in OECD countries, so that, contrary to what happens in developed countries, the 20 years from filing period in developing countries will be almost fully devoted to patent protection. Furthermore, pharmaceutical companies file for patent protection in different countries not at the same time and generally much later in less lucrative markets. As a consequence developing countries might be able to benefit from the expiration of patents and the consequent introduction of generics at a much later stage, if at all.

3. Generics

Following the expiration of a patent, the patent-holder can no longer prevent other manufacturers from producing and distributing copies of the patented drug. Drugs which are bioequivalent to formerly patented drugs are known as “generics”. The competitive impact of generics can be quite substantial and prices, after their introduction, can fall by

2. See “Drug Abuses”, Financial Times, 20 April 2000, p12.

3. “Drug Abuses”, Financial Times, 20 April 2000, p12.

30-50%. Pharmaceutical companies try to impede or delay entry by generics manufacturers. Legislation to prevent this has therefore emerged.
Under Canadian legislation, companies can conduct development work and product testing prior to patent expiration. Under US rules, the first generic manufacturer to the market receives a period of six months of exclusivity from the date it starts marketing its generic drug.
Incumbent manufacturers will go to substantial lengths to prevent the entry of rival manufacturers. In the US the incumbent may directly pay the first generic manufacturer out of the blocks to not start marketing. The two can then share the monopoly profits without fear of further entry[4].
One alternative strategy that has been adopted in the EU. It is based on the fact that under EU law generic manufacturers do not need to replicate the extensive clinical trials necessary to obtain the original marketing approval of a new drug. Instead they only need to show "bioequivalence" with the original branded "reference" product provided that the reference product "is marketed in the member state for which the application is made". Recognising this, some manufacturers have taken to removing the original product from the market shortly before patent expiration and replacing it with a "new and improved" version. AstraZeneca has been accused of using this strategy to protect Losec, its valuable ulcer drug.

4. Controls on Prices

One of the primary mechanisms by which health insurers, either public or private, can control drug expenditures is by directly controlling the price at which the drug will be sold. The key question to be addressed by regulators is how to fix the price for each drug. Allowing a price which is too high will inflate pharmaceutical expenditures and will over-compensate manufacturers. Insisting on a price which is too low may lead to the withholding of certain beneficial pharmaceutical products from the market. The question of the efficient price is relatively straightforward in those therapeutic classes where there are many competing manufacturers producing products which are close substitutes, such as is often the case in markets for off-patent medicines. In this case, a simple approach is simply to select one product by way of a tender.
The setting the efficient price is significantly more difficult in therapeutic classes dominated by a single manufacturer or in which there are two or more manufacturers producing imperfect substitutes (all of which are protected by patents). The assessment of the benefit-price ratio of a drug is known as pharmaco-economic analysis. Such analysis, which involves assigning quantitative monetary values to various "health outcomes"(i.e., various levels of disease, disability and death) inevitably involve a degree of subjectivity. But some form of analysis of this kind is essential to ensure that only the most cost-effective treatments are covered. Otherwise, a health insurer could obtain better health outcomes at the same level of expenditure by reorganising its coverage policies, eliminating coverage of therapies with low benefit-to-price and using the money saved on therapies with a high benefit-to-price.
The difficulty of performing pharmaco-economic studies has led many countries to use several alternative mechanisms for controlling the price of drugs. The most "popular" is international benchmarking (i.e., establishing the price for a pharmaceutical according to the prices in other reference countries). International benchmarking sets the price of a pharmaceutical according to the prices prevailing in several other reference countries.

[4] The FTC has filed charges against Aventis and Abbott Laboratories, and the generic manufacturers Andrx and Geneva Pharmaceuticals alleging that the brand-name companies were following just this strategy.

This approach has the advantage of avoiding the need for costly evaluation and ensures that domestic prices are not out-of-line with international levels. However, this approach amounts to free-riding on the efforts of others in establishing price levels. It is not possible for all the countries in a group to use the same approach, basing domestic prices on those prices prevailing in the other countries in the group, as the resulting price would be indeterminate. Where just one of the countries in a group uses an alternative approach to fixing prices, international benchmarking amounts to a decision by all the countries in the group to "import" the same price control approach.

5. Parallel Trade, Exhaustion Regimes and Competition Concerns

Given that countries have different incomes, different preferences, in short different elasticities of demand, the incentive of a company with enough market power as to be able to discriminate is to set prices according to the ability to pay of different consumers, making sure at the margin that prices never fall below marginal costs. Such a discrimination is welfare enhancing in so far as it leads to greater output. It also leads to greater profits for the companies involved and there are no reasons why companies, should they be able to prevent arbitrage, would not voluntarily engage in it. Indeed, given that the cost structure of pharmaceuticals is so heavily tilted towards fixed costs, in particular R&D costs, it is an optimal strategy on the part of producers to discriminate, setting prices according to the different elasticities of demand which characterise the various geographical markets.

If price differentials exist and parallel trade is not impeded, every trader of every country would purchase from the low price source of supply; such a concentration of demand in the low price country, would influence the decision making of the firm, that would introduce less discrimination as considered optimal in the hypothesis of market segmentation.

When prices are regulated and pharmacist's percentage margins are fixed, the pharmacist has an incentive to increase, rather than decrease, the prices of the drugs it sells. At the same time, as long as the pharmacist's retail price is fixed, the pharmacist faces a very strong incentive to reduce his/her wholesale purchasing price. Since wholesale pharmaceutical prices vary from country to country, an obvious alternative is to purchase pharmaceuticals from wholesalers in a low-price country and import them for sale in a high-price country. The primary effect of parallel trade is that it increases the profitability of pharmaceutical wholesalers and retailers. Parallel trade may or may not lower the prices for pharmaceuticals in the high-price country. If the regulator is able to observe the prices paid by the pharmacist for the imported pharmaceuticals, it may be able to adjust the regulated retail price accordingly, otherwise only the parallel trader would gain.

Even short of parallel trade there is a second channel in the pharmaceutical industry by which low prices in one country can be exported to other countries as well. As already mentioned, in most countries price regulation of prescription drugs is carried out by averaging out prices of the same medicine in different countries. Therefore, even in the absence of parallel trade, low price countries may be used as a benchmark for regulation influencing pricing in all other countries.

As for a substantive economic analysis, absolute territorial restrictions should not be considered anticompetitive when they lead to greater consumer surplus. Such a conclusion is by the way coherent with most competition laws that protect the competition process by implementing a consumer welfare standard. Market segmentation, even though it reduces intra-brand competition, can in fact increase the degree of competition between brands, stimulated by the increase in sales efforts associated with the granting of an absolute territorial restriction. Absolute territorial

restrictions can also facilitate the entry of new firms: often in order for new products to enter into new markets, the key is heavy sales promotion rather than low prices.
However absolute territorial restrictions can also have undesirable effects especially when they are put in place by most firms in an industry characterised, like the pharmaceutical industry, by high barriers to entry. In these circumstances, for example, they may be used by competitors - indeed also in pharmaceuticals patents give exclusive rights, not necessarily a monopoly - to segment markets that structurally have different degrees of competition, making sure that the benefits of greater competition be strictly limited to those markets where it already exist and should not be exported elsewhere. The outcome of a network of absolute territorial restrictions, or more in general of vertical agreements, such as for example resale price maintenance, exclusive dealing, tie-in sale agreements, or quantity forcing, is frequently to reduce the degree of inter brand competition, generally not leading to a full cartel, but to a strong reduction in competition on some of the most important dimensions on which firms compete, for example on pricing.
Absolute territorial protection can also be restrictive when a dominant firm imposes it. This can be so for the same collusive reasons that were already mentioned, since dominance does not imply a full monopoly, but just a firm sufficiently large relatively to the market in which it operates and a reduced competition by smaller competitors. Furthermore, should the downstream market be difficult to enter, a dominant firm can use absolute territorial protection, when associated with exclusive dealing, to raise rivals costs, by making entry by competitors more costly.
The European Commission practice is not completely in line with economic analysis. In fact it is the political agenda of the Commission, the creation of the European single market, that leads the Commission to consider a per se violation of competition law the segmentation of national markets achieved by vertical agreements. As a result, the Commission has consistently decided that any absolute territorial restriction (which is equivalent to impeding parallel trade) represents a violation of the rules against restrictive agreements.
In general allowing parallel trade leads to price uniformity. On the other hand, in the presence of price regulation, parallel trade only very indirectly may lead to price uniformity. Also in such cases the European Commission believes that allowing parallel trade is the better policy option.
While the European Commission has consistently ruled against any constraint in parallel trade within Europe, it has generally allowed parallel trade to be impeded between Europe and third countries. In fact Council Directive 89/104/EEC states that single member States cannot adopt rules that introduce the principle of international exhaustion for trademarks. The reason for this is that if member States would have a different regime for exhaustion, some of them a national one while some others international, then those countries that continue to have national exhaustion system would have to introduce trade restraints in order to protect their markets from imports from member States that have a broader regime, a situation considered to be contrary to the objective of unifying Europe into a single market.
Regarding the interrelationship between intellectual property rights and competition rules, the Court of First Instance has recently argued that competition law can impose parallel trade, even if absolute territorial protection is perfectly in line with the exhaustion regime actually in place. In the *Micro Leader Business* case the Court argued that although Microsoft might have been justified under copyright law to prohibit its Canadian distributors from exporting into third countries, such a justifications is not an absolute one. Indeed the Court ruled that such parallel trade cannot be prohibited

according only to the exhaustion theory. Instead there should be an evaluation whether such a prohibition violates the competition rules, and in particular in the specific case article 82 of the EU Treaty which prohibits abuses by a dominant firm.
The fact that under competition principles an absolute territorial restriction can sometimes be restrictive introduces a possible tension between antitrust interventions and national exhaustion regimes. If a patent is granted under a national exhaustion regime, than the patent holder is confident to be able to segment national markets and to impede parallel trade. If such an impediment is found to be anticompetitive under antitrust law, than some very artificial reasoning has to be introduced in order to justify the antitrust intervention, that is the now common distinction between the existence of the right, that is not questioned, and its exercise, that might be anticompetitive. The artificiality of such a reasoning is related to its outcome: if impeding parallel trade is considered anticompetitive, than a company, in order to comply with competition law, has to allow parallel trade. In this way, however, the exhaustion regime ceases to be national and becomes international. In essence by applying the competition law on the exercise of an intellectual property right, the right itself may be effectively put into question.
A different regime which would leave competition concerns fully to the antitrust authority would be less rigid and more efficient: The introduction of an exhaustion regime, either national or international, coupled with the admitted possibility of antitrust interventions with respect to anticompetitive territorial restrictions, would make an antitrust decision, which would for example impede private restrictions on parallel trade, not out of line with intellectual property rights concerns.

6. Conclusion

The pharmaceutical industry is a major source of R&D investment and through the continual flow of new and innovative drugs for the treatment of all kinds of human illnesses, has made a highly significant contribution to overall health and well-being.
Yet, few sectors are more heavily regulated that the pharmaceutical sector. Every step in the life-cycle of a pharmaceutical product – from initial conception, to marketing approval, commercialisation, patent expiration and generic competition – is influenced by regulation. Each actor in the pharmaceutical industry – the manufacturer, the wholesaler and retailer, the prescribing doctor, the health insurer and the health consumer – is profoundly influenced by the rules and incentives established by regulation, including the rules on intellectual property rights. So it is quite amazing that there is such a discussion of the wrong functioning of the market mechanism with respect to the problem of differential pricing for pharmaceuticals. The problem, as I tried to argue in this paper, is first a problem of regulation, than of market behavior.
As for the need of assuring the supply of low price drugs to the poorest countries of the world, the best solution would be an international agreement that would identify those countries and would impose on the pharmaceutical companies to supply at cost. A voluntary agreement on the part of pharmaceutical companies to achieve the same results could be challenged as an antitrust violation, but, more importantly, would make it more likely that such low prices would be “reimported” into developed countries via parallel trade or international referencing.
In any case low producer prices do not imply that patients actually pay those low prices. Competition among pharmacies and freer entry into the profession of pharmacist would help in keeping retail prices low. As for the problem of assuring a continuous flow of drugs also in the most remote regions of the world, this requires an efficient “infrastructure” capable of performing all logistic functions, an effort which goes much beyond the issues addressed in this paper.