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THE PHARMACEUTICAL INDUSTRY, PARALLEL TRADE AND ANTITRUST ENFORCEMENT

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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 all these regulations is that competition takes a different form than in other industries. On the supply side, competition by new drug producers is 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 drugs 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

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practices, with a final emphasis on the impact on competition of parallel imports.

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 agreements 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 extends 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 instrument

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 Committee of the OECD.

and the market power which it generates. The primary advantages are that patents provide the exclusivities necessary fro the profitability of R&D investment and, in the filing process, they make new innovations public information, providing the incentives for others to innovate around it. 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. For example, SmithKline Beecham was granted a US patent on its brand-name antibiotic Augmentin. Just before the end of the patent protection 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

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

drugs affected by these new chemical techniques include very well known brands, such as Prozac (an anti-depressant drug), Claritin (a hay-fever medication) and Losec (an anti ulcer medicine)[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 these distortions 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

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

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 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. According to the Waxman-Hatch Act the new entrant generic company has:

1) to show that the approved drug is not covered by a patent; ot
2) to show that the relevant patent has expired; or
3) to postpone marketing the generic version until the patent expires; or
4) claim that the relevant patent is invalid or that the generic drug would not infringe it.

According to the Act, if the generic manufacturer prevails in showing that the patent is invalid or not infringed (option 4), he receives a period of six months of exclusivity from the date he starts marketing its generic drug (180 days of duopoly profits). In such litigation, the litigating firms have a strong temptation to settle their dispute on collusive terms. Indeed the firms’ combined profits will be larger if the patent is upheld than if the patent is invalidated. As a result they can structure a settlement that allows them to divide the monopoly profits.

As an example I will refer to a US case, Shering Plough v FTC. It involved the settlement of a patent infringement litigation between Schering Plough, the manufacturer of “K-dur 20”, and two generic manufacturers of a

bioequivalent drug. Schering Plough sued the generic manufacturers for patent infringement and settled by paying the two $ 60 million and $10 million respectively in exchange for them agreeing to stop producing and delaying the entry of generics in the market (the parties claimed that the payment was in exchange for a license given to Schering Plough by the two generic manufacturers, but the FTC argued that this was an excuse because the two manufacturers were excessively compensated for that). According to the FTC both Schering Plough and the generic manufacturers benefited from the settlement. On the other hand the consumer was damaged. The FTC first blocked the agreement in 2003 and the eleventh circuit annulled (vacated) the FTC decision, arguing that a "reverse payment" was fully within the "exclusionary potential of the patent", implying that the settlement was in complete coherence with the exclusionary rights provided by the patent.

The US Supreme Court did not rule on the Shering Plough case. However in 2013 the Court, examining a a different case, Aventis, ruled on the issue of payments for delay. The Court held that a branded drug manufacturer's payment to a generic competitor to settle a patent litigation can violate U.S. antitrust laws when it is large and out of proportion with the value of any possible license being exchanged, as the FTC had argued already in Shering Plough.

Since the *Actavis* decision, the FTC announced in 2015 a $1.2 billion settlement resolving its antitrust suit against Cephalon for allegedly illegally blocking generic competition to is sleep disorder drug Provigil. The settlement ensures that Teva Pharmaceutical Industries, Ltd., which acquired Cephalon in 2012, will make a total of $1.2 billion available to compensate purchasers, including drug wholesalers, pharmacies, and insurers, who overpaid because of Cephalon's illegal conduct. The settlement originated from a 2008 FTC decision which maintanied that

Cephalon had violated the antitrust rules by paying four generic manufacturers in 2005 and 2006 over $ 300 million in exchange of them not entering the market occupied by Progivil until 2012.

The real problem is that much litigation on patents originates from the lack of rigor in patent granting. Indeed all matters related to patent validity have a very strong competition implications because even fraudulent patents restrict competition and sometimes substantially. Ever since the 1965 US Supreme Court decision in *Walker Process Equipment Inc. v. Food Machinery and Chemical Corp.* it has been recognized in the United States that a monopolization case could be made against a fraudulently achieved patent. However according to First (2007)[4] there have been no cases in the United States challenging invalid patents under the antitrust statutes.

In the European Union the Commission has actively intervened with antitrust provisions against the anticompetitive effects originating from invalid or fraudulent patents. In 2005 the Commission fined Astra Zeneca EUR 60 Million because it had abused the dominant position it held with its product "Losec" in the market for proton pump inhibitors (PPIs) by misusing public procedures in a number of EEA States with the objective to exclude competition from generic rivals.

Astra Zeneca abuse consisted in misleading representations before patent offices which led them to grant Astra Zeneca an extension of the term of patent protection, delaying the entry of cheaper generic versions of Losec (with costs for health systems and consumers). Furthermore Astra Zeneca obtained the deregistration of its market authorisation for Losec capsules in several Nordic countries, thus removing the reference market authorisation on which generic firms rely at the time to enter or remain on

[4] See First, Harry (2007), "Controlling the intellectual property grab: Pritect innovation not

the market[5]. Especially deregistration is very detrimental to competition because it does not allow the entry of generics once the original patent expires and follow on patents maintain the monopoly profits with the incumbent for many years to come. Astra Zeneca was fined 90 million EUR. The case has been confirmed by the European Court of Justice.

Besides blocking the entry of generics, high prices can be maintained by reducing competition between patented drugs. In Italy in 2015 the Competition Authority imposed a large fine on the companies Roche (€ 90.5 million)and Novartis (€ 92 million) for infringing article 101 TFEU by participating in an anticompetitive agreement in the market for ophthalmic treatments, which is used to cure some serious vascular eyesight conditions, including age-related macular degeneration (AMD), the main cause of blindness in developed countries. The Authority maintained that starting in 2011 Roche and Novartis set up a complex collusive strategy, with a view to avoiding the commercial success of Lucentis (authorized for ophthalmic treatment and distributed by Novartis) being hindered by the off label ophthalmic applications of Avastin sold at a much cheaper price, distyributed by Roche and authorized for the cure of some intestine tumors. Indeed the significant difference in price between the two drugs - while an injection of Lucentis in Italy costs € 900 (down from an earlier price of € 1 700), the price of an off-label injection of Avastin tops at € 81 – led the two firms to collude in order to create an artificial product differentiation between Avastin and Lucentis (which are based on the same molecule), in order to influence prescriptions by doctors for eyesight conditions.

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innovators", *Rutgers Law Journal*, 38: 365-98.

[5] Note that EC legislation has recently been modified to address this problem: since the October 30 2005 it is no longer be possible to prevent generic entry by withdrawing a European reference product.

According to the Italian Authority, the economic rationale of the companies' conduct stemmed from the relationship between the Roche and Novartis groups: while Roche collects significant royalties from the sales of Lucentis, which was developed by its subsidiary Genentech, Novartis benefits directly from Lucentis' sales and furthermore holds a share of over 30% in Roche. The efforts of Roche and Novartis to maintain the use of the two drugs separate intensified as a growing number of independent comparative studies supported the equivalence of the two drugs for ophthalmic uses. However one scientific paper showed that the use of Avastin for ophthalmic use could be dangerous for the health of the patient.

The case is under appeal and the reviewing judge may hopefully give some indications on how to treat contradictory scientific evidence in an antitrust case.

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 identification 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 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. 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 characterized, like the pharmaceutical industry, by high barriers to entry. In these circumstances, for example, they may be used by competitors 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 be 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.

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.

While the European Commission has consistently ruled against any constraint in parallel trade within Europe, in the Glaxosmithkline judgment the European Court of Justice that the possibilities of exemptions under article 101.3 have to be considered and seriously evaluated also for agreements blocking or weakening parallel trade within the Union. Indeed in pharmaceuticals, the Court argued, the financing of R&D expenses may require differential pricing among countries characterized by different abilities to pay.

In the EU while some exceptions have been made with respect of allowing the elimination of parallel trade in pharmaceuticals, parallel trade could be totally 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 192 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, commercialization, 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. Antitrust enforcement can impede some very vicious practices such as price for delay and anticompetitive price discriminations that are clearly to the disadvantage of consumers and health authorities.

As for the need of assuring the supply of low price drugs to poor countries, 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 price 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.

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