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

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),

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 severan other reference countrity.

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,

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