Price Differentiation in Pharma and the Conundrum of Exhaustion Principles

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1. The Need for Affordable Pharmaceuticals

It is generally accepted that effective, even the most modern and newly developed, drugs should be made available to patients in need on an affordable basis everywhere. Obviously, to achieve this goal, it is first of all necessary that effective pharmaceuticals are continuously developed, and, secondly, it must be made sure that such pharmaceuticals are not only distributed/sold to consumers/patients in countries with a high price-level ("high-price countries"), but also in countries with low price levels, like less or even least developed countries("low-price countries"). In view of the above mentioned dilemma, namely, on one side to make effective pharmaceuticals available by developing them, and, on the other side, to make them available on locally affordable prices everywhere to consumers/patients, the author has outlined a model for price differentiation as a contribution to the 9th IEEM IP Seminar at Macao, June 25, 2008. A more elaborated version of the aforementioned model has been presented by the author as a contribution to a workshop on "Differential Pricing of Pharmaceuticals inside Europe" at Bremen on October 10, 2008. Based on an article on "Price Differentiation and the Conundrum of Exhaustion Principles" published in Christine Godt (ed.), /Differential Pricing of Pharmaceuticals inside Europe - Exploring Compulsory Licenses and Exhaustion for Access to Patented Essential Medicines/, Nomos, Baden-Baden, 2010, pp. 125-131, the above mentioned model will be explained in this presentation.

2. Price Differentiation between high-price and low-price countries a "must"

It is apparently meanwhile generally accepted that researching pharma companies, usually acting world-wide, in the following, without any discriminatory intention, called "Big Pharma", need the promise of a high Return-Over-Investment (ROI) at least in certain high-price countries, like OECD countries, in order to make it attractive for them to develop new drugs. It seems to be generally accepted, too, that in order to encourage Big Pharma to develop new drugs, and, on the other hand, to make them available in low-price countries,

price differentiation between high-price countries, where the high ROI expectation of Big Pharma can be fulfilled, and low-price countries, where patients need to get that drug at a very low price, is an absolute necessity.

In a slightly different scenario, namely taking into consideration the differences in price level in different EU countries, with sometimes, even mostly, government-controlled price level for pharmaceuticals, even the ECJ in the newest development of the Syfait I/Syfait II cases seems to accept that even a pharma company with a dominant position must be entitled to take appropriate measures to defend its commercial interests against uncontrolled parallel importation and thereby erosion of the prices for its products all over the European Union (EU). This follows from the explanations as given in the EJC Judgment relating to Joint Cases C-468/06 to C-478/06 of September 16, 2008, with regard to Article 82 EC.

3. How to achieve price differentiation?

From the above mentioned consideration it appears as clear that only a high price level for newly created pharmaceuticals in high-price countries combined with a low price level in low-price countries guarantees the creation of new drugs as well as the distribution of them at locally affordable prices everywhere. The question is, how such cross-border price differentiation can be achieved.

3.1. Outside the European Union (EU)

3.1.1. Patent system with national/regional exhaustion ideal instrument

If the patent system would not yet exist, obviously it would have to be invented in order to enable the creation of new drugs and at the same time secure the distribution thereof at locally different, affordable prices everywhere. That is accepted world-wide. The EU, in this context, plays a specific role insofar as it has to be considered, for patent exhaustion purposes, as one single “country”, i. e. territory. Insofar, it has to be duly noted that in the EU, the free movement rules of Articles 28 and 30 EC mean that patent exhaustion cannot be limited to individual countries inside the EU in which a patent is granted, but must extend to the whole of the EU: As soon as a certain product, like a pharmaceutical, is sold in any country of the EU by the patentee or with its explicit or implicit consent, that pharmaceutical, in principle,

can freely move inside the EU. This principle of free movement of goods applies even if the first sale of the product, i.e. the pharmaceutical, inside the EU does not take place in a "patented" country, but in an "unpatented" EU-country. It is only decisive as to whether the first sale took place either by the patentee himself or with his implicit or explicit consent, e. g. by a licensee. A merely "legitimate" first sale would not be sufficient, however, i. e., if the product was sold under a compulsory license, free circulation of goods would not be given.

The aforementioned principle, which applies inside the EU, however, is not applicable on a world-wide basis. Rather, internationally the principle of national/territorial exhaustion is still widely accepted. That means that a patentee who has sold a certain pharmaceutical in a low-price country, or has permitted that the sale of such pharmaceutical takes place in a low-price country with his consent, can still use his patent in e.g. Germany, for the purpose of this explanation considered as a high-price country (which, at least for pharmaceuticals, it really is!), to prevent importation of the respective pharmaceutical from the low-price country into Germany Under this principle of national/territorial exhaustion, in other words, Big Pharma, being the patentee, could develop – using the aforementioned example -, enjoying the expectation of a high ROI in Germany, a new drug at high cost, sell it at high price in Germany, sell it at a low price in Brazil, and could keep, and this is the importance of price differentiation, the price difference between Brazil and Germany in place. The patent system would guarantee, on one side, high ROI in high-price countries, but on the other hand allow low sales prices in low-price countries, as long as parallel importation can be prevented. Obviously, patents with national exhaustion give that possibility.

Simply said: If the patent system, as far as circumstances outside the EU are concerned, would not have been invented, one should create it in order to achieve price differentiation as discussed above.

3.2. Inside the EU

The patent system, however, is not useful to create any price differentiation inside the EU, however, because of EU-wide regional exhaustion.

Whether “intelligent” sales restrictions (“quota system”) are a solution, will have to be further developed, following the recent rulings of the ECJ relating to Syfait I/Syfait II, as briefly discussed above.

It might even be not a bad idea, taking into due considerations the problems with quota systems and similar mechanisms, to revisit the question of full, unconditioned EU-wide exhaustion of patents, in order to use the “beauty” of the patent system even inside the EU in a more intelligent manner in future, with the aim of giving a possibility of price differentiation. The considerations as outlined below, relating to exhaustion problems outside of EU might, mutatis mutandis, be transferable to the problems with (justified) price differentiation inside the EU, too.

4. National vs. international exhaustion of patents – a matter of principle

4.1. Pro international exhaustion: remuneration/award for inventors only justified once

There a very good reasons, of course, to accept the principle of international exhaustion. Essentially, the argument is that patents are granted as a reward to the inventor disclosing the invention, which reward only can be obtained once, i. e. is, in a financial/monetary manner, achieved by the patentee already by the first sale in a first country of this world. Then, it would no longer be justified to allow the patentee to use parallel patents with the aim of obtaining another monetary advantage in other countries. This is essentially the argumentation of the defenders of the principle of international exhaustion.

4.2. Pro national exhaustion: national/territorial character of patents – remuneration/award per patent/country justified

On the other hand, the defenders of the national exhaustion system usually argue that, since patents are only granted nationally, the owner of such patents should be entitled to get a financial advantage out of the grant/existence of such a patent in each and every country, which could only be achieved by the principle of national exhaustion. Obviously, another argument in favour of national exhaustion would be, as discussed at length above, that price differentiation can be easily achieved, going into solutions like quota systems, export restrictions etc., that might cause competition law problems.

5. “Modified” international exhaustion of patents a solution for pharma?

Even for pharma, a “modified” international exhaustion mechanism in principle could be accepted.

That would depend, however, on the question as to whether it might be possible to introduce into a patent system with international exhaustion safety mechanisms which would still allow price differentiation between low-price and high-price countries, particularly in case of pharmaceuticals.

In pharma, specific conditions should justify the use of parallel patents for restricting re-importation and parallel imports, respectively.

In the following, a model is developed how this could be realized in case of pharma:

Prevention of parallel imports by patents could/would be permitted only if the sales price used by Big Pharma patent owners in less/least developing countries would be sufficiently low. One could, then, create a mechanism which would allow Big Pharma to use parallel patents in high-price countries to prevent parallel importation from low-price countries, if certain conditions with regard to the sales price accepted by Big Pharma in low-price countries would be fulfilled, i.e. the sales price in low-price countries would be sufficiently low.

A third possible scheme could be as follows: Only if the sales price in less/least developed country/countries is less than, e. g., 10% of the average sales price in all (or a selected number of) OECD countries (or country of origin), the prevention of re-importation by patent(s) would be permitted.

Such a scheme would allow Big Pharma to sell, or allow to sell, pharmaceuticals needed in less/least developed countries at very low prices. One could set a limit, say: 10%, of average sales price in all or a selected number of OECD countries, i. e. high-price countries, or country of origin, which, if not exceeded, would allow Big Pharma to use parallel patents in high-price countries in order to prevent parallel importation and re-importation, respectively.

Another possibility for a useful scheme could be that one compares the GDP-per-capita in a certain number of OECD-countries, average-wise, with the GDP-per-capita in the low-price country of sale where Big Pharma sells the pharmaceutical at a locally affordable, possibly very low price. If the sales price in the aforementioned low-price country would be less than the average sales price in the selected number of OECD-countries, multiplied by the following factor:

$$\frac{GDP-per-capita\ in\ country\ of\ \ sale}{GDP-per-capita\ in\ OECD-country/countries},$$

prevention of parallel importation by patents could be accepted, i. e. a "modified" principle of international exhaustion applied.

The aforementioned schemes would give Big Pharma the possibility to keep price differentiation in place, still enabling a high ROI with regard to new drugs, at the same time accepting the principle of one-award-only for patented inventions, as soon as they are sold once.

One could consider the above mentioned "modified" international exhaustion scheme as one in which, unless the conditions for "allowed" price differentiation would be met, in principle keeping national exhaustion applicable, Big Pharma would undergo a "partial" compulsory license of its patents in the OECD countries, with the effect that they would have no effect against re-importation, i. e. insofar the subject to "international exhaustion", if the pricing criteria, as outlined above, would not be met.

The model as suggested here might be worth to be considered further by patent and competition experts accepting the principle of necessity of availability of pharmaceuticals world-wide on locally affordable prices, with the necessary, accompanying principle of price differentiation.

6. Conclusion – Do we wish "international desaster" by unconditioned "international exhaustion"?

From the above, one may see that a patent system with national exhaustion gives an easy possibility to obtain the necessary price differentiation for pharma between low-price and high-price countries. A “modified” international exhaustion regime, as also indicated above, might be a second-best solution.

Enclosure:

8 transparencies