Compulsory Licensing of Drugs: TRIPS Context

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PATENTS PLAY an important role in the cost of drugs developed after around 1980. They are, of course, critical to the question raging around the world of how to provide affordable access to drugs since without patents there would be far fewer drugs around for people to access. One cannot have access to something that does not exist. This simple fact is often forgotten in the heated debates about affordable drugs and compulsory licensing. In any event the patent system is designed to require that each generation pay for research and development costs associated with the development of new drugs with the understanding that the next generation will get them free of those costs. Thus we are all the beneficiaries of all the drug development that occurred prior to around 1980 and our children will get all of what we have developed to date free. Moreover, the patent system is designed to require that those who need new drugs bear the cost of their development. This is the capitalist method of pricing, he who wants the goods or services pays for them.

The actual period of patent protection worldwide may be up to 20 years with the possibility of an extension of up to five years in certain countries. Because of a variety of practical considerations, the most important of which is the need to get marketing approval, the actual period of protection tends to be far less than 20. In any event patents play no role in the furnishing of drugs developed before 1980. There is little doubt that if all the drugs developed before 1980 were widely distributed to people who could use them, the health status of many people of the world would be dramatically improved. To properly distribute such drugs may require efforts to create more competitive markets and suitable subsidies to help those who cannot afford to pay. It may also require governments to subsidize other governments. This process is of no concern to the professional, as opposed to the civic, interests of intellectual property lawyers.

Now let me turn for a moment to drugs developed after 1980. Although many adults are willing to pay for what they need willingly and are generous

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with their time and money, many are not. Sometimes it is because they can't pay, but for others it is because they don't want to pay. In any event there used to be countries in the developed world that refused to pay for the research and development necessary to develop drugs. They preferred to let others do the paying. Some of us might call this stealing. An example of such a country was Canada. Canada did this through not providing product patent protection for drugs as well as by expropriation of patents under the rubric of compulsory licensing. Canada abandoned this practice because of NAFTA. Now, as the result of the TRIPS, most countries will have to protect drugs developed after around 1995 at least by 2005 or so. The legal situation is actually complicated as to when all of the provisions of TRIPS must be fully implemented, but the world will surely in a few years be one where it will become much more difficult for countries to behave as Canada behaved for most of the twentieth century.

Many commentators and scholars motivated by the desire to spare the inhabitants of some countries from the obligation to pay their fair share of research and development costs have suggested a number of strategies for weakening the patent system in the hopes that such strategies will lead to lower prices for patented pharmaceuticals. One such strategy goes under the heading of compulsory licensing. To understand compulsory licensing, it is first necessary to understand that ordinarily a patent owner is given the right to obtain an injunction against infringement of its patent. However, there are cases where such an injunction is refused. In that case the remedy for the patent owner is a monetary award that is no lower than the damages caused to it by the infringement. In one sense this constitutes a compulsory license since the infringer in effect obtains an involuntary license from the patent owner. Nevertheless, the denial of an injunction is not generally termed compulsory licensing. However, instead of denying a patent owner an injunction, a government can decide to grant an involuntary license to a third party or to itself and provide for a royalty that is much less than the actual damages that a court would award for infringement in the absence of that license. This is what is commonly referred to as compulsory licensing. As I have defined it, it is simply a taking. In effect a Government grants a patent and then takes it back or part of it back. However, if the royalty rate is the same as what a court would award as actual damages, then there is no taking and the patent owner is awarded the economic value of its patent.

The damage to a patent system by compulsory licensing with reduced or no damages as was the case in Canada for pharmaceuticals is obvious. Thus, the TRIPS Agreement permits compulsory licensing under conditions defined in Article 31, but only if the licensee pays a royalty equal to adequate damages. The actual language of Article 31(h) is: the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization. If these words are taken

literally, then actual damages caused by the grant of a compulsory license is the measure of adequate remuneration (any other measure is by definition inadequate and arbitrary). Under such conditions compulsory licensing is only useful when the patent owner is unwilling or unable to provide a sufficient supply of a needed patented drug. That may have seemed to be the case in the well-publicized CIPRO affair where the U.S. government wanted an immediate supply of CIPRO. If the patent owner, Bayer, would have been unable to provide the needed supply, then purchase from another source would make sense and Bayer would not have been able to assert a lost profits claim in the Court of Federal Claims had the U.S. government purchased it from an unlicensed source. However, if Bayer could supply the drug, but the U.S. went ahead and purchased it from an unlicenced source, then Bayer could have asserted a claim for lost profits in the Court of Federal Claims. The award by that court of such damages to Bayer would have made it economically foolish for the U.S. government to purchase the drug elsewhere unless Bayer wanted an unreasonably high price that could not be asserted to be a profit maximizing price.[1] Ultimately, of course, the U.S. government did purchase from Bayer. The teaching of this example is that if the patent owner is willing and able to supply the needed drug, there is no economic advantage to purchasing it elsewhere using the mechanism of a compulsory license or using the power of eminent domain possessed by governments. All of this is independent of the argument raging since Doha as to when the requirement that the licensee manufacture in the country of the grant found in Article 31 should be waived.

However, If compulsory licensing is not the answer, what is? The answer is provided in a paper authored by Scherer and Watal[2] where on page 49 the authors conclude:

> A nuanced policy that makes the best of an inherently imperfect situation is likely to have the following characteristics:
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> > 1) To encourage the low-price provision of drugs to low-income nations, low-income nations should be allowed to bar parallel exports of drugs received at preferential prices. Pharmaceutical manufacturers should be given the legal means to discourage parallel

1. The proper calculation of damages where a patent has been taken involuntarily is demonstrated by a recent case from the Court of Appeals for the Federal Circuit where the court makes it clear that one needs sophisticated economic models to properly calculate damages, *Crystal Semiconductor Corp.* v. *Tritech Microelectronics International, Inc.*, 246 F.3d 1336 (Fed. Cir. 2001).
2. Frederick M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines for Developing Countries*, WHO Commission on Macroeconomics and Health (2001). This paper may be found at www.cmhealth.org/docs/wg4_paper1.pdf.

> importation into high-income markets of the patented drugs they have sold at lower prices in nations identified as less-developed under United Nations criteria.
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> 2) To reduce the adverse consequences from multinational drug providers' niche-pricing strategies, parallel imports into low-income nations should be allowed.
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> 3) To reduce the product misallocations and impairment of research and development capacity caused by price controls in affluent nations, parallel exports would not be permitted from price-controlled jurisdictions. High-income nations should also agree not to base the prices they allow under their price control regimes on the prices observed in low-income nations, i.e., to limit the geographic scope of any external reference price-based controls. Since foregoing external reference pricing may not be in the interest of high-income nations, an international covenant may be required to achieve this desirable result.

There are two key aspects of these recommendations. First, there is an absolute insistence that all precautions be taken to prevent any export of drugs sold in low-income nations. The best way to do this is to insist that no country should adopt the principle of international exhaustion. Thus, for all countries importing the genuine product would be patent infringement in the country into which the drug is imported. Unfortunately this is the easy part. The more difficult part is to stop countries from using the low prices in low-income nations against the pharmaceutical companies by using them formally or informally in reference price-based controls.

All of this is part of the psychological problem with recommendation number 3. When people in the more developed world learn that the same drug is sold by the same company at a lower price, they naturally clamour for that price. Similarly when authorities are fixing prices or deciding what price they will pay for a drug it is hard to convince them not to use the low prices that would be used in the low-income world. However, if the markets can be properly isolated then low-income countries will essentially have what they seek from compulsory licensing, low prices, while preserving incentives for the highly competitive pharmaceutical industry to develop new and better drugs which will be the subject of strong patent protection.

Of course it may turn out that even these low prices are too high for the low-income countries. In such a case there is the need for a subsidy, but that

is the same situation as we have in the absence of patent protection and should be solved in the same way. If, of course, a pharmaceutical company refuses to sell its patented pharmaceutical in a low-income country at its profit maximizing price which would, of course, be a low price, then there should be a compulsory licensing remedy with damages based on the profit-maximizing low price.[3]

3 The Scherer and Watal paper discusses the possibility that the prices would not be low because of niche-pricing strategies. This special case, if it exists at all, is beyond the scope of this paper.