Big Pharma's Patent Woes

Ernest V. Linek

Ernest V. Linek is a principal shareholder of Banner & Witcoff, Ltd, in Boston, MA, a firm dedicated to the practice of intellectual property law, with offices in Chicago, Washington DC, Boston, and Portland, OR. He may be reached at elinek@bannerwitcoff.com.

Development costs for new drugs are staggering. Some estimates put the cost in the range of about $900 Million to about 1 7 Billion Dollars for each new drug. This fact, combined with the short patent lifetime afforded new drugs after regulatory approval, explains the high prices charged for most new drugs. The pharmaceutical industry, "Big Pharma," must recoup development costs, and make adequate profits in order to continue to innovate. Development costs continue to rise as more and more new drugs either fail in clinical trials, or a drug that passed through the trial phase, and became a market success, was later withdrawn due to adverse reactions found after the patient population expanded dramatically after launch. Patents are often secured for new drugs in every country where that drug is expected to be sold. The protection afforded by such patents is universally recognized by Big Pharma—only the patent owner has the right to make, use, or sell the patented drug in a country in which patent protection has been granted. One problem, this universal truth is neither universal, nor always true.

On May 4, 2007, Brazil signed a compulsory license for the production of efavirenz, an HIV/AIDS drug that is patented in Brazil (and elsewhere) by Merck & Co. Now the drug will be manufactured in India for Brazil, and the cost per pill will be about 45 cents verses the $1 59 price charged to Brazil by Merck. This move by Brazil's President Luiz Inacio de Silva marks the first time that Brazil has broken a patent to provide more affordable drugs for its citizens. Brazil offers free universal access to HIV/AIDS drugs and spent almost $500 million dollars on such drugs in 2005, according to a Brazilian report to the United Nations. A one-year supply of efavirenz for one patient in Brazil used to cost $580. Now, it will cost only $166.

The World Trade Organization

The World Trade Organization's (WTO) IP treaty, known as TRIPS (Trade-Related Aspects of Intellectual Property Rights), specifically says that countries can break patents under so called dire conditions. Thus, patent protection can be ignored, so that drugs that are crucial to public health can be made available at low cost The compulsory license can allow a country to make a patented drug or have it made by others.

Brazil took the first step toward breaking an AIDS drug patent held by Merck & Co. on in April 2007, when the Health Ministry decreed the drug was in the public interest and too expensive to buy from Merck. It would be hard to argue that the AIDS epidemic in Brazil does not qualify as dire conditions, as the government expects to be treating 215,000 patients by 2008.

A ministry spokeswoman said the breaking of the patent would make local production of a copy of the drug possible, although the statement did not mention that. So, for now Brazil's HIV/AIDS patients will have low cost medicine, but what will the future bring?

Brazil's decision to break the Merck patent has been denounced by the International Federation of Pharmaceutical Manufacturers and Associations. Merck has publicly stated that it was disappointed by the decision:

> Merck is profoundly disappointed by the decision of the Government of Brazil (GOB) to issue a compulsory license for STOCRIN™ (efavirenz), which would break Merck & Co., Inc.'s patent and make it possible for efavirenz to be produced by a generic manufacturer.
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> Merck has attempted to negotiate in good faith with the GOB, but a fair offer on STOCRIN has been rejected. While we remain flexible and committed to exploring a mutually acceptable agreement with the Brazilian government to help the country achieve its objective of universal access to treatment, we believe their action is not in the best interests of patients in Brazil and around the world
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> Merck continues to share with the GOB the common objective of improving the health and welfare of those living with HIV/AIDS. In fact, Merck's global HIV pricing policy offers Brazil access to both STOCRIN™ and CRIXIVAN® at the lowest price of any country with a comparable wealth and disease burden.
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> This expropriation of intellectual property sends a chilling signal to research-based companies about the attractiveness of undertaking risky research on diseases that affect the developing world, potentially

hurting patients who may require new and innovative life-saving therapies.

Research and development-based pharmaceutical companies like Merck simply cannot sustain a situation in which the developed countries alone are expected to bear the cost for essential drugs in both least-developed countries and emerging markets. As such, we believe it is essential to price our medicines according to a country's level of development and HIV burden, thereby ensuring equitable access as well as our ability to invest in future innovative medicines. As the world's 12th largest economy, Brazil has a greater capacity to pay for HIV medicines than countries that are poorer or harder hit by the disease.

This decision by the GOB will have a negative impact on Brazil's reputation as an industrialized country seeking to attract inward investment, and thus its ability to build world-class research and development.

Merck hopes the government of Brazil will reconsider its stance in the interests of HIV patients around the world.

Breaking Merck's patent was a drastic move by Brazil, and it will likely lead to undesirable future consequences. For instance, trade sanctions could be sought by the US government over this matter. In the past, this same action has been threatened, not only by Brazil, but by other countries as well, though usually an agreement could be reached, preserving the patent, and obtaining a lower price for the drug of interest.

In 2005, Abbott Laboratories Inc. reached an agreement with Brazil that has been lauded as a salutary breakthrough in international relations by some and, by others, as an act of industrial blackmail that threatens the efficacy of intellectual property protection throughout the world.

It remains to be seen whether or not this particular agreement serves as a model for future negotiations between corporations and nation states. As with most such matters, unforeseeable social pressures and political vagaries will determine how or if any current international agreement translates into long-term standard practice.

The implications of the agreement for intellectual property law and policy are, however, more easily discussed. It is clear that the agreement does not vitiate international patents or threaten worldwide IP systems. And, it is important for businesses to understand why it does not.

Most important, perhaps, the agreement is extremely significant if only because it puts patent law and patent practice into a wider perspective for all businesses.

The agreement was reached two weeks after Brazil formally threatened to break Abbott's patent on the AIDS drug Kaletra unless the company drastically reduced the price. Abbott had ten (10) days to respond to the ultimatum, which Brazil said was justified in accordance with a WTO provision that allows compulsory licenses for drug production as a matter of public interest or during national emergencies.

Brazil claimed it could produce a generic Kaletra for 68 cents per pill and would do so unless Abbott further reduced its offering price of $1 17, which was already marked down from $1.60 and represented the lowest AIDS medication cost outside Africa. After some back-and-forth, Abbott agreed to a plan that would price Kaletra at 99 cents per pill, with further reductions to 72 cents in five years. All told, Abbott is agreeing to leave around $260 million on the table. As part of the agreement, Abbott also agreed to a technology transfer facilitating Brazilian production of a generic drug after 2015, when Abbott's patent expires.

At first blush, it might appear that this is a case of a developing nation operating essentially outside the law, or that the TRIPS agreement itself is an ill-conceived provision that encourages a frontier mentality among various members of its signatories. The fact that Brazil actually has a robust GNP raises additional concern that it's not really just a Third World issue, but an umbrella for all sorts of countries to play fast and loose with governing law.

Most nations, in fact, have socialized medicine. Brazil, for one, has garnered international praise for its aggressive free distribution of AIDS medicine to anyone who needs it. No, not just the poorest countries, but nations throughout the world, with more liberal healthcare policies than the United States, are thus single-source buyers and suppliers. That, of course, puts them in a powerful bargaining position with Big Pharma.

Yet even when free market forces drive healthcare (to one extent or another), such pressures on drug companies are not at all unheard of. In 2001, the United States considered invoking the "compulsory license" provision of 28 USC § 1498 to force Bayer to lower costs for Cipro, the world's best-selling anthrax drug. The provision says that the government need not seek a license or negotiate for use of a patent or copyright. Any federal employee can use or authorize the use of a patent or a copyright. The holder is entitled to compensation but cannot enjoin usage by the government or an authorized third party.

In that case, there was no anthrax epidemic, only the fear of one. The situation was at least arguably less exigent than what Brazil is facing with AIDS.

What Brazil did was simply ratchet up the dialogue. The United States (along with Canada, which also participated in the Cipro negotiations and invoked the WTO provision to support its position) never quite got around to explicitly threatening to break a patent. The Brazilians did and—lest we overstate the Abbott agreement as a unique watershed—it wasn't the first time either.

In 2001, Brazil successfully pressured Roche Holding AG to cut the price of Nelfinavir, another AIDS drug. In the 2005 round of negotiations, Brazil was even better positioned because Kaletra, along with Efavirenz and Tenfovir, represents 67 percent of its annual budget for imported AIDS medicine. As such, Brazil could more readily justify the position that it is indeed facing just the sort of public crisis provided for by the WTO.

In any event, it is not in essence an international issue—not when corporations may well face the same pressure from officials in Washington, DC as in Ottawa or Brasilia. It is instead a global fact of life with which all manufacturers selling potentially vital goods and services must grapple.

A Business Decision

The way corporations can grapple with the Abbott decision, and with the many other similar arrangements that are bound to be negotiated in the future, is to understand it as a business decision. From an IP standpoint, it is also an essentially sound business decision.

To understand why, three basic questions need to be asked and answered.

> **Question 1.** In 2005, why didn't Brazil simply break the patent and start distributing Kaletra anyway? After all, the savings that were negotiated are not likely as great as if the government were to spend 68 cents per-pill to handle manufacture and distribution itself. The WTO provision could have justified such a decision.

The answer is that Brazil still wants global companies filing patents in Brazil. Patents are filed in countries where products are either manufactured or widely marketed. An outlaw nation, or even a nation that can justify its actions on the basis of existing law or treaty (in this case, the WTO IP pact), but that cannot be trusted as a good business partner, impoverishes itself by violating patents except as a last resort. Now having broken Merck's patent, Brazil may find that global companies may now be less willing to invest there; patent filings may decrease; etc.

Back in 2005, Brazil negotiated with Abbott in good faith. Then Brazil was essentially saying that it honors the idea of patents in general and is only threatening to break this particular patent because it cannot afford to treat 215,000 infected people. In fact, there is almost a subliminal message, a reminder that, in Brazil, only so drastic a situation as an AIDS epidemic could ever undermine the safety of a bona fide patent.

> **Question 2.** Why did Abbott agree to the 2005 deal with Brazil? Doesn't it set a dangerous precedent and expose the company, and other companies, to cost-gouging throughout the world?

The answer is that Abbott still had a lot to gain by filing other patents in Brazil and reaping the benefits there of protected intellectual property. Again, if anything, the Kaletra deal affirmed the overriding value of patent filings.

Presumably, Abbott thus figures to generate revenue on two fronts. Not just patents on other drugs, it will still be selling Kaletra in Brazil and no doubt profitably. Again, there is an implicit reaffirmation of the value of patents in Brazil, otherwise Brazil would have had nothing to offer and Abbott would have had no reason to negotiate.

At the very least, the fact that both Abbott and Brazil felt they won something creates a positive mood for future negotiations. It creates a precedent on many levels. Patents in general were reaffirmed even as one specific patent was threatened. The WTO provision was invoked fairly responsibly. And, the corporate party at risk still stands to profit at the end of the day.

The Abbott/Brazil agreement confirmed that, in such situations, solutions are possible, which is a most salutary message for future negotiators.

Look at Merck's comment regarding the failed negotiations with Brazil—Merck offered a price that was "the lowest price of any country with a comparable wealth and disease burden." Brazil wanted to pay no more for efavirenz than Thailand was paying (65 cents per pill), but these two countries are very different in terms of economic strength. One published report stated that Merck was willing to cut the cost to Brazil by 30 percent.

The real losers in all of this, if there are real losers, could be the smaller nations. If they are not desirable markets for high-volume patent filings, they have nothing to offer If they are not able to manufacture the drugs themselves, they can't even invoke the WTO provision. The patent-holders remain in the strong position one way or another

> **Question 3.** Isn't the integrity of the patent system threatened by the very fact that it can be put in play during such a negotiation? What is a patent worth if, every time there's an emergency, a nation can break it if it wants?

The answer to this question speaks most directly to the real value of a patent.

A Business Tool

Governments are *sui generis*. In the recent past, some of them have been rapaciously confiscatory. Never mind patents; Fidel Castro, for one, simply seized corporate property and kept it.

There are always contingencies in dealing with governments, including our own. Government contracts signed and sealed in Washington, DC are often subject to conditions that could not likely arise in any business-to-business transaction. Companies make exceptions when doing business with governments because such exceptions are the cost of doing that business.

The point is, absolutely nothing in Brazil's negotiations with Big Pharma can possibly minimize the legal obligations that companies have to each other. Even if a country were to break a patent under the WTO terms, that patent would still be worth holding if sufficient revenue were to be gained, simply because other companies could not then also break it. Brazil may create a precedent for South Africa or Pakistan, but not for Pfizer or Eli Lilly.

What's interesting about the Brazil decision to break the Merck patent is that it underscores just this essential difference between private/public and private/private relationships with respect to intellectual property.

There's also a larger lesson here for businesses and, to be sure, for the lawyers who represent them. A patent is not an absolute in the sense that it cannot be compromised or put at risk under certain circumstances. In the last analysis, patents are business tools. As long as they can be shown to still be effective business tools in some areas, they may be negotiable in others.

Lawyers who do not understand intellectual property in the broadest business context are disserving their clients. The role of the IP counselor is to help companies succeed.