Brazil's Agreement with Abbott: A New Perspective on Patent Prosecution as a Business Process

By Ernest V. Linek and John P. Iwanicki

Several months ago, Abbott Laboratories Inc. reached an agreement with the nation of 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 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.

A Direct Ultimatum

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 10 days to respond to the ultimatum, which Brazil said was justified in accordance with a World Trade Organization (WTO) provision that allows compulsory licenses for drug production as a matter of public interest or during national emergencies.

The WTO's IP treaty, known as TRIPS (Trade-Related Aspects of Intellectual Property Right), specifically says that countries can break patents under such dire conditions. It is indeed hard to argue that the AIDS epidemic in Brazil is anything but a national emergency, as the government expects to be treating 215,000 patients by 2008.

Brazil claimed that 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, one might surmise 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 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 health care policies than our own, are thus single-source buyers and suppliers. That, of course, puts them in a powerful bargaining position with Big Pharma.

Yet, even where free market forces drive health care (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 U.S.C. § 1498 to force Bayer to lower costs for Cipro, the world's best-selling anthrax drug. In 2001, the United States considered invoking the compulsory license provision of 28 U.S.C. § 1498 to force Bayer to lower costs for Cipro, the world's best-selling anthrax drug. The statute recognizes the government's ability to use the US patent rights of others without negotiating a license. The patent holder has the right to sue the government in the US Court of Claims to recover "reasonable compensation," but cannot enjoin usage by the goverment or 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.

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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.

In 2001, Brazil successfully pressured Roche Holding AG to cut the price of Nelfinavir, another AIDS drugs. In this latest 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.

Efavirenz and Tenforvir are manufactured by, respectively, Merck & Co. and Gilead Sciences Inc. As of this writing, Brazil is negotiating with both companies over the price of those drugs.

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 that 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 should be asked and answered.

> 1. Why did Brazil not 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.

By negotiating with Abbott in good faith, Brazil is 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.

If anything, the fact that Brazil could break the patent if it wanted to, but preferred a negotiated arrangement, reinforces the country's IP commitments.

> 2. Why did Abbott agree to the deal? Does it not set a dangerous precedent and expose the company, and other companies, to cost-gouging throughout the world?

The answer is that Abbott still has 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 affirms, it doesn't vitiate, the overriding value of patent filings. Don't be surprised if there were other drugs discussed during the negotiations.

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 because otherwise Brazil would have had nothing to offer and Abbott would have had no reason to negotiate.

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.

As of this writing, the Abbott/Brazil deal still faces a possibly serious glitch. On July 18, Brazil's new health minister, Jose Saraiva Felipe, said that "no deal had been sanctioned," that the price reductions were insufficient, and that negotiations would continue.

It was no surprise, 10 days earlier, when Abbott as well as Brazil came away from the table sounding happy. They had every right to be happy, as did interested onlookers. There will certainly be similar "events" in the near future. The African AIDS problem only gets worse, and in the face of so much human misery, global sentiment is not particularly warm to patent-holders.

At the very least, the fact that both Abbott and Brazil felt that they had 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.

It would therefore be extremely unfortunate at many levels if this deal were to now fall through.

> 3. Is the integrity of the patent system not 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 that 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/Abbott deal 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.