

INTELLECTUAL PROPERTY

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Brazil and Abbott Labs reach accord on AIDS drug

Brazil considered issuing a compulsory license for generic version of drug.

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IN MID-OCTOBER, Abbott Laboratories Inc. reached an agreement with Brazil to lower the price Brazil pays for Abbott's patented AIDS drug Kaletra from \$1.17 to 63 cents per pill. Brazil obtained this rock-bottom price by threatening to issue a low-royalty, compulsory license to its country's generic drug industry to copy and distribute the drug. In view of this development, pharmaceutical companies selling in Brazil and other countries having generic drug industries may want to change their patenting strategies.

A compulsory license is a government-granted exception to the exclusive rights granted to a patent owner. It allows a competitor to use the invention without the permission of the patent owner. Under long-standing international

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law, compulsory licenses are allowed only rarely, "to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."

Paris Convention for the Protection of Industrial Property, July 14, 1967, Art. 5(a)(2). Failure to work means either refusing to practice the patented technology or practicing the patented technology on a limited scale without satisfying market demand, thus withholding the benefits of the patented invention from the public.

Brazil's action respecting Kaletra does not fit the Paris Convention standard because Abbott had been selling Kaletra in Brazil at a low price and apparently has the capacity to satisfy the market demand in Brazil. At \$1.17, Brazil reportedly paid the lowest price for Kaletra outside sub-Saharan Africa.

National governments may also grant compulsory licenses under certain other circumstances specified by international law. One limitation on this right is that "such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such

efforts have not been successful within a reasonable period of time. This requirement may be waived by the country granting the license in the case of a national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use." Agreement on Trade-Related Aspects of Intellectual Property Rights, TRIPS, April 15, 1994, Art. 31(b). If a compulsory license is granted, "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization." TRIPS, Art. 31(h).

More recently, international law has subtly shifted, and is now perceived as somewhat more amenable to a compulsory license. The Doha Declaration of Nov. 14, 2001, Art. 6, states in part: "We recognize that under [World Trade Organization] rules no country should be prevented from taking measures for the protection of human, animal or plant life or health, or of the environment at the levels it considers appropriate." Art. 17 of the Doha Declaration states in part, "We stress the importance we attach to implementation and interpretation of the [TRIPS agreement] in a manner supportive of public health, by promoting both access to existing

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medicines and research and development into new medicines.”

Reserved for dire situations

But compulsory licenses remain rare. An indication of the gravity of awarding a compulsory license under current international law is that no compulsory license has so far been granted by any country for an AIDS drug patent. This is true despite the worldwide struggle for more than 20 years to contain AIDS and the availability of significant AIDS drugs for about 10 years. Brazil has threatened to issue compulsory licenses for AIDS drugs before, but has not carried out the threat.

In practice, compulsory licenses have been reserved for dire situations, and have not been regarded as an appropriate negotiating lever to reduce prices. In the United States, which has generally granted strong protection to owners of patents, there is essentially no tradition of granting compulsory licenses. One rare example is *City of Milwaukee v. Activated Sludge Inc.*, 69 F.2d 577 (7th Cir. 1934). In that case, the 7th U.S. Circuit Court of Appeals provided a de facto compulsory patent license by refusing to grant an injunction stopping the city of Milwaukee from infringing a patent on a sewage treatment method. An injunction would have injured the public by forcing Milwaukee to discharge untreated sewage into Lake Michigan until alternative technology was installed.

Brazil, however, did not grant any patent protection at all to drugs or other chemical compositions until

1996, when it changed its law to implement the TRIPS agreement. Compare Brazil, Industrial Property Code, Law 5772/71, 21 Dec. 1971, with Law 9279/96, 14 May 1996. In essence, before 1996, all drugs were effectively subject to a royalty-free compulsory license in Brazil.

Earlier this year, the government of Brazil claimed it was in an emergency situation requiring protection of the lives and health of its citizens. Brazil, however, has an AIDS problem not significantly greater than the problem in the United States, in terms of the proportion of its people infected with HIV. Therefore, it appears that other motivations were also at work.

One additional reason for Brazil's actions may be the need to simply save money. Brazil gives free AIDS drugs to all citizens who need them, regardless of their ability to pay. Since patients diagnosed with AIDS now have more effective treatments than before, they live longer and thus require more drugs over their lifetime. Although it is a developed country, the government of Brazil has less money than that of the United States to spend on all programs, including those that deliver AIDS drugs.

Another possible reason for Brazil's actions may be the need to gain political favor with Brazilians. Brazilians may not want to see their tax money used to pay foreign producers for Kaletra or other AIDS drugs that could be produced locally.

Another possible motivation is Brazil's desire to maintain a strong domestic generic drug industry producing drugs for its internal use. Brazil developed its generic industry

before it had patent protection for drugs. Its generic industry is still free to copy drugs that were never patented in Brazil. But to remain viable, Brazil's generic industry may need rights to make newer drugs.

If Brazil had issued a license

Brazil's actions forced Abbott into a difficult situation. Had no agreement been reached, Brazil might have issued a compulsory license to its well-established generic drug industry, allowing others than Abbott to make, use and sell a generic version of Kaletra in Brazil. As well, Abbott may have anticipated that some of the generic drug made in Brazil would find its way into the United States and other countries where AIDS drugs are now more expensive.

Had Brazil granted a compulsory license, Abbott would have been entitled to reasonable compensation, “taking into account the economic value of the authorization,” and further would have been able to obtain judicial review of the validity of the compulsory license and the amount of compensation. TRIPS, Art. 31(h)-(j). But this judicial review would have been provided in the courts of Brazil. TRIPS, Art. 31(i)-(j). This may not be a favorable forum for a U.S.-based pharmaceutical company. Abbott's battle to recover compensation in the courts of Brazil for the use of its patent rights under this license could have been expensive and drawn out. Brazil may also have won in the “court” of public opinion.

Since Abbott and Brazil reached agreement, there may now be greater pressure on pharmaceutical prices worldwide. It seems likely that Brazil will continue to use its successful

**Cheaper,
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negotiating strategy of threatening to issue compulsory licenses if the drug prices it pays are not reduced severely. In this environment, international pharmaceutical companies are advocating to keep worldwide patent laws strong to provide them the legal protections they rely upon when conducting business overseas.

That being said, drug-discovering companies should continue to seek strong patent protection for their inventions, in Brazil and elsewhere, even in the absence of stronger national laws. Pharmaceutical patents remain the primary defense by pioneering pharmaceutical companies to protect their investment in research. Without them, it is very difficult for pharmaceutical companies to justify significant research and development investments.

Of course, pharmaceutical companies already are aggressive in patenting their blockbuster drugs worldwide. But they may find it useful to do more. One way pharmaceutical companies can obtain strong patents is to aggressively disclose any possible defenses in foreign patent applications. Particularly, they can disclose prior work of others, although they will then need to distinguish their own claimed inventions from the disclosed prior work to obtain patents.

At first blush, this proposal is counter-intuitive; lawyers learn early to assert their strongest position and leave it to others to find any weaknesses in that position. Moreover, in many countries outside of the United States, the patent applicant has little or no duty to disclose prior developments that might prevent or limit the applicant's right to a patent. During litigation in most countries outside the United States, little or no discovery is available to allow an opponent to find defenses.

But in today's world, much of the

prior work of others can easily be found online by anyone in the world who chooses to look for it. Only a few minutes' work on the Internet is needed to identify the U.S. and foreign patents granted on a new drug in principal patent-granting countries, review those patents and see the arguments and information considered by the granting authority, including the prior work of others that frames a starting point for any defenses that might be raised. Litigation records can also provide additional information not considered by patent-granting authorities.

Under these modern circumstances, pharmaceutical companies may find it unproductive to simply play the "numbers game" of getting as many patents as possible on their inventions in Brazil or elsewhere around the world. In the event of a negotiation with Brazil or other countries, if many of the local patents held by the negotiating company on the drug at issue do not stand up under scrutiny, the negotiating government may feel it is free to issue a compulsory license, on the basis that the patent should never have been granted. One weak patent in an otherwise stronger portfolio may be spotlighted.

Similarly, when reviewing the local decision to grant a compulsory license, the courts of the negotiating government may take into account any weakness of the patents, both in deciding whether the compulsory license was legitimately granted and in reviewing the amount of compensation awarded the patent owner for the grant of the compulsory license.

The negotiating company may also find that its home country will not exert pressure on the negotiating government if the negotiating government can legitimately show that

the patents in question are overbroad or represent little improvement over prior work by others.

Therefore, a company seeking patents in Brazil should actively disclose defenses such as the prior work of others that were considered in other patent offices worldwide, so only patents able to overcome these difficulties will be granted. The local government will have granted the patents in question with full knowledge of all relevant facts and prior work. Key prior work should also be translated into Portuguese, the national language of Brazil, to ensure consideration. Fewer patents may be obtained, but they will be more focused and resistant to defenses.

These more-focused, less-numerous patents may be less subject to legal and political arguments that they are of dubious validity. This approach may make it more difficult for a foreign country to award a compulsory license, or pay little compensation to the patentee for the grant of the license. Also, if a compulsory license is less easily justified or defended, the threat of a compulsory license may not provide as much negotiation advantage to the negotiating government.

The Abbott/Brazil situation, although "resolved" in the short term, undoubtedly will generate long-term ramifications. It is important for pharmaceutical companies today to consider new strategic approaches that help them avoid both negative publicity and the potential of compulsory licenses. **NLJ**