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Introduction

On December 30, 2010, India’s patent office in Mumbai rejected the Chicago-based pharmaceutical company Abbott Laboratories’ application for a patent on a new version of Kaletra.1 Kaletra is a second-line antiretroviral HIV/AIDS drug that is a combination of lopinavir and ritonavir, and is widely considered the best treatment for patients who are resistant to the first-line medicines.2 After a process that took nearly four years, Abbott’s patent application was rejected because the version of Kaletra under consideration was deemed not to be an “inventive step” beyond previous lopinavir/ritonavir combinations that are already under patent.3 Although this may sound like a routine patent rejection, civil society groups like Doctors Without Borders have already hailed the decision as “a major victory for public health” because of its potential to make generic drugs available in the developing world by preventing pharmaceutical companies from extending patents on products that are only improvements on existing treatments.4 Pharmaceutical companies and intellectual property advocates have been quick to point out, however, that the decision is just the latest sign that India is not complying with its obligations under the World Trade Organization’s (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agree-

41. See GAVI, Annual Report, supra note 39, at 15.
ment. Under the TRIPS agreement, countries are required to, at a minimum, provide protection for products when a product contains an "inventive step," but the agreement only clarifies that the term may be considered synonymous with "non-obvious" and intentionally leaves the standard vague to allow for flexibility in domestic laws. Given that ambiguity, this decision will likely spark a debate on whether India is ignoring its commitments or exercising appropriate discretion. That debate may have wide-ranging consequences for both access to medicine and the protection of intellectual property in the developing world.

The Evolution of India’s Patent Laws
India’s patent regime has undergone a series of major transformations over the second half of the 20th century that, taken together, have produced the current clashes between multinational pharmaceutical companies and domestic generic manufacturers over intellectual property. Although India gained independence from Great Britain in 1947, it took over 20 years before the country was able to enact its own patent law. Perhaps the most notable feature of this first law, “The Patent Act of 1970,” is that it removed the “patentability of pharmaceutical products.” As a result, pharmaceutical companies were unable to receive patent protection over the actual compounds and drugs they developed. It was still possible, however, to receive a patent for the process of making a substance, but only then for a relatively short maximum time of seven years from the date of the patent.

The impact of India’s lax patent laws was the development of a thriving generic drug-manufacturing sector. Indian companies were able to reverse engineer medicines developed in other countries, and then produce the same substances through different processes while still receiving full protection of the law. These legal protections resulted in the emergence of major generic firms like Ranbaxy and Cipla and the construction of more U.S. Food and Drug Administration-approved manufacturing centers than any country outside of the United States. This has not only allowed India to provide access to cheap medicine to its own citizens, but also enabled India to become so prolific as a drug exporter that it is often referred to as “the pharmacy to the world.”

India’s patent laws began to evolve when the country became an original member of the WTO in 1995. As a condition of membership, India was required to bring its domestic intellectual property laws into compliance with international standards that were elaborated as part of the TRIPS agreement. Since India had not previously extended patents to pharmaceutical products, as part of the agreement it was allowed a 10-year grace period to fully incorporate the international agreement into its domestic patent regime. The result was a three-stage process for amending the Patent Act of 1970, ultimately culminating in the Patent (Amendment) Act of 2005, which finally put pharmaceutical patent protection into full effect.

Despite the increased protection for intellectual property that the reforms provide, many limits were included within the amended patent laws to ensure “the availability and access of medicines.” These limits included only allowing patents to be granted for applications that were filed after 1995, and any Indian generic manufacturer, which began to produce a drug before 2005, to continue to produce that product. Additionally, Section 3(d) of the new amended patent law was included with the hope of only allowing protection for innovative products that are not derivative of other substances, and the act defined an “inventive step” as “a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.” These provisions were designed to take advantage of the flexibility allowed by the TRIPS agreement, but it has remained an open question whether India would interpret the requirements in a way that was consistent with the understanding of other signatories of the TRIPS agreements. This was the backdrop against which Abbott Laboratories filed its patent application in India.

Background on Abbott’s Application
In 1992, Abbott was awarded its first patent in the United States for the drug Ritonavir. Ritonavir is an antiretroviral drug that was developed to treat HIV/AIDS. Ritonavir was later combined with another drug, Lopinavir, developed by Abbott; the combination is marketed as Kaletra. Since its emergence in the world marketplace, the WHO has identified Kaletra as a preferred second-line treatment to fight drug-resistant HIV/AIDS, and recommended its inclusion by governments on their lists of essential drugs. As a result, Kaletra is an essential part of the battle against the global HIV/AIDS epidemic.

On March 24, 2006, Abbott filed a patent application for a new version of Kaletra in India. Abbott had previously filed a patent application for a soft-gel formulation of the drug, but ultimately withdrew the application after it faced opposition during the pre-grant review process. The new application was an attempt to patent a “solid pharmaceutical dosage form” of Kaletra. Abbott argued that this represented a substantial improvement over the previously marketed soft-gel tablets. Specifically, Abbott argued that the new solid dosage form of Kaletra made the drug more heat resistant and that it could now...
be taken solely with water. Since the previous version of the drug required refrigeration and had to be taken with food, Abbott was able to argue that this presented a potentially critical advancement of special significance to those battling drug-resistant forms of HIV/AIDS in the developing world.

Despite Abbott’s claimed innovations, the patent application faced substantial objections. In addition to complaints from health advocacy groups like Doctors Without Borders, four organizations filed formal opposition. Three of the official opponents were the generic manufacturers Cipla, Okasa, and Matrix. The fourth opponent, the Initiative for Medicines, Access & Knowledge (I-MAK), was a U.S.-based non-profit. I-MAK is a group of doctors and lawyers that has waged an international campaign to increase access to affordable medicines by limiting what it views as abuses of the patent system by large multinational corporations. Given its importance in the fight against HIV/AIDS, I-MAK has made increasing access to generic versions of Kaletra a top priority. As a result, I-MAK made two official filings in opposition to Abbott’s patent application, arguing that the new form of Kaletra was a modification of a known substance, and that the process to convert the soft-gel tablets to a solid dosage form was already well known.

### The Decision

After nearly four years of proceedings, India’s patent office in Mumbai released an opinion rejecting Abbott Laboratories’ application to patent a “solid pharmaceutical dosage” form of Kaletra. The decision by Dr. Ruchi Tiwari, Deputy Controller of Patents of suitable surfactants,” which means that it “cannot be a mere admixture... and Designs, begins by repeating the history of the filings by Abbott and the four official opponents to the applications. The decision then proceeds to recount the amended 22 claims on file from Abbott, and then document the arguments and exhibits of the four opponents.

The decision employs an interesting argument discussing the merits. The decision agrees with Abbott Laboratories that the new version of Kaletra is “not a mere discovery of a new form of a known substance.” As a consequence, the decision finds that the product “cannot be held as not patentable under the provisions of Section 3(d) of the amended Patents Act.” The decision proceeds to again agree with Abbott Laboratories that in the new version of Kaletra “the invention lies in the selection of suitable surfactants,” which means that it “cannot be a mere admixture... [and]...be held as not patentable as per provisions of section 3(c)” of the amended Patents Act. In these two concessions, the decision made it clear that it was not using either of the two sections in India’s new domestic patent regime that were designed to limit the extension of patents to minor improvements on existing pharmaceutical products.

Instead, the decision directly con-
As a result, without discussing the exact standard required by either the Indian Patent Act or the TRIPS agreement, the decision rejected Abbott’s application to patent the new version of Kaletra because the product’s innovations “clearly do not involve [an] inventive step.”

Potential Impact

There are at least four potential impacts that may result from India’s decision to reject Abbott’s application. First, the most immediate ramification of the decision may be to increase access to the drug for people living with HIV and AIDS in the developing world. The leading opponent to Abbott’s application, I-MAK, has already claimed that the impact of the case will be “tremendous.”

I-MAK argues that there are over 33 million individuals living with HIV, and 15 million of them require access to HIV drugs. According to I-MAK’s calculations, the cost savings from introducing generic versions of Kaletra that can now be legally produced and imported by Indian manufacturers are sufficient to make the treatment available to 130,000 new patients a year. This sentiment has been echoed by Doctors Without Borders and the Health Global Access Project.

Second, the decision has the potential to set a precedent in which multinational pharmaceutical corporations are held to a higher standard when seeking to gain new patents for improvements on existing innovations in India than in other countries party to the TRIPS agreement. In the first month following the rejection of Abbott’s application for a new Kaletra patent on December 30, 2010, at least five major patents were rejected or revoked on similar grounds. Analysts have argued that this is part of a trend in India of favoring process over product when evaluating patent applications, and that applying new process to improve upon existing products will be increasingly less likely to receive protection. Given India’s large domestic market and generic drug industry, this shift has the potential to make it even more difficult for U.S.- and European-based pharmaceutical companies to compete in the developing market.

Third, the decision has the potential to change the behavior of Abbott and other multinational pharmaceutical companies. After being denied a patent in 2006, Novartis claimed that there is “no faster way to kill access to the latest life-saving drugs for people in India than to avoid offering patent protection.” This proved to be true in Thailand, where in 2007 the Ministry of Public Health decided to issue a compulsory license on Kaletra to allow the import of generic drugs from India. Abbott’s response was to reduce the price for Kaletra in 40 countries, but also to withdraw registration for all new products in Thailand. A similar response may occur in India if multinational pharmaceutical companies feel that they are not being provided with adequate protection for their intellectual property. This may lead to a lag between when drugs are available in Western markets, and when patients in the developing world are able to benefit from new pharmaceutical innovations.

Fourth, the decision will lead to an increase in claims that India’s domestic patent regime falls short of its obligations under the WTO’s TRIPS agreement. Since Europe has already signaled its intention to extend patent protection to the new solid dosage form of Kaletra, this case only highlights the drift between the protections being afforded multinational corporations in the West and in India. The Office of the United States Trade Representative (USTR) had already placed India on its priority watch list as a result of its actions “to limit the patentability of potentially beneficial innovations, such as temperature-stable forms of a drug or new means of drug delivery.” Since this decision took exactly that course of action, it is likely that India will face increased pressure to either clarify or amend their existing patent laws to be most consistent with the United States’ interpretation of the TRIPS agreement.

Conclusion

The decision by the Indian Patent Office in Mumbai to reject Abbott Laboratories’ application to patent a new solid dosage form of Kaletra highlights the fact that the TRIPS agreement did not end the tug of war between groups hoping to increase access to life-saving medications in the developing world and those seeking to provide robust protection to intellectual property to ensure that incentives exist to guarantee the continued development of innovative treatments for diseases. As a result, it remains to be determined whether the long-term impact of this decision will be to increase the availability of generic drugs, or alternatively, to reign in the existing discretion that allows nations to define what constitutes an “inventive step” when reviewing pharmaceutical patent applications.

References

5. See Industry Briefing, supra note 2.

7. See generally Mueller, supra note 5.

8. Id., at 512.

9. Id.


12. Id.


16. See Mueller, supra note 6, at 519.

17. See Gopakumar, supra note 6, 326.

18. See Mueller, supra note 6, at 542-43.

19. Id. See also Gopakumar, supra note 6, at 335.


26. Id., at 21-25.

27. See Doctors Without Borders, supra note 4.


29. Id.

30. Id.


34. Id., at 25.

35. Id.

36. Id., at 21-25.

37. Id., at 25.

38. Id.


40. See Doctors Without Borders, supra note 4.


43. See Mueller, supra note 11, at 541.


45. See Economic Intelligence Briefing, note 2.
