Regulatory and Judicial Implementations of Patent Law Flexibilities

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Director-General of the WTO Pascal Lamy recently suggested that a fundamental change taking place in international trade is “the rise of key emerging economies and the shift in economic realities that this implies.” Indeed, during the long course of the Doha round negotiations, these emerging economies have been grouped at times with developed countries and at times with other developing countries, indicating their unique needs and interests as countries in transition. The standpoint of emerging countries can be seen in portions of the WTO agreement, with flexibilities negotiated that allow for the medical needs of their populations and simultaneously further economic development. With India in the spotlight for its recent grant of a compulsory license and for its patent eligibility rules, it is a good time to reflect on the flexibilities negotiated into the TRIPS Agreement and their implementation through domestic legal regimes. Although world focus is on developing countries, these flexibilities are also present to some degree in the United States, albeit judicially determined and applied. To the extent some flexibility in implementation is inevitable, these instances raise universally applicable questions about the proper role of administrative agencies and courts in implementing policies that are influenced by both trade and patent policies.

During the negotiations leading to TRIPS, developed countries favored a uniform, baseline level of patent protection for all member countries. Developing countries sought to retain flexibility in various provisions particularly those implicating access to lifesaving drugs. Two cases coming out of India illustrate applications of these flexibilities and their implementation through the Indian administrative regime. The recent issuance of a compul-

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sory license by the Indian Patent Office is the result of the flexibility reserved to member countries to permit certain, otherwise unauthorized uses of patented articles or processes. In addition, a case now before the Indian Supreme Court will determine the legality of a regime that denies protection to newer forms of known chemical compounds that do not exhibit significantly improved efficacy.

The Indian compulsory license order covers Bayer’s “Nexavar”, a cancer-fighting drug, and is the country’s first compulsory license in the seventeen years since TRIPS took effect. The patent office granted the license after determining that the reasonable requirements of the public were not met, that the patented drug was not available to the public at a reasonable price, and that the patented invention was not worked in India. This last element of the rule – a requirement of local working – derives from early patent laws in now-developed countries, but its roots are firmly planted in trade considerations. Although TRIPS requires developed countries to encourage technology transfer to developing countries thus spurring local industry, the “working requirement” has been criticized as a possible violation of the non-discrimination provision of Art. 27 of TRIPS.

The battle over India’s patentability rules centers on “Gleevec”. Also a cancer-fighting drug, Gleevec targets leukemia. Novartis, the Swiss company that manufactures Gleevec, has challenged the Indian Patent Office’s denial of its application. The Indian Patent Law prohibits the grant of patents to new forms of known substances. The law seeks to limit a practice called “evergreening,” whereby pharmaceutical companies may effectively extend the lives of their patents by applying for patents on slightly different chemical entities with only marginal improvements to effectiveness. In parallel to this concern about patent overreach, however, the law also clearly vindicates the interests of the robust domestic generic drug industry in India.

Both of these cases highlight the implementation of flexibilities in TRIPS negotiated by developing countries and legislated and implemented through regulatory agencies. They stand in contrast to the practice of developed countries. In the United States, for example, there is no compulsory licensing provision, nor is there a requirement that a patent be worked domestically for a patent holder to exercise her right to exclude. However, there may be court-implemented deviations from the strong, exclusive right that was negotiated for under TRIPS. Thus, in recent years, courts have been denying permanent injunctions to patent holders that are not competitors and fail to show a loss of market share due to the infringing activities. This trend stems from a Supreme Court decision, eBay v. MercExchange, which on its face affirmed the application of traditional rules of equity to the grant of permanent injunctions in patent law. However, the Court also addressed, through concurring opinions, growing concern over entities that do not practice their patents but seek arguably excessive compensation from those who would. The same analytical framework may also lead courts to deny injunctions in situations that implicate urgent, public health concerns, although this provi-
sion has been invoked only rarely. Nonetheless, the equitable concerns encompassed in the test for injunctive relief as applied by courts in the United States can be mapped to the roles of both public health and local industry evident in the analysis of the Indian Patent Office.

To the extent uniformity among patent laws is important, we might question flexibilities – such as those embodied in the Indian law – that allow for denials of patents or subsequent grants of compulsory licenses. However, if flexibility is inevitable – perhaps even desirable – important institutional questions arise as to its implementation. Institutional competence reasons to value agency implementation may not apply to issues that sound so strongly in trade concerns. Thus, public health concerns and the changing needs of domestic industry may best be decided by a patent office in the first instance, but this is not a foregone conclusion. However, judicially imposed flexibilities also raise concerns. Although case law may be slowly tailored and course-corrected over time, this type of implementation does not lend itself to harmonization with other regimes. As uniformity and harmonization become the norm, the deviations implemented by TRIPS signatories will continue to receive scrutiny. The methods of this implementation are one aspect of these flexibilities that is bound to prove central to a fair comparison and analysis of this important and dynamic area of international law.