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Price wars undermine patent usefulness

Given the high price of research and development, and the decreasing budgets for health care, innovation in the pharmaceutical industry has become an increasingly troublesome proposition. Even in the best of times, only one in six new drugs makes it successfully through the critical human-testing phase. Worse, drug innovation requires a substantial up-front investment, with no possible return until after the new drug has not only proven effective, but received marketing approval from the appropriate government agency.

Patents can take the edge off this problematic investment model by assuring investors of lucrative exclusivity rights for qualifying new drugs. Theoretically, the legal monopoly of a patent should enable drug companies to price their products at levels that both assure their recovery of the costs of innovation and earn them a reasonable profit. Recent events in India this past month, however, signal that patents may no longer secure such marketing practices. To the contrary, they may be used to prevent them.

Patent protection for pharmaceuticals has never been an easy sell. Until the latter decades of the 20th century, most countries specifically excluded drugs from patent protection. The landscape changed overnight when the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) required member countries to provide patents for inventions "in all fields of technology." Categorical exclusions for pharmaceuticals were clear treaty violations that could result in trade sanctions, as India discovered in 1997 when its failure to accord patent protection for pharmaceuticals was held a sanctionable violation.

Because of the critical role drugs play in treating pandemics such as AIDS and malaria, phar-

maceutical patents have become the poster child for the adverse impact of intellectual property rights on the access to information. Like copyright protection for music, patent protection for drugs has increasingly been challenged as interfering with basic human rights, free speech for copyrights and access to medicines for patents.

The Internet has similarly complicated patent protection. Today, most countries publish patent applications on the Internet 18 months after filing, which virtually eliminates the window for marketing a new drug without competition from unauthorized "generic" manufacturers. Just as rogue websites offer pirated music, others offer counterfeit drugs, often with similar impunity. Worse, some countries do not link marketing approvals to patent ownership. This leaves the patent owner unable to market his patented drug because some other company has been granted the marketing rights.

All of these challenges pale in the face of India's most recent actions. On March 9, in a case of first impression under India's laws, the controller of India's patent office granted an Indian company, Natco Pharma Ltd., a compulsory license to sell sorafenib, the generic version of the Germany-based Bayer AG's patented kidney and lung cancer drug Nexavar. In support of his decision to grant the compulsory license, the controller cited three factors: the high price Bayer charged for the drug, (\$5,600 a month as opposed to Natco's claimed \$177 per month), the small amounts of the product Bayer had imported to meet domestic needs and its failure to manufacture the drug in India.

Under Indian law, a compulsory license can only be granted if the patent owner fails to provide the drug at "reasonably affordable prices to the public."

GLOBAL IP



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In establishing the lack of affordability, the controller relied on the limited amount of the drug Bayer sold in light of anticipated need. He held: "It stands to common logic that a patented article ... was not bought by the public due to only one reason, i.e., its price was not reasonably affordable to them."

Bayer countered that its drug was reasonably priced since it was charging the same price in all countries, but the controller rejected that defense. He also rejected Bayer's attempt to support its limited importation with evidence of substantial domestic sales of infringing drugs by an unauthorized Indian drug company. Instead, the controller held that the activities of this third party company could play no part in his decision. Ultimately, he granted Natco a nonexclusive license to manufacture and sell the drug in India for \$177 per month in exchange for a 6 percent royalty.

There is little doubt this decision will start a run on compulsory licenses for other patented pharmaceuticals in India. But its impact could run much deeper. The Bayer case

provides problematic international precedent that high prices can be used to support findings of anti-competitive conduct sufficient to sustain compulsory licenses. Since countries such as China already have anti-monopoly laws that allow compulsory licenses for "abuse of intellectual property rights," there is a significant risk others will begin to challenge the pricing and distribution structures of foreign IP owners on the basis of perceived high prices. In the face of a general industry practice favoring global pricing structures, this puts virtually every pharmaceutical patent holder at risk.

To reduce this threat, the Bayer case provides some helpful guidelines. First, serious consideration should be given to establishing rational differential pricing formulas, not only among countries, but also among classes within a country. Second, while the controller in the Bayer case recognized that patent owners have a right to recoup their investment, he considered such recovery based on the global sales history for the drug, rather than a more localized history. If a drug has been on sale in other countries, high prices become less defensible, particularly in developing countries. Finally, the selection of foreign manufacturers should be carefully considered since the failure to establish such facilities locally despite Bayer's history of establishing similar sites in other countries was relied on to support the compulsory license grant.

Authorized drugs will always be more costly than "generic" versions because "generic" manufacturers do not have R&D costs to recover. The challenge is to create rational pricing systems globally or face even lower cost recoveries under unwanted compulsory licenses. The time to create such new global systems is now.