

Price controls, worldwide access take center stage for IP owners in 2017

Global IP

By [Doris Estelle Long](#)

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One of my clearest memories as a child, pre-internet, was going to a large toy warehouse called Dwayne's the day after Thanksgiving to shop for Christmas gifts.

Holiday shopping sales have gotten more organized since then. Black Friday. Cyber Monday. Small Saturday. But the result is the same. Shoppers jam stores at odd hours to look for bargains because price matters.

Price matters for intellectual property-based products as well. But there are no shopping holidays internationally for pharmaceuticals, climate-control devices or smart technology.

Recent events, however, demonstrate that we may have reached critical mass in the demand to impose international controls on IP owners' pricing rights. Although this mass has largely been created around the issue of access to patented pharmaceuticals, its impact may not be so limited.

There is little doubt that access to medicines and other critical technologies is not resolved solely by requiring bargain basement rates for innovative products. To the contrary, if prices drop too low, private funding for future innovations becomes even more problematic. But bad conduct makes for worse press.

Price increases up to 600 percent for off-patent products such as EpiPen injectors and insulin formulations in the United States have resulted in congressional hearings and public demands for relief. They are not alone.

This past year, both the United Nations secretary general's High Level Panel on Access to Medicines and the World Health Organization have issued reports detailing the "patent barriers" to reasonably priced access to medicine. WHO's report, "Global



Those who believe this focus on price controls is a new development or, worse, a fad destined to disappear when a new issue arises, have not been paying attention.

Since 2000, patents have been condemned by members of the human rights community in diverse multinational documents for their “conflict” with “the right of everyone ... to enjoy the benefits of scientific progress and its applications, the right to health, the right to food and the right to self-determination.” (Office of the United Nations High Commissioner, Subcommission on Human Rights, Resolution 2000/7). Such “conflict” arose as a direct result of the monopolistic prices permitted by IP exclusivity.

By 2015, this “conflict” had evolved into declared second-class status for patents on the human rights scale. Numerous international instruments, such as the International Covenant on Economic, Social and Cultural Rights treaty, grant an “author” of a “scientific production” the right “to benefit from the protection of material interests resulting from [it].” (Article 15). Despite this grant, the UN special rapporteur on culture specifically found no protectable human rights interests in patents.

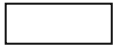
Condemning patents because they “generally enable patent-holding firms to charge higher prices, raising concerns about access to essential technologies,” the special rapporteur recommended: “Patent laws should place no limitations upon the rights to health, food, science and culture, unless the state can demonstrate that the limitation ... is strictly necessary for the promotion of general welfare in a democratic society.”

By 2016, this “recommendation” had morphed into a U.N. report by the secretary general’s High Level Panel on Access to Medicines that specially found that adopting Agreement on Trade-Related Aspects of Intellectual Property Rights-plus measures for patent protection without empirical evidence would not harm public health “is tantamount to neglect of state duties to safeguard the right to health.”

Concerns over price are not limited to human rights and international health organizations. To the contrary, various international forums have increasingly found a correlation between price and competitive abuse.

The Natco Pharma Ltd. decision in India (covered in my March 2012 column) marks the rallying point for those who seek to control patent owners’ distributional choices.

The controller of India’s patent office specifically held that the high prices Bayer AG charged for its cancer drug Nexavar (\$5,500 per month) prevented “reasonable access” for Indian consumers. The penalty imposed was the grant of a compulsory license to an alleged domestic counterfeiter, Natco Pharmaceutical, at a price discount of more than 97 percent (\$170 per month).



For example, in 2015, China's National Development and Reform Commission found that Qualcomm Inc. was liable because it charged excessive royalties for its patented chip technology. The commission specifically found Qualcomm's basing patent license fees on the net wholesale price of its chips abused its patent rights.

Ultimately, the case settled when Qualcomm lowered its royalties by 35 percent.

Although most anti-monopoly cases implicating pricing involve licensing practices for standard essential patents, they have left the door open for more searching price inquiries in other situations in the future.

Pricing controls and access are also the moving factors behind the re-emergence of exhaustion as a restraint on an IP owner's distribution rights.

Even in the United States, the Supreme Court has granted certiorari this term specifically to determine whether its previous grant of international exhaustion rights to copyrights in *Kirtsaeng* should be extended to patents. (*Impression Products v. Lexmark International*).

Such extension would largely eliminate a U.S. patent owner's present ability to prevent the importation of patented goods lawfully sold abroad.

This growing demand to impose international controls on IP owners' pricing rights reached critical mass in December.

Each year, substantive committees of the World Intellectual Property Organization meet in the fall to establish the agenda for the following year's discussions. In December, organization's standing committee on the law of patents failed to set an agenda for 2017.

The reason for this failure: A majority of attending countries refused to agree to any agenda that did not include price/access issues.

There is no easy resolution to these issues. Support for differential pricing appears the most likely result. Yet differential pricing among countries only succeeds when its differential nature is defended through enforceable prohibitions against unauthorized cross-border transit.

Such defense will be easier to secure as a policy matter if IP owners begin now to create rational differential prices. Such rationality requires an elimination of the worst abuses.



If that happens, compulsory licenses for pricing “abuses” may be the mildest rebuke they can expect.



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