BREAKING PATENTS

Daniel R. Cahoy[*]

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ABSTRACT

Patent breaking to eliminate market exclusivity has occurred in a surprisingly large number of contexts. There are examples in a variety of technologies, ranging from medicine to military, and the countries that break patents include least developed nations like Rwanda as well as developed, intellectual-property-centric nations like the United States. It is a useful legal mechanism that can provide an essential relief valve to intellectual property control. Unfortunately, evidence suggests that current international rules regarding patent breaking are ad hoc, rife with exploitation opportunities, and generally incapable of responding when the public good is truly in danger. In part, the sorry state of the law is due to the narrow political and academic focus on a single context, namely access to medicines. While extraordinarily important, this is only part of the picture and has led to an effort to shoehorn a useful tool into a setting where it does not fully fit, while ignoring its optimization in contexts where it could be more important. Three recent stories highlight the incoherence: the current failure of "access to medicines" legislation to deliver on its promise; the opportunistic patent breaking of developed and middle-developed countries; and the inability to secure licensed goods in emergency contexts. This paper uses the threads of these lessons to weave a coherent fabric of future compulsory license policy. It looks to the essence of compulsory license policy and proposes a revised analytical framework centered on human rights norms that would constitute an improvement over the current rules.
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* Associate Professor of Business Law, Smeal College of Business, and Affiliate Professor of Law, Dickinson School of Law, the Pennsylvania State University.

…This article departs from the narrow focus of the existing patent compulsory license literature by considering the mechanism more broadly, as a general intellectual property tool. This approach presents unique challenges because compulsory licensing can encompass so many different types of problems and actors, and general recommendations are difficult to conceive in the abstract. Indeed, one must look only to the original negotiations underlying the current system to see how hard it is to find consensus.[13] To address the complexity, this article employs a unique experiential approach, looking to real-world failures to frame the issues for reform. In particular, it considers three recent stories: (1) the failure of "access to medicines" legislation to deliver on its promise; (2) the opportunistic or political patent breaking of developed and middle developed countries; and (3) the inability to secure licensed goods in emergency contexts in the face of confusing rules. This article finds that each provides an important lesson that can be incorporated into international law to create a truly effective patent breaking rule. It uses the threads of the three lessons to weave a coherent fabric of compulsory license policy.

In Part I, the article recounts three stories of policy failure. In Part II, the article extrapolates the takeaway lessons from the stories that must be incorporated into a functional patent breaking system. In Part III, the article provides the structure of a functional system that provides the best incentives to encourage innovation and respect basic human rights. Importantly, it neither discourages nor encourages the use of compulsory licensing, but rather suggests that more intelligent policy can benefit all stakeholders.(p.4)

… ***A. Compulsory Licenses will be Underutilized as Long-Term Humanitarian Relief***

In order for a compulsory license to be an attractive option, there must be a substantial and sustained difference in the price of the patented good and the costs of manufacturing a licensed good. This is particularly true if a for-profit company will be manufacturing under the license (which would be the case unless a government-owned facility is involved108). Such a company must be able to pay a royalty, offer a price advantage, and still obtain a profit (see Figure 1).

But the existence of such a "profit gap" depends on a patentee's monopoly power in the relevant markets as well as its inability or unwillingness to take advantage of revenue opportunities by engaging in differential pricing. These conditions have not historically occurred in the context of least developed countries. And, as described below there is good reason to believe that they may not occur in the future. The absence of such a profit gap will mean that compulsory licensing may have minimal utility as a humanitarian aid mechanism. Although the underutilization may cause many to conclude that the mechanism is a failure requiring radical reform, what is really going on is a simple misapplication of a specialized tool. (p.21)

… Therefore, the first lesson to learn from compulsory licensing to date is that, in an established market wherein the demand is relatively clear and predictable, true humanitarian compulsory licenses from least-developed countries directed at developed country manufacturers will probably not be used. The mechanisms will tend to sit fallow because developing countries will see no advantage in using them, particularly given the potential for some foreign direct investment backlash. Even in the face of the best intentions on the part of developed nations, with no requests, there will be no licensing. After the emergence of patents in generic producing countries like India, there may be limited compulsory licensing. But it will be countered by branded price cuts and authorized licensing, and will be limited by its procedural complexities.

Will compulsory licenses have any function in an established market? Most certainly, in the form of pressure on patent owners to maintain pricing that more closely conforms to Ramsey or tiered pricing ideals.[154] But that is a far cry from substituting for a country's foreign aid contribution. The power to break patents is a check on the system, rather than a future solution. And, as discussed below, there are many other instances where breaking patents is useful. The lesson is as much about the narrowness of the conclusions as it is about licensing ineffectiveness.

B. If Licenses Provide Significant Advantages Over Bargaining, They Will be Disruptive

What if the goal is not simply to gain access to important technology, but to take advantage of legal rules in order to obtain an advantage that would not be possible through bargaining? In some cases, accessing a product or service on a reasonable basis is not the objective, but rather the license is a means of simply getting lower prices. While a country's efforts to spend less to provide basic and essential services to its citizens is reasonable and laudable, if this is achieved through the unexpected use and unpredictable application of an *ex post* legal regime, economic disruption may occur.155 This is particularly true if the regime is not available to all countries due to political and exogenous economic pressure. (p.28)

In general, a firm with patent rights will expect to negotiate prices that will enable it to generate the most profit globally. It should be willing to make concessions in low-income countries so long as profits in higher income countries are sufficient.[156] Conversely, it will resist rock-bottom pricing in larger, higher income countries, even if there is a public health use for the medicine. Still, negotiation can reduce information asymmetries and provide a pricing structure that is mutually acceptable for the firm and the purchasing entity. The predictable use of a Ramsey-like, tiered pricing scheme becomes very important to rolling out a global marketing strategy.[157] It is key to funding research and development through overall firm profits. When the patent expires, the firm can no longer depend on the ability to control pricing, so there is a limited window for action. Most economists agree that the

potential for obtaining a profit structure like this is the basis for innovation through a patent system[158] (though alternative innovation incentive systems might exist[159]).

When the pricing scheme is circumvented by a legal mechanism that discourages negotiation, this can be disruptive. Such discouragement can occur if the legal mechanism simply permits a country to establish a rock bottom pricing scheme regardless of need. In this case, assuming there is a manufacturer at the ready (particularly a domestic one), there is no reason to negotiate with a firm seeking some level of monopoly pricing.160

160 Although there is some disagreement, it has been alleged that Thailand did not negotiate with pharmaceutical companies before imposing several compulsory licenses in 2006 and 2007. Lybecker & Fowler, *supra* note 35, at 228-29. Some has described the circumstances as opportunistic. *Id.* (noting that the Thai government pharmaceutical company which operated under the compulsory license is increasing viewed as a profitable player). The same allegation has been leveled against Brazil. Lawrence A. Kogan, *Brazil's IP Opportunism Threatens U.S. Private Property Rights*, 38 U. MIAMI INTER-AM.L. REV. 1, 98-1-2 (2006) (arguing that Brazil issues compulsory licenses to gain trade advantages and engage in protectionism).
(p.29)