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**Compulsory Licensing of Patented Inventions:
Comparing United States Law and Practice
with Options under the TRIPS Agreement**

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Introduction

In articles 8.2 and 40.2, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) of 1994 leaves WTO Member countries broad latitude to regulate the interface between their domestic competition laws and internationally protected intellectual property rights.¹ Existing WTO jurisprudence further suggests that when tensions arise between the Members' efforts to provide domestic public goods, including competition law and policy, and the private rights of patentees, Members should look to both the codified exceptions to those rights under article 30 and to the broad possibilities for imposing compulsory licenses under articles 31 and 31*bis*, before invoking still untested claims for waivers under the hardship escape clauses of articles 7 and 8.

This framework means that policymakers responsible for the provision of such essential public goods as education, public health, the environment, competition, and scientific research² need to understand the full range of options available under articles 31 and 31*bis* of the TRIPS Agreement. These provisions regulate the grounds for, and conditions of, imposing compulsory licenses on patented products and processes.

At least six prototypical types of compulsory licenses are widely recognized around the world in one form or another, and they are all fully consistent with articles 31 and 31*bis* of the TRIPS Agreement. They are:

1. Compulsory licenses imposed to rectify *violations of competition law* (antitrust law).
2. Compulsory licenses imposed to rectify *abuses of the patentee's exclusive rights*.
3. Compulsory licenses issued in the *public interest*, to address environmental, public health, national security or economic development concerns by promoting third-party production of the patented products (at lower prices).
4. Compulsory licenses issued on behalf of owners of *dependent patents*, that is, to allow holders of improvement patents to make use of dominant patents that would otherwise block technical progress.

¹ See generally INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, K.E. Maskus & J.H. Reichman eds. (Cambridge U. Press 2005) (chapters on "The Role of Competition Law" by Drexler, Ullrich, Fox, Fink, Janis, and Ghosh)

² See generally Keith E. Maskus and Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 1, 3-45.

5. Compulsory licenses imposed by governments to permit them and their contractors to make non-commercial public use of the patents without the consent of the rights holders (*government use*).
6. A new compulsory license for the *exportation of pharmaceutical products* to poor countries that lack the capacity to manufacture needed drugs under their own compulsory licenses.

With this background in mind, let us compare United States law and practice with the larger framework found in foreign and international law. The prevailing ethos maintains that “unlike many countries, the United States takes a dim view of compulsory licensing.” That widely accepted thesis turns out to misstate and distort a considerably more complex and nuanced situation than is generally understood. It would be more accurate to say that the United States takes a dim view of the compulsory licenses that other countries prefer to employ, but it loves those compulsory licenses it routinely continues to impose.³

I. Remedies the United States Frequently Used in the Past (and Still Uses More Than is Commonly Supposed)

Here we are talking about compulsory licenses used to remedy antitrust violations, which normally require a showing of market power, and common law doctrines of misuse (abuse) that historically did not require any showing of market power. Both statutory and case law have been changing in the latter regard.

A. Competition Law (Antitrust Law)

Under current U.S. law, one cannot challenge a patentee for charging “excessive prices” unless there is other compelling evidence of an attempt to monopolize the market. Otherwise, the power to charge high prices is viewed as inherent in the granting of a patent, which imposes short-term social costs in exchange for long-term social gains through innovation. By the same token, refusals to deal without evidence of monopolization cannot normally qualify as antitrust violations in the U.S., although there remains a split in the circuits on the limits of this doctrine. International law clearly allows states to treat both excessive prices and refusals to deal as actionable abuses under the Paris Convention and the TRIPS Agreement.

If the interface between antitrust law and intellectual property law thus appears more rigid in the U.S. than in the E.U., this follows in part because the U.S. has not adopted the doctrine of “abuse of a dominant position.”⁴ In the European Union, “dominance” as typically shown by market power may spawn more adverse market effects than control

³ See generally J.H. Reichman with Catherine H. Hasenzahl, *Nonvoluntary Licensing of Patented Inventions, Part I, Historical Perspective, Legal Framework Under TRIPS and an Overview of the Practice in Canada and the United States of America* (UNCTAD/ICTSD 2002); *Part II, The Canadian Experience*, UNCTAD/ICTSD 2002); *Part III, The Law and Practice of the United States*, (Draft 2003) (available online from ICTSD, Geneva, Switzerland).

⁴ This section draws from Emanuela Arezzo [SJD candidate, Duke Law School], *Monopolization, Abuse of Dominant Position and Intellectual Property Rights* (unpublished paper on file with the author).

over prices and restrictions of output. The 1997 *Eastman Kodak* decision in the Ninth Circuit, which produced a compulsory license for refusals to deal in ancillary service markets, approximates the spirit of the European Commission's view of abusive leveraging by a dominant player. However, the Federal Circuit rejected that approach in the *Xerox* decision of 2003, and the Supreme Court seems likely to support a patentee's unfettered power to refuse to deal absent proof of monopolization or attempt to monopolize.

About 75 to 80 per cent of all civil cases end in consent decrees. A surprisingly large number of these decrees have entailed divestiture or compulsory licenses, including know-how, at low royalty rates, especially in cases of mergers and acquisitions. Between 1995 and 1999, for example, the FTC brought no fewer than eleven actions challenging mergers concerning medical and health care products, "the largest number in any single industry," and numerous compulsory licenses were imposed. However, the antitrust authorities currently seem less concerned about mergers and acquisitions than in the recent past.

B. Misuse of Patents

To make a claim of patent misuse, a party must demonstrate that the patent has been wrongfully "broadened" in some manner and that the broadening has an effect on competition, or that the patentee's actions have undermined the integrity of the patent system. Proof of misuse in response to a claim of patent infringement renders the patent unenforceable, although there remains some tension between this remedy and article 5A of the Paris Convention. The Supreme Court's 2006 decision in *Illinois Tool Works* has made it difficult to claim either refusals to deal or tying as actionable misuses without also proving both market power and the ability to restrict output or control prices.

It is fair to ask whether the common law patent misuse doctrine in the United States retains much force if it cannot be invoked to deal with excessive prices, refusals to deal and, now, even tying without evidence of monopolization or attempted monopolization. From a comparative perspective, the Supreme Court's 2006 decision in *Illinois Tool Works* seems to have widened the distance between the U.S. and the E.U. with respect to notions of abuse of intellectual property rights.

II. Remedies Sometimes Available in Theory but Almost Never in Practice

A. No General Provision Allowing Compulsory Licenses on Public Interest Grounds

United States patent law differs from the laws of most other countries in that it has no general provision allowing the authorities to override patents in the larger public interest. Congress has consistently and repeatedly declined to enact any such provision enabling the authorities, purely on grounds of public interest, to allow third parties to use a patented invention without the patentee's permission and thus to supply the market at more competitive prices.

The Bayh-Dole Act of 1980 does allow the government to exercise "march in" rights with regard to government-funded research results that universities might otherwise patent; and there is also a built-in anti-abuse clause requiring products manufactured under the resulting patents to be made available to the public on reasonable terms and conditions, including affordable prices. However, the National Institutes of Health (NIH)

have so far declined to exercise these powers, even in a clamorous case of price gouging with regard to at least one HIV/AIDS drug, and the statute makes triggering these measures subject to cumbersome procedures at best. In contrast, Brazil has used public-interest compulsory licenses to manage its nationwide AIDS program with success.

B. No General Provision for Compulsory Licensing of Dependent Patents

So-called “dependent patents” arise when a patented improvement, however substantial in character, cannot be practiced without infringing a pre-existing patent, known as the dominant patent. The United States has not codified a compulsory license for dependent patents, and there is accordingly no provision to prevent the parties from bargaining to impasse, unless their refusals to deal rise to the level of a full-fledged antitrust violation.

While the laws of many countries formally allow the compulsory licensing of dependent patents to avoid blocking effects, the authorities in these countries seldom issue such licenses in practice. An apparent exception is Italy, where dominant patentees reportedly respond promptly to requests for voluntary cross-licensing of patented improvements, lest the authorities should be requested to intervene. The frequency with which these requests for voluntary licensing are reportedly accepted under the shadow of a statutory compulsory license suggests that Italy has a *de facto* liability rule governing patented improvements, and that parties routinely bargain around it. We intend to test this hypothesis in future research.

Greater use of compulsory licenses for dependent patents could enable developed countries to reduce litigation costs pertaining to cumulative and sequential innovation by allowing courts to impose liability rules to avoid blocking effects. Developing countries should adopt legislation allowing compulsory licenses for patented improvements, in keeping with article 31(l) of the TRIPS Agreement, to enable innovators to adapt foreign inventions to local needs.

III. Government Use: The Remedy of Choice in the United States

When assertions are made about extensive compulsory licensing of patented inventions in United States practice, the source of law most logically being referenced is the government use provision, codified at *28 United States Code 1498*. This provision empowers the government, or its contractors, to make any use or manufacture of a patented product or process “by or for the United States without license” and without incurring liability for infringement, other than a duty to pay “reasonable and entire compensation” to the patentee or his assignees for such use and manufacture. It was, indeed, the necessity of accommodating the United States’ reliance on this provision that ultimately led the TRIPS negotiators to allow WTO Members to grant compulsory licenses for virtually any purpose under article 31.

A divided panel of the Federal Circuit has just ruled that patentees can not sue for the taking of a property interest under the Constitution, but only for compensation under a tort theory within the parameters of section 1498.⁵ A vigorous dissent argued that, in later cases, the Supreme Court itself had implicitly changed its view and authorized a “takings” rationale; but the majority held that the Supreme Court itself would have to

⁵ *Zoltek*, 442 F.3rd 1345 (Fed. Cir. 2006) (citing *Schillinger v. United States*, 155 U.S. 163 (1894) and *Crozier v. Fried. Krupp Aktiengesellschaft*, 224 U.S. 290 (1912)).

make that decision. For the moment, therefore, and subject to further developments, section 1498 must be viewed as a limited waiver of sovereign immunity that rests on its own bottom, and the relevant case law can neither be expanded by reference to the “takings” jurisprudence of the Constitution nor limited by invoking a “reserved rights” theory of the patent grant.

Properly understood, section 1498 codifies a form of “statutory inducement of patent infringement;” and because this goal is usually accomplished by means of government contracting, it has been further characterized as facilitating the “contracting of patent infringement.” The statute requires payment of “reasonable and entire compensation” for the government’s use of a patent or copyright, and the right holder has a statutorily protected right to challenge the royalty determination before the Court of Federal Claims.

Determining a hypothetical licensing rate under today’s methodology is more refined and complex than in the past, because it now entails a consideration of some fifteen or more distinct evidentiary factors. These factors, known as the *Georgia Pacific* factors, were adopted by the United States Court of Federal Claims in a 1993 decision under section 1498, and this court has routinely applied them ever since.

Until 1992, a 6% royalty rate was commonly applied, and awards reportedly never exceeded 10%. Since 1993, when the fifteen *Georgia Pacific* factors were first applied, there has been an upward trend. Some rates falling in the range of 10-17% have been reported, although the government seldom proposes more than a 5% base royalty. Delay damages based on Treasury Bill interest rates may be considerable.

One study in 1994 found that the various claims tribunals had cumulatively resolved about 279 government use cases between 1917 and the first quarter of 1994. Of these, some 240 cases had arisen under section 1498 alone, which Congress adopted in 1948 to replace previous government use provisions. Once section 1498 was enacted, in other words, the relevant tribunal- then the Court of Claims- “experienced a virtual explosion of the number of reported cases.” Another rough survey of reported cases from 1994 to mid-2002 yielded about 32 additional items, or an average of about four a year. However, these figures tell only part of the story, because, a plaintiff patentee suing for compensation under section 1498 may have little better than a one in three chance of success.

One should also consider the possible pro-competitive effects of section 1498 itself, which frees potential bidders on complex government projects from some of the Research & Development constraints they might otherwise face. Firms that lack the capacity to develop certain components of a project can nonetheless bid on that project in the knowledge that section 1498 enables the government to authorize use of existing patents pertaining to those components and that patent owners cannot hold out or otherwise impair the government’s access to the relevant technology. Conversely, the government knows that, at the end of the day, it will have to compensate all those owning patents used on any given project. In this respect, section 1498 provides government procurement officers with the possibility of converting exclusive property rights to liability rules as and when the situation so requires, and the use of this tool merits further study in this light.

What has been omitted from this picture, but which palpably influences any overall assessment of section 1498, is the frequency with which the government and the affected patentees negotiated settlements without resort to litigation. Equally important is the government's power to indirectly regulate the patentees' prices by the mere threat of subjecting patented inventions to governmental use under section 1498. A clamorous illustration of this power occurred in the very recent Cipro case, which arose during a panic triggered by still unknown terrorists, who disseminated anthrax spores in the wake of other attacks on September 11, 2002.

The evidence shows that selective use of patents for specific governmental purposes can be effective without incurring unacceptably high social costs, especially when aggrieved patentees are assuaged by compensation that is both "reasonable and entire." Neither the defense industries in general, nor the atomic energy sector in particular, seem to have languished in the United States merely because private investment strategies are often influenced by the threat, or actual imposition, of liability rules that override exclusive property rights.

The question that governments must resolve is not whether they possess the power to override the patentee's exclusive rights in the name of government use (always assuming, in the case of foreign patentees, that the parameters of the TRIPS Agreement have been observed), but when such action is to be preferred to the operations of the open market. Once governments decide to wield these powers, moreover, the end result will depend on the skill with which it is wielded and the relative costs and benefits of operating through the public rather than the private sectors.

If a "government use" provision is overused or over-extended in scope, it will certainly deter foreign investors and licensing, and it may deter local investors and innovators as well. Agencies that invoke a government use provision should, therefore, know what the likely social costs will be, and they should take such action only if the government is prepared to pay those costs.

While it remains true that a government use provision can effectively discipline patentees whose technologies are needed for vital government endeavors of all kinds, it remains equally true that the exercise of such powers is a long way from formulating and implementing a well-conceived national system of innovation. Stimulating local innovation and fostering the economic policies to support it are, or ought to be, primary goals of all developing countries. It is the adoption of sound innovation policies, and a legal framework consistent with international intellectual property law to implement them, that will ultimately determine a developing country's long-term growth potential. The use of nonvoluntary licensing of patented inventions for any legitimate purpose may ultimately stand or fall only insofar as it advances these higher policy goals.