

**COMPULSORY LICENSING  
OF INTELLECTUAL PROPERTY:  
THE EXCEPTION THAT ATE THE RULE?**

By

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# **COMPULSORY LICENSING OF INTELLECTUAL PROPERTY: THE EXCEPTION THAT ATE THE RULE?**

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## **I. PROPERTY AND SECURITY**

The United States Supreme Court's June 2005 decision in *Kelo v. City of New London*,<sup>1</sup> permitting state and local governments to take private property for private development projects that would pay more in taxes, set off a firestorm of criticism. Although the Court's decision was anchored in legal precedents that gave broad deference to government determinations on the appropriate uses for property taken through eminent domain, ordinary citizens across America – and around the world – understood what the lawyers and judges did not: that the security of private property is substantially reduced if government can take it by force for any and every use the authorities want.

The most fundamental right of private property is the right to control who uses it, when, under what conditions, to decide whether to keep or sell it, and on what terms. Even though government use of eminent domain power in the United States and virtually all other nations requires payment of reasonable compensation, judicially determined payments seldom provide as much as would be needed to induce property owners voluntarily to give up the rights that are being taken. If you bought your home or your car with the understanding that a neighbor could take it from you at any time for any reason, even if the neighbor was required to pay a sum that the neighbor (or a local tribunal) later determined was

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<sup>1</sup>545 U.S. 469 (2005).

reasonable, you would have less security in your property and would pay less to attain it. That was the effect of *Kelo*. While ownership of private property nowhere in the world gives complete license free from any restrictions, the *Kelo* decision opened a door that was far too wide, removing critical constraints to governmental impositions on private property that serve the immediate, short-term interests of politicians, not the long-term interests of the polity. The public understood that point and recognized the threat to their security that this change presented.

A similar threat to property and security – and also to innovation and growth – is presently being mounted in the realm of intellectual property through the expansion of compulsory licensing authority. As with *Kelo*, the threat comes in the guise of a modest extension of established legal precepts. As with *Kelo*, the extension increases the ability of government to abridge private property rights. As with *Kelo*, holders of the property rights that would be taken by government would, in theory, receive reasonable compensation for the taking. And as with *Kelo*, the expansion of government authority over property would permit a potentially dramatic expansion of government interference that ultimately could eliminate any security in intellectual property rights.

Understanding the threat, and the strong parallel to the *Kelo* setting, is imperative if governments are to address compulsory licensing issues appropriately. Although some advocates of expanded compulsory licensing hope that this will lead to the demise of strong intellectual property rights, many other proponents simply have not identified the risks that compulsory licensing poses. This WORKING PAPER examines what compulsory licensing is, when it is appropriate, what changes in its use are under way, and what risks those changes present.

## II. BASICS OF INTELLECTUAL PROPERTY RIGHTS

Although much popular discussion of intellectual property rights – patents, copyrights, trademarks, and trade secrets – treats them as relatively recent contributions of modern law, these rights trace back hundreds, and in some cases thousands, of years. They have been recognized since the creation of the first modern patent system in 15th century Venice as critical to innovation and creativity.<sup>2</sup> The connection of innovation to intellectual property rights was made explicit also in the U.S. Constitution, which authorized Congress to “promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>3</sup>

Four basic insights lie behind the design of intellectual property rights: an appreciation that financial rewards motivate investment in innovation and creative work; that the form of rewards most conducive to appropriate investment in innovation is to confer exclusive rights over the innovation or creative work; that novelty or creativity is essential to making the award of exclusive rights worthwhile; and that a limitation of the time period, rather than the nature, of the property rights conferred best accommodates interests opposed to the creation of intellectual property rights. All four of these can be seen at work in the Venetian patent system, English copyright law, the “patent and copyright” clause of the American Constitution, and every other successful intellectual property rights system. Volumes have been written about each of these components and about their relation. What follows here is a minuscule synopsis of the major analytical points – losing some of the detail that would attend a fuller discussion but capturing the essential core of each insight.

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<sup>2</sup>See, e.g., Craig Allen Nard & Andrew P. Morriss, *Constitutionalizing Patents: From Venice to Philadelphia* (Case Research Paper Series in Legal Studies, Working Paper No. 04-12, Aug. 2004).

<sup>3</sup>U.S. CONST., Art. I, Sec. 8, cl. 8.

The first insight is self-evident – except to a few activists who favor governmental command-and-control solutions to a broad range of problems and oppose virtually all private financial incentives that pull away from such government control. Of course, some innovation and creative works will be produced without any direct financial incentive. The pleasure of creation and of discovery, and the fame that can come with success at such endeavors, is enough for some. But an extraordinary range of human endeavor, including the pursuit of new discoveries, responds very strongly to financial rewards. And the costlier and more time-consuming the work necessary to produce innovations – for example, new drugs or software, which can take many years and billions of dollars to create and perfect – the stronger the tie between the needed investment and the promise of financial reward.

The second insight is only slightly less obvious today. Private property rights, including the right of exclusive control, have many advantages as a means of providing incentives to innovation. Unlike other mechanisms, they require relatively little advance knowledge by a central planner of the scope of investment needed, the particular innovations to be supported, the best route to innovation, or the best means for assuring diffusion of the innovation. Exclusive rights to property – whether intellectual property or physical property – provide an incentive for investment that is calibrated to the individual investor’s expectations respecting the value of the property (here the innovation) and the difficulty of accomplishing the tasks needed to secure it. They also provide a means for aligning use of the innovation with the most intense demands for it. Just as private property rights operate to induce more (and more efficient) investment in physical property, they also induce greater (and more socially valuable) investment in intellectual property.

The case for exclusive rights to intellectual property differs in one respect, however, from that for physical property: intellectual property generally differs from physical property in that many people can use it at the same time without

significantly diminishing the value of each use. For that reason, the cost of granting exclusive rights to its use can be greater than in the case of physical property, where selecting among uses is a virtual necessity. This is the third insight: some alteration of the property rights is needed to account for this difference.

This argument can be – and in recent years has been – overplayed. The difference between physical and intellectual property is not so great as sometimes asserted. Some uses of intellectual property do interfere with other uses; some diminish the value of a brand or a creative work or a discovery. Consider a few examples. Misuse of a trademark – use by those who are not the mark’s originator – can reduce its value to consumers. Association of a children’s character – one that teaches children lessons about good behavior, for instance – with sex or violence or illicit drugs can diminish the value of the creation. Incorrect use of software platforms to produce complementary software can create problems with the way computers and computer programs function to the detriment of consumers and of the firms that produce the platforms. And overuse of certain pharmaceutical products can lead to drug resistance, undermining the disease-fighting value of the drug.

Exclusive rights to intellectual property, like exclusive rights to physical property, provide both the incentive and the capacity for the owner to license use in the way that best preserves the value of the property. Still, intellectual property law recognizes the risk associated with granting exclusive rights too readily and places some constraints on those rights.

The final basic insight behind intellectual property law is that the balance between incentives to innovate and assuring the widest availability of the innovation is best struck not by limiting the *scope* of the exclusive rights in the innovation but instead by setting a *threshold* for award of the right and limiting the *time* period during which exclusive rights are given. As a rule, governments will not have the information or the incentive to set the terms of access to an innovation

in the manner that is most conducive to encouraging and promoting future innovations, nor will it be able best to assess how to preserve and protect the value of innovation.

The better approach, then, to balancing the competing interests in encouraging new discovery and making the fruits of discoveries widely available is to assure that the rights are accorded in a way that rewards innovation and to set limits on the period for which innovators and creators receive exclusive rights to their innovation.

The threshold set in recognition of the risk of excessively broad intellectual property rights is that IP rights must be tied to the feature of intellectual property that specially benefits society: the novel idea, innovation, or creative aspect of the work. From the outset, intellectual property rights have required that the innovator or creator must demonstrate the novelty or creativity of his work to secure an exclusive franchise and have limited the protection offered by intellectual property rights to those aspects of the work. This requirement also prevents the use of monopoly rights as political favors that protect against competition without the benefit of innovation that promises wider societal benefits.

The timing issue generates more debate, with some commentators taking the position that IP rights, like other property rights, should be permanent, but generally it has been accepted that some limitation is in order. Although there is no way to know exactly what time frame will set the trade-off at the ideal mark – and no reason to think that the answer will be the same at different times and places and for different types of innovation – certain standards for patents and copyrights have been accepted as providing an acceptable trade-off.

### III. COMPULSORY LICENSING

For physical property rights most governments, even those sensitive to personal liberty, provide a safety valve for occasions when there is a compelling public need to use the property and special reason for concern that the owner may not make it available in a timely manner. The right of eminent domain is the Anglo-Saxon embodiment of that principle, which scholars explain as necessary to solve a special category of problem in negotiation, known as the hold-out problem.<sup>4</sup> The problem arises where there are many small properties that need to be aggregated for a public project, such as a reservoir or military base. Because there are many owners, any one of whom could block the entire project under the ordinary rules of private property's exclusive rights, each one potentially can hold out for a payment equal to the value of the entire project.

While the eminent domain power solves that problem, it creates another one: governments – and especially the interest groups that promote actions by government that invoke eminent domain power – have incentives to pay too little to property owners when force replaces negotiation. Various legal provisions have been adopted to address that concern. The U.S. Constitution, for example, contains three provisions that are designed to prevent government from abusing this power. The most well-known is the “takings clause” of the Fifth Amendment, at issue in the *Kelo* case, limiting the reasons for which property can be taken by government and the payments that are required. Two other provisions in the Third Amendment regulate the use of private property for quartering troops.

For intellectual property, there are also special provisions for government use in special circumstances, but these have been even more limited than in the case of physical property. The reason for the greater limitation in the case of intellectual property is that it is less common to encounter the sort of hold-out

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<sup>4</sup>See, e.g., RICHARD A. EPSTEIN, *TAKINGS: PRIVATE PROPERTY AND THE POWER OF EMINENT DOMAIN* (1985). That explanation, however, does not justify expansive use of eminent domain. See Thomas W. Merrill, *The Economics of Public Use*, 72 *CORNELL L. REV.* 61 (1986).

problem that justifies eminent domain than in the case of physical property, but the same considerations apply to both settings.

The term generally applied to government taking of intellectual property is “compulsory licensing.” The terminology comes from the concern that a patent owner would gain rights to a new technology but then not put it into use (or put it only into such limited use that it technically, but not realistically, qualified as “working” the patent). Because this failure to “work” the patent essentially voids the trade-off underlying patent protection – which uses exclusive rights as the inducement to innovate and put the innovation into productive use – it was viewed as a ground, under special circumstances, for government intervention to compel the patent holder either to begin production of goods using the patent or license someone else to do so, a compulsory license.<sup>5</sup>

Compulsory licensing also occurs in two other contexts. One is where there is a collective action problem, as can happen at times in the copyright realm. The problem here is that there are many holders of IP rights that are only modestly valued for particular uses and many potential users, so that the costs of finding out who has the rights and negotiating terms for use generally exceed the value of the use. In that case, the best solution for everyone – rights holders and potential users alike – is to find some mechanism for lowering the costs. While form contracts and “copyright collectives” – such as the American Society of Composers and Producers (ASCAP) – can play a role, governments sometimes find it advisable to solve the problem through imposition of a compulsory license. United States law, for example, creates forms of compulsory licensing for certain audio recordings and for broadcast television programs that are then re-transmitted over cable television.<sup>6</sup> A true collective action problem is rare, however, and U.S. law

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<sup>5</sup>See, e.g., Kurt M. Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, 15 HARV. J.L. & TECH. 389 (2002).

<sup>6</sup>See 17 U.S.C. § 115 (compulsory license for phono-recordings of non-dramatic works); 17 U.S.C. § 115 (statutory license for cable transmission of broadcast programming).

contains few instances in which lawmakers concluded that statutory intervention was required.

The other context for compulsory licensing is even more unusual, involving inventions of critical public interest that the rights holder has withheld from public use. United States law also contains legal provisions that fit this description, such as Section 153 of the Atomic Energy Act and Section 308 of the Clean Air Act. A compulsory license is possible under the Atomic Energy Act for patents that the U.S. Atomic Energy Commission (now subsumed within the U.S. Department of Energy) deems of special importance to the creation or utilization of nuclear material if the government also determines that the mission of the Act cannot be achieved without the license.<sup>7</sup> Although this provision allows the government then to issue a compulsory license authorizing specially selected third parties to use the patent after the patent holder has declined to license the use by the applying parties, no such compulsory license has been issued in the more than 50 years since the legislation was enacted. Section 308 of the Clean Air Act likewise provides a theoretical, but never-used, authorization for compulsory license of patents (withheld from a putative licensee) that are essential to accomplishing the environmental goals of the Act and for which no alternative technology exists.<sup>8</sup> In both instances, the critical nature of the technology is not enough; some element of withholding the patent from use is required, though not formally the same as the complete “failure to work” that supports traditional compulsory licensing.

All three contexts for compulsory licensing rest on substantial economic justifications and all three impose remedies of a very limited nature. Historically, thus, compulsory licensing has played only an extremely marginal role in discourse on intellectual property rights in the U.S. and other nations.

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<sup>7</sup>42 U.S.C. § 2183.

<sup>8</sup>45 U.S.C. § 7608.

A related matter – distinct from compulsory licensing but sometimes confused with it – provides special remedies for certain governmental uses of intellectual property that are found to infringe intellectual property rights. In the U.S., for example, doctrines of sovereign immunity limit the availability of liability actions against state or federal governments. A constitutional provision prohibits most actions against states in federal court.<sup>9</sup> A federal law consents to suits against the U.S. government for patent infringement, but permits only damages (monetary compensation) not injunctive relief.<sup>10</sup> The federal law also covers infringement by contractors engaged in work for the government, making the U.S. government exclusively liable for damages caused by the infringement.<sup>11</sup>

The federal law (generally referred to as Section 1498) is justified as necessary to allow important governmental functions to proceed without fear of interruption through issuance of injunctions against the government or its contractors,<sup>12</sup> but its roots lie in broader doctrines of sovereign immunity from suit that go well beyond concerns with remedies in IP litigation. This limitation on remedies rightly is viewed as a limitation on IP rights, as it reduces the property owners' effective control over exclusive use – unless damage remedies are as threatening to infringers as injunctive remedies, the limitation on remedies will alter the willingness of government and its contractors to engage in potentially infringing conduct. It is not, however, the same as a compulsory license that formally removes a right owner's control over the use of the IP.

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<sup>9</sup>U.S. CONST., Amendment XI.

<sup>10</sup>28 U.S.C. § 1498(a).

<sup>11</sup>*Id.* A similar provision applies to copyright infringement. *See* 28 U.S.C. § 1498(b).

<sup>12</sup>*See, e.g., Windsurfing International, Inc. v. Ostermann*, 534 F. Supp. 581, 587 (S.D.N.Y. 1982).

## **IV. COMPULSORY LICENSING UNDER INTERNATIONAL LAW**

Despite its well-developed rationale and limited scope, the compulsory license's interference with the patent holder's exclusive control over decisions on when and how his invention would be used was universally deemed a taking of property on a par with takings under eminent domain. For that reason, international agreements on IP rights, dating from the earliest accords, reflect concern about misuse of even the very limited government power to compel rights holders to license their inventions associated with classic compulsory licensing of patents. For example, the Paris Convention on Industrial Works states that "a compulsory license (license not granted by the owner of the patent but by a public authority of the State concerned) based on failure to work the patented invention may only be granted pursuant to a request filed after three or four years of failure to work or insufficient working of the patented invention and it must be refused if the patentee gives legitimate reasons to justify his inaction."

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), administered under the aegis of the World Trade Organization (WTO),<sup>13</sup> likewise contains only a very limited provision for compulsory licensing and substantial limitations on the use of IP without express approval of the IP right holder. Before describing the TRIPS provisions on compulsory licensing and other unauthorized uses of IP, a word of introduction to the agreement is in order.

The TRIPS accord responded to concerns in developed nations that the intellectual property rights of their nationals were not sufficiently respected internationally and that remedies for addressing international derogations from

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<sup>13</sup>Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, in *LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND*, vol. 31, 33 I.L.M. 81 (1994).

intellectual property rights were not sufficiently strong.<sup>14</sup> The TRIPS agreement was a *quid pro quo* for developed nations' consent to other parts of the Uruguay Round of trade liberalization that were favored by less developed nations and by nations that enjoyed lower success rates in generating innovations protected by intellectual property rights.<sup>15</sup> TRIPS – which is mandatory for WTO membership – requires certain levels of protection for IP rights, standardizes some parts of IP law, and provides better mechanisms for international IP rights' enforcement (mechanisms that do not depend on the local judiciary in less IP-friendly jurisdictions or on reciprocal investment in IP to be effective).

Understanding the genesis for TRIPS is critical to understanding the current debate over compulsory licensing. Commentary today by individuals and organizations that opposed TRIPS because it strengthened international IP protections now describes the agreement as including compulsory licensing provisions that effectively undermine all the IP-protective parts of TRIPS.<sup>16</sup> Had that been the case, TRIPS would never have been adopted – certainly, its strongest proponents would never have drafted or supported such an agreement.

When agreed to, TRIPS was thought to embody the same sort of limited scope for compulsory licensing – and, indeed, for other, less intrusive, government derogations from strong protections for IP owners' exclusive property rights – typical under the laws of developed nations strongly committed to IP rights. The only TRIPS provision expressly using the term “compulsory licensing” is Article 21, which flatly prohibits compulsory licensing for trademarks. Although the term is

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<sup>14</sup>See, e.g., Rochelle Dreyfuss, *Coming of Age with TRIPS: A Comment on J.H. Reichman, The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 33 CASE W. RES. J. INT'L L. 179 (2001).

<sup>15</sup>See, e.g., Frederick M. Abbott, *The WTO TRIPS Agreement and Global Economic Development*, in PUBLIC POLICY AND GLOBAL TECHNOLOGICAL INTEGRATION 39 (Frederick M. Abbott & David J. Gerber, eds., 1997).

<sup>16</sup>See, e.g., James P. Love, *Measures to Enhance Access to Medical Technologies and New Methods of Stimulating Medical R&D*, 40 UC DAVIS L. REV. 679 (2007).

not used in respect of copyrights or patents, two TRIPS articles, Articles 30 and 31, commonly are referred to as authorizing compulsory licensing. That is a fair reading, but not a necessary one, and in all events the text evidences a very restrictive approach to derogations from exclusive control rights for patent owners.

The first of the two articles, Article 30, titled “Exceptions to Rights Conferred,” says:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Although Article 30 does not spell out specifically how limited the exceptions may be or how the exceptions could operate so as not to unreasonably conflict with the normal exploitation of the patent, the clear meaning of the provision – and intent of those who agreed to it – was to provide for a restricted opportunity for governments to address special needs while also protecting the economic interests of rights owners.

The limited nature of the exceptions contemplated by the TRIPS agreement appears even more clearly when Article 30 is read together with Article 31, titled “Other Use Without Authorization of the Right Holder,” which sets out specific requirements for any other interference with patent holders exclusive control rights. Article 31 states:

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain

authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use [subject to requirements to notify the right holder as soon as possible]. . . . ;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized . . . ;

(d) such use shall be non-exclusive; . . .

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use; . . .

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member; . . .<sup>17</sup>

Far from authorizing invasion of exclusive IP rights and expansive compulsory licensing, Article 31 contemplates a limited set of circumstances in which governments authorize use of a patent by a government or its contractors without express authorization by the right holder, and mandates that any such use be non-exclusive, be compensated fully, and – except in a small set of truly extraordinary circumstances – be permitted only following efforts to arrive at a consensual agreement from the right holder that would allow the use with compensation set on terms acceptable to the right holder.

While Article 30 permits the sort of very modest exception for compulsory licensing that, for example, U.S. law authorizes in theory under the Atomic Energy

Act, Article 31 permits governments to depart from ordinary licensing conventions in a more modest way such as provided for under U.S. law by Section 1498. Even then, the long list of required actions to protect patent right holders signals the concern of those who drafted and ratified TRIPS that recognition of unauthorized use should not open a path to undercutting the protections mandated by the rest of TRIPS. The fact that these provisions were crafted primarily by developed nations championing strong IP rights through TRIPS, rather than by less developed nations opposing those efforts, confirms this view that the understood meaning of Article 31 was to restrict – not expand – occasions for unauthorized government use of IP.

The requirement of consultation except in extraordinary situations such as a national emergency, for instance, is not a mere formality. It is intended to provide a means for tailoring government actions to fit with the protection of intellectual property rights. The process of consultation allows the right holders and government officials to explore ways to promote critical government needs without harm to the system of intellectual property rights safeguarded by TRIPS. The requirement that governments seek authorization for patent use on reasonable commercial terms and conditions sets the background expectations for consultations and also suggests the proper parameters for any potential use not expressly authorized by the right holder, parameters designed to be protective of the right holders' interests. Provisions mandating judicial review, non-exclusivity, and so on, also make that intention plain.

## **V. DOHA, PHARMACEUTICALS, AND LATER DEVELOPMENTS**

The adoption of TRIPS, although a relief to IP-intensive industries that had complained about inadequate protection for IP and poor international enforcement of IP rights, was a source of dismay to groups opposed generally to market-based

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<sup>17</sup>Footnote 7 to the TRIPS, omitted from the text above, states that Article 31 covers circumstances outside the purview of Article 30.

approaches to economic development and specifically to strong IP rights. Complaints about TRIPS also were lodged by health activists seeking immediate, low-cost access to advanced pharmaceuticals and related therapies. Those groups soon combined forces in an effort to carve out exceptions to TRIPS requirements.

Pharmaceutical manufacturers were among the most ardent champions of TRIPS. The investment needed for research and development of new drugs approaches \$1 billion per drug, an investment that frequently dwarfs the actual cost of production once a drug is perfected and approved. This asymmetry between up-front cost and marginal cost makes drugs particularly vulnerable to IP infringement – copies of new pharmaceutical products may not be as safe or efficacious as the original, but they often can come tolerably close at a fraction of the cost, given the absence of research and development investment.

Copying is not the only route to lower prices. If pharmaceuticals are protected against copying and against re-exportation of drug products, the manufacturers can charge differential prices, providing lower prices where (because of lower incomes, for instance) there is lower demand for high-priced drugs. So long as the manufacturer can cover the marginal cost of production plus some contribution to the drug's research and development costs, the manufacturer can provide a drug at a relatively low price to the least developed nations, the same drug at somewhat higher prices to other developing nations, and sell at a price that provides the greatest contribution to R&D costs in developed nations. For both economic and humanitarian reasons, that has been the route followed by pharmaceutical firms.

An alliance – composed of nations interested in reducing their costs for drug access to levels afforded nations lower down the development scale, health activists interested in the broadest possible immediate access to advanced pharmaceutical products, groups interested in exporting generic drugs for profit, and those simply opposed to IP and markets altogether – put pressure on international trade

negotiators to weaken the protections in TRIPS. Largely as a result of concerns about the on-going HIV/AIDS crisis in Africa, that pressure ultimately bore fruit.

In 2001, at the start of the Doha Round of trade negotiations, the WTO ministerial conference adopted a declaration that, while “recogniz[ing] that intellectual property protection is important to the development of new medicines,” stressed that “the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.” Stating that TRIPS contains the “flexibility” to address public health needs – singling out in particular “the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics” – the declaration said TRIPS permits nations to issue compulsory licenses and to determine the grounds for granting them. The resolution concluded with an instruction to the TRIPS Council to address the difficulty encountered by nations with “insufficient or no manufacturing capacities in the pharmaceutical sector” in making “effective use of compulsory licensing.” Subsequent resolutions in 2003 and 2005 permitted a temporary, and then (if sufficient numbers of WTO members approve) a permanent, amendment of TRIPS to allow under certain conditions imports of pharmaceuticals produced or sold without authorization of the patent holder under Article 31.<sup>18</sup>

Apart from the pending amendment to Article 31(f), the recent declarations and resolutions do not purport to alter the TRIPS agreement.<sup>19</sup> Nonetheless, some

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<sup>18</sup>The amendment would take effect if two-thirds of the WTO’s approximately 150 members approve it by December 2007. As of April 2007, only seven nations had taken that step. *See* WTO – TRIPS and Public Health: Countries Accepting Amendment of TRIPS Agreement, available at [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm) (site visited Aug. 6, 2007).

<sup>19</sup>Even the most aggressive proponents of radically expanded compulsory licensing have recognized this point. *See, e.g.*, IPN, Quotes on Doha Declaration on Patents and Public Health, Nov. 13, 2001, available at <http://legalminds.lp.findlaw.com/list/info-policy-notes/frm00134.html>, quoting James Love’s reaction to the Doha Declaration: “The declaration is a political statement that did not modify in any way the TRIPS agreement, and the decision to settle for a political statement was controversial in the negotiations. The developing countries had asked for legally binding interpretations of the agreement [but were disappointed not to obtain it]. “Recognition that the Declaration does not actually bind members in

activists have used the recent activity to promote a view of TRIPS broadly antagonistic to its original design and have encouraged nations to issue compulsory licenses for drugs under the banner of the “flexibility” referenced in the Doha Declaration. Thailand took the first step in 2006, announcing that it would issue compulsory licenses for certain drugs used to treat HIV/AIDS and also for a drug used in treating coronary artery diseases. Shortly afterward, a senior adviser to the Thai Health Ministry garnered attention by declaring, at a World Health Organization meeting, that Thailand should take international visitors from Western nations hostage until the drug companies provided the drugs Thailand wanted.<sup>20</sup> Despite the negative reactions from many quarters to that threat, a few months later, Brazil announced its own intention to issue a compulsory license for an HIV/AIDS drug.

Both actions have drawn criticism from commentators concerned with the protection of intellectual property and the structure of international law. Neither Brazil nor Thailand qualifies as a least developed nation. Indeed, both rank among the largest economies in the world, with Brazil standing 10<sup>th</sup> and Thailand 33<sup>rd</sup> among 183 nations ranked in 2006 (based on nominal GDP).<sup>21</sup> Neither faced a real emergency. Neither dealt with a situation in which the drugs at issue were not being offered for sale – that is, a situation in which the relevant patents were not being “worked” – and neither complied with provisions set forth in Article 31

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the fashion of a formal amendment follows from the WTO’s structure, permitting Ministerial Council interpretations of TRIPS only when those interpretations are consistent with the document and do not, in the guise of interpretation, modify its terms. *See* Marrakesh Agreement Establishing the World Trade Organization, Article IX:2, available at [http://www.wto.org/english/docs\\_e/legal\\_e/04-wto\\_e.htm#articleIX\\_2](http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm#articleIX_2).

<sup>20</sup>*See* *Bangkok’s Drug War Goes Global*, WALL ST. J. ASIA, Mar. 7, 2007.

<sup>21</sup>*See* WORLD BANK, DATA AND STATISTICS (2007), available at <http://siteresources.worldbank.org/DATASTATISTICS/Resources/GDP.pdf>. Thailand ranks far higher (19<sup>th</sup>) on a purchasing power parity basis, which removes distortion caused by disparities between nominal exchange rates and effective market rates for currency. *See* WORLD BANK, DATA AND STATISTICS (2007), available at [http://siteresources.worldbank.org/DATASTATISTICS/Resources/GDP\\_PPP.pdf](http://siteresources.worldbank.org/DATASTATISTICS/Resources/GDP_PPP.pdf).

before announcing the decision to authorize compulsory licenses. Neither set out terms for the compulsory license that appeared to meet Article 30's mandate that exceptions to exclusive patent rights "do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner."

Activists who have applauded the actions, however, have asserted that they are justified because the Doha declaration says that TRIPS allows compulsory licensing and also allows each nation to determine the ground for granting compulsory licenses.<sup>22</sup> The activists also assert that the compulsory licenses are designed to permit public non-commercial use of the patented products and respond to health emergencies because they deal with serious health threats affecting large populations.<sup>23</sup>

Those assertions cannot be valid. Accepting them would permit the "flexibility" referenced in the Doha declaration to undo the remainder of the TRIPS agreement, as they essentially grant any government *carte blanche* to determine when TRIPS' disciplines will – or will not – apply. Were that the meaning of the agreement, there would be no need for elaborate dispute resolution provisions, nor would there have been any reason to spend so much time and energy during the TRIPS negotiations debating the minimum standards of protection applicable to different forms of IP. The "emergency" reference is specious, as the existence of a health threat that is being contained by current measures – and, in Thailand's case, is actually contracting, not expanding<sup>24</sup> – can hardly be thought to constitute a

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<sup>22</sup>See, e.g., Martin Khor, *Global Trends: Getting Cheap Medicines to the Sick*, posted on Third World Network, Apr. 26, 2004, available at <http://www.twinside.org.sg/title2/gtrends11.htm>.

<sup>23</sup>See, e.g., KEI, *Notes from March 16th 2007 Capitol Briefing on Thailand's Compulsory Licenses* (reporting comments of Robert Weissman and James Love), available at [http://www.keionline.org/index.php?option=com\\_content&task=view&id=37](http://www.keionline.org/index.php?option=com_content&task=view&id=37).

<sup>24</sup>Prior to announcing its compulsory licensing decisions, Thailand had dramatically reduced the rate of new infections, cutting the annual increase to about thirteen percent of its level a decade before, and also had seen a dramatic decrease in its AIDS death rate since 2000. See USAID, *Health Profile: Thailand – HIV/AIDS*, available at [http://www.usaid.gov/our\\_work/global\\_health/aids/Countries/ane/thailand\\_05.pdf](http://www.usaid.gov/our_work/global_health/aids/Countries/ane/thailand_05.pdf).

national emergency or circumstance of “extreme urgency.” Certainly, there are very serious health issues in Thailand, Brazil, and many other nations that deserve their governments’ attention. But the entire range of health concerns does not plausibly fall within the definition of national emergencies.

The reference to public non-commercial use is even further off the mark. Activists take the position that this encompasses virtually all government activity, including activity carried out through private, profit-making firms, so long as the government asserts a public purpose for its conduct. That is essentially the same position advanced by the local government in *Kelo* (with respect to permitted uses of eminent domain power) that has been so roundly condemned. While TRIPS contemplates the use of patented inventions without authorization for public non-commercial operations, such as military or infrastructure projects, the sale of pharmaceutical products by generic drug producers falls outside the limited range of conduct that would be excepted from prior negotiation requirements.<sup>25</sup> If that were not sufficiently clear, the fact that the non-commercial use exception follows as a second alternative to the exception for a “national emergency or other circumstances of extreme urgency” makes evident that the TRIPS drafters did not believe they were authorizing a sweeping exception of all government activity from normal TRIPS requirements.

Moreover, the basis asserted for the exception invoked by Thailand and Brazil – and advocated vigorously by activists as a reason for other nations to follow in their footsteps – shows how far the activists view of Article 31 departs

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*See also* UNAIDS, *Report on the Global AIDS Epidemic 2006*, at 6, available at [http://data.unaids.org/pub/globalreport/2006/2006\\_GR-ExecutiveSummary\\_en.pdf](http://data.unaids.org/pub/globalreport/2006/2006_GR-ExecutiveSummary_en.pdf). Prior to its compulsory licensing announcement, Brazil also had substantially reduced HIV/AIDS-related deaths and, like Thailand, lowered its rate of new infections as well. *See* Kaiser Family Foundation, *Proven HIV Prevention Strategies – Real-World Evidence of Effectiveness*, available at [http://www.kff.org/hivaids/upload/050106\\_HIVPreventionStrategies.pdf](http://www.kff.org/hivaids/upload/050106_HIVPreventionStrategies.pdf).

<sup>25</sup>The private non-commercial use of patented pharmaceuticals in order to comply with government testing and reporting requirements is also exempted from liability for infringement in many nations under so-called “Bolar” provisions. *See, e.g.*, 35 U.S.C. § 271 (e)(1).

from the intent and structure of TRIPS. Thailand and Brazil do not assert an inability to secure the drugs they seek or to secure them in the quantity needed. Instead, they justify their decisions to violate established patent rights as advancing their interest in reducing the price of these drugs. That justification on its face seems incompatible with TRIPS Article 31(h)'s requirement that "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization" and the requirement in 31(j) that remuneration for unauthorized use be subject to review by an independent authority. If simple price-cutting were the goal for Article 31 – and especially if that were sufficient basis for an exception to the advance negotiation requirement, on a par with the existence of a national emergency – a very different provision would have been drafted.

The same activists aggressively promoting use of compulsory licenses as price-cutting measures show little attention to the use of precedent in citing a variety of other examples – not involving compulsory licensing – as parallels to the actions of Thailand and Brazil. Their litany of "compulsory licensing" examples includes cases in which patent right holders reach voluntary accords with government or others in exchange for research funds or to promote business deals,<sup>26</sup> cases in which patent licenses are permitted as remedies to violations of antitrust laws,<sup>27</sup> and cases in which courts balancing traditional concerns for equitable awards decide to use damages remedies in place of injunctive relief for patent infringements that are thought to be technical rather than substantial or that concern a minor element in a complex product. In none of these cases is the

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<sup>26</sup>See, e.g., James P. Love, *Some Recent Examples of the Use of Compulsory Licenses on Patents*, Mar. 2007, at 4, available at [http://www.keionline.org/misc-docs/recent\\_cls\\_8mar07.pdf](http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf). Voluntary agreements to allow subsequent use of patents by the government or other parties, such as those reached to obtain research funding under the Bayh-Dole Act, 35 U.S.C. §§ 200-212, manifestly do not constitute *compulsory* licensing.

<sup>27</sup>See Love, *supra* note 26, at 5.

term “compulsory licensing” appropriate.<sup>28</sup> While the TRIPS text might be misconstrued – especially after the recent declarations respecting the flexibility it allows to address public health crises such as HIV/AIDS and tuberculosis – the very fact that so few precedents are available is testament to the limited nature of the exceptions authorized in that accord.

## CONCLUSION

The cornerstone of the IP rights that have spurred so much innovation and contributed so much to progress over the past century is the exclusive right given, for limited periods, to authors and inventors over the use of their creations. The system of IP rights built on that foundation has fostered improved communication and transportation, better health, longer life, and enormous economic progress in much of the world.

A newly expansive view of compulsory licensing being pressed by opponents of strong IP rights in the name of improved public health – and especially in the name of fighting HIV/AIDS – threatens to undermine the primary international agreement that supports those rights. The goal of fighting diseases, including the scourge of HIV/AIDS, is laudable, but the inflated use of compulsory licensing advocated by some activists ultimately will reduce the incentives to innovate that now promote the search for cures for HIV/AIDS and other diseases along with other inventions that make our world safer, more convenient, or more efficient.

The expansion of compulsory licensing being promoted today in one corner of the IP realm – the corner that has the most political salience at the moment – if not checked now, inevitably will provide the basis for expanded compulsory licensing elsewhere. That is the goal of some of the most ardent proponents of

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<sup>28</sup>*Id.* at 6-7. The cases that have followed the Supreme Court’s decision in *eBay Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837 (2006), have clearly distinguished the decisions they make respecting injunctive relief from compulsory licensing, not only in respect of patents, *see, e.g., Z4 Technologies, Inc. v. Microsoft Corp.*, 434 F. Supp. 2d 437 (E.D. Tex. 2006), but also in respect of

compulsory licensing; it is a goal incompatible with the structure of TRIPS and with the established system of IP rights.

As with *Kelo*, the current movement toward greater use of compulsory licensing should be seen not just for its immediate effects but for what it portends. In that light, the changes should be rejected as changing the law in ways that take us a step too far, risking fundamental changes in the system of exclusive rights for innovators that has contributed so much to human progress. If compulsory licensing becomes the exception that ate the rule of intellectual property protection, our health as well as our economic future will suffer.

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copyright, *see, e.g., Christopher Phelps & Associates, LLC v. Galloway*, Docket no. 05-2266, (4<sup>th</sup> Cir., slip op., July 5, 2007).