TRIPS' REBOUND: HOW THE AGREEMENT ON TRADE-RELATED ASPECTS OF

INTELLECTUAL PROPERTY RIGHTS ("TRIPS") CAN RICOCHET BACK AGAINST THE

UNITED STATES: AN HISTORICAL ANALYSIS

by DONALD P. HARRIS'

Recently, scholars and commentators around the world have reexamined the role intellectual property rights (IPRs) play in hindering or helping developing countries. These scholars have questioned the doctrine that IPRs help developing countries by promoting economic development, increasing foreign direct investment, stimulating domestic innovation, and improving access to new technologies, and have concluded that imposing "Western-styled" intellectual property regimes (e.g., the U.S. patent regime) on developing countries harm those countries. In particular, such regimes fail to bring any of the purported benefits, while they impose many costs, including preventing people from obtaining life-saving drugs. This Article argues that it is not simply IPRs that cause these problems but that it is the increased focus of intellectual property regimes on private interests rather than public interests. The Article examines the historical role that intellectual property has played in the United States and its contrasting role in the world community, as evidenced by the international intellectual property treaty (TRIPS). The Article argues that the traditional role of U.S. patent policy was to advance the public interest, while the new role, now advanced by the United States, is to primarily advance private interests. This is perhaps understandable given the change in environment to a more advanced, interdependent global economy. Nevertheless, the new role severely distorts the traditional balance between public and private interests and should be reexamined to determine whether the intellectual property system still promotes the public good, i.e., is it good for society. The Article argues, as do the many scholars and commentators, that TRIPS and this new role harm developing countries; but, the Article goes further and argues that this new role also will have a rebound effect and harm the United States by, among other things, stifling innovation and withholding rather than disseminating knowledge. The rebound effect results from two factors. The first is that TRIPS will constrain the United States' ability to tailor its intellectual property laws because TRIPS impinges upon U.S. sovereignty in this area. The second factor is that, as mentioned, TRIPS is inconsistent with traditional U.S. policy. The Article concludes by examining the harms caused to the United States and the reasons for such harms.

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"That grounded maxim So rife and celebrated in the mouths Of wisest men; that to the public good Private respects must yield."

-- Milton¹

INTRODUCTION

United States' intellectual property law is often regarded as the result of a careful balancing between private and public interests. More specifically, it is regarded as balancing the public interest in gaining access to new products and knowledge against the private interest in recouping research and development costs and earning profits for inventions and creative works. This view is puzzling in view of Congress' and the Supreme Court's repeated admonitions that the United States' intellectual property laws are based on promoting public interests.² Indeed, enshrined in the U.S. Constitution over two centuries ago is the primacy of the public interest.³ The Constitution grants Congress

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¹ John Milton, Samson Agonistes, line 865.

² Consumer politics theory states that consumers should have the widest possible access to products and goods at the lowest possible cost and is grounded in the principle that "the good of the people is the chief law." *See* GILLIAN DAVIES, COPYRIGHT AND THE PUBLIC INTEREST 1 (1994) (citing Cicero, De Legibus III, iii 8). *See also* BANKOLE SODIPO, PIRACY AND COUNTERFEITING: GATT TRIPS AND DEVELOPING COUNTRIES 1-2 (1997) [hereinafter SODIPO, PIRACY]. Stated slightly differently, all laws should be enacted not only with the public interest in mind, but with the public interest being the paramount, if not the exclusive, consideration. "National laws are only enacted if they are in the public interest, or at least it must be assumed that the enacting body so regards them." DAVIES, *supra* at 3. With respect to patents, Professor Lessig similarly states that patent are not evil per se, but are so "if they do no social good." He explains that patents do no social good "if they benefit certain companies at the expense of innovation generally." LAWRENCE LESSIG, THE FUTURE OF IDEAS 259 (2001). This is the fear of this Article, namely that patents and the U.S. patent policy are increasingly affecting no social good because they benefit certain companies at the expense of innovation and the public interest.

³ Art. I, Sec. 8, cl. 8 of the Constitution is referred to as the Intellectual Property Clause. It states: "The Congress shall have the power . . . [t]o 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." The clause is generally interpreted as two proposals that "got packaged together." Giles S. Rich, *The Principles of Patentability*, 42 J. PAT. OFF. SOC'Y 75, 77-78 (1960). Under this interpretation, Congress is

the power to promote the Progress of Science and useful Arts," which has been interpreted as promoting progress with the sole aim of benefiting the public.

This is not to suggest private interests play no part. The public benefits through the system of private rewards. In other words, the intellectual property laws provide incentives to private individuals to create new and useful discoveries, which will ultimately benefit society. The intellectual property laws encourage invention and investment by, on the one hand, providing inventors with a limited monopoly to commercially exploit their inventions and, on the other hand, by protecting intellectual property from piracy and misappropriation. Nonetheless, the Supreme Court has held that because the public interest is the "chief law," any true conflict between the public and private interests must be resolved in favor of the public interest. Despite this, there still seems to be considerable confusion regarding the purpose of the intellectual property laws in the United States. Specifically, despite the traditional and Constitutional focus on public interests, many argue for intellectual property laws that benefit primarily private interests. Indeed, there appears to be a gradual, but perceptible shift in the focus, as evidenced by the United States' approach towards *international* intellectual property,

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given the power: (1) to promote the progress of science by securing for limited times to authors the exclusive right to their writings; and (2) to promote the progress of useful arts by securing for limited times to inventors the exclusive right to their discoveries.

⁴ Piracy and misappropriation reduce the profit the private patent owners receive for their technology and discourage innovation and invention; it also weakens the owners' ability to conduct future research and development.

⁵ See Davies, supra note, at 1.

⁶ "[C]opyright statutes must serve public, not private, ends." Eldred v. Ashcroft, 123 S. Ct. 769, 803 (2003) (Justice Breyer dissenting). Also emblematic of the importance placed on the public interest were: (1) Congress' limit on the period an inventor enjoyed exclusive rights (the patent term); (2) the law's limitation on what can be patented (patentable subject matter); and (3) the remedies available when a patentee abuses a patent (e.g., compulsory licensing). These are discussed in greater detail in Sections IV. and V., *infra*.

which can be seen through the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS").⁷

Through TRIPS, the United States sought an international intellectual property regime that advances private interests, most notably, pharmaceutical companies' interests. TRIPS was designed to strengthen and harmonize worldwide intellectual property rights protection. It requires member countries to implement and enforce minimum standards for protecting those rights. TIRPS wassuccessful in providing such increased standards, with the result that increased revenue flowed back to intellectual property exporting countries, particularly the United States.

As much of the current literature has detailed, TRIPS causes devastating harm to developing countries. These harms include retarding technological development, mass transfers of wealth out of these countries, and other social costs such as the lack of access to medicines. Because of the increased revenue flowing into the United States, there is less attention to deleterious effects for the United States. Indeed, many consider the United States "the big winner" with TRIPS. This view is based on the increased revenue

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While technically speaking all such laws are national, as international laws are implemented through domestic legislation, as will be discussed later (Section II. A.., *infra*), in effect, the international laws are being implemented without regard to traditional domestic interests. Accordingly, throughout this Article, the two are distinguished. Certainly, there are different considerations with international and national intellectual property regimes. Most importantly, social costs (e.g., higher prices) imposed through national laws are generally offset by the domestic benefits obtained through patents. International patenting imposes the same social costs but does not provide the same benefits, as revenue generally flows out of the country to the patent owner's country. *See* International Intellectual Property Law 248-249 (Anthony D'Amato and Doris Estelle Long, eds. 1998) [hereinafter D'Amato, International Intellectual Property]. Also, granting foreign patents can retard further research in the patented technology by reducing competition, and can affect countries disproportionately, depending on the level of protection in each country. *Id.* Thus, there are reasons to treat national regimes differently in response to international concerns. However, when doing so frustrates the very purpose of national laws, such different treatment should not be countenanced.

⁸ See Section II. B., *infra*.

⁹ See Section II. C., *infra*.

flowing back to the United States without fully considering the impact of increased intellectual property protection that also must flow back.

This Article argues that TRIPS' focus on private interests will not only harm developing countries, but also will "rebound" or "boomerang" back against the United States. This is the result of two related factors. The first is that, traditional arguments notwithstanding, intellectual property is no longer a matter left solely within the sovereign power of the domestic nation. Rather, intellectual property is in substance governed by international law. As such, the United States loses sovereign power over intellectual property policy.

The United States' loss of sovereignty is exacerbated because of the second factor – TRIPS' inconsistent focus with traditional U.S. intellectual property law and the Constitution's mandate the intellectual property laws promote progressto benefit the public TRIPS is inconsistent with this mandate because it places remuneration to intellectual property holders above the benefit to the public.¹⁰ Taken together, these

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¹⁰ It is important to make here a distinction about the "public" interest. Throughout the article two different public interests are revealed. The first public interest is the U.S. domestic public interest. It is this interest that Congress must consider in passing intellectual property laws. The second public interest is the global public interest. We can roughly approximate this interest with developing countries and with benefiting the world society as a whole. The developed countries can be equated with private interests and the developing countries with public interests. Of course, this is a broad generalization. But, without question, the developed countries are the major intellectual property exporting countries, and, in this sense, can be seen as private patent owners. The developing countries, lacking meaningful exportable intellectual property products, can be seen as public consumers. Many commentators have recognized the need for an international scheme to take into account countries' different levels of economic development. Reichman, for example, states that "the norms of international economic law represent a delicate balance between the interests of states at different stages of development, and the absorption of intellectual property will have to accommodate these norms and that balance Premature efforts to accelerate the process of harmonization without due regard to these differences and to the social costs of overcoming them could boomerang against those countries pressing for rapid change and could even widen the initial differences in the end." Reichman, supra note , at 255. In any event, these two interests may not always coincide. It is possible that the United States can pursue goals that at once fail to promote the global public interest while promoting the U.S. public interest. For example, arguments can be made that even though protection of private rights for pharmaceutical products may harm impoverished developing countries, the revenue received from this protection flows back to benefit the U.S. domestic public. In some sense this may be true; however, the two interests are not mutually exclusive. Indeed, a benefit to the public interest such as

factors suggest that in implementing enacting legislation to be TRIPS' compliant, the United States is failing in its duty to inquire whether, and ensure that, such legislation in fact promotes progress and is in the public interest.

This Article looks at the United States' efforts and underlying philosophy in promoting TRIPS and the United States' contrasting domestic intellectual property policy, as seen from the perspective of the history and development of United States' patent law. Part I introduces intellectual property harmonization and TRIPS. This Part provides a brief background to TRIPS, examining specific TRIPS provisions, including the compulsory licensing, patent term, patentable subject matter, and parallel import provisions.

Part II introduces the rebound effect. This part argues that TRIPS results in a loss of sovereignty over intellectual property matters for all countries, but notes the increased significance for the United States. Here, we focus on the inconsistency between TRIPS and traditional U.S. intellectual property policy, and demonstrate this inconsistency by examining the history of U.S. patent law and focusing on the factors that influenced that law including the need to promote the public interest. This Part also examines the reasons underlying TRIPS and the specific interests TRIPS furthers. It argues that unlike United States' patent law, private interests – those of the pharmaceutical industry –

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providing for access to low costs medicines also benefits the global interest. Conversely, the U.S.'s shift in focus to protect private rights harms both the global public and the U.S. public. The wealth transfer from international revenue is more than offset by the harm to the domestic public, where only a relative few benefit from the wealth transfer. A large segment is disadvantaged. Moreover, progress (as a synonym for public interest) means more than a transfer of wealth to a privileged few. It means economic and technological progress through the dissemination of knowledge and access to a wide variety of goods at the lowest possible price. The focus on private rights through TRIPS falls short of achieving this, both as to the domestic and the global public interest.

largely motivated TRIPS.¹¹ This Part details the United States' strategy to promote stronger international intellectual property protection through TRIPS.¹² In sum, this Part argues that TRIPS, although promoted as a balanced private and public scheme, is in reality a private rights regime. Parts III and IV attempt to ground the above analysis by examining the history of and TRIPS' current effect on two specific areas: compulsory licensing and the patent term.

The Article concludes by recommending that the United States refocus its position regarding intellectual property matters to promote the public interest. While the United States certainly may give up some discretion, it cannot allow narrow economic interests to dictate national policy. Rather, the United States must ensure that its intellectual property legislation promotes the progress of science and useful arts. While the determination may be difficult, it nonetheless must be made.¹³

I. THE TRIPS AGREEMENT

A. Increased Worldwide Intellectual Property Protection

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¹¹ Martin Kohr, *How the South is Getting a Raw Deal, in* VIEWS FROM THE SOUTH, THE EFFECTS OF GLOBALIZATION AND THE WTO ON THIRD WORLD COUNTRIES 22 (2000) (listing the motives for the North (developed countries) as: (1) enabling transnational companies in developed countries to "capture more profits through monopolistic higher prices and through royalties and the sale of technology products"; and (2) to put barriers in place to prevent technological development of "potential new rivals from the South." Kohr notes the hypocrisy of using "trade liberalization" as the new vehicle to impose stronger intellectual property laws. He declares that developed countries "would promote their own commercial interests, whether that meant through liberalization or protectionism.")

¹² See Section II. B., *infra*. For example, Reichman states that the United States used market access as a "bargaining chip" to be exchanged for stronger intellectual property protection. Jerome H. Reichman, *The TRIPs Component of the GATT's Uruguay Round: Competitive Prospects for Intellectual Property Owners in an Integrated World Market*, 4 FORDHAM INTELL.PROP.MEDIA & ENT. L.J. 171 (1993).

¹³ We also must move from relying on rhetoric and general theories regarding intellectual property and conduct the necessary empirical research to demonstrate what is and is not in the public interest. *See* Claude E. Barfield, FREE TRADE, SOVEREIGNTY, DEMOCRACY: THE FUTURE OF THE WORLD TRADE ORGANIZATION (2001) (arguing that much of international policy is based on rhetoric, theory and "mantras.")

In April 1994, countries, including the United States, concluded the "Uruguay Round" trade negotiations under the General Agreement on Tariffs and Trade ("GATT"). The Uruguay Round Agreements established the World Trade Organization ("WTO") and include the TRIPS Agreement, an intellectual property treaty that significantly strengthens intellectual property rights worldwide. ¹⁴ TRIPS has been hailed as "the most far reaching and comprehensive legal regime ever concluded at the multinational level in the area of intellectual property rights . . . " and "unquestionably the most important development in international intellectual property law [in the last century]." ¹⁵

Prior to TRIPS, countries had widely varying levels of intellectual property protection and enforcement. Understandably, because each country had widely different and oft times divergent goals, values, history, culture, tradition and political climate, countries protected intellectual property at different levels. Indeed, some countries provided very little in the way of protection. Moreover, because countries are at very different levels of economic and technological development and thus at vastly different levels of producing and exporting intellectual property goods, countries have divergent views and interests regarding intellectual property protection and the scope of such protection. Quite simply, the benefits and harms from intellectual property protection depend upon the individual country. Despite this, TRIPS mandates that all countries increase intellectual property protection at certain "minimum" levels. TRIPS most significant accomplishments

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¹⁴ As of January 2002, the WTO has 144 members. See INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY, REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, London, September 2002, found at www.iprcommission.org (last visited July 20, 2002) [hereinafter CIPR Report]at Introduction Box 01.

¹⁵ INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT xvii (Carlos M. Correa and Abdulqawi A. Yusuf eds. 1998); Charles McManis, *Intellectual Property and International Mergers and Acquisitions*, 66 U. CIN. L. REV. 1283, 1286 (1998). TRIPS is considered by many to be a major accomplishment in the effort to harmonize patent laws throughout the world. Adelman, *supra* note ___, at 512 (1996) ("The importance of TRIPS cannot be easily overemphasized.")

include: (1) linking intellectual property rights to trade for the first time in a multilateral international intellectual property agreement, and (2) requiring member countries to implement and enforce minimum standards for protecting intellectual property rights.¹⁶ The impact of these cannot be overstated.

By linking intellectual property to trade, intellectual property-exporting countries can use GATT's dispute settlement mechanism against recalcitrant or noncomplying member countries. This includes imposing trade sanctions against these countries. By requiring minimum standards, TRIPS mandates that all countries revise their laws to meet certain heightened standards of intellectual property protection. These standards greatly increase the level of intellectual property protection beyond those previously established in an international intellectual property treaty.

This section examines TRIPS objectives and a number of the more important TRIPS patent provisions to understand the changes TRIPS requires of member countries. The following sections then take a more detailed look at the provisions in the context of how they affect public and private interests in general and the United States in particular.

1. TRIPS' Objective

TRIPS' objective is to liberalize the international trading system while protecting the private rights of intellectual property owners by reducing piracy and misappropriation.¹⁷

Another of TRIPS' principal objectives is to eliminate "free-riding" distortions resulting from the fact that some countries did not protect intellectual property rights. TRIPS'

¹⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights Article 1, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1197 [hereinafter TRIPS]. Enforcement includes trade sanctions, which consists of compensatory and retaliatory withdrawal of trade concessions and the imposition of tariffs and quotas.

¹⁷ TRIPS, *supra* note ___, Article 7 and Preamble.

Preamble also explicitly refers to the "trade-related" aspects of intellectual property and the need to protect private interests: "Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights"¹⁸

2. TRIPS Minimum Standards

a. Patentable Subject Matter

As to the minimum standards, TRIPS Article 27's patentable subject matter requires WTO members to provide patent protection for any invention regardless of the field of technology. This prevents countries from discriminating based on field of technology. This provision has evoked the most protest and controversy and has the most far-reaching deleterious effects. "No provision of the TRIPs Agreement sweeps away national limitations on intellectual property protection more completely than the first sentence of Article 27(1)."²⁰

Article 27 is extremely broad in its grant and greatly expands previous agreements regarding subject matter. Article 27(1)'s first sentence stating that patents shall be available "in all fields of technology" means that countries cannot discriminate based on

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TRIPS, *supra* note ___, Preamble. The overarching theme of the TRIPS Agreement was to reduce barriers to trade by protecting intellectual property rights. TRIPS' title, Agreement on Trade-Related Aspects of Intellectual Property Rights, and the very first line of its Preamble "to reduce distortions and impediments to international trade [...]" reflects its commitment to trade. One of its objectives as set forth in its Preamble is: . . . the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international trade relations." Interestingly, at the turn of the century, intellectual property *protection* was thought to inhibit trade. See A. David Demiray, *Intellectual Property and the External Power of the European Community: The New Extension*, 16 MICH. J. INT'L L. 187, 200 (1995).

¹⁹ The relevant portion of TRIPS, Article 27(1), provides: "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application [P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the filed of technology and whether products are imported or locally produced." TRIPS, *supra* note ___. ²⁰ PAUL GOLDSTEIN, INTERNATIONAL INTELLECTUAL PROPERTY LAW CASES AND MATERIALS 307 (2001).

subject matter. In other words, countries cannot exclude from protection certain inventions. Thus, for example, developing countries, many of which previously excluded inventions in fields such as food, agriculture, and medicines, can no longer exclude inventions in these fields. Article 27(1)'s first sentence also prevents countries from discriminating against inventions based on whether they are "processes" or "products."

b. Patent Term

Another key provision is TRIPS' patent term. TRIPS harmonizes the patent term by providing for a minimum 20-year term.²¹ The new term is longer than that previously provided by countries, including the United States, which had a 17-year term.²² Moreover, previously countries were able to provide different periods for different inventions. India, for example, provided for 5 years of patent protection for patent processes on pharmaceuticals.²³ Because of TRIPS' nondiscrimination clause, countries are no longer able to distinguish in this manner.

c. Parallel Imports

Parallel importation allows countries to seek lower-priced products abroad, which countries then import, rather than purchase higher-priced versions from local distributors. Parallel importation exists as a consequence of price disparity among different countries' product; this price disparity allows countries to "price shop" and obtain the lower-priced

²¹TRIPS, *supra* note ___, Article 33 provides: "The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."

²² The previous U.S. patent term calculated the term from the issuance date, rather than the filing date. 35 U.S.C. § 154 (1993).

²³ Baldia, *supra* note __, at 523.

goods. Prior to TRIPS, countries were free to do just this, i.e., chose the policy that best advanced their interests.

During the TRIPS' negotiations, the controversy over parallel importation was "intense." Developing countries pushed for a standard that would allow them to continue purchasing the lowest priced drugs from anywhere in the world. Developed countries pushed for a standard that would prevent the free movement of goods after the initial sale of the product. No agreement could be reached. Reflecting this, Article 6 states that: "For the purposes of dispute settlement . . . nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." This language allows each country to choose the system it deems most suitable, thus retaining the status quo. 25

d. Compulsory Licensing

Compulsory licensing was another area of intense TRIPS' negotiations. A compulsory license is a state-granted license issued to a third party to manufacture and produce a patented invention without the patent owner's consent. As with the other measures, countries' policies regarding the availability and use of compulsory licensing varied. TRIPS Article 31 sets forth the framework regarding compulsory licensing. That section, entitled "Other Use Without Authorization of the Right Holder," gives countries

²⁴ Marco C. E. J. Bronckers, *The Exhaustion of Patent Rights Under WTO Law*, 32(5) J. WORLD TRADE 137 (1998)

²⁵ This interpretation was challenged by the United States; however, at the 2001 WTO Ministerial meeting at Doha, Qatar, the Council made clear that Article 6 allows each country to design their own exhaustion of rights regimes. See Doha Declaration, ¶5 (d); CIPR Report, *supra* note ___, at 42.

²⁶ See, e.g., P. Gorecki, Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection, and Government Reimbursement Programs, (Economic Council of Canada, 1981) (defining a compulsory license as "an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state.").

broad discretion on government use of compulsory licensing.²⁷ However, while the grounds on which a government can grant a compulsory license are not limited, TRIPS contains numerous conditions that must be met before the government can authorize licenses. Three of the main conditions are that, as a general rule: (1) an effort should be made to negotiate a voluntary license on reasonable commercial terms;²⁸ (2) the government must provide for "adequate remuneration" to the right holder;²⁹ and (3) the license use must be "predominantly for the supply of the domestic market." Other conditions include: (1) the scope and duration of the license must be limited to the purpose of the authorization;³¹ (2) the license is non-exclusive and is generally nontransferable; (3) the license is terminated when "the circumstances which led to it cease to exist and are unlikely to recur;" and (4) the government's decision is subject to independent judicial review.³² Thus, while governments can grant compulsory licensing, they cannot do so with unfettered discretion but must comply with these sometimes onerous conditions. By adopting TRIPS, each country had to implement each of the above changes. For some countries, the changes were minimal. For other, these changes resulted in drastic changes in their intellectual property laws.

²⁷ Arguably, countries also might justify compulsory licenses based on a public-interest exception, Article 8(1), and as a means to prevent abuses by intellectual property rights holders, Article 8(2). Compulsory licenses based on these principles still must be consistent with Article 31.

This requirement may be waived in case of "national emergency," "other circumstances of extreme urgency," or "in cases of public non-commercial use." TRIPS, *supra* note ___, Article 31. These exceptions allow a government to bypass the step of negotiating compensation with the patent holder in the interests of expediency. In 2002, Zimbabwe invoked this exception to override patents on antiretroviral drugs in response to the AIDS crisis gripping the country. Medecins Sans Frontieres, *Zimbabwe Government Takes Emergency Action Against HIV/AIDS*, May 29, 2002. *Available at* http://www.msf.org (last visited August 17, 2003).

²⁹ TRIPS, *supra* note ___, Article 31(h).

³⁰ TRIPS, supra note ___, Article 31(f).

³¹ TRIPS, *supra* note ___, Article 31(c).

³² TRIPS, *supra* note ___, Article 31(f). Other bases for compulsory licenses include the need to correct anti-competitive practices and in preventing blocking patents. *Id.* Article 31(k) and (l). The detailed set of conditions do not apply when anti-competitive practices are being remedied. TRIPS, Article 31(k).

B. The Next Frontier: TRIPS-Plus ("Pigging out at the IP trough")³³

The full impact of TRIPS is only now becoming clear. It has resulted in deleterious social and economic effects for developing countries. TRIPS' impact on these countries has been enormous. It was touted as a vehicle for economic development, foreign direct investment, technology transfer, and increased market access to developed world markets for agriculture and textiles. These perceived long-term benefits have not yet materialized and indeed are questionable. The short-term disadvantages are not. Developing countries must cope with TRIPS' monopolization effects and increases in government expenditures and costs associated with implementing and enforcing a new intellectual property system. Developing countries also effectively are denied access to products protected by intellectual property rights, including life saving drugs.

What is most troubling about TRIPS and the strengthening of countries' intellectual property regimes from a developing country (and, as will be argued, the United States') perspective is that even before countries can come to terms with current TRIPS problems, TRIPS proponents are pushing onward. Extending the period of protection, achieving equal treatment for all technologies, and limiting the use of compulsory licensing were just the beginning. Many developed countries are asking for more – what is commonly referred to as TRIPS-plus. TRIPS-plus includes a ban on compulsory licensing and parallel imports; pipeline protection for inventions still under development; no early registration or stockpiling of generic drugs before the patent expires; and liberal patent

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³⁴ See McManis, *supra* note ___, at 1286-97.

³³ This phrase is taken from Professor Robert Merges' article about the 1998 Sonny Bono Copyright Term Extension Act. Robert Merges, *One Hundred Years of Solicitude: Intellectual Property Law*, 1900-2000, 88 CAL.L.REV. 2233 (2000). It applies just as well to TRIPS and TRIPS-plus.

extension rules.³⁵ The logic of TRIPS-plus is that if strong intellectual property rights are good, even stronger protection is better.

C. The United States: The Big Winner?

In contrast to developing countries, the United States, in one sense, it is the big winner with TRIPS, as it will receive rent in the form of royalties in the range of millions a year. Maskus calculated that the United States overwhelmingly would gain the most income in terms of "static rent transfers" with an estimated increased rent net inflow of \$5.8 billion per year. (Germany was next with less than \$1 billion.) Maskus attributes this inflow "to the fact that U.S.-headquartered firms owned numerous patents in many countries that were required by TRIPS to upgrade their intellectual property protection The calculations represent only "what the additional income on existing patents would have been under TRIPS." The latest estimate, by the World Bank, also suggests that most developed countries would be the major beneficiaries of TRIPS in terms of the enhanced value of their patents, with the benefit to the U.S. estimated at an annual \$19 billion. Developing countries, and a few developed ones, would be the net losers. The country sustaining the largest loss in the study by the World Bank was Korea (\$15 billion).

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³⁵ Heinz Klug, *Patents and Pandemics: Can South Africa Survive Legal Harmonization*, paper presented at the Rutgers University (Camden) law faculty speakers series, Camden, February 12, 2001 at 9.

³⁶ Keith E. Maskus, *Intellectual Property Rights and Economic Development*, 32 CASE W.RES.J.INT'L L. 471, 493 (2000) [hereinafter Maskus, *Economic Development*]. Maskus qualifies his calculations as being inherently sum-zero and static. McCalman, whose work Maskus builds upon, worked out the required changes in patent laws as measured by the index developed by Ginarte and Park in 1997. Maskus then applied these changes to 1998 patent portfolios owned by each country to determine how TRIPS and the stronger patent laws would affect the transfer of rents if TRIPS had been in place. *Id.* at 476-477.

³⁷ *Id.*

³⁸ *Id*.

³⁹ World Bank (2001a) "Global Economic Prospects and the Developing Countries 2002: Making Trade Work for the World's Poor," World Bank, Washington DC, p. 133. Source: http://www.worldbank.org/prospects/gep2002/.

Not too much should be read into the exact value of these figures, which depend on a number of debatable assumptions, but it can safely be said that the perceived effect of applying patent rights globally will be to benefit very considerably the holders of patent rights, mainly in developed countries, at the expense of the users of protected technologies and goods in developing countries. However, for the United States, the numbers do not tell the entire story. The inflow of money to a narrow few is only one aspect of TRIPS. The full effect of TRIPS also involves the loss of sovereignty and the retardation of technological development that will occur.

II. TRIPS REBOUND

TRIPS' and TRIPS-plus' emphasis on stronger intellectual property will not only exacerbate the problems for developing countries, but also will harm the United States because they will rebound back against the United States. The rebound effect results from the fact that as a WTO signatory, the United States will have to strengthen its intellectual property regime to comply with TRIPS and TRIPS-plus. By doing so, the United States relinquishes its sovereign power regarding intellectual property laws, and more to the point, relinquishes power to enact patent laws consistent with the constitutional mandate of promoting the progress of the useful arts. The rebound effect also results from the inconsistent focus of U.S. intellectual property law and TRIPS. It is not clear that the TRIPS' revisions meet the constitutional mandate of promoting the public interest. It is even less clear that the proposed TRIPS-plus revisions do.

A. TRIPS Results in Loss of Sovereignty over Intellectual Property

1. Sovereignty

Sovereignty is about decision-making.⁴⁰ It refers to a state's unlimited power, which is subject to only those rules of international law that the state has expressly accepted.⁴¹ Neither other states nor international organizations such as the WTO have any right to intervene in matters which are essentially within the domestic jurisdiction of that state.⁴²

The interplay between sovereignty and international governance raises a host of questions, many of which are beyond the scope of this article. As pertinent here, however, because international governance gives a "central place to values" as the basis for delegating to the international community collective decision-making authority, the question becomes: What are the issues upon which states share common values? While difficult to identify, generally, these issues are matters that because of their affect on other states become matters that must be solved within the international community. Such matters may include human rights, genocide, apartheid, systematic killing of people, ethnic cleansing, torture, nuclear energy and weapons, labor, and the environment. It can be argued that while there is consensus that the international community must speak to issues such as human rights, genocide, ethnic cleansing, etc. countries do not share common values with respect to them. Issues within these categories upon which there is no consensus include, for example, the death penalty, mutilation of female genitalia, child labor, and the cause and effects of global warming.

⁴⁰ The first explicitly formulated doctrine of sovereignty was in Jean Bodin's 1576 De Republica. *See* STATE, SOVEREIGNTY, AND INTERNATIONAL GOVERNANCE 27 (2002) (Gerard Kriejen, et al. eds. 2002) [hereinafter, INTERNATIONAL GOVERNANCE]. Bodin's idea of sovereignty, which represented the situation of States in Europe during that time, was "as a source of strength and power for the State with a view to confining this status to institutions that did in fact enjoy this kind of power. . . ." Sir Robert Jennings, *Sovereignty and International Law*, in INTERNATIONAL GOVERNANCE at 27. Decision-making can occur on vertical and horizontal levels. "The vertical allocation involves which level of social organization should decide. In particular, what amount of deference should be granted to national regulation vis-à-vis supranational rules? The horizontal allocation involves choices between political and administrative processes, global market processes and international judicial processes." Gregory Shaffer, *Power and Global Governance: The Need for A Comparative Institutional Approach*, in POWER AND GLOBAL GOVERNANCE 12(Michael Barnett and Bud Duvall eds.) (Cambridge University Press, forthcoming 2004) [hereinafter Shaffer, Global Governance]. Here, we deal exclusively with vertical decision-making (i.e., the United States vs. the WTO).

⁴¹ Barfield identifies two separate categories of sovereignty: (1) Westphalian sovereignty; and (2) interdependence. Westphalian sovereignty refers to excluding foreign actors from domestic decision-making. Interdependence concerns a nation's ability to control the cross-border movement of goods, services, capital, labor, and information. Claude E. Barfield, *supra* note ____, at 8.

⁴² International Governance, *supra* note ___, at 185. The difference between sovereignty and international governance, which is defined as "the process by which we collectively manage and govern resources, issues, conflicts and values in a world that is increasingly a global neighborhood," can be viewed as "one of degree and gradation along a spectrum." International Governance *supra* note ___, at 4. At one end of the spectrum is the notion that the world is made up of individual states that operate without – or with very little – thought of its actions on other states. At the other end is the notion that the world is made up of individual states that are interdependent and have common values and problems that can be solved only through common efforts, with respect for universal legal rules. Along these lines, Marcel Brus argues that governance of world affairs and conflicts "can no longer be based on purely voluntary cooperation of sovereign States, but will be based on shared normative concepts" International Governance *supra* note __, at 4.Of course, the reality is that the world community is somewhere in between. See generally Shaffer, *Global Governance*, *supra* note __, at 2 (citing Neil Walker, *The EU and the WTO: Constitutionalism in a New Key*, in eds. Grainne de Burca and Joanne Scott, The EU and the WTO: LEGAL AND CONSTITUTIONAL ISSUES 33 (2001)).

The reason for jealously guarding sovereign power should be readily apparent. States are in the best position to address constituent, domestic concerns. As Professor Shaffer notes, "participation in democratic decision-making at the national level is of a much higher quality" because of, among other things, the closer relation between citizen and state. Surrendering authority to others – the international community – to address essentially domestic concerns could result in these concerns either going unaddressed or

On the other hand, if values are not shared amongst the individual countries, conflict arises which can or cannot be resolved. As a result, individual values either must grow towards each other or the international community must adopt rules that deal with the unavoidable conflict. With respect to intellectual property values are intensely different. Oversimplifying, there is a sharp division between on the one hand treating intellectual property as the preservation of the "cultural heritage of mankind," where creations form the "accumulated material heritage of humankind as a whole" and all persons in society enjoy free access to these creations and on the other hand treating intellectual property as creative works of individual artists, providing for "the right of individuals to freely create their cultural 'oeuvres' with no restrictions." Rosemary J. Coombe, Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed By the Recognition of Indigenous Knowledge and the Conversation of Biodiversity, 6 IND.J.GLOBAL LEGAL STUD. 59, 74 (1998). Coombe distinguishes the two views based on the meaning of the term "culture." She contends that the term has different meanings in the international human rights arena and these differences are at the heart of the various debates about the appropriate scope and level of intellectual property rights protection. Id. at 72-73. The former view relies on communal sharing and the passing down of cultural tradition, while the latter view places an emphasis, indeed an insistence, on individual authorship as the hallmark of intellectual property protection. Coombe, supra note 219, at 76. Coombe identifies a third understanding of culture, which is the material and spiritual activities, products, meanings, and values of a given social group that distinguish it from other groups. Id. at 73 (citing Asbirn Eide & Allan Rosas, Economic, Social and Cultural Rights: A Universal Challenge, in ECONOMIC, SOCIAL AND CULTURAL RIGHTS: A TEXTBOOK 230 (Eide et al. eds., 1995)). Coombe refers to this understanding as an "anthropological" meaning. Developing countries are more inclined to view intellectual property under a common heritage of mankind notion while developed countries view it under a protecting creative works of individual artist approach. This is of course an extreme generalization. There are developing countries that treat intellectual property under the individuality approach. There also is often an overlap in individual countries in the manner they treat intellectual property. The point is that there is no one view towards intellectual property held by all countries and thus no "common values" regarding it. We thus can legitimately question whether intellectual property is a matter that reflects shared values appropriate for international governance. Marcel Brus, The Authority of Law in STATE, SOVEREIGNTY AND INTERNATIONAL GOVERNANCE 5 (Kriejen et al. eds., 2002). Cf. Coombe, supra, at 115 ("As a consequence of the Uruguay Rounds, State sovereignty over IPRs no longer appears especially significant in terms of ensuring that intellectual property protections meet domestic public interests.")

Beyond these questions, yet others remain. Such questions involve implementation and enforcement of international norms, i.e., determining how best to have individual states adopt policies resolving "community issues," and assuring that states not only implement but also enforce these universal policies. Related, what is the best way to promote or achieve these common values? And, finally, in cases where there are no shared or common values, do we defer to the States or to the international community to resolve these conflicts?

⁴³ Shaffer, *Global Governance, supra* note ___, at 20. Shaffer also notes that the reduced cost of organization and participation and common identity and "communal cohesiveness" contribute to the higher quality of decision-making. *Id*.

unsatisfactorily resolved. Here again Shaffer notes that "international procedures are generally unsuited to respond to local norms, needs, and conditions."44 Moreover. "serious biases" inherent in the international political processes militate against delegating decision-making authority to the international community. 45

With respect to intellectual property, traditionally this has been a matter within the exclusive jurisdiction of individual countries. In the United States, for example, the court in Robertson v. General Electric⁴⁶ observed:

"Patent rights differ from many other rights which are the subject of treaties, in that they are created by and dependent upon statutes which only Congress has the power to enact.

Furthermore, a right under a patent is not one which extends across national boundaries, and is therefore necessarily a matter for regulation by treaty, but is one which may be enjoyed within the territory of the nation."⁴⁷

In the late nineteenth and early twentieth century this sentiment was understandable, as the world community more reflected a group of individual and sovereign nation states, as opposed to an interdependent community. Changes in the international society have changed views regarding allocating decision-making authority.

In particular, the post WWII period saw a rise in efforts to retain (or gain) sovereign powers, in large part because the many newly decolonized States equated sovereignty with freedom. 48 Now, in the post-decolonization and post-cold war period, with the new

⁴⁴ Shaffer, *Global Governance*, *supra* note , at 20.

⁴⁶ Robertson v. General Electric Co., 32 F.2d 495 (4th Cir. 1929).

⁴⁷ Robertson, 32 F.2d at 500. The issue before the court was whether treaties affecting patent rights were self-executing. The court held they were not, unless the language of the treaty compelled a different interpretation. Id.

⁴⁸ In the 1930s sovereignty was thought of as an obstacle to the development of international law. To better advance international law many believed States had to surrender sovereignty. INTERNATIONAL GOVERNANCE, *supra* note ___, at 29.

globalized economy and technological advances we again are redefining sovereignty. 49

While the traditional view remains dominant, 50 this article presents a different view. The view here is that the dogged traditional position of intellectual property rights is more form over substance. 51 TRIPS has transformed intellectual property rights into internationally governed rights, leaving what seems like very little discretion to sovereign states. 52

The traditional and dominant view is premised on the fact that an intellectual property owner's right to protect their property in a foreign country depends on whether the foreign country's domestic laws recognize such a right. The foreign country's national laws determine the nature of such rights even if those laws are constrained by the country's obligations under international intellectual property law.⁵³ Because TRIPS is a non self-executing treaty,⁵⁴ in order to comply with its provisions, countries including the United States must enact implementing legislation. Thus, because countries must still enact implementing legislation they retain their sovereign power over intellectual property. In this sense, intellectual property is indeed territorial. TRIPS changes this.

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⁴⁹ A different problem associated with sovereignty is how to think of States that are sovereign in the independent sense, but are in fact lacking sovereign power either because the government is not responsive to its citizens or because it is being run by warlords or individuals who are behaving irresponsibly. International Governance, *supra* note ___, at 29-30. This problem is not addressed here.

⁵⁰ D'Amato, *supra* note ___, at 233.

The global and interdependent world have made scholars question whether the traditional territoriality view regarding intellectual property remains viable. *Id.*

⁵² Some argue that sovereignty is a myth because in fact, "most, if not all, sovereign governments have limited choices in the exercise of the supposed sovereignty because their theoretically important areas for decisions are much restricted and hemmed in by treaties, by customary international law, and by the consequences, and especially the economic consequences of the sheer interdependence of all sovereign states of today." INTERNATIONAL GOVERNANCE, *supra* note ___, at 31-32.

⁵³ GRAEME B. DINWOODIE, WILLIAM O. HENNESSEY, SHIRA PERLMUTTER, INTERNATIONAL INTELLECTUAL PROPERTY LAW AND POLICY 28 (2001) [hereinafter Dinwoodie, INTERNATIONAL IP]. ("intellectual property laws operate territorially, and intellectual property rights are thus national in scope.").

⁵⁴ Self-executing treaties do not require implementing legislation and automatically become effective as domestic law immediately upon entry into force. Non self-executing treaties need implementing legislation and then it is the legislation, not the treaty, that is the law of the land, unless the legislation simply incorporates the treaty. *See* Dinwoodie, INTERNATIONAL IP, at 61-62.

First, countries were successful in bringing TRIPS and intellectual property under GATT/WTO by labeling intellectual property as trade-related, asserting that inadequate protection of intellectual property rights in developing countries had trade-distorting effects. By becoming WTO members, countries are required to accept the whole body of agreements that are administered by the WTO, including TRIPS, as the agreements are a "package deal." Countries have no discretion to choose individual agreements. Countries became WTO members, and accepted TRIPS, not as much for what TRIPS offered but because they perceived that they would be worse off without the WTO. This had a profound effect on how countries treated intellectual property. Their discretion was constrained.

Second, TRIPS establishes minimum standards that far exceed previous standards.⁵⁸ Thus, even though a country has discretion to provide *more* protection than that required by TRIPS, it does not have discretion to provide *less* protection.⁵⁹ This is viewed "as a drive to overcome preexisting territorial limitations on intellectual property rights."⁶⁰ Under these circumstances, countries lose sovereign power within the minimum standards set by TRIPS.⁶¹

⁵⁵ Section II. B., *supra*.

⁵⁶ Previously, countries would be bound by only those agreements they chose to ratify. INTERNATIONAL GOVERNANCE, *supra* note ___, at 517. Thus, for example, under GATT, countries would individually negotiate each tariff reduction or trade-reducing barrier; countries could agree to different elements of GATT without being bound by GATT's other provisions. Klug, *supra* note ___, at 18.

⁵⁷ Shaffer, *Global Governance*, *supra* note ___, at 8. The obvious harm in not becoming a WTO member is the loss of trade concessions, national treatment, and most-favored nation status. "The risk of exclusion can induce developing countries to agree to comply with international rules that may contravene their interests such as the TRIPs Agreement" *Id*.

⁵⁸ Section I. A., *supra*.

⁵⁹ This is of course if the country decides to become a member of the WTO. The country could also become a member without complying with TRIPS provisions but, as explained later, the sanctions that can be applied against a noncomplying member makes this option unattractive.

⁶⁰ D'Amato, *supra* note , at 376.

⁶¹ The sovereignty argument is based on the premise that intellectual property is a matter that should be left within a state's decision-making process. But see n. ___, *supra*. On the other hand, there are situations

Finally, and perhaps most importantly, TRIPS adds to the minimum substantive standards *minimum enforcement standards* of the states' international obligations. ⁶²

These enforcement standards occur at both national and international levels. Nationally, TRIPS requires enhanced domestic legal procedures. Internationally, TRIPS makes compliance subject to the WTO dispute settlement procedures, which authorize retaliation against countries failing to comply with WTO/TRIPS provisions. More specifically, the rules allow members to use and threaten to invoke the WTO remedy of withdrawing trade concessions. ⁶³ This puts enormous pressure on countries to enact TRIPS legislation and then to comply with such legislation. The highly efficient WTO settlement dispute system and the very real threat of retaliatory trade sanctions make talk of the territoriality of intellectual property laws ring hollow. ⁶⁴ Not becoming WTO members (and obtaining the trade benefits that go along with being a member) is not an option. Neither is not complying with TRIPS in light of the harsh retaliatory sanctions.

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where states must cede some control. In these circumstances, countries must balance sovereignty against grants of authority over their economic and social policy to international organizations such as the WTO. International Governance, *supra* note __, at 3. Paradoxically, by assuming international legal obligations by entering into a treaty such as TRIPS countries both manifest sovereignty and at the same time restrict their sovereignty. International Governance, *supra* note __, at 424. Of course, consent to be bound by a treaty limits a State's sovereignty no further than follows from the correct interpretation of the treaty. International Governance, *supra* note __, at 16. States can also forfeit sovereign power, e.g., by massively violating the rights of an ethnic minority as in Kosovo in the 1990s.

⁶² Part III of the TRIPS Agreement concerns procedures and remedies to be provided at the national level for the enforcement of intellectual property rights.

⁶³ Gregory Shaffer, Making the WTO Dispute Settlement System Work for Developing Countries: Some Proactive Developing Country Strategies, 2003, available at http://www.ictsd.org, at 7.
⁶⁴But cf. David Palmeter, National Sovereignty and the World Trade Organization, 2 J.WORLD

INTELL.PROP. 77, 90 (1999) (arguing that failure of a member to comply with its WTO obligations results in a cancellation of the bargain to do so, which does not amount to a loss of sovereignty; rather, the complaining party, i.e., the party that wins a WTO dispute, is the party that loses sovereignty because that party is restrained from deciding how to react to the action of the breaching party, the complaining party must limit itself to withdrawing trade concessions).

In reality, TRIPS transforms intellectual property from a domestic matter to a matter for international governance. ⁶⁵

2. Consequences of the United States' Loss of Sovereignty

Relinquishing sovereignty to the WTO over intellectual property has obvious consequences for developing countries with little or no bargaining power. What may be less obvious are the consequences for the United States. These consequences can be grouped into two categories. The first relates to the inappropriateness of having the WTO dictate U.S. intellectual property law. The second set of consequences relates to increased intellectual property protection, as required by TRIPS, and whether this increased protection in fact promotes the progress of science and useful arts, as required by the Constitution. Here, because the WTO arguably has been captured by industries seeking stronger intellectual property laws, these industries can make an "end run"

WTO.

⁶⁵ Even assuming countries believed intellectual property was an appropriate subject for international governance, one may legitimately conclude that in granting international organizations such as the WTO authority over domestic affairs, countries, particularly developing countries, believed that the WTO would act in a relatively just or quasi democratic manner. These countries' hope was that the WTO would give due weight to that particular state's interests while also considering other states' interests. Many have questioned whether the WTO is in fact such an organization. Barfield argues that the WTO lacks democratic legitimacy because of the imbalance between its rule-making procedures and effective dispute settlement procedures. In effect, the dispute settlement panels create law which often is biased in favor of developed countries. Barfield, *supra* note ___, at 7.

Governance, supra note ___, at 517. Note also that developing countries previously had low level of protection for intellectual property, if they had protection at all. For a good discussion on how the WTO's Understanding on Rules and Procedures Governing the Settlement of Disputes (Dispute Settlement Understanding or "DSU) harms developing countries see Shaffer, WTO Dispute Settlement, supra note __. For developing countries, the question is not only how to balance sovereignty with international governance but also when moving to the arena of international governance how to ensure that dominant States do not frustrate less powerful States' legitimate aspirations to social and economic development. INTERNATIONAL GOVERNANCE, supra note __, at 18. Also, although sovereignty can be seen as exchanging internal for international power, in the case of LDCs, there is less of a true exercise of economic sovereignty because the LDC is severely constrained by the lack of economic power in the legal system of the world trade order. INTERNATIONAL GOVERNANCE, supra note __, at 511.

67 On the other hand, one could argue that because of the United States' power in global governance it is less likely that it will suffer as much loss of sovereign power. See, e.g., Shaffer, supra note __. This view does not adequately distinguish between the decision makers at the different vertical levels of the U.S. and

around Congress. In other words, these industries may be able to obtain favorable legislation in the WTO – and ultimately in the United States – that they could not have obtained directly in the United States because it does not promote progress. Although there are highly persuasive argument that TRIPS does not promote "progress" in this sense, the point of this article is not necessarily to demonstrate that the TRIPS' revisions to the U.S. intellectual property laws do not do so and are therefore unconstitutional.⁶⁸ Rather, the article argues that we must *in fact* determine whether TRIPS implementing legislation promotes the progress of science and useful arts.

As to the first category of WTO inappropriateness, the Constitution directs

Congress to decide intellectual property issues: "Congress shall have the power . . . to

Promote the Progress of Science and the useful Arts by securing for limited Times to

Authors and Inventors, the exclusive Right to their respective Writings and

Discoveries." This Clause is clear: Congress has the power and the duty to determine the scope of U.S. intellectual property rights. This applies equally to domestic intellectual property laws as to international intellectual property obligations, which are implemented through domestic laws. Thus, delegating to, or placing decision-making in the WTO is suspect.

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⁶⁸ No provision in any treaty has been held unconstitutional by the Supreme Court, and "few have been seriously challenged there." LOUIS HENKIN, FOREIGN AFFAIRS AND THE UNITED STATES CONSTITUTION 185 (1996) [hereinafter, HENKIN, FOREIGN AFFAIRS]. But see notes therein regarding commentators challenging the constitutionality of certain provisions.

⁶⁹ Art. I, Sec. 8, cl. 8 (emphasis added). In *Eldred v. Ashcroft*, 123 S.Ct. 769, 784-785 (2003), the Supreme Court did not consider whether this preamble of the Clause placed a substantive limit on Congress' legislative power, as petitioners apparently did not argue this point, but the Court nevertheless found that the "preambular language identifies the sole end to which Congress may legislate," i.e., to promote the progress of science. The Court concluded that the Copyright Term Extension Act did promote the progress of science. *Id.* Even so, the Court stressed that this was a determination properly left to Congress. *Id.* at 785.

Placing decision-making authority in the WTO is exacerbated by the difficulty in amending or interpreting WTO law through the rigid WTO political process. "Unlike national or EC law, WTO law requires consensus to modify, so that the WTO political/legislative system remains extremely weak." Moreover, "[c]hanges in WTO rules only take place through infrequent negotiating rounds (held around once per decade), involving complex tradeoffs between over one hundred and forty countries with widely varying interests, values, levels of development and priorities." This results in WTO members delegating significant *de facto* power to the WTO dispute settlement process. It also results in intellectual property protection being enshrined in international agreements such as TRIPS and makes it near impossible to change.

The TRIPS' Doha Declaration is a prime example. In November 2001, when the WTO Fourth Ministerial Conference met in Doha, Qatar, the WTO clarified that TRIPS was not to stand in the way of developing countries regulating public health matters.⁷³ The ministers confirmed that developing countries could set aside patents in the interests of public health and agreed that a solution must be found to allow developing countries with limited or no manufacturing capability to make effective use of TRIPS' compulsory

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⁷⁰ Shaffer, *WTO Dispute Settlement System*, *supra* note ___, at 8. Schott and Watal note that the GATT also was operated by consensus but point out that the systems are different because the WTO has more active participants representing more diverse interests and objectives and WTO members are compelled to abide by all of the negotiated agreements, whether or not they were part of the negotiation. *See* Jeffrey J. Schott and Jayashree Watal, *Decision Making in the WTO*, in THE WTO AFTER SEATTLE 283-84 (Jeffrey J. Schott ed., 2000).

⁷¹ Shaffer, *WTO Dispute Settlement System, supra* note ___, at 8. To exacerbate matters, there is considerably less transparency in the WTO process, as many negotiations involve "backroom dealing." See generally Barfield, *supra* note

⁷² Barfield, *supra* note ___, at 1. Moreover, The WTO is seen as having an imbalance between its "consensus-plagued, inefficient rule-making procedures and its highly efficient dispute settlement system." This creates an organization that legislates through adjudication; hence, dispute settlement judgments can add or diminish WTO members' rights and obligations.

⁷³ Doha Declaration; see also Section IV. (B), infra.

licensing provisions. The ministers left the details to be decided in the next negotiating round and set December 2002 as the compliance deadline.

WTO members were unable to agree to rules allowing developing countries to use compulsory licensing to import essential medicines.⁷⁴ In short, the impasse was about which countries could take advantage of the rules and which diseases would be covered. The developing countries (and many developed countries, excluding the United States) noted that the Doha Declaration was all-encompassing, allowing for countries to import affordable medicines for any condition that undermines public health.⁷⁵ The United States sought a more narrow interpretation. It sought to limit the list of covered diseases to malaria, tuberculosis, and AIDS, and sought to limit the countries that could take advantage of the provision to the poorest developing countries.⁷⁶ Solutions to this impasse included either amending TRIPS or re-interpreting certain TRIPS' provisions.⁷⁷ The deadline passed with no solution.⁷⁸

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short, the decision allows least developed countries to import drugs without restriction as to the type of

⁷⁴ See Sarah Boseley and Charlotte Denny, Prescription for world's poorest stays unwritten: WTO Conference Deadlock as U.S. shows no signs of loosening veto on pharmaceutical patent rights, THE GUARDIAN, February 20, 2003, available at

http://www.guradian.co.uk/international/story/0.3604,899073,00.html (last visited on February 20, 2003). 75 *Id*.

⁷⁶ *Id*.

At least five main solutions have been proposed: (1) delete Article 31(f); (2) interpret Article 30 to provide for compulsory licensing as not conflicting with the "normal exploitation of the patent"; (3) declare a moratorium or waiver for exports in the "Doha circumstances"; (4) interpret TRIPS such that settlement disputes would not be used in relation to exports as envisioned under the Doha Declaration; and (5) permit countries with manufacturing and reverse engineering capabilities to issue compulsory licenses in accordance with their own legislation and offer export to developing countries a proportion of the manufactured supplies. CIPR Report, *supra* note ___, at 47-48.

⁷⁸ At the September 2003 Cancun ministerial meeting the stalemate finally ended. The WTO members adopted an interpretive decision that allows any WTO member to manufacture and export patented medicines under a compulsory license to certain developing and least developed countries ("eligible importing members"). WTO Council for TRIPS, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (August 30, 200), http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (last visited February 21, 2004). While the details of this decision are "complex and technical, and include several side statements in which specific countries have unilaterally agreed to refrain from acting either as importers or as exporters," in

WTO decision-making has further problems. In certain circumstances, not only will TRIPS constrain Congress' ability and discretion to pass intellectual property laws, but, in turn, it will bind the United States because of a lack of effective judicial review. This is because the United States Supreme Court may be unwilling to "second-guess" Congress in this area. The *Eldred v. Ashcroft* case highlights this point. *Eldred* involved a constitutional challenge to the Copyright Term Extension Act (CTEA). The CTEA increased the copyright term for existing and future copyrights by 20 years (for a total term of "life-plus 70 years"). In part, the CTEA was passed to satisfy the United States' international copyright obligations. In reaching its decision that the CTEA was constitutional, the *Eldred* majority was concerned about intruding on Congress' decisionmaking authority regarding intellectual property. The Court stated that in such matters it had to "defer substantially to Congress," and stressed "that it is generally for Congress, not the courts, to decide how best to pursue the Copyright Clause's objectives."⁷⁹ Thus, despite the CTEA's questionable public benefit, the Court remarked that it was "not at liberty to second-guess congressional determination and policy judgments of this order, however debatable or arguably unwise they may be."80 It is a problem when Congress cannot effectively question the constitutionality of intellectual property laws. It is aggravated when the Supreme Court also cannot.

disease. See id.; see also Laurence R. Helfer, Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking, 29 Yale J. Int'l. L. ___ (forthcoming 2004).

Eldred v. Ashcroft, 123 S. Ct. 769, 785 (2003) (citing Stewart v. Abend, 495 U.S. at 230).

⁸⁰ Id. at 782-783. See also Stewart v. Abend, 110 S. Ct. 1750, 1765 (1990). ("The evolution of the duration of copyright protection tellingly illustrate the difficulties Congress faces It is not our role to alter the delicate balance Congress has labored to achieve."); Sony Corp. of America v. Universal City Studios, Inc., 474 U.S. 417, 429 (1984). ("It is Congress that has been assigned the task of defining the scope of [rights] that should be granted to authors or to inventors in order to give the public appropriate access to their work product.")

Moreover, Congress must constantly monitor intellectual property laws to shape those laws based on history, experience and theory. Perceptions and contexts change with time and experience. Congress should have the ability to change laws consistent with these changed perceptions and contexts. The patent regime, for example, is a balance between the costs of innovation and the benefits derived therefrom. Congress grants patents when the benefits outweigh the costs. When implementing legislation, Congress must be able to reassess this balance based on experience, further thought, and new information. This is an ongoing process. This is a process that is best not left to the unyielding WTO legislative process.

Further, the WTO balances different interests than those required by the Constitution. The Constitution places limits on foreign affairs as they do other government action.⁸¹ Treaties such as TRIPS are subject to the constitutional limitations that apply to all exercises of federal power.⁸² In other words, TRIPS cannot "extend so far as to authorize what the Constitution forbids."83 The Constitution requires that TRIPS' implementing legislation promote the progress of science and the useful arts. The WTO may not (indeed, likely will not) balance the very interests the Constitution requires. Analytically, TRIPS balances private interests against the public interest. TRIPS balances developing countries' needs in technology transfer against developed

⁸¹ Reid v. Covert, 354 U.S. 1, 16-17 (1957) ("It would be manifestly contrary to the objectives of those who created the Constitution . . . to construe Article VI [the Supremacy Clause] as permitting the United States to exercise power under an international agreement without observing constitutional prohibitions.") Some have urged, however, that courts should refuse to hear such cases under the political question doctrine. See, e.g., HENKIN, FOREIGN AFFAIRS, *supra* note ___, at 457 n. 45.

⁸² HENKIN, FOREIGN AFFAIRS, supra note ___, at 185. Cf. Potter, Inhibitions Upon the Treaty-Making Power of the United States, 28 AM.J.INT'L L. 456 (1934) (treaty is not subject to constitutional limitations because Constitution cannot effectively limit the treaty power of sovereign nation).

⁸³ Geoffrey v. Riggs, 133 U.S. 258, 267 (1890); The Cherokee Tobacco, 78 U.S. (11 Wall.) 616, 620-21 (1871) ("It need hardly be said that a treaty cannot change the Constitution or be held valid if it be in violation of that instrument."); Doe v. Braden, 57 U.S. (16 How.) 635, 637 (1853); Asakura v. Seattle, 265 U.S. 332, 341 (1924). More precisely relevant here, TRIPS enacting legislation also cannot extend beyond constitutional limits.

countries' needs to guard against piracy. But, these are not the domestic public interests the United States must consider. Such interests include domestic access to goods and knowledge and appropriate limits on intellectual property rights. By implementing TRIPS, Congress may be embracing norms that have a different focus than the Intellectual Property Clause.

Still further, the WTO is a multi-issue institution. As such, it must deal with many issues, including trade, intellectual property, goods, services, and investment measures. The WTO must take into account the needs of over 145 other countries. Inevitably, and certainly, these countries' policies will conflict with U.S. intellectual property law. Indeed, U.S. intellectual property law and European intellectual property law originated from different backgrounds and thus will promote different interests, values, and goals. U.S. intellectual property law should not be dependent upon world trade law or other countries' intellectual property policies (even if it recognizes and attempts to reconcile such policies).

Lastly, all of this suggests that TRIPS constrains the United States' own internal debates about the appropriate balance in intellectual property law so as to advance the public interest. Recent litigation such as Napster, ⁸⁵ Eldred, ⁸⁶ and Kazaa, ⁸⁷ and recent legislative proposals have dramatically increased domestic public awareness of intellectual property issues. There are fierce debates raging within the United States

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⁸⁴ Peter K. Yu, *Four Remaining Questions About Copyright Law After Eldred*, February 2003, *available at* www.GigaLaw.com, (last visited February 20, 2003) ("While European copyright law was developed from an author's right (droit d'auteur) tradition, which covers both personal and economic rights, American copyright law emerged from a utilitarian tradition, which emphasized primary economic rights.) Yu notes that the United States and the EU have "strong disagreements" over such copyright issues as the first sale doctrine, moral rights, and the work-made-for-hire arrangements, among others.

⁸⁵ A&M Records, Inc. v. Naptser, 284 F.3d 1091 (9th Cir. 2002).

⁸⁶ Eldred v. Ashcroft, 537 U.S. 186, 123 S. Ct. 769 (2003)

⁸⁷ Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 259 F.Supp.2d 1029 (C.D.Cal., 2003).

about the appropriate level of intellectual property protection regarding, inter alia, prescription and generic drugs, 88 compulsory licensing, 89 patent and copyright terms, and, in general, the scope of intellectual property. These debates cannot be framed with the international community first in mind, but instead must be done with the U.S. public first in mind. Complying with TRIPS, without engaging in these debates, and, more importantly, without resolving these debates based on internal politics, may well harm the United States.

- B. TRIPS Is Inconsistent With Traditional U.S. Intellectual Property Policy: To Promote the Progress of Science and Useful Arts
 - 1. The United States' Patent System was Designed to Advance the Public Interest of Promoting the Progress of Useful Arts

The problems above should be sufficient to make one wary of delegating to the WTO intellectual property matters, even if the WTO decision-making were consistent with U.S. intellectual property policy. But it is not. The problems previously identified are intensified because WTO policy is inconsistent with U.S. policy. This is the second arm of the rebound effect. To better appreciate the inconsistency, we must compare the United States' approach to national patent law with TRIPS' focus. 90 This section provides a brief overview of United States' patent law. It identifies some of the early

⁸⁸ See infra Section III. C.

⁸⁹ See *infra* Section III. C.

⁹⁰ The patent system comprises the patent laws and the customs, practices, and interpretations. It should be noted here that while this section refers to "law" in the general sense of legislative enactments, it also refers to law as judicial interpretation of those enactments, even where there are no specific "laws." Much was done by judicial interpretation rather than legislative modification. Thus, for example, even though there are not specific laws providing for general compulsory licensing (other than government use), there is no doubt this remedy is part of United States patent law. See, e.g., Hartford-Empire Co. v. United States, 323 U.S. 386 (1945).

factors that influenced the law, then focuses on the chief factor – advancing the public interest by promoting "the progress of science and useful arts." This emphasis on the public interest, grounded in the Intellectual Property Clause of the Constitution, is achieved through encouraging the widest possible access to inventions for the public and in promoting the widest possible dissemination of knowledge to the public. This section traces the history and underpinning of U.S. patent law showing, in general, the role the public interest has played. The following section then looks again at TRIPS, this time to evaluate whether TRIPS' focus is inconsistent with the United States' historical focus.

a. Promoting the Public Interest: The Intellectual Property Clause

The United States' patent system can trace its origins to the 1474 Venetian patent system, ⁹² England's 1624 Statute of Monopolies, ⁹³ and the patent systems being

⁹¹ While this article focuses exclusively on patent law, as should be expected the copyright laws also have as their primary purpose the public benefit. *See generally* DAVIES, *supra* note ___, at 69 ("Within reasonable limits, the interests of authors coincide with those of the public. Both will usually benefit from the widest possible dissemination of the author's works. . . . There are many situations in which copyright restrictions would inhibit dissemination, with little or no benefit to the author. And the interests of authors must yield to the public welfare where they conflict.") (Citing to the Register's report on the general revision of the U.S. Copyright Law of July 1961.)

⁹² The Venetian system is generally regarded as the first true patent system. BRUCE W. BUGBEE, THE GENESIS OF AMERICAN PATENT AND COPYRIGHT LAW 21 (1967) citing Giulio Mandich, Venetian Origins of Inventors' Rights, trans. and abr. Frank D. Prager, J. PAT. OFF. SOC'Y, XLII (June, 1960), 176-177. Bugbee credits a June 19, 1421 patent from the Republic of Florence to architect Filippo Brunselleschi as the world's earliest true patent of invention. See BUGBEE, at 17. For further discussion regarding the early origins of patent law see Frank D. Prager, A History of Intellectual Property from 1545 to 1787, 26 J. PAT. & TRADEMARK OFF. SOC'Y 714; Max Frumkin, The Early History of Patents of Invention, 26 TRANS. NEWCOMEN SOC. 47 (1947); Frumkin, The Origins of Patents, J. PAT. OFF. SOC'Y XXVII (March, 1945). The Venetian patent system was based on the 1474 Venetian Act, which set forth many of the requirements found in modern patent statutes. BUGBEE, supra note ___, at 20. In particular, the Act: (1) provided exclusive rights for inventors to disclose their inventions to society; (2) required that the invention be new to the Commonwealth (precursor to the "novelty" requirement); (3) required that the invention be useful ("utility" requirement); (4) set a standard patent term (ten years); and (5) provided for an infringement remedy. The 1474 Act also authorized Government use of the invention without compensation. Bugbee points out that this government authorization did not compel the patentee to assign his rights to the Government, but did require the patentee to extend to the government a license. BUGBEE, supra note ___, at 171, n. 64 citing Mandich, *supra* note ___, at 179-180.

developed in the various state colonies before U.S. independence. These systems were established to encourage the introduction of new techniques and industries into the territories for the benefit of the public.

The call to develop a federal patent statute began immediately after the United States' independence from England. Many of the framers had experience with the state legislatures that had enacted copyright and patent statutes. The framers thus were aware of the need to protect authors' and inventors' rights, and of the need for a uniform federal statute. The framers also were aware of the need to develop domestic manufactures, rather than rely on English and French trade. Perhaps most importantly,

⁹³ The 1624 Statute of Monopolies was not a true patent statute protecting inventor's rights. Instead, it was a statute reaffirming previous English court decisions banning royally granted privileges and monopolies. The Statute also codified the court's recognition that not all monopolies were evil and that some benefited the public. Clothworkers of Ipswich, 78 Eng. Rep. 147 (K.B. 1615). There, the Court held:

If a man hath brought in a new invention and a new trade within the kingdom, . . . or if a man hath made a new discovery of any thing, . . . [the King] may grant by charter unto him, that he only shall use such a trade or trafique for a certain time. . . . But when that patent is expired, the King cannot make a new grant thereof; for when the trade is become common, and others have been bound apprentices in the same trade, there is no reason that such should be forbidden to use it.

⁷⁸ Eng. Rep. 148 (K.B. 1615).

⁹⁴ By 1787 state patent grants to inventors applying for protection for the same inventions in several U.S. states made it apparent that a centralized federal system was needed to resolve conflicting claims. John M. DiJoseph, *The One and the Many—The Expropriation of Intellectual Property by the States: Copyright and the 11th Amendment*, 9 LOY. ENT. L. J. 1 at 4-5 (1989). *See also* BUGBEE, *supra* note __, at 133 noting that the state patent acts heavily influenced the drafters of the first federal patent act, the Patent Act of 1790. *But cf.* WALTERSCHEID, *supra* note __, at 33 n. 37 challenging Bugbee's conclusion.

⁹⁵ One notable example was Charles Pinckney, who served on the South Carolina legislature when it enacted the 1784 general copyright-patent statute; he was also a member of the Constitutional Convention. Both Pinckney and Madison submitted proposals to promote the progress of science and knowledge. Madison proposed to give national legislature power to "encourage by premiums & provisions, the advancement of useful knowledge and discoveries," and "to secure to literary authors their copy rights for a limited time." BUGBEE, *supra* note ___, at 126. Pinckney proposed to grant the national legislature the power to "grant patents for useful inventions" and "to secure to Authors exclusive rights for a . . . certain time." *Id.* Both Bugbee and Walterscheid credit Pinckney as submitting the proposal that ultimately led to the Intellectual Property clause. BUGBEE, *supra* note ___, at 125-127; WALTERSCHEID, *supra* note ___, at 46-48. ⁹⁶ In his address to the First Congress, President Washington remarked:

[&]quot;The advancement of agriculture, commerce, and manufactures, by all proper means, will not, I trust, need recommendation: But I cannot forbear intimating to you the expediency of giving effectual encouragement, as well to the introduction of new and useful inventions from abroad, as to the exertions of skill and genius in producing them at home"

the framers were aware of the evils of the English abusive monopolistic practice. As to this, Thomas Jefferson stated:

It seems pretty generally understood that this should go to *** Monopolies. *** [I]t is better * * * to abolish * * * Monopolies, in all cases, than not to do it in any. * * * The saying there shall be no monopolies lessens the incitements to ingenuity, which is spurred by the hope of a monopoly for a limited time, as of 14 years; but the benefit even of limited monopolies is too doubtful to be opposed to that of their general suppression."97

However, as with England and the colonies, this fear of monopolies was tempered by the recognition that some limited monopolies were indeed for the public good. In responding to Jefferson's concern, Madison stated:

With regard to Monopolies they are justly classed among the greatest nusances [sic] in Government. But is it clear that as encouragements to literary works and ingenious discoveries, they are not too valuable to be wholly renounced? Would it not suffice to reserve in all cases a right to the public to abolish the privilege at a price to be specified in the grant of it? Is there not also infinitely less danger of this abuse in our Governments than in most others? Monopolies are sacrifices of the many to the few. Where the power is in the few it is natural for them to sacrifice the many to their own partialities and corruptions. Where the power, as with us, is in the many not the few, the danger can not be very great that the few will be thus favored. It is much more to be dreaded that the few will be unnecessarily sacrificed to the many.⁹⁸ It is against this backdrop that the framers expressly granted to the federal

government the power to promote manufactures and to advance knowledge and science.⁹⁹

More specifically, the framers unanimously gave Congress the power "to promote the

LAURENCE I. WOOD, PATENTS AND ANTITRUST LAW 22 (1942).

97 WALTERSCHEID, *supra* note ___, at 56 citing to Letter from Jefferson to James Madison (July 31, 1788), in I THE REPUBLIC OF LETTERS at 545 (James Morton Smith ed., New York 1995).

⁹⁸ WALTERSCHEID, *supra* note ___, at 56-57 citing Letter from Madison to Jefferson (Oct. 17, 1788), in I THE REPUBLIC OF LETTERS at 566 (James Morton Smith ed., New York 1995).

⁹⁹ Little is actually known as to how the intellectual property clause came to be included in the Constitution. What is known is that it was adopted without dissent. Other than this, commentators contend that the framers were involved in state legislatures and were trained lawyers and thus were aware of the English patent grants, the individual state grants, and the need to encourage invention and protect the rights of inventors. See generally WALTERSCHEID, supra note ___, at 28-37. Walterscheid suggests that the framers felt the need to include the intellectual property clause in the Constitution because "they desired to follow the English practice of granting exclusive rights through the issuance of patents or something similar and were not at all certain that the Congress would have the power to do so without an explicit grant of authority." Id. at 36.

progress of science and the useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."¹⁰⁰ This has become known as the Intellectual Property Clause (also referred to as the Copyright and Patent Clause).

One thing stands out about the Intellectual Property Clause: It explicitly declares the primacy of the public interest. The Clause specifies that Congress may pass statutes for one, and only one policy goal: "to promote the progress of science and useful arts." Congress has advanced this goal in a number of ways. For one, Congress enacted patent laws that protected the public interest by giving the public access to the benefits of inventions. Also, while the inventor obtained a monopoly, Congress ensured that it

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¹⁰⁰ Art. I, Sec. 8, cl. 8.

¹⁰¹ Two additional things stand out about the Intellectual Property Clause. First, the clause is unique in that it is the only constitutional grant of authority to Congress that specifically sets forth a means to exercise the granted authority. The Clause directs Congress to promote the useful arts by securing to inventors exclusive rights in their discoveries. The Clause is unusual not only because it is the only clause that directs a precise method of promoting the public interest, but also because of the specific method provided (securing exclusive rights), as there were a number of different ways to promote the progress of useful arts. Amog the methods that have been used to promote the progress of useful arts are medals, honorary titles, premiums, and bounties. Edward C. Walterscheid, To Promote the Progress of Science and Useful Arts: The Anatomy of Congressional Power, 43 IDEA 1 (2002) at n. 43. One commentator suggests this was simply another example of the United States following English practice. WALTERSCHEID, supra note ___, at 36. Second, the Clause limits grants to inventors for their discoveries. Unlike English and colonial practice, which granted rights to inventors and to the first to introduce an invention into the realm, this limitation significantly changed the definition of a new invention (i.e., novelty). It effectively excluded from protection importation franchises. In a newly independent country in desperate need of inventions and industry it may appear strange that Congress excluded importation franchises. Walterscheid suggests that this demonstrates the primacy of private interests over public interests. However, one could equally plausibly conclude that the framers intended to limit the number of patents burdening society and intended to allow the public access to inventions from abroad without the concomitant onus of a patent grant. Along these lines, Richard Wells, arguing at that time against importation franchise patents, cautioned that "America will be deprived of the advantage she now enjoys of imitating any of the English inventions." Because "every person hath a right to examine the rolls in the high court of Chancery & to demand copies of the patent specifications there filed," it would have been "very unreasonable to grant 14 years exclusive benefit to the man who first imports such copies." WALTERSCHEID, supra note , at 123-124 (citing a March 3, 1790 petition and letter from Wells to Rep. Henry Wynkoop of Pennsylvania, which are in the House of Representative papers, National Archives, HR1A-ER1.1.)

¹⁰² It is socially efficient to provide wide access to new technologies and products, once they are developed, at marginal production costs. Keith E. Maskus, *Intellectual Property Rights and Economic Development*, 32 CASE W.RES.J.INT'L L. 471, 474 (2000) [hereinafter Maskus, *Economic Development*].

was short-lived. The laws limited the time inventors could exercise their rights, thus getting the inventions into the public domain relatively quickly. 103

The Supreme Court, the Constitutional framers, and leading scholars have stressed the primacy of the public benefit. As early as 1829, the Supreme Court stated:

While one great object was, by holding out a reasonable reward to inventors, and giving them an exclusive right to their inventions for a limited period, to stimulate the efforts of genius; the main object was to promote the progress of science and useful arts; and this could be done best by giving the public at large a right to make, construct, use, and vend the thing invented, at as early a period as possible; having a due regard to the rights of the individual. 104

Thereafter, the Court consistently and repeatedly justified the patent laws based on their benefit to society. For example, in Kendall v. Winsor, the Court stated: 105

It is undeniably true, that the limited and temporary monopoly granted to inventors was never designed for their exclusive profit or advantage; the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly. . . . The true policy and ends of the patent laws enacted under this government are disclosed in that article of the Constitution, the source of all these laws, viz., 'to promote the progress of science and the useful arts,' contemplating and necessarily implying their extension, and increasing adaptation to the uses of society.

Again, in 1916, the Court stated: 106

¹⁰³ The laws further ensured that inventions already possessed by the public were not thereafter taken from the public domain and granted protection. Thus, the protection was only for truly new inventions. The patent laws also elevated the public benefit by widely disseminating knowledge. Here, the specification played a dominant role. The patent laws required inventors to disclose their inventions, i.e., required a written description of the invention and the method for making it. The public benefits from having access to the disclosure, which allows the public to improve upon the invention. Professor Merges notes that the importance of the specification requirement reflected a changed perception about what the inventor was contributing to society. He states: "Under the original patent systems, society's benefit was the introduction of a new art or technology into the country. By the late eighteenth century, the primary benefit was seen as the technological know-how behind the inventor's patent." MERGES, supra note ___, at 5-6. Merges concludes that this was a "major change" in the economic role of patents as it emphasized new and useful information instead of the introduction into commerce of finished products. Id. He goes on to state that the beneficiaries "were not just the public at large, but instead others skilled in the technical arts who could learn something from the patentee's invention." Id. In either case, the public benefited. ¹⁰⁴ Pennock v. Dialogue, 2 Pet. 1, 7 L.Ed 327 (1829).

¹⁰⁵ 21 How. 322, 328-329, 16 L.Ed. 165, 167 (1859).

¹⁰⁶ Motion Picture Co. v. Universal Film Co., 234 U.S. at 511, 37 S.Ct. 418, 61 L.Ed. 871, 876.

Since Pennock v. Dialogue was decided in 1829, this court has consistently held that the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents, but is 'to promote the progress of science and the useful arts. . . .' This court has never modified this statement of the relative importance of the public and private interests involved in every grant of a patent, even while declaring that, in the construction of patents and the patent laws, inventors shall be fairly, even liberally, treated."

This interpretation held throughout the mid-twentieth century. In 1932 the Court stated: "[t]he sole interest of the United States and the primary object in conferring a monopoly lie in the general benefits derived by the public from the labors of authors." And in 1944, the Court succinctly stated, "[i]t is the public interest which is dominant in the patent system." 108

James Madison, one of the chief architects of the Intellectual Property Clause, stated that "[t]he constitutional clause empowering Congress to enact a copyright [and patent] statute reflects the belief that property rights, properly limited, will serve the general

¹⁰⁷ Film Fox Corp. v. Doyal, 286 U.S. 123, 127 (1932). Interestingly, Walterscheid describes the "modern view" of patent law as being "directed to the public purposes of fostering technological progress, investment in research and development, capital formation, entrepreneurship, innovation, national strength, and international competitiveness," with no attempt to "justify the patent system on the rationale that it is intended to reward inventors." WALTERSCHEID, supra note ___, at 19 Walterscheid believes the early view of the patent system focused heavily on rewarding patent owners, *Id.* at 18-19 citing Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512 (Fed.Cir. 1995) (Newman, Cir. J. concurring). He also claims that the public interest "would have been almost completely foreign" and "totally alien" to the framers of the Intellectual Property Clause. WALTERSCHEID, supra note ___, at 18. This considerably overstates the case. As support for this proposition, Walterscheid relies almost exclusively on two things. The first is a comment from an 1831 circuit court case, Whitney v. Emmett, 29 F.Cas.1074, 1082 (C.C.E.D. Pa. 1831), which states that "congress have declared the intention of the law to be to promote the progress of useful arts by the benefits granted to inventors; not by those accruing to the public." Walterscheid's other support is the actions of the first commissioner of patents, William Thornton, who believed that the patent laws were intended primarily to reward inventors. WALTERSCHEID, supra note ___ 19 n. 50, and 281-304. Walterscheid notes that because of this, Thornton kept patents secret until they expired. As Walterscheid notes, however, Thornton's efforts to amend the patent laws to keep patents secret were rebuffed by a number of attorney generals, by President John Quincy Adams, by a number of prominent attorneys, and, most importantly, by Congress. Moreover, the same justice that wrote the opinion upon which Walterscheid relies, also two years earlier contradicted Thornton's position. More to the point, the majority of commentators and judicial opinions agree that the purpose of the patent laws was to benefit the public. ¹⁰⁸ Mercoid Corp. v. Mid-Continent Inc. Co., 320 U.S. 661, 665, 64 S.Ct. 268, 271 (1944).

public in an abounding national culture." Similarly, Laurence Wood stated "[i]t is fundamental that the primary purpose behind the patent laws is for the benefit of the public rather than of the individual inventor." Davies also stressed that "[t]he dominant idea in the minds of the framers of the Constitution appears to have been the promotion of learning. . . . The idea next in importance seems to have been the protection for the author. 111

b. A Secondary Interest: Private Owners' Interest

While the "main and primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but 'to promote the progress of science and useful arts," there must be some, indeed significant, attention paid to private patent owners' interests. Without offering adequate incentive to the patent owners to invent, there may be less inventions and no public benefit. As Woods states: "it is necessary to remember that the key to the entire bargain is the incentive which is offered the patentee. To narrow his benefits is correspondingly to lessen the incentive to invent. Consequently, any resolution of conflict between the patentee's rights and the public policy . . . must be achieved with the object of balancing the two public interests against each other." 113

Not surprisingly, inventors have sought expansive rights. In fact, they have argued that they have a natural right in their inventions, which rights the law should protect.

This finds support neither in the literal language of the Intellectual Property Clause nor in

¹¹¹ DAVIES, *supra* note ___, at 50-51.

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¹⁰⁹ DAVIES, *supra* note ___, at 50 citing PAUL GOLDSTEIN, COPYRIGHT PRINCIPLES, LAW AND PRACTICE 5, n.2 (Little Brown and Company, 1989).

WOOD, supra note ___, at xiv.

Pennock v. Dialogue, 2 Peters 1 (1828); Motion Picture Co. v. Universal Film Co., 243 U.S. 502 (1917).

¹¹³ WOOD, *supra* note ___, at 21.

any of the European or colonial precedents. 114 Even the framers were wary of providing such rights. For example, in arguing against such rights, Jefferson cautioned against an "embarrassment to society." 115

The Supreme Court also rejected a natural rights theory. In Wheaton v. Peters, 116 the Court held:

That congress, in passing the act of 1790, did not legislate in reference to existing rights, appears clear, from the provision that the author, &c. 'shall have the sole right and liberty of printing,' &c. Now if this exclusive right existed at common law, and congress were about to adopt legislative provisions for its protection, would they have used this language? Could they have deemed it necessary to vest a right already vested. Such a presumption is refuted by the words above quoted, and their force is not lessened by any other part of the act. 117

In so stating, the Court expressly relied on the lack of a natural right in inventions. 118 It stated:

The word secure, as used in the constitution, could not mean the protection of an acknowledged legal right. It refers to inventors, as well as authors, and it has never been pretended, by any one, either in this country or in England, that an inventor has a perpetual right, at common law, to sell the thing invented. 119

The Court concluded that "Congress, then, by this act, instead of sanctioning an existing right, as contended for, created it."120

¹¹⁴ France's 1791 Patent Act was based on the concept of patents as a natural right.

Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in THE WRITINGS OF THOMAS JEFFERSON at 333-335 (Andrew A. Lipscomb and Albert Ellery Bergh eds., 1905):

[&]quot;Considering the exclusive right to invention as given not of natural right, but for the benefit of society, I know well the difficulty of drawing a line between things which are worth to the public the embarrassment of an exclusive patent, and those which are not."

¹¹⁶ Wheaton v. Peters, 33 U.S. 591, 661 (1834).

¹¹⁷ *Id.* at 657. Modern courts also have rejected this view, *see*, *e.g.*, Graham v. John Deere Co., 383 U.S. 1,9 (1966) ("The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge.") ¹¹⁸ *Id*. at 657-58.

¹¹⁹ *Id.* at 661.

¹²⁰ Id. at 661-62. The Court added that "it may be proper to remark that the court are unanimously of the opinion, that no reporter has or can have any copyright in the written opinions delivered by this court; and that the judges thereof cannot confer on any reporter any such right." *Id.* at 668.

Although inventors do not have a perpetual common law right to their inventions, the Intellectual Property Clause does secure to them exclusive rights "for limited times." This limited monopoly presumably provides the necessary incentive for inventors to create and to allow them to recoup money spent in research and development. It also allows them to earn profits on their inventions. Nevertheless, because the patent laws' primary purpose is to benefit the public, in any conflict between private and public interests, the private interest must be subordinated to the public interest. On this, the Supreme Court is clear:

The Copyright law, like the patent statutes, *makes reward to the owner a secondary consideration*. The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in "Science and Useful Arts." ¹²²

Accordingly, for our purposes, we must determine if TRIPS is truly inconsistent with U.S. policy, and, if so, must subordinate those interests to the U.S. public interest.

2. TRIPS: An Illusory Attempt to Balance Public and Private Interests?

¹²¹ See Wood, *supra* note ___, at xiv. *See also* Diamond v. Chakrabarty, 447 U.S. 303, 303-304 (1980) ("The patent laws promote [the progress of science and useful arts] by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts. The authority of Congress is exercised in the hope that '[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.")

¹²² United States v. Paramount Pictures, 334 U.S. 131, 158 (1948) (emphasis added). The government pursued broad social goals by encouraging individual creative economic energy. It is oversimplified to think of law as promoting either simply the public interest or the private interests. Nevertheless, while the patent system does pursue broad social goals through encouraging private economic interests, various provisions within the patent system quite clearly promote the public interest by limiting the unfettered or absolute right of private parties.

As noted above, TRIPS requires many member countries to dramatically strengthen and increase intellectual property protection and enforcement. Despite these increased levels of protection and enforcement, TRIPS purports to balance public and private interests. Whether TRIPS in fact balances these two interests and, if so, whether that balance is "fair" remains open to discussion. Certainly there are those who claim that TRIPS is nothing more than "old-fashioned, Western-style imperialism," with an emphasis on aiding developed countries and private rights at the expense of developing countries and public interests. 123 Others claim TRIPS appropriately protects intellectual property rights and benefits developing and developed countries alike by promoting economic and technological development. 124 Here, to better evaluate whether TRIPS fairly balances public and private interests or whether instead TRIPS falls squarely on the side of either public or private interests, we examine in more detail TRIPS' objectives, purpose, and the same few critical "minimum standards" as above, that is, the patent term, patentable subject matter, and compulsory licensing provisions.

a. Objectives and Principles

One of TRIPS' stated objectives is the "protection and enforcement of intellectual property rights," which TRIPS recognizes as "private rights." On the other hand, the objectives seek to promote the transfer and dissemination of technology "to the mutual

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¹²³ See, e.g., Marci Hamilton, *The TRIPS Agreement: Imperialistic, Outdated, and Overprotective*, 29 VAND. J. TRANSNAT'L L. 613 (1996); A. Samuel Oddi, *TRIPS – Natural Rights and a Polite Form of Economic Imperialism*, 29 VAND. J. TRANSNAT'L L. 415 (1996); Martin Kohr, *How the South is Getting a Raw Deal, in* Views from the South, the Effects of Globalization and the WTO on Third World Countries 22 (2000).

 ¹²⁴ See, e.g., Martin J. Adelman & Sonia Baldia, *Patentable Inventions: Prospects of Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 Vand. J. Transnat'l L. 507 (1996).
 ¹²⁵ TRIPS, *supra* note ___, Article 7 and Preamble.

advantage of producers and users of technological knowledge" and attempt to do so "in a manner conducive to social and economic welfare"126

TRIPS' "Principles," Article 8, purports to balance the right holders' private rights against the public need to prevent abuses, protect public health and nutrition, and to promote sectors important to a country's socio-economic and technological development. Members may adopt measures that promote the public interest and prevent abuse by intellectual property rights holders, as long as such measures are consistent with the more specific TRIPS' provisions. The provisions with which such measures must be consistent are those that establish TRIPS' minimum standards.

b. Minimum Standards

(i) Patentable subject matter

Ostensibly, through TRIPS's minimum standards, the private patent owners' interests in being rewarded for their invention and the encouragement of future inventions are balanced against the public's interest in gaining the benefits from the inventions. ¹²⁹ For example, by requiring member countries to provide patent protection in "all fields of technology," Article 27 – TRIPS' subject matter provision – protects private interests by preventing countries from excluding certain inventions. These exclusions were

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¹²⁶ TRIPS, *supra* note ___, Article 7 states in full: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

¹²⁷ TRIPS, *supra* note ___, Article 8(1) and 8(2).

¹²⁸ TRIPS, *supra* note ___, Article 8.

¹²⁹ World Trade Organization fact sheet on TRIPS, *available at* http://www.wto.org. In theory, TRIPS balances the developing countries' need in having access to intellectual property and technology transfer with the developed countries' need in reducing piracy and misappropriation. *Id; See also* James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistent with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 FLA. L. REV. 727 (2000).

"profoundly controversial" with this being particularly true with respect to the proposed exclusion of pharmaceuticals. 130 The United States firmly considered this provision preventing such exclusions as "nonnegotiable". 131

The expanded patentable subject matter also does away with the distinction made by many countries – particularly developing countries – regarding *product* patents and process patents. This distinction is most visible with respect to pharmaceutical and chemical patents. Previously, some countries issued patents on pharmaceutical and chemical processes, but denied protection for pharmaceutical and chemical products. By this distinction, local manufacturers could produce patented pharmaceutical products as long as they did not use the same patented process. This they can no longer do.

To balance this broad grant, Article 27 provides limited exceptions. Specifically, it provides that members may exclude inventions when necessary to protect "ordre public or morality" and may exclude "diagnostic, therapeutic and surgical methods for the treatment of humans and animals." 132 Members also may exclude plants and animals other than micro-organisms as long as members provide for sui generis protection. 133

(ii) Patent term

With respect to the patent term, generally speaking, a shorter patent term promotes the public interest as it delivers earlier to the public domain a patented product or

¹³⁰ Abbott, Cottier and Gurry note that patents were the most contentious subjects of the Uruguay Round and solutions in the field of exclusions of patentability were of a "profoundly controversial nature." FREDERICK ABBOTT, THOMAS COTTIER, AND FRANCIS GURRY, THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM 694-695 (1999).

¹³² TRIPS, *supra* note ___, Articles 27 (2) & (3).

¹³³ TRIPS, *supra* note ___, Article 27(3)(b).

process.¹³⁴ A shorter patent term also benefits the public because it guards against inordinately high prices for licenses, encourages improvements to patented products, and results in lower prices spurred by the competition that occurs when the invention or product is off patent.¹³⁵ On the other hand, to provide incentives to private parties to engage in beneficial activities, the patent term must take into account their interests.

These parties benefit from a longer duration as it allows them time to recover the costs associated with bringing the invention to market and allows them to earn profits for the risks taken. TRIPS Article 33's minimum 20-year term is considerably longer than many countries previously provided. Additionally, countries are no longer able to selectively determine appropriate or different terms for different products. Here, private parties made significant gains.

(iii) Parallel importation

By allowing price shopping, TRIPS' parallel importation provision benefits developing countries and consumers because they can obtain lower-priced drugs. 136

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¹³⁴ This is an oversimplification and generalization. One might argue that a shorter term does not promote the public interest and/or that a longer term promotes the public interest. These arguments are based on the incentives provided to private parties. A longer term may benefit the public because it provides more incentives to private parties. Similarly, a shorter term may not provide sufficient incentives to private parties. Admittedly, it is difficult, if not impossible, to predict the optimum term that provides the maximum level of incentive. This again underscores the difficulty in distinguishing between the public good and private gains. At some point, though, increasing the term will provide no additional incentive while denying the public access to the invention. The question, of course, is when that point is reached. ¹³⁵ See generally Edward C. Walterscheid, Defining The Patent And Copyright Term: Term Limits And The Intellectual Property Clause, 7 J. INTELL. PROP. L. 315, 330 (Spring 2000); see also Robert P. Merges and Richard R. Nelson, On the Complex Economics of Patent Scope, 90 COLUM. L. REV. 839, 878-879 (1990). 136 Bess-Carolina Dolmo, Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example, 7 Buff. Hum. Rts. L. Rev. 137 (2001). In addition, parallel imports benefit many European Community countries, where the government is the chief payer for health care services, including pharmaceuticals. For example in 1995, an identical amount of the antibiotic Amoxil, made by SmithKline Beecham, cost \$ 8 in Pakistan, \$ 14 in Canada, \$ 36 in the United States, \$40 in Indonesia and \$60 in Germany. Id. The benefit of parallel importation also can be viewed as a disadvantage for lesser developed countries. Specifically, parallel importation avoids the need of lesser developed countries to develop local manufacturing capabilities. While a benefit in the short term because

Patent owners lose profits because their products must compete with lower-priced imported alternatives. Patent owners and developed countries also fear a backlash from consumers and countries purchasing the products at higher prices. The fear is that parallel importation will expose the price disparities and cause higher paying countries and consumers to demand the lower prices. TRIPS allows each country to determine its own policy regarding parallel importation.

(iv) Compulsory licensing

The final minimum standard provision is that for compulsory licensing. Compulsory licenses are seen as a limit on a patentee's rights, indeed, the primary limit on a patentee's rights. This is usually justified to benefit the public. More specifically, compulsory licensing schemes attempt to balance the private interests of rewarding the inventor with the public interest of having access to new products. Compulsory licensing allows consumers access to goods by increasing the availability of the product in the country, while at the same time increasing competition for the product, which often results in a sharp decrease in price. These licenses also serve as incentives for patent owners to license the product on fair and reasonable terms.

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it provides needed products, including drugs at reduced prices, parallel importation hurts those countries attempting to develop such capabilities, unless concurrent strategies are used.

¹³⁷ It is important to note that parallel imports are not imports of counterfeit products or illegal copies. These are products made and marketed by the patent owner in one country and imported into another country without the approval of the patent owner.

¹³⁸ GEORGE FOLK, PATENTS AND INDUSTRIAL PROGRESS 263 (1942).

¹³⁹ See Michael D. Scott, Compulsory Licensing of Intellectual Property in International Transactions (1998) reprinted in D'Amato, supra note ___, at 361. For developing countries, compulsory licensing can also compel the transfer of technology. *Id.* According to Gianna Julian-Arnold, the most prevalent compulsory licensing provisions are those concerning blocked dependent patents, failure to work a patent, and patents related to foods or medicines. Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA J.L. & TECH. 349 (1993).

Opponents attack compulsory licensing proposals as efforts to derogate or interfere with the exclusive rights afforded patentees. Such interference, the argument goes, will reduce the incentives to invent, impermissibly limit the patentee's ability to set their own prices, and eventually will harm the public because less inventive activity will take place. TRIPS provides for compulsory licensing. However, as noted above, it contains numerous conditions that members must satisfy before granting such licenses.

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¹⁴⁰ See Kirby W. Lee, Permitted Use Of Patented Inventions In The United States: Why Prescription Drugs Do Not Merit Compulsory Licensing, 36 IND. L. REV. 175, 180 (2003). These arguments notwithstanding. the patentee "benefits" by receiving reasonable compensation for his invention, albeit less compensation than the inventor would receive without compulsory licensing. Compulsory licensing also is a less drastic alternative than revoking the patent, which some countries authorize when a patentee fails to make the invention available in that country. Indian patent law, for example, emphasizes the need for an inventor to work their invention or suffer revocation of the patent. Baldia, supra note ___, at 524. The basic premise underlying compulsory licenses is that for one reason or another a valuable invention is being withheld from or is unavailable to the public. This can occur when: (1) the patentee suppresses or fails to work the invention in the country; (2) there is an inadequate supply of the invention; or (3) the use of the patent results in unreasonable, anti-competitive and monopolistic prices. To address these situations, compulsory licensing schemes take two different forms; unrestricted and restricted. At an extreme, a government can grant *unrestricted* (blanket) compulsory licenses. These are licenses granted to any manufacturer to produce a patented product without regard to the availability or underlying circumstances. Under this type of scheme, anyone could obtain a license upon paying a reasonable fee to the patent owner. This increases competition, assures product availability, and provides competitive prices. Opponents attack this type of scheme as harming small businesses and individuals because larger competitors can obtain licenses and sell products at a price that undercuts the smaller businesses. See, e.g., FOLK, supra note ___, at 266. The larger competitor would be able to do so because they would not have expended any money on research and development to bring the product to market. Smaller companies would, however, receive royalties for the licenses, which may offset their projected losses. Moreover, small companies also would have access to larger companies' technology and products through licensing and would be able to also "benefit" from not having research and development expenditures for those products. The small companies thus would be able to offset their purported disadvantages. Further, because a licensee could step in and essentially share the profits of the person who invested considerable time, effort, and money into commercializing the product, many businesses would be unwilling to perform the necessary research and development, and many investors would be reluctant to invest in these enterprises. Id. A reasonable royalty can take into account the costs of research and development. Also, the answer to this is not to do away with all compulsory licensing schemes, but to avoid blanket or general compulsory licensing schemes. See e.g., Neal Seegert, Compulsory Licensing by Judicial Action: A Remedy for Misuse of Patents, 47 Mich.L.Rev. 613, 638 (1949) (citing Coburn, Compulsory Licensing by the Courts, 28 PAT.OFF.Soc'Y. 180 (1946)); see also Sylvester Petro, Patents: Judicial Developments and Legislative Proposals, 12 CHI.L.REV. 80 (1942), at 409; EDITH T. PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM 173 (1951) (arguing that compulsory licensing may retard technological development because it may reduce the "greater inventiveness" of the United States, which is due to the "almost unconditional" monopoly the patent system provides). Penrose lists six arguments advanced against compulsory licensing: (1) It is an unacceptable violation of property rights; (2) it reduces incentives to invent; (3) it harms large research and development firms that depend on patents; (4) it hurts small companies that must license to large companies; (5) it does not provide a mechanism for determining a "reasonable royalty;" and (6) it does not reduce restrictions on industry. Id. at 172. In contrast to the blanket schemes, more common are restricted compulsory licensing

(v) Limitations and exceptions

As an attempted balance to TRIPS' expansive minimum substantive rights, Article 30 states that members may provide exceptions to the rights TRIPS confers on patentees. The exceptions, however: (1) must be "limited"; (2) cannot "unreasonably conflict with a normal exploitation of the patent"; and (3) must not "unreasonably prejudice the legitimate interests of the patent owner." This tripartite test must be met before any member can limit a patentee's rights.

To be sure, these various patent provisions are only a part of the entire TRIPS Agreement. TRIPS includes additional patent provisions, copyright provisions, and trademark and trade secret provisions, among others. Moreover, the TRIPS Agreement is part of the overall WTO package, which contains numerous additional agreements covering not only intellectual property but also goods and services. Nevertheless, it is contended here that, on the whole, these TRIPS' provisions bear out that TRIPS is more a private rights regime. First, TRIPS, while only one of many WTO agreements, purports within its contained area (intellectual property) to balance public and private interests. Second, the above provisions arguably are the provisions which have had the greatest impact and most far-reaching consequences. Without question, the greatly expanded subject matter protection and the inability of countries to exclude previously excluded inventions benefits private interests. The lengthened term, and that it is applied to all products regardless of field, benefits private interests. While TRIPS is facially neutral with respect to parallel importation, arguably, its effect is to benefit private interests as

schemes. These schemes tie the grant of compulsory licenses to specific abuses. In addition to those named above (unavailability, suppression and nonuse), compulsory licenses are granted when a patent owner misuses the patent, or when the national interest mandates it.

¹⁴¹ TRIPS, *supra* note ___, Article 30.

developed countries with large lucrative markets such as the United States can – and do – restrict patented products from reentering the country under national exhaustion principles. Because TRIPS Article 31 permits compulsory licensing, arguably, it favors the public interest. However, the carved-out exceptions and numerous mandatory conditions have caused considerable harm to developing countries and the public and threaten to continue to do so unless addressed and/or amended. Moreover, the push for fewer restrictions on intellectual property rights, including efforts to completely eliminate compulsory licensing, will further harm countries, including the United States. In short, while the provisions and the objectives seek to achieve the proper balance between the private and public interests, the balancing is more myth than reality; in practice, the balancing tips clearly in favor private interests.

c. TRIPS Was Designed To Remedy Piracy And Misappropriation

The background and origins of TRIPS also serve as indicia of TRIPS' focus on private interests. Indeed, arguments that TRIPS focuses on private rights is not surprising in view of the impetus for this most recent push for worldwide intellectual property

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¹⁴² See Jazz Photo Corp. v. International Trade Comm'n, 264 F.3d 1094, 1105 (2001). The legal principle behind parallel importation is exhaustion. Once a patented product is sold or placed on the market by the patent owner (or with their consent), the seller no longer has control over the sale (or export) of that particular product, their rights are "exhausted" by the first sale of the product. Under *national* exhaustion, a patent right is exhausted only with respect to the country where the product was placed on the market. This does not exhaust patent rights in another country. Thus, for example, if a firm sold a product in India, the firm's rights would be exhausted in India, i.e. the buyer could sell the product in India, but not in Kenya. *International* exhaustion means that the patent right is exhausted anywhere in the world when placed on the market anywhere in the world. The sale of a product in India would allow the sale of that product in Kenya, without infringing the patent. Regional exhaustion, which exists in the European Union, means that exhaustion is relegated to a number of specific countries or region, generally broader than the national market.

¹⁴³ Others also have argued that TRIPS severely distorts the traditional balance between private and public interests. This is a result of its "single-minded protectionist goal." *See, e.g.*, Jerome H. Reichman, *Compliance with the TRIPS Agreement: Introduction to a Scholarly Debate*, 29 VAND. J. TRANSNT'L L. 363, 385 (1996).

protection. The leading motivation behind the international intellectual property movement was the developed countries' – largely the United States' – need to benefit from globalization and the increased economic importance of intellectual property. ¹⁴⁴ In the United States, far and away the world's leading intellectual property exporter, the increased economic importance was dramatic. In less than four decades the percentage value of U.S. intellectual property exports produced tripled, from 9.9% in 1949 to 27.4% in 1986, and is still rapidly increasing. ¹⁴⁵

The United States contended it was disadvantaged in the competitive global marketplace because of widespread intellectual property "piracy" occurring in the developing countries. ¹⁴⁶ In particular, because each country has its own patent laws,

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¹⁴⁴ See, e.g., Demiray, supra note ___.

In short, the United States was concerned that worldwide piracy drastically affected and jeopardized its dominance and competitiveness in manufacturing. By demanding protection, the U.S. could secure the competitive edge of U.S. intellectual property exports. James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistent with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 Fla. L. Rev. 727 (2000) ("Given this trend, the new locus of the United States' competitiveness now largely depends on its capability not only to generate research, software designs, entertainment, engineering concepts, advertising, marketing, styling, legal and financial innovations and information-based inventions, but also to protect these forms of intellectual property as rights. Such protection would in turn secure the competitive edge of United States intellectual property exports.") This sentiment is somewhat belied by the United States' own position that stronger intellectual property protection is not the sole reason for it losing its global competitiveness. Other factors include managerial and manufacturing failures resulting in low productivity, and high labor costs. FRIEDRICH-KARL BEIER, GATT OR WIPO? NEW WAYS IN THE INTERNATIONAL PROTECTION OF INTELLECTUAL PROPERTY 131 (1996).

¹⁴⁶ Legislative comments provide insight on U.S. sentiment concerning piracy. Representative Dingell remarked before the House Energy and Commerce Subcommittee:

[[]A]ll the companies and workers of this country ask is a level playing field. Yet, with a few exceptions, this Administration continues to turn the other cheek when country after country targets industry after industry \dots . First, the intellectual property of our industry is stolen. Then our foreign markets are flooded with counterfeits. \dots Finally, our firms are driven out of business, or close to it – and, all the while, their markets are insulated from meaningful competition.

³² PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 799, at 609 (Oct. 2, 1986)).

Similarly, Senator Wilson remarked:

In the area of intellectual property protection, plainly stated, criminals around the world are costing American companies billions of dollars by cranking out millions of unauthorized copies of

again, these countries excluded from protection certain inventions. Notably absent from protection were pharmaceutical and agricultural inventions, which countries excluded to implement efforts to maintain public health and adequate food security through affordable medicines and foods.¹⁴⁷

The United States contended that countries' refusal to protect intellectual property had trade-distorting effects. Specifically, it argued that international trade was at peril because countries that did not respect intellectual property rights could gain unfair advantages over countries that did respect and protect such rights by reducing any trade benefits they obtained. By reducing piracy, the United States and other intellectual property-exporting countries would receive stolen "rents" (royalties) from developing countries for the use of patented technology. While the amount of lost rents is difficult to accurately calculate, the United States International Trade Commission (ITC) estimated that in 1984 alone the United States lost 6 to 8 billion dollars in annual sales from the "stolen" use of patented technology. The ITC estimated that in 1986 the United States

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U.S. records and tapes, movies, books, toys, computer programs, as well as by expropriating patents and process patents, developed at great expense by U.S. companies, to make bootleg pharmaceuticals and chemicals. What makes this illegal activity all the more outrageous is that it is often protected by governments we consider friendly to the United States. Indeed, in many cases we have provided special trade benefits in order to help them develop their economies."

¹³² CONG. REC. S5752 (daily ed. May 12, 1986)).

¹⁴⁷ For example, Brazil refused to give patent protection to pharmaceuticals on the grounds that its low-income population would be unable to afford pharmaceuticals protected by patent laws. Frank Emmert, *Intellectual Property in the Uruguay Round- Negotiating Strategies of the Industrialized Countries*, 11 MICH. J. INT"L L. 1317, at 1327 (1990). Another example is Thailand. Thailand excluded pharmaceutical, agricultural, and biological products from patent protection out of concern for the price increases that would result from paying royalties on patented technology in such critical areas. Stefan Kirchanski, *Protection of U.S. Patent Rights in Developing Countries: U.S. Efforts to Enforce Pharmaceutical Patents in Thailand*, 16 LOY. L.A. INT"L & COMP. L. J. 569, at 572 (1994).

¹⁴⁸ It is estimated that piracy accounts for 5% of the world trade. SODIPO, PIRACY, *supra* note ___, at 9. ¹⁴⁹ David I. Wilson, *A Trade Policy Goal for the 1990s: Improving the Adequacy and Effectiveness of Intellectual Property Protection in Foreign Countries*, 1 TRANSNAT'L LAW 421, 422 (1988), in INTERNATIONAL INTELLECTUAL PROPERTY LAW (Anthony D'Amato and Doris Estelle Long eds., 1997).

lost 23.8 billion dollars.¹⁵⁰ A more recent article estimates that the United States loses from \$43 to \$63 billion annually from intellectual property infringement.¹⁵¹ The problem was particularly acute in the pharmaceutical area.¹⁵² The United States' pharmaceutical industry charged that it, more than any other industry, was harmed by this piracy.¹⁵³

d. The Pharmaceutical Industry Influence

The pharmaceutical industry argued that patent protection was the cornerstone of its industry.¹⁵⁴ Because it costs millions of dollars to successfully develop and bring new drugs to market,¹⁵⁵ the industry explained that without worldwide patent protection it would not be able to: (1) recover its large research costs; (2) earn profits; (3) lure investors to invest in valuable research and commercialization;¹⁵⁶ and (4) invest in future research and development.¹⁵⁷ In the late 1970s, the industry devised a strategy to

¹⁵⁰ *Id.* It should be noted that these figures are based on self-reporting within industries. These numbers are necessarily speculative. That is not to say there are no losses; to be sure there are. However, the extent of the loss may be exaggerated to further support strengthening of intellectual property laws. For a critical analysis of the report upon which much of this is based *see* Paul J. Heald, *Misreading a Canonical Work: An Analysis of Mansfield's Canonical 1994 Study*, 10 J. INTELL. PROP. L. 309 (Spring, 2003).

¹⁵¹ Patricia Montalvo, Comments: How Will the New Twenty-Year Patent Term Affect You? A Look at the TRIPS Agreement and the Adoption of a Twenty-Year Patent Term, 12 SANTA CLARA COMPUTER & HIGH TECH. L.J. 139, 140 (1996).

¹⁵² John A. Harrelson, TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance Between Intellectual Property Rights and Compassion, 7 WIDENER L. SYMP. J. 175, 184 (Spring 2001).

¹⁵³ See Robert Weissman, A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries, 17 U. PA. J. INT'L ECON. L. 1069 (Winter 1996).

¹⁵⁴ See CIPR Report, *supra* note ___, at 29. *See also* Paul Durman, *Pay What You Can-The New AIDS Medicine*, TIMES NEWSPAPER LIMITED, (April 22, 2001).

¹⁵⁵ A recent study states that it costs \$802 million to bring one new medicine to market. Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 JOURNAL OF HEALTH ECONOMICS 151 (2003). These numbers are not free from doubt. Moreover, despite these enormous costs, the drug industry is the most profitable industry in the country. *Id*.

¹⁵⁶ Murray J. Elston, *Improving Access to Medicines in Developing Countries*, CNN DISCLOSURE (March 8, 2001).

¹⁵⁷ This fails to take into account the enormous part played by publicly funded research. *See* DiMasi, *supra* note ___, at 151 noting that 5 of the top selling drugs were developed with critical help from the National Institute of Health, the leading publicly funded research organization.

improve intellectual property protection internationally "until American standards became the international norm, especially in developing countries." Intellectual property's increased economic importance, the advances in technology, the globalization of the economy, and piracy precipitated the United States' push for TRIPS and for specific provisions that: (1) protected all inventions, including pharmaceutical products and processes; (2) limited the ability of states to use compulsory licensing to override pharmaceutical patents; and (3) extended the term of protection for pharmaceuticals. ¹⁵⁹ The pharmaceutical industry got much of what it sought.

TRIPS' background, stimulus, and provisions thus reflect this focus on private interest – a focus that is at odds with the United States' historical public interest focus.

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 $^{^{158}}$ Michael Ryan, Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property 68 (1998).

¹⁵⁹ It is not unusual that an industry can influence international governance; international governance, just as national governance, is subject to pressures on the decision makers by societal forces such as multinational corporations, NGOs and other non-state actors. INTERNATIONAL GOVERNANCE, supra note , at 19. Nevertheless, we must recognize this and consider carefully whether we have gone too far in protecting the narrow economic interests. We should worry whether "emergences of large single-cause machines and politically powerful NGOs diminish significance and power of sovereign states." *Id.* at 34. In more pointed terms, we should be wary of having these narrow interests dictating our national interests. Nonetheless, this begs the question: How was the industry able to accomplish on the international level what it could not on the domestic level? There are a couple of factors that may explain this. Although international governance (and national governance) can be viewed as being shaped by internal pressures from competing stakeholders, in some instances, such as here, the non-existence of a competing stakeholder tips any decision and benefit decidedly in favor of the remaining stakeholders. The same domestic constituent forces that actively oppose the pharmaceutical industry domestically were simply not present during the initial negotiating strategy for increased intellectual property protection. Moreover, the WTO process is vastly different from the previous WIPO process, where the industry's efforts were much less successful. The private sector plays a significant role during WIPO negotiations, as NGOs are permitted to not only observe but participate in meetings and formal negotiating sessions. DINWOODIE, INTERNATIONAL IP, supra note ___, at 58. The WTO process is less transparent and less open; the private sector is excluded from meetings and negotiating sessions. Id. Finally, different transnational industries, e.g., software, database, chemical and pharmaceutical industries with common goals and interests (increased intellectual property protection) combined to help pass legislation at the international level that individually each of these industries may not have been able to accomplish at the domestic level. See, e.g., Gathii, supra note, at (discussing the Intellectual Property Committee, a coalition of twelve American-based transnational corporations formed to promote increased protection for intellectual property rights though trade regimes).

C. Harms from Overprotecting Intellectual Property

The rebound effect, i.e., the United States' loss of sovereignty and the inconsistent focus of TRIPS and U.S. intellectual property law, might be acceptable but for the harms caused by overprotecting intellectual property, as TRIPS does. Simply put, overprotection does not benefit the public.

Scholars and commentators have questioned whether increasing intellectual property rights will benefit the public. At first blush, increased protection can lead to increased incentive and thus to a public benefit. But, as these academics note, overprotecting intellectual property is as – if not more dangerous – as underprotecting it. For example, in discussing the harms caused by broadening intellectual property protection (by granting patents on software inventions and business methods) Professor Lessig states: "While it is clear that patents spur innovation in many important fields, it is also clear that for some fields of innovation, patents do more harm than good." Lessig identifies a number of harms caused by increased patent protection, including the "hold-up" problem and the "anticommons" problem. 161 The "hold-up" problem occurs when an innovator who is about to release a product discovers that it violates a patent. The innovator then must decide whether to withhold the product from the market, or pay hold-up fees (royalties) that she may have avoided, e.g., by "designing around the patent," if she previously were aware of the patent. 162

The "anticommons" problem involves the underuse of a resource. This underuse results from many inventors having the right to block the use of the resource through

¹⁶⁰ Lessig, *supra* note ___, at 209. ¹⁶¹ *Id.* at 214.

blocking patents, i.e., "multiple and overlapping patent protection." The result is that "innovators are afraid to innovate in a field because too many people have the right to veto the use of a particular resource or idea." 164

Judge Kozinski has similar concerns about overprotecting intellectual property. In his dissent in *White v. Samsung Electronics America, Inc.*, ¹⁶⁵ Judge Kozinski wrote:

"[R]educing too much to private property can be bad medicine. . . . Public parks, utility rights-of-way and sewers reduce the amount of land in private hands, but vastly enhance the value of the property that remains.

So too it is with intellectual property. Overprotecting intellectual property is as harmful as underprotecting it. Creativity is impossible without a rich public domain. Nothing today, likely nothing since we tamed fire, is genuinely new: Culture, like science and technology, grows by accretion, each new creator building on the works of those who came before. Overprotection stifles the very creative forces it's supposed to nurture."

More recently, in *Eldred*, ¹⁶⁷ Supreme Court Justice Stephen Breyer voiced these concerns in the copyright area. In a scathing dissent, Justice Breyer argued that the Copyright Term Extension Act's ("CTEA") increased copyright protection unconstitutionally harmed the public. He argued that the CTEA's *economic effect* made the copyright term unlimited, and its *practical effect* inhibited, not promoted, the progress of science. ¹⁶⁸ Specifically, Justice Breyer found that the Act imposed "higher than necessary" royalties, caused "substantial harm to efforts to preserve and to disseminate works that were created long ago," restricted "traditional dissemination of copyrighted works," and would "likely inhibit new forms of dissemination through the use of new

¹⁶⁵ 989 F.2d 1512 (1993).

Lessig, *supra* note ___, at 214-215. Lessig also opines that the potential abuse "makes it irrational for an innovator to develop a particular idea." *Id.* at 215.

¹⁶⁴ *Id.* at 214-215.

¹⁶⁶ White v. Samsung Electronics America, Inc., 989 F.2d 1512 (1993).

¹⁶⁷ Eldred v. Ashcroft, 537 U.S. 186, 123 S.Ct. 769 (2003).

¹⁶⁸ Eldred, 123 S.Ct. at 801 (Justice Breyer dissenting).

technology."¹⁶⁹ He thus concluded that the CTEA was unconstitutional as violating the Intellectual Property Clause because it did not fulfill the Clause's true purpose of promoting the progress of science and useful arts.¹⁷⁰

Justice Stevens also dissented in *Eldred*. He too argued that *ex post facto* extension of the copyright term frustrated the Copyright Clause's purpose and instead transferred wealth from the public to copyright holders.¹⁷¹

Justices Breyer's, Justice Stevens', Judge Kozinski's, and Professor Lessig's comments evidence a growing concern that more is not better. ¹⁷² Instead, increased protection through expanded subject matter protection, increased patent term, and limited use of compulsory licensing, *inter alia*, will result in products being withheld from the public for longer periods, will result in artificially inflated prices, will severely limit the public domain of technical information, and will inhibit the progress of science.

As should be obvious, these concerns apply with equal force to TRIPS and implementing legislation. TRIPS involves exactly the kind of overprotection that hurts the public. By constraining Congress' ability to address and correct for this, TRIPS will

¹⁶⁹ *Id*, at 813.

¹⁷⁰ *Id.* at 803-804 ("For present purposes, then, we should take the following well established: that copyright statutes must serve public, not private, ends; that they must seek 'to promote the Progress' of knowledge and learning; and that they must do so both by creating incentives for authors to produce and by removing the related restrictions on dissemination after expiration of a copyright's 'limited Time. . . .") *See also* Holland Furniture Co. v. Perkins Glue, 277 U.S. 245, 257 (1928) (if patent law too strongly favors private interests and creates further incentives to innovate, it discourages add-on inventions because "the patent monopoly would thus be extended beyond the discovery and would discourage rather than promote invention.")

¹⁷¹ Eldred, 123 S.Ct. at 792 (Justice Stevens dissenting).

¹⁷² See also CIPR, *supra* note __, at 4 ("[M]ore intellectual property rights may lead paradoxically to fewer useful products for improving human health. Companies may now incur considerable costs, in time and money, determining how to do research without infringing other companies' patent rights, or defending their own patent rights against other companies. This gives rise to a question as to whether the substantial costs involved in patent searching, analysis and litigation are a necessary price to pay for the incentives offered by the patent system, or whether ways can be found to reduce them.")

¹⁷³ Indeed, Justice Breyer's and Stevens' criticisms were against an act that was passed, in part, to comply with the United States' international copyright obligations.

eventually come back to harm the U.S. public.¹⁷⁴ To make this argument more concrete, we use as examples the U.S. compulsory licensing and patent term provisions. In these areas, consistent with promoting the public interest, Congress and the courts have limited the term of protection and have provided for compulsory licensing, both general and specific provisions, to address public needs.

III. COMPULSORY LICENSING REBOUND

A. To Promote the Public Interest

1. In the National Interest

As noted, compulsory licensing limits the patentee's exclusive rights. It is "the standard form of remedial action" curbing the patentee's almost boundless rights. 175

Compulsory licenses balance the public interest in having access to goods at affordable prices against the private owners' interests in setting prices and enjoying monopoly privileges. To guard against patentees suppressing, making unavailable, and not using inventions, and to ensure the public is not harmed by a patentee's misuse or abuse of his patent, countries, including the United States, issue compulsory licenses. 176 In the United

There are contrary arguments. First, Perlmutter argues that we need not decide whether each provision in a treaty or statute promotes progress. As she explains: "As a practical matter, it would be virtually impossible for the United States to play a leadership role [in international copyright policy] if each individual element in each negotiation had to independently promote the progress of science in order to make the implementing legislation constitutional." Sheila Perlmutter, *Participation in the International Copyright System as a Means to Promote the Progress of Science and Useful Arts*, 36 LOYOLA LA. L. REV. 323, 332 (2002). However, as Professor Solum correctly notes, "this argument suggests that an unconstitutional CTEA might be resurrected via treaty." Lawrence B. Solum, *Congress's Power to Promote the Progress of Science: Eldred v. Ashcroft*, 36 LOYOLA LA. L. REV. 1, 69 (Fall 2002). It cannot. *See* Section II. A., *supra*. In any event, it is not clear that TRIPS implementing legislation on a whole (let alone each individual element) promotes the progress of science.

¹⁷⁵ DINWOODIE, *supra* note ___, at 497.

¹⁷⁶ Almost every country has some form of a general compulsory licensing scheme. Generally, compulsory licensing schemes address patent nonuse and suppression. It has been argued that there is no evidence of this in the United States; thus, there is no need for compulsory licensing, at least to address these situations. FOLK, *supra* note ___, at 262.

States, compulsory licensing has been used quite extensively to address situations that benefit the public through a number of specific compulsory licensing statutes, and a general compulsory licensing statute authorizing government use of patented products. Compulsory licensing also is used quite extensively as a remedy for patent misuse and antitrust violations.

Early uses of compulsory licensing in the United States began with efforts to address national concerns. More specifically, these efforts began at the state level to encourage compulsory *working* of patents.¹⁷⁷ Because a purpose of the patent laws is to encourage development by introducing new industries and new and useful inventions,¹⁷⁸ many have argued that implied in the patent grant is an agreement to "work the patent."¹⁷⁹ In other words, a patentee must manufacture the patented invention domestically to ensure that the public has access to a sufficient number of inventions. This prevents the suppression of patents or deliberate non-use of patents, which deprives the public of new inventions.¹⁸⁰ When the owner fails to work the patent, the government issues compulsory licenses so that others can produce the invention, thus ensuring the invention's availability. States such as South Carolina passed compulsory working and licensing provisions as early as 1784.¹⁸¹

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¹⁷⁷ Pennsylvania's patent statute included a clause requiring the inventor to commence working the invention within the state within eight months. Edward C. Walterscheid, *The Early Evolution of the U.S. Patent Law: Antecedents*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 665, 669 (1996) (citing Pennsylvania Statutes at Large).

PENROSE, supra note __, at 34.

¹⁷⁹ It is more accurate to say work the *invention* rather than the *patent*, as the idea is to introduce the invention into society. However, because the common phrase is to work the patent, that phrase is used here.

¹⁸⁰ FOLK, *supra* note ___, at 261. The patent system, through this mechanism, also develops natural resources, increases the supply of technicians and skilled labor, and increases the number and variety of domestic manufacturing concerns. Penrose, *supra* note ___, at 137.

The 1784 South Carolina copyright/patent statute compulsory licensing provision is an early example. The statute, "An Act for the Encouragement of Arts & Sciences," provided for state intervention if the patent owner did not work the invention or charged exorbitant prices. Bugbee, *supra* note ___, at 94;

While the federal government did not follow the states' lead regarding compulsory licensing for failure to work, it did provide for compulsory licensing in other areas where the public interest necessitated it. One such instance was the national defense.

Compulsory licensing in this area dated back to at least WWI. Immediately prior to WWI, Congress believed that patents on critical military supplies could cripple America's wartime efforts. It thus enacted the Act of June 25, 1910, which permitted the federal government to authorize any company to manufacture a product despite an existing patent if needed to protect the welfare of the country. The import of the

VAUGHAN, *supra* note ___, at 17. The state could intervene and grant a license to a complainant, who also had this obligation. Id.

¹⁸² In the federal context, efforts to introduce compulsory licensing began with the first patent act, the 1790 Act. After the House introduced and passed H.R. Bill 41 (the first patent bill), the Senate proposed amending it. The Senate added a compulsory licensing provision modeled after various state statutes. BUGBEE, supra note ___, at 143-44; see also PENROSE, supra note ___, at 166, n. 9; WALTERSCHEID, supra note ___, at 139. Walterscheid states that the framers did not want the court setting compensation. Id. at 141 n. 107. This is generally regarded as "the first reference to compulsory licensing appearing in literature of the history of patents." PENROSE at 51; VAUGHAN, supra note ___, at 17. It is ironic that the United States was the first country to propose compulsory licensing but is the only major country that did not incorporate into its patent laws a compulsory licensing provision. The provision authorized compulsory licenses when the patentee failed to offer for sale "a sufficient number" of the invention in the country or sold the invention "beyond what may be judged an adequate compensation." PENROSE, supra note ___, at 165-166. The House rejected the Senate's proposed amendment. Thereafter, and after extended discussion, Congress passed the 1790 Act without the compulsory licensing provision. BUGBEE, supra note ___, at 144. Although rejected, the 1790 proposed amendment was typical of later compulsory licensing schemes in that it sought to prevent the suppression or non-use of inventions. In these schemes, if the patentee did not work the patent and introduce the invention into public use, the patent could be revoked. These schemes were being used in other countries, most notably, France, England, and Germany. PENROSE, supra note ___, at 177-187. The call for compulsory licensing diminished with the later increased role of the written description requirement. Patentees used the written description requirement to clearly distinguish their invention from all other things before known, and to provide an enabling disclosure to one skilled in the art. PENROSE, supra note ___, at 138 (compulsory working requirements were all but abandoned when "replaced" with the written description requirement).

¹⁸³ Act of June 25, 1910, c.243 Stat. 851, amended July 1, 1918, c. 114, 40 Stat. 704, 705. The modern version of this statute is 28 U.S.C. § 1498.

¹⁸⁴ *Id. See also* Richmond Screw Anchor Co. v. United States, 275 U.S. 331, 341 (1928). *See also* M. SILVERMAN AND P. LEE, PILLS, PROFITS AND POLITICS 158 (1974). In full, the statute provided:

[&]quot;That whenever an invention described in and covered by a patent of the United States shall hereafter be used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, such owner's remedy shall be by suit against the United States in the Court of Claims for the recovery of his reasonable and entire compensation for such use and manufacture."

statute was that the government was a compulsory, nonexclusive licensee and could grant to any manufacturer compulsory licenses. The United States has used this provision extensively. 185

2. Patent Misuse and Antitrust Remedies

Compulsory licensing also has been used in the United States to protect the public against patent misuse and abuse. Such conduct occurred during the high point in patentee's rights. The industrial revolution and the changing face of the United States' economy combined to afford patentees new uses for their patents. These uses, while technically within an owner's rights, had deleterious social effects. For example, uses included forming cartels, ¹⁸⁶ patent pools, ¹⁸⁷ and monopolies. ¹⁸⁸ Inventors used these

28 U.S.C. § 1498.

"The purpose of the amendment was to relieve the contractor entirely from liability of every kind for the infringement of patents in manufacturing anything for the Government and to limit the owner of the patent and his assigns and all claiming through or under him to suit against the United States in the Court of Claims for the recovery of his reasonable and entire compensation for such use and manufacture. The word 'entire' emphasizes the exclusive and comprehensive character of the remedy provided."

Richmond Screw, 275 U.S. at 343.

¹⁸⁵ Cotter, *supra* note __. One early example was in 1917, when the development of the United States aircraft industry was seriously retarded by a chaotic situation regarding aeronautical patents. In particular, two competing companies, the Wright Brothers and the Curtiss Company, were threatening all other airplane and seaplane manufacturers with patent infringement suits. These manufacturers refused to manufacture planes because they feared being sued. The government was able to use the Act to secure favorable royalty rates. Manufacturers Aircraft Association v. United States, 77 Ct. Cl. 481, 1933 U.S. Ct. Cl. Lexis 277 (1922); *see also* Hughes Aircraft Co. v. United States, 717 F.2d 1351 (Fed. Cir. 1983) (suit for reasonable and entire compensation for the unauthorized manufacture of use by the United States of patent claiming synchronous communications satellite). More recent examples where the government has used § 1498 to obtain a license on patented inventions include Hughes Aircraft Company v. United States, 86 F.3d 1566 (1996) and Gargoyles, Inc. v. United States, 113 F.3d 1572 (1997).

¹⁸⁶ Cartels are described as monopolies or restraint of trade on an international basis. VAUGHAN, *supra* note ___, at 136. These arrangements involve the use of patent pools, licensing, or the use of patents to control the market among nations.

¹⁸⁷ Vaughan describes a patent pool as "an arrangement by which two or more patent owners put their patents together and receive in return a license to use them." VAUGHAN, *supra* note ___, at 39. Each member of the pool then has exclusive use to the others' patents, usually without paying a royalty. After pooling or cross-licensing their patents, members then divide the market. *Id.* at 138. He credits the sewing machine patents in 1856 as the first patent pool among manufacturers. *Id.* at 40. Vaughan gives an excellent account of the history of patent pools and other anti-competitive arrangements.

Monopolies, also referred to as patent consolidations involve the "outright and single ownership by an manufacturer of all patent rights in pertaining to a particular industry." VAUGHAN, *supra* note ___, at 69.

arrangements to exploit the patent system. More precisely, these arrangements allowed corporations to dominate an industry and to manipulate and fix prices within that industry. 189

To address this, in 1890 Congress passed the Sherman Antitrust Act. ¹⁹⁰ The general thrust of the Act was to promote competition in a free market. ¹⁹¹ The Sherman Act sought to achieve competition by making illegal all arrangements or agreements that restrained trade or commerce. The Clayton Act, ¹⁹² which followed, prohibited acts that "substantially lessen[ed] competition or tend[ed] to create a monopoly." It dealt with conduct that fell outside the ambit of the Sherman Act. ¹⁹³ Because the antitrust acts prohibited monopolies, and the patent law created monopolies, there was considerable confusion as to where one law began and where the other ended. The dilemma was this: could patentees exercise their patent rights even if in doing so they violated the Antitrust Acts?

Initially, the Supreme Court allowed such conduct to continue, holding that these arrangements were acceptable uses of patentee's rights. ¹⁹⁴ However, as such abuse and

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The very object of these [patent] laws is monopoly, and the rule, with few exceptions is, that any conditions which are not in their very nature illegal with regard to this kind of property, imposed

¹⁸⁹ Corporations accomplished this using patents; two or more patent owners would put their patents together and receive in return a license to use them. VAUGHAN, *supra* note ___, at 39. Manufacturers would also consolidate patents to obtain the outright and single ownership of all patent rights pertaining to a particular industry. VAUGHAN, *supra* note ___, at 69. Industry domination and other anticompetitive practices were widespread. Indeed, they occurred in the glass container, aluminum, incandescent lamp, telephone, oil production, steel and wire, shoe machinery, and farm machinery industries, to name a few. PETRO, *supra* note __, at 371; *see also generally* VAUGHAN, supra note __.

¹⁹⁰ 26 Stat. 209 (1890), amended 15 U.S.C. Sec. 2603 (1964) Section 2 Sherman Act, 15 U.S.C. sec. 2 (2001).

^{(2001).} 191 Stephen P. Ladas, Patents, Trademarks, and Related Rights: National and International Protection 708 (1975).

¹⁹² 38 Stat. 730 (1914).

¹⁹³ LADAS, *supra* note ___, at 708.

At least for the early part of the 20th Century, the Supreme Court viewed patent pools and similar arrangements as a patentee's acceptable use of their patent rights. The Court's 1902 opinion in the *National Harrow* case is illustrative:

anticompetitive behavior became rampant and flourished – as a direct result of "almost absolute" patent rights – the Supreme Court reacted. 195

The Supreme Court issued a number of opinions attacking monopolies.¹⁹⁶ The Court held that various practices made possible by patent arrangements impermissibly restrained trade. Notably, these practices were similar to those practices the Court previously viewed as legitimate uses of patent rights. These practices eliminated competition, discouraged improvements, improperly maintained high prices, and, most

by the patentee and agreed to by the licensee for the right to manufacture or use or sell the article, will be upheld by the Courts. The fact that the condition is in the contracts keep up the monopoly or fix prices does not render this illegal."

Bement v. National Harrow Co., 186 U.S. 70, 91 (1902). The Court was no less protective of patentee's rights when dealing with suppression and nonuse. The Court found that, as was anti-competitive behavior an acceptable use of a patentee's exclusive rights, so too was the deliberate withholding from the public of inventions. This despite the fact that suppression was recognized as "one of the greatest evils of the patent system." Walther E. Wyss and Richard R. Brainard, Compulsory Licensing of Patents, 6 GEO.WASH.L.REV. 499 (1939). Again illustrative is the Court's holding in Patent Continental Paper Bag Co. v. Easter Paper Bag Co., 210 U.S. 424 (1908). There, the Court held that a patent imposes no duty on the patentee to use his invention or permit others to use it and thus, the patentee has the right to withhold the benefits of his invention from the public – even if for the full term of his patent monopoly. The Paper Bag case left open, however, whether if the public interest was directly at stake a court could withhold injunctive relief for patent infringement. Patent Continental Paper Bag Co., 210 U.S. at 430 ("Whether, however, a case cannot arise where, regarding the situation of the parties in view of the public interest, a court of equity might be justified in withholding relief by injunction, we do not decide.") Although the Court left undecided this question, one could argue that the deliberate withholding of the patent is itself always against the public interest. The Court's unwillingness to peel back the scope of patentee's rights led two commentators of that time to suggest that "desires to limit or abolish patent nonuse or suppression must come from the legislature." Wyss & Brainard, supra note 244, at 499. This did not happen. Instead, Congress exhibited the same reluctance to interfere with patentee's rights. See, e.g., FOLK, supra note ___, at 259-261.

¹⁹⁵ According to Petro, patents made these particular abusive practices "a practical necessity." PETRO, *supra* note ___, at 371. In many of these instances, competitors owned patents on the same or closely related aspects of a product. This required that competitors either risk expensive and uncertain litigation or cooperate in some fashion. Patent pooling, cross-licensing, or cartels were the result. See also VAUGHAN, *supra* note ___, at 138 (Vaughan remarks that the chief reason for the major growth in monopolies was "a definite program to exploit the patent system in order to accomplish certain economic and political objectives.") Vaughan also states that the dominant objective of cartels is to control the market, which provides "economic gains and, in some instances, political power in peace and military strength in war." *Id.* at 140.

See, e.g., Interstate Circuit v. United States, 306 U.S. 208 (1939); Hartford-Empire Co. v. United States,
323 U.S. 386 (1945); United States v. Paramount Pictures, 334 U.S. 331 (1948); International Salt Co. v.
United States, 332 U.S. 392 (1947); United States v. U.S. Gypsum Co., 340 U.S. 76 (1950).

importantly, now violated the Sherman Antitrust Act (or were considered patent misuse). 197

The shift in the Supreme Court's view of monopolies, patent rights, and the purposes of the patent laws is captured by Justice Douglas in *Special Equipment v. Coe*: ¹⁹⁸

"It is a mistake . . . to conceive of a patent as but another form of private property. The patent is a privilege 'conditioned by a public purpose.' The public purpose is 'to promote the Progress of Science and useful Arts.' The exclusive right of the inventor is but the means to that end. . . . But the *Paper Bag* case marked a radical departure from that theory. It treats the 'exclusive' right of the inventor as something akin to an 'absolute' right. It subordinated the public purpose of the grant to the self-interest of the patentee."

Similarly, in *United States v. Line Material Co.*, ²⁰⁰ the Court remarked:

"The effort through the years has been to expand the narrow monopoly of the patent. The Court, however, has generally been faithful to the standards of the Constitution, has recognized that the public interest comes first and reward to the inventors second, and has refused to let the self-interest of the patentees come into the ascendancy."

In *Hartford-Empire*, 323 U.S. 386, 65 S.Ct. 373 (1945); 324 U.S. 570, 65 S.Ct. 815 (1945), Justice Black remarked: "The history of this country has perhaps never witnessed a more completely successful economic tyranny over any field of industry than that accomplished by these appellants." 323 U.S. 386, 436-437 (Black, J.) (dissenting in part). Justice Black identified patents as "the major weapons in the campaign to subjugate the industry." *Id.* at 437 (Black, J.) (dissenting in part). As a remedy for this misuse, the lower court ordered that Hartford-Empire license its products to anyone who requested a license on a royalty-free basis. The Supreme Court upheld the compulsory licensing decree; however, it held that Hartford-Empire was entitled to a reasonable royalty on its licenses. *Id.* at 573. ¹⁹⁸ 324 U.S. 370 (1945).

"The result is that suppression of patents has become commonplace. Patents are multiplied to protect an economic barony or empire, not to put new discoveries to use for the common good. . . . The use of a new patent is suppressed so as to preclude experimentation which might result in further invention by competitors. A whole technology is blocked off. The result is a clog to our economic machine and a barrier to an economy of abundance."

Special Equip. Co. v. Coe, 324 U.S. 370, 381-383 (1945) (Douglas, J.) (dissenting). ²⁰⁰ 333 U.S. 287, 316 (1948).

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¹⁹⁷ VAUGHAN, *supra* note ___, at 40, 62. Initially, the Supreme Court merely denied relief to a complaining patentee on the ground that the patentee misused the patent (i.e., the patentee impermissibly broadened the physical or temporal scope of the patent grant with anticompetitive effect). Morton Salt Co. v. G.S. Suppinger Co., 314 U.S. 488 (1942) (patent misuse recognized as an equitable defense to patent infringement). Many of these cases involved "tying" contracts, where the patent owner tied the sale of unpatented products to the sale of a patented product. Carbice Corp. v. American Patents Development Corp., 283 U.S. 27, 51 S.Ct. 334 (1931), *reh'g granted*, 283 U.S. 420 (1931); Morton Salt Co. v. G.S. Suppinger Co., 314 U.S. 488 (1942); Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661 (1944).

¹⁹⁹ Special Equip. Co. v. Coe, 324 U.S. 370, 381 383 (1945). Douglas believed that suppression was inconsistent with the Constitution and with patent legislation. *Id.* at 381. Douglas then noted the harmful effects of suppression:

During this time, courts increasingly ordered compulsory licenses in cases as remedies for patent misuse and antitrust violations.²⁰¹

3. Specific Compulsory Licensing Schemes

Other United States' statutes for compulsory licensing include the Atomic Energy Act, ²⁰² the Clean Air Act, ²⁰³ and the Bayh-Dole Act. ²⁰⁴ The Atomic Energy Act permits any person at any time to apply to the government for a license to use a patented invention or discovery useful in the production or utilization of special nuclear material or atomic energy. ²⁰⁵ The Nuclear Regulatory Commission may grant a nonexclusive license to use the invention if it finds that such use "is of primary importance to the conduct of an activity" by a person authorized under the section and the Commission declares the patent to be "affected with the public interest."

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²⁰¹ The court identified the following types of patent misuse: illegal tying contracts; sham litigation (used to interfere with competitor's business relationships); and fraud in the Patent and Trademark Office (Walker Process claims). In re Independent Service Organizations Antitrust Litigation, 203 F.3d 1322, 53 U.S.P.Q.2d 1852 (Fed. Cir. 2000); See also Zenith Radio v. Hazeltine Research, 395 U.S. 100, on remand, 418 F.2d 21 (7th Cir. 1969), cert. granted, 397 U.S. 979 (1970), rev'd, 401 U.S. 321 (1971), reh'g denied, 401 U.S. 1015 (1971) (holding as misuse the licensing of products on the basis of the percentage of licensee's total sales, without regard to the actual use of the licensor's patent); Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172, 177 (1965). From the view of advancing the public interest, the 1970s and 1980s began a negative shift in focus in the compulsory licensing arena as changes resulted in the dismantling of the patent misuse doctrine and antitrust law. Professor Merges attributes this to the founding of the Federal Circuit (1982) and the academic "law and economics" revolution. ROBERT PATRICK MERGES, PATENT LAW AND POLICY 865 (2d. 1992) [hereinafter MERGES, PATENT LAW]. See also Windsurfing Int'l v. AMF, Inc., 782 F.2d 995, 1001 (Fed. Cir. 1986) ("Recent economic analysis questions the rationale behind holding any licensing practice per se anti-competitive."); Senza-Gel Corp., v. Seiffhart, 803 F.2d 661, 665 n. 5 (Fed. Cir. 1986) ("Commentators and courts have questioned the rationale appearing in Supreme Court opinions dealing with misuse in view of recent economic theory and Supreme Court decisions in non-misuse contexts.")

²⁰² 42 U.S.C. § 2183(g) (1970).

²⁰³ 42 U.S.C. § 7608 (2003) (formerly 42 U.S.C. § 1857h-6 (1970)).

²⁰⁴ 35 U.S.C. § 200 et. seq.

²⁰⁵ 10 C.F.R. § 780.41. The applicant must file a petition containing a statement that the applicant "cannot otherwise obtain a license from the owner of the patent on terms which are reasonable for the applicant's intended use of the patent." *Id.* The applicant must include the steps taken to obtain a license, and the effects denial will have on the applicant's activities. The applicant also must include proposed terms the applicant believes are reasonable.

Under the Clean Air Act,²⁰⁷ whenever the Attorney General determines that a right under a U.S. Patent is necessary to enable a person required to comply with the statute to so comply, the Attorney General may so certify to a U.S. district court, which may issue an order requiring the patent owner to license the patent on "reasonable terms and conditions." The Attorney General must determine that the patent is being used or intended to be used for public or commercial use and "not otherwise reasonably available," that there are "no reasonably alternative methods to accomplish" the purpose, and that "the unavailability of such right may result in a substantial lessening of competition or tendency to create a monopoly in any line of commerce in any section of the country."

Finally, the Bayh-Dole Act²⁰⁹ establishes a federal policy regarding the patenting and licensing of federally funded inventions. The Act allows nonprofit and small businesses that enter into a funding agreement with the federal government for experimental, developmental, and research work to elect to retain patent rights.²¹⁰ The Act also retains for the federal funding agency certain residual rights in subject inventions, such as a non-exclusive, irrevocable license to practice the inventions throughout the world. The federal government thus retains the right to use any patented research tool arising in the course of federally-sponsored research without liability for patent infringement.²¹¹

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²⁰⁷ 42 U.S.C. § 7608 (2003).

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²⁰⁹ 35 U.S.C. §§ 200 et seq. The Act seeks to promote technology transfer and economic development by encouraging universities to patent inventions made with federal support, and to license those inventions to private industry.

private industry.
²¹⁰ By a Presidential Memorandum (February 18, 1983), the same policy has been extended to federally funded research and development contracts with other types of contractors.

[&]quot;In practice, however, this license has been of little practical value to NIH in obtaining research tools from its grantees, either for its own intramural scientists or for dissemination to others. Some grantees have

A. Post-TRIPS Developments

1. TRIPS-Plus' Proposed Complete Ban on Compulsory Licensing

Despite the fact that over 96 countries (or 71% of the countries worldwide) have some form of compulsory licensing, proponents of increased intellectual property protection have pointed out that these countries have rarely invoked them. As such, they seek in TRIPS-plus a complete ban on compulsory licensing.

The response to this is two-fold. For one, while it is true that compulsory licensing has not been used as extensively as it could be, it is used nonetheless, as shown above. Moreover, as recent experiences in both Brazil and the United States demonstrate, the mere existence of compulsory licensing schemes and the threat of a compulsory license can lead the patent owner to license products on commercially reasonable terms and obviate the need to issue a license in practice.²¹⁴ Further, as Abbott and Cottier note there are many possible explanations for the lack of use (particularly for developing countries),

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taken the position that the statute provides protection from infringement only, and have refused to provide samples of the materials in question to facilitate the actual use." REPORT OF THE NATIONAL INSTITUTE OF HEALTH WORKING GROUP ON RESEARCH TOOLS, June 1998, available at http://www.nih.gov (last visited August 3, 2003), Appendix D. The Bayh-Dole Act also has a mandatory licensing provision commonly referred to as the "march-in" authority. 35 U.S.C. § 203(1). The purpose of the march-in authority is to prevent the underutilization of federally funded inventions. Similar to the government-use license, marchin applies to those research tools that could be defined as patentable "subject inventions." Prior to exercising march-in rights, "the agency must determine that such action is necessary because of the failure of the contractor or its licensees to take effective steps to achieve practical application of the inventions in a particular field of use, to satisfy health or safety needs, or to meet requirements for public use specified by Federal regulations." JAMES LOVE AND MICHAEL PALMEDO, EXAMPLES OF COMPULSORY LICENSING OF INTELLECTUAL PROPERTY IN THE UNITED STATES, CPTech Background Paper 1, September 29, 2001. Compulsory licensing also has been ordered on patents needed to implement a standards based technology when the patent owner fails to disclose the pending patent. See generally, Mueller, supra note 414. ²¹² Carlos Correa, The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: New Standards for Patent Protection, 16 E.I.P.R. 327, 330-333 (1994); Abbott, supra note 85, at 717-718. ²¹³ See Klug, *supra* note ___, at 9.

²¹⁴ Reichman, *supra* note ___, at 13, noting that "Brazil obtained major price reductions on HIV retrovirals from Hoffman-La Roche after threatening to invoke its local working requirement." See also Jennifer L. Rich, *Roche Reaches Accord on Drug with Brazil*, NEW YORK TIMES (Sept. 1, 2001) ("Brazil also obtained significant price discounts from Merck in March of 2001 after threatening to impose a compulsory license."); Miriam Jordan, *Merck Vows ADIS Help for Brazilians*, WALL ST. J. (Mar. 30, 2001).

including the lack of a sufficiently sophisticated industrial and technological infrastructure and thus the inability to take advantage of the license.²¹⁵

2. Anthrax Episode

Second, and more importantly for our purposes, there are possible deleterious effects in the United States from a TRIPS-plus proposal. Two recent developments bear this out. The first development concerns the anthrax episode. Immediately after the "September 11" terrorist attacks, the United States was concerned that terrorists would use anthrax in biological warfare against the United States. The United States sought to obtain an adequate supply of Cipro, the antibiotic used to treat anthrax. A German company, Bayer, owned the patent on Cipro. The United States threatened to override the patent and instead have generic manufacturers produce the drug under compulsory licenses. The United States was concerned that Bayer would not be able to provide enough of the drug. The United States claimed its actions had nothing to do with the price, but instead was about the "national interest." Not surprisingly, as a result of the United States' actions, it was able to "persuade" Bayer to sell the drug to it at half Bayer's original asking price. 217

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²¹⁵ Abbott, *supra* note __, at 717-718. Also, patent disclosures oft times do not provide sufficient detail and background information to enable a person skilled in the art to work the invention. The CIPR similarly noted the following as reasons for the lack of use: (1) developing countries' fears that sanctions may be threatened; (2) the fact that developing countries may have no manufacturers with the know-how to reverse engineer and manufacture the drug; and (3) the fact that these manufacturers may not see a sufficiently large market to justify the costs of investment and manufacture. CIPR Report, *supra* note __, at 42.

²¹⁶ On September 11, 2001, terrorists attacked the United States by flying airplanes into the World Trade Center buildings, killing over 2,700. At about the same time, other terrorist organizations also threatened to use, and in small instances did use, biological warfare against the United States. The United States sought to prepare for increased, large-scale attacks by ensuring that it had an ample supply of antibiotics for all of its citizens.

all of its citizens.

217 The United States government, through secretary of health and human services, publicly demanded that rather than charge its original price that Bayer charge the same amount generic manufacturers charged. Bayer agreed to sell the drug to the United States at almost half its original asking price. This conduct belies the United States' statement that ignoring Bayer's patent was not about the price. It also belies the

In defending its action against charges of threatening Bayer, the United States, through the Department of Health and Human Services stated:

'The United States may procure items without first obtaining a license, so long as it pays 'reasonable and entire compensation.' There was no need for the Secretary to exercise this power. The Secretary was able to negotiate an historic agreement with Bayer that ensured an unprecedented production of Cipro. When negotiations with Bayer were pending, the Secretary did make clear that if he needed authority to produce generics, he would ask Congress. Offering to work with Congress on a matter of such importance is hardly the same as 'threatening' a company. The Secretary acted properly and with deliberation in the matter of Bayer's Cipro patent." 218

The duplicity here is glaring. The United States' stance with respect to the Doha Declaration and developing countries' ability to use TRIPS' compulsory licensing provisions to address the tragic AIDS pandemic is indistinguishable from the anthrax incident. Further, the anthrax incident emphasizes the importance of compulsory licensing provisions in protecting and advancing the public interests here in the United States. TRIPS-plus may undermine this.

3. Prescription and Generic Drug Proposals

The second development is the renewed and ferocious debate regarding prescription and generic drugs and efforts at both the state and federal level to "rein in drug companies." For example, in 1994, H.R. 4151, entitled the "Essential Pharmaceuticals Act of 1994," provided for making pharmaceutical patents subject to compulsory licenses. This would occur when the Department of Health and Human Services

United States' concern that Bayer may not be able to provide enough of the drug. Moreover, although the United States contends it is usually against interfering with patents, Christopher Shays, chairman of the House Government Reform subcommittee, said that Congress would probably back any request to bypass the Bayer patent.

Brazil is another example of a country that was able to successfully use the threat of compulsory licensing to obtain drastically reduced prices on AIDS drugs.

²¹⁸ CIPR Report, *supra* note ___, at 54 n. 69.

See Melody Petersen, Vermont to Require Drug Makers to Disclose Payments to Doctors, THE NEW YORK TIMES, Business (May 12, 2002).

determined: (1) that a patent holder "has not taken all the reasonable steps toward the commercial marketing" of the patented drug; and (2) that the "availability of the product to the public is of vital importance to the public health or welfare." In 1999, H.R. 2927, entitled "Affordable Prescription Drugs Act," was introduced. This provided for compulsory licensing of certain patented medical inventions. In 2001, two proposals, H.R. 1708 ("Affordable Prescriptions Drug Act") and H.R. 3235 ("Public Health Emergency Medicines Act") were introduced, both providing for compulsory licensing under certain circumstances. These are but a few examples, both past and present, documenting the need for compulsory licensing and demonstrating that the debate regarding compulsory licensing is far from dead. 226

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²²¹ H.R. 4151, 103rd Congress.

²²² H.R. 2927, 106th Congress, 1st. Sess. (September 23, 1999).

²²³ H.R. 1708 was designed to "correct unjustifiably high prices that (1) inflate private and public health care spending; and (2) undercut access to prescription drugs," and also required drug companies to publicly disclose the financial information necessary to evaluate the prices charged for patented drugs.

²²⁴ H.R. 3235, 107th Congress, 1st Sess. (November 6, 2001).

²²⁵ Recently, Congress also introduced bills concerning pharmaceutical companies' "skyrocketing" advertising and marketing costs, which contribute to exorbitant drug prices. Washington (Reuters) [Imphealth], *Senate Bill Would Limit Drug Ad Tax Deductions* (May 7, 2002). PhRMA contends that this "single[s] out one industry and attempt[s] to penalize it for these legitimate business interests." Savings from the bill would help pay for Medicare. *Id.* (In 1996, drug companies spent \$9.1 billion on advertising and promotion; in 2001, they spent \$19 billion.) *Id.* One proposal would have limited pharmaceutical companies' tax deductions for advertising to that amount spent on research and development. *Id.* In another effort to curb high drug prices, Vermont became the first state in the nation to require pharmaceutical companies to disclose cash payments and gifts to doctors, hospitals, and health care facilities. Such gifts (e.g., theater tickets, sporting events, free dinners, flights to Florida for vacations) influence doctors to prescribe expensive drugs rather than similar less expensive ones. Peterson, *supra* note 292. Hawaii signed a law that requires drug companies to report the amount of money spent on marketing. Peterson, *supra* note __. By limiting promotion costs, these bills sought to reduce drug costs. Reducing drug costs could then alleviate the need for compulsory licensing or be used in connection with other efforts such as compulsory licensing to reduce costs overall.

²²⁶ The pharmaceutical industry has legitimate concerns about protecting its interest and providing appropriate incentives for innovation and has spent massive amounts of money successfully lobbying against these bills. However, it may overstate its case. For years the pharmaceutical industry has argued any laws passed weakening patent protection (such as through compulsory licensing) or affecting companies' ability to reap profits would slow the introduction of new drugs, work to the detriment of Americans' health, and cripple research efforts. After each projected demise, however, the pharmaceutical companies survived and continued earning unrivaled profits. As one pharmaceutical company attorney said over three decades ago after the 1973 Supreme Court decisions (Weinberger v. Hynson, Wescott and Dunning, Inc., 412 U.S. 609 (1973); Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645 (1973);

TRIPS Article 31 may constrain national government's, including the United States', ability to continue using compulsory licensing. Article 31 severely limits the ability of countries to use compulsory licensing. While the United States still may subject patents to compulsory licensing for the public interest, for example, by basing such use on TRIPS Article 8 "principles", which allows parties to adopt measures necessary to protect public health and to promote the public interest, the licenses must satisfy the detailed set of conditions and limitations under Article 31. These conditions are more stringent than those examined under U.S. law by, among other things, requiring prior negotiation with the patent owner, using the patent predominantly for the supply of the domestic market, and making the legal validity of any decision relating to the authorization of license use subject to judicial review. TRIPS-plus, and the effort to completely eliminate compulsory licensing is even more troubling to the U.S. public.

Ciba Corp. v. Weinberger, 412 U.S. 640 (1973); USV Pharm. Corp. v. Weinberger, 412 U.S. 655 (1973)) that required adequate and well-controlled clinical evidence to demonstrate a drug's safety and efficacy:.

The trouble with that line of chatter is that the industry has been using it too long, and we've lost our credibility. For nearly seventy years, the industry has bucked almost every proposed new drug law by warning that it would wreck the industry, make us cut down on research, destroy American medicine, ruin the public health, and probably bring on communism. The problem now is that there are too many people – especially in Congress – who won't swallow it. They know only too well that, with all the new laws, drug industry profits are higher than ever. Drug research has been expanded. American medicine has never been more productive. And the health of the public has never been better. For too many years, the drug industry has been crying 'wolf.' Now, we're convincing each other – but nobody else. The new Supreme Court decisions? Our people can live with them."

MILTON SILVERMAN & PHILIP LEE, PILLS, PROFITS AND POLITICS 134 (1974).

²²⁷ As a matter of political strategy, the United States is unlikely to make such an argument as it would open the door for other countries to follow suit, thus undermining the United States' current position and jeopardizing the "gains" made by the pharmaceutical industry.

²²⁸ See TRIPS, *supra* note ___, Article 31(b), (f), (i). Cries that compulsory licensing will ruin the industry and significantly impact United States' technological advantage also may overstate the case. While there is a slight chance that compulsory licensing may reduce the incentive to innovate, this risk is justified to assure the public has complete access to products for which the patent is granted and to assure "more complete utilization and commercialization of innovative products." Cole M. Fauver, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 J. INT'L. L. BUS. 666 (1998). Moreover, not all recent economic analysis suggests that compulsory licensing is bad. In responding to arguments that compulsory licensing retards technological progress, Scherer states that a "substantial amount of evidence

IV. PATENT TERM REBOUND

A. Promoting the Public Interest

Similarly, limiting the term an owner enjoys a monopoly is a necessary limit on the owners' rights for the public's benefit. The proper length of the patent term has been the subject of much debate throughout the history of the United States' patent regime.²²⁹ Congress, however, has rejected requests to increase the term and has instead kept the term relatively short. For example, in the first U.S. Patent Act, the 1790 Act, Congress defined the "limited times" requirement of the Intellectual Property Clause by setting the initial patent term "not to exceed fourteen years." Despite repeated requests to extend

now available suggests that compulsory patent licensing . . . would have little or no adverse impact on the rate of technological progress. . . ." F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 457 (2d ed. 1980). Scherer confines instances for compulsory licenses to cases in which patent-based monopoly power has been abused. *Id.* As such, arguments that compulsory licensing actually serves to hinder the public interest indeed may overstate the case. Instead, as United States history demonstrates, in specific circumstances, such licensing furthers the public interest and is a necessary limit on patentee's rights.

Again, in general, a short patent term promotes the public interest as it delivers inventions earlier to the public domain, guards against long monopolistic prices for licenses, and encourages improvements, among other things. Early advocates for short terms included Benjamin Franklin, who believed that inventions should be quickly placed into society to continuously serve others. He eschewed a term of years for his "Franklin stove" stating: "That as we enjoy great Advantages from the Inventions of others, we should be glad of an Opportunity to serve others by any Invention of ours, and this we should do freely and generously." BUGBEE, GENESIS, *supra* note ___, at 72. Bugbee notes, however, that Franklin, unlike most inventors, was a man of "independent wealth," which may explain his seemingly altruistic views. The patent term recognizes private interests by allowing these interests sufficient time to commercialize their inventions, recover costs, and reap profits. Patentees have long argued that patent terms were insufficient. Walterscheid, supra note ___, at 370 (quoting Oliver Evans, The Young Mill-Wright and Miller's Guide (2d ed. Philadelphia 1807) quoted in Greville Bathe et al., Oliver Evans: A Chronicle of Early AMERICAN ENGINEERING 101, 140 (1935)). Walterscheid also states that the New England Association believed the 14-year term was too short; and that the Massachusetts Association argued for a 14-year renewal term for patents. WALTERSCHEID, supra note ___, at 308-312. Brazenly, some sought rights in perpetuity. An early inventor and staunch supporter of patent owner's rights, Oliver Evans expressed this view often. WALTERSCHEID, supra note __ at 310. This concept is based on a natural rights theory of patent law, i.e. that inventors had a natural right in their inventions and that the law rather than create rights needed simply to protect these existing natural rights. The natural rights theory played a very minimal role in the evolution of the patent system. For views challenging this see Rethinking the Development of Patents: An Intellectual History, 1550-1800, 52 HASTINGS L.J. 1255 (2001). Others sought a slightly less ambitious term of "life of the invention." WALTERSCHEID, *supra* note , at 310. Neither the Intellectual Property Clause ("for limited times") nor the purpose of the patent laws ("to promote the sciences and useful arts") justified inventors' cries for these terms. Congress properly rejected such requests. ²³⁰ The time had to be limited to that sufficient "to promote the progress of science and useful arts." Pennock v. Dialogue, 27 U.S. (Pet.) 1, 16-17 (1829) (This language "contemplates . . . that this exclusive

the term, Congress rejected such requests. The term remained fourteen years for the next eighty years.²³¹

When Congress did increase the term in 1861, it did so as an apparent compromise between providing term extensions and increasing the initial patent term.²³² As to the extensions, however, they were expressly limited to patents issued before March 2, 1861 and were based "solely on its effect on the public interest."²³³ The patent term remained

right shall exist but for a limited period, and that the period shall be subject to the discretion of [C]ongress."). In the first U.S. Patent Act, the 1790 Act, Congress set the term "not to exceed fourteen years." WALTERSCHEID, *supra* note ___. It is not contended here that this was the time sufficient to promote the progress of the useful arts. Rather, Congress merely copied the English term, without considering the appropriate term for the states. Walterscheid, *Defining the Patent Term, supra* note ___, at 363 (emphasis added). Jefferson's comment here is instructive:

Certainly an inventor ought to be allowed a right to the benefit of his invention for some certain time. It is equally certain it ought not be perpetual; for to embarrass society with monopolies for every utensil existing, & in all the details of life, would be more injurious to them than had the supposed inventions never existed: because the natural understanding of its members would have suggested the same things or others as good. How long the term should be is the difficult question. Our legislators have copied the English estimate of the term; perhaps without sufficiently considering how much longer, in a country so much more sparsely settled, it takes for an invention to become known & used to an extent profitable to the inventor.

Walterscheid, *supra* note ___, at 311 (Letter from Thomas Jefferson to Oliver Evans (May 2, 1807), *reproduced in* G. Bathe & D. Bathe, Oliver Evans: A Chronicle of Early American Engineering 127 (1935)).

That the term remained so should not suggest it was without controversy. On the contrary, in the area of patent term *extensions* the debate was fierce. Patentees argued that Congress should extend terms if patentees did not fully exploit their inventions within the initial 14-year term. Extending a patent beyond its original term would harm society by keeping from it new and useful inventions. Thus, despite repeated and numerous requests from inventors, to serve the public interest Congress severely restricted the number and circumstances for granting extensions. Oliver Evans was the first inventor to petition Congress for an extension of his invention concerning the improvements in the milling of flour. Walterscheid, *Defining the Patent Term*, *supra* note ___, at 368. Congress did not act on it. It was not until 1832 that Congress passed any legislation providing for term extensions. *Id.* at 369-370. From 1790 to 1836 Congress extended patent terms in only seven cases. These extensions were passed by special acts of Congress, rather than under a general patent statute providing for extensions. According to Walterscheid, Congress "exhibited no interest whatever in either statutorily extending the term of the patent grant or providing for a statutory right of renewal" and "exhibited considerable caution in granting term extensions." Walterscheid, *Defining the Patent Term*, *supra* note __, at 374.

²³² Walterscheid suggests that the seventeen-year term was Congress' perception that this term "was sufficient to remove the need for any administrative extension process." Walterscheid, *Defining the Patent Term*, *supra* note ___, at 379.

²³³Walterscheid, *Defining the Patent Term*, *supra* note ___, at 378. This was the result of Congress "questioning its earlier assumption that a primary role of the patent system was to reward inventors as opposed to promoting the public interest." *Id.* at 379.

seventeen years for the next one hundred-thirty years.²³⁴ This was essentially the status before TRIPS.

A. Post TRIPS Developments

1. 20-year term

When the United States became a WTO/TRIPS signatory the patent term changed yet again. TRIPS required the United States to enact legislation to conform to it. One of the changes was to extend the patent term to twenty years from the filing date. ²³⁵ In the hearings regarding TRIPS implementation, the most controversial and contentious testimony focused on this change. ²³⁶ Yet, TRIPS – and its focus on private rights– was

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²³⁴ In 1984, as a result of a ferocious debate about, the skyrocketing costs of prescription drugs and the need to support more extensive research and development for drugs, Congress passed The Drug Price Competition and Patent Term Restoration Act of 1984 (the Act is also known as the Hatch-Waxman Act or Bolar Amendment). Drug Price Competition and Patent Term Restoration Act of 1984 § 101 (codified as amended at 21 U.S.C. § 355(j)(1) (1984). As the name implies, the Act combined two proposals. The "drug price competition" component provided for an abbreviated application procedure to approve new drugs, allowing manufacturers to market generic drugs shortly after a patent expired. The Drug Patent Term, supra note ___, at 138. The "patent term restoration" component amended patent law by providing the requested drug patent extension. The Act provided for a five-year extension for drug patents for regulatory delays such as the time spent complying with FDA pre-market testing requirements. The Drug Patent Term, supra note ___, at 138 citing Drug Act, 98 Stat. 1585, 1598 (codified as amended at 35 U.S.C. § 156(a) (1984)). Drug Price Competition & Patent Term Restoration Act of 1984. This happens because drug manufacturers file patent applications before their drugs enter the clinical testing stage, which stage takes typically from 8-9 years. The Drug Patent Term, supra note, at 119-121. The Act allows drug manufacturers to extend their patent term by the sum of two periods of time: the time taken by the final FDA review and half the time spent in clinical testing after the patent is granted. The manufacturers argued that these delays shortened a patent's "effective life," and owners were entitled to that lost time. Patent owners and drug manufacturers were allowed the "lost" time, but extensions were capped at five years. 35 U.S.C. § 156 (1994). However, it is highly unlikely that both a regulatory delay extension and an issuance delay extension are both granted; thus, a patent term extending more than twenty-five years is "most unusual." Walterscheid, Defining the Patent Term, supra note ___, at 380. Drug manufacturers have been able to extend their patents even further. As part of the Act, generics were provided a streamlined process so that they could enter as soon as the drug patents expired. However, if the drug manufacturer seeks additional patents on a particular drug (usually several years before the drug is set to expire), they gain an automatic 30-month injunction against any generic competition by claiming the new patent is being infringed. The new patent can be on unapproved indications for the drug, specific drug formulations, or even tablet shape. Id.

²³⁵ All other patent terms previously discussed ran from the issuance date rather than the filing date.

²³⁶ Hearings at *3. In short, some argue that the change in the patent term could seriously diminish the patent protection for inventions that had long pendency periods, as the new term begins on filing the patent

able to accomplish indirectly what others could not do directly, increase the term to 20 years. ²³⁷

While the change in the term itself may not be of major significance, there is no evidence Congress considered whether the changes would meet the constitutional mandate of promoting the progress of useful arts.²³⁸ Indeed, the increase in additional term protection is thus not linked to Congress' intellectual property power. In other words, it is not "to promote the progress of useful arts," but rather to harmonize the term with other WTO countries.²³⁹ The fear here is that once we create this gap between the Constitution and the patent laws, there will be no sensible, definable stopping point.

2. Copyright Term Extension – A Return to the Concept of Guaranteed Income?

Lest one think this fear is unfounded, the copyright term provides a meaningful comparison, as both the copyright and patent laws derive from the same Intellectual Property Clause. The copyright term also was initially a 14-year term. Since then, it has increased almost exponentially. It has gone from 14 years to 42 years (1831), to 56 years (1909), to life-plus-50 years (1976) to the current life-plus-seventy years under the

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application, rather than upon issuance of the patent. (Ironically, these include biotech and pharmacological inventions.)

²³⁷ Since at least 1898 there have been efforts to change the patent term to 20 years from the filing date. Seegert, *supra* note ___, at 620 (citing First Report of National Patent Planning Commission pp. 18-19 (1943)). *See also* Folk, *supra* note ___, at 298-299 stating that in 1898 Commissioner Duel proposed a 20-year term, and noting that the T.N.E.C. in its final report recommended a 20-year term from the filing date. All of these proposals were properly rejected because, among other reasons, they did not promote the public interest.

public interest.

238 Congress did consider the advantages and disadvantages of U.S. inventors and companies in relation to foreign inventors and companies, but did not adequately consider the advantages and disadvantages vis-àvis the U.S. public and inventors.

²³⁹ Under the "necessary and proper" clause, Congress can pass legislation to fulfill treaty obligations. Missouri v. Holland, 252 U.S. 416 (1920). This does not resolve the possible conflict between the term change and the Intellectual Property Clause mandate.

Copyright Term Extension Act (1998). Sonny Bono, after whom the latest copyright extension act is named, desired life in perpetuity, but knew that this would be unconstitutional. His widow and congressional successor proclaimed Congress should consider a term of "forever less one day." What should be noted with respect to the copyright term increases is that the primary rationale for those increases was almost entirely for the benefit of the author. The extensions were to assure authors a fair economic return. In particular, copyright owners argued that because of the substantial increased life expectancy and the growth in communication media that substantially lengthened the commercial life of great works, they were no longer being adequately compensated.²⁴¹ The other rationale was to harmonize the term with WTO countries.

Opponents of the CTEA argued that the term extension would not benefit the public; if it were applied prospectively it would provide very little, if any, incentives to produce copyrighted work, and if applied retroactively, it would provide no incentive whatsoever.²⁴² The Supreme Court nonetheless was able to find a public purpose in the Act, even intimating that harmonization could further that interest.

²⁴⁰ Ochoa, *supra* note ___, at 19, 45.

²⁴¹ Walterscheid states that the reasons offered for increased protection include: (1) the 56-year term under the 1909 Act was not long enough to assure an author and his dependents a fair economic return, given the substantial increase in life expectancy; (2) the growth in communication media has substantially lengthened the commercial life of a great many works, particularly serious works which may not initially be recognized by the public; (3) the public does not benefit from a shorter term, but rather the user groups derives a windfall, as the prices the public pays for a work often remain the same after the work enters the public domain; (4) a system based upon the life of the author avoids confusion and uncertainty, because the date of death is clearer and more definite than the date of publication; and it means that all of a given author's works will enter the public domain at the same time instead of seriatim as under a term based on publication; (5) the renewal system is avoided with its highly technical requirements which often cause inadvertent loss of copyright; (6) a statutory term of life-plus-fifty (seventy) years is no more than a fair recompense for those who under the 1909 Act owned common law copyrights which continued in perpetuity as long as a work remained unpublished; and (7) a majority of the world's countries have a term of life plus fifty; to adopt the same term expedites international commerce in literary properties, and opens the way for membership in the Berne Convention.) Walterscheid, Defining the Patent Term, supra note ___, at 386 (citing Melville B. Nimmer and David Nimmer, 8 NIMMER ON COPYRIGHT 9-8 Section 9.01 [A][2] (1999)). ²⁴² Ochoa, *supra* note ___.

This issue was squarely before the Court in *Eldred*,²⁴³ where the majority held that increased copyright protection did indeed promote progress. The *Eldred* majority identified a number of factors supporting its holding. Specifically, the Court found that Congress passed the CTEA to be consistent with a European Directive establishing a similar term.²⁴⁴ This, according to the majority, "sought to ensure that American authors would receive the same copyright protection in Europe as their European counterparts." The Court found that this would provide incentives for American authors to create and disseminate their work in the United States.²⁴⁵ In addition to the "international concerns" the Court relied on projections that longer terms would encourage copyright holders to invest in restoration and public distribution of their works.²⁴⁶ The majority held these considerations promoted the progress of science and demonstrated Congress acted rationally in enacting the CTEA.

Eldred is at once both a good opinion and a bad opinion. It is first worth noting that the Eldred case was concerned solely with the increased copyright term. It did not involve increased patent subject matter protection, reduced exceptions to intellectual property protection (e.g., compulsory licensing), or possible future term extensions (as sought in TRIPS and TRIPS-plus)). Beyond this, Eldred is a good opinion because it makes clear that even in the context of fulfilling international obligations, Congress cannot abdicate its responsibility and must ensure that intellectual property laws promote the public interest.

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²⁴³ Eldred v. Ashcroft, 537 U.S. 186, 123 S.Ct. 769 (2003).

²⁴⁴ Justice Breyer notes that the statute does not in fact produce uniformity with respect to the "lion's share" of the copyrighted works – all those works made for hire and all existing works created before 1978. *Eldred*, 123 S.Ct. at 808-809 (Breyer, J., dissenting).

²⁴⁵ To this, Justice Breyer retorts that "few, if any, potential authors would turn a 'where to publish' decision upon this particular difference in length of the copyright term." *Id.* at 809. ²⁴⁶ *Eldred*, 123 S. Ct. at 782 (Breyer, J., dissenting).

Eldred is a bad opinion because the Supreme Court abdicated *its* responsibility to critically assess whether Congress' action was constitutional. Instead, the Court noted the deference it must give to Congress in this area and took Congress' purported public benefits without testing them. As it now stands, increases in terms may now be predicated on an inventor receiving "a fair economic return." The patent term may be heading in the same direction. ²⁴⁸

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In 1836, Congress again provided for term extensions, and once again based these term extensions on the patentee's private interests. The 1836 Act provided for possible seven-year extensions when a Patent Board determined that the patentee "failed to obtain, from the use and sale of his invention, a reasonable remuneration for their time, ingenuity, and expense bestowed upon the same, and the introduction thereof into use" Walterscheid, *Defining the Patent Term, supra* note ____ at 375 (citing Act of July 4, 1836 § 18, 5 Stat. 117). Wilson v. Rousseau, 45 U.S. 646, 675 (1846) ("The statute is . . . founded upon the idea . . . of rewarding to [the individual] an enlarged interest and right of property in the invention itself, with a view to secure to him, with greater certainty, a fair and reasonable remuneration.) The Board was also to give "due regard to the public interest," however, as Walterscheid notes "this was mere lip service." Walterscheid, *Defining the Patent Term, supra* note ___, at 375. Because both the 1832 and 1836 provisions were predicated on the patentee receiving adequate remuneration, each patentee could, theoretically, extend the patent term indefinitely depending upon what Congress deemed adequate or reasonable. In effect, patentees were assured guaranteed income by continually seeking renewals until they were fully compensated for their time and effort. Christine P. Benagh, *The History of Private Patent*

²⁴⁷ Post TRIPS, patent owners secured additional legislation providing for further extensions, this time based on PTO delays. This was not required by TRIPS and was ostensibly designed to both encourage prompt responses by the PTO and compensate owners for lost time due to PTO delays. The new legislation – the Patent Term Guarantee Act – ensured that the PTO would issue patents within three years, otherwise, owners were granted extensions for the entire period after three years. The Act also removed the 5-year cap previously established. PL 106-113 §§ 4401-4403, 113 Stat. 1501, 1501A-557-560 (Nov. 29, 1999) (amending 35 U.S.C. § 154(b)).

²⁴⁸ 1832 marked a significant shift in Congress' perception of the patent laws' underlying purpose. In that year, Congress revised the patent laws and as part of that revision responded to the patentees' persistent lobbying efforts by setting forth conditions for term extensions. Because the Supreme Court interpreted the Intellectual Property Clause as giving Congress the discretion to say "when and for what length of time and under what circumstances the patent for an invention shall be granted" there was little question but that Congress could provide for term extensions. Blanchard v. Sprague, 3 F.Cas. 648, 650 (C.C.D. Mass. 1839) (No. 1,518); Walterscheid, *Defining the Patent Term*, supra note , n. 224. (However, extending patent protection does nothing to promote new creativity while subverting the concept of "limited times.") Rather than being tied to the purpose of the Intellectual Property Clause, i.e., to promote the useful arts, these conditions focused exclusively on whether the patentee received adequate remuneration during the original patent term. Specifically, the statute required that a petition for extension include "a statement of the ascertained value of the discovery, invention, or improvement, and of the receipts and expenditures of the patentee, so as to exhibit the profit or loss arising therefrom." Walterscheid, Defining the Patent Term, supra note ___, at 374. What makes this provision extraordinary is that there was no support for it anywhere in the constitutional clause granting Congress the power to grant patents. In other words, the Constitution provided for patents to promote progress, not to make sure patentees received what they considered adequate remuneration. Moreover, the provision elevated the private rights of patentees over that of the public. Unfortunately for the public, this sentiment and new perception would continue with the next patent law revision.

CONCLUSION

The arguments in support of increased protection are premised on one belief: increasing protection increases the incentives for inventors and investors. The argument is straightforward. Increased protection reduces piracy and encourages more inventive activity and more innovation. This was the driving force behind TRIPS and the resulting increased international patent protection required of WTO members. However, the myopic view of increasing protection internationally so as to benefit the public at home is not only inaccurate but shortsighted. While TRIPS benefits some economic interests at home, these narrow economic interests are not the public interests we are concerned with. In fact, the public is harmed because of TRIPS' constraining nature and its effect of shrinking of the public domain.

Moreover, this increased protection is at odds with traditional U.S. patent law.

Traditional U.S. patent law has always been understood as promoting public interests through incentives to private parties. The United States' intellectual property system is not nor has it ever been simply for the benefit of private interests. Accordingly, throughout the history of the United States increased intellectual property protection has been not simply for the sake of increasing protection but to continue to promote the progress and benefit the public.

TRIPS corrupts this balance because it does not disseminate knowledge or provide information in the ways that U.S. framers envisioned, but rather simply encourages objectionable monopolies, which the framers feared. By developing intellectual property

Legislation the House of Representatives, Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the house Committee on the Judiciary 8, 96th Cong., 1st Sess. (1979) (Comm. Print 1979). The House Committee on Patents feared just this. Walterscheid, *Defining the Patent Term*, *supra* note 36, at 377 citing Benagh, *supra* note ___, at 8.

rights by bartering between a trade regime and an intellectual property regime, in an effort to protect private intellectual property rights, TRIPS fails to adequately take into account the public interest, and may actually harm the United States and retard innovation. While the harm may have been unintended, a shift in emphasis which favors one interest (private) will probably be achieved only at the expense of the other interest (public).

In light of the harms caused in the U.S. and abroad, TRIPS must be reevaluated and reinterpreted. The United States must pursue an interpretation that will reduce inconsistencies between TRIPS and enacting legislation and willpromot e progress and benefit the public. Articulating a commitment to the public interest in the Constitution is one thing; practicing it is another.