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Mr. Philippe Baechtold
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and Global Intellectual Property Issues
World Intellectual Property Organization
34, chemin des Colombettes,
1211 Geneva, Switzerland

Re: ITSSD Comments Concerning (Document SCP/13/3)
Exclusions from Patentable Subject Matter and
Exceptions and Limitations to the Rights

Dear Mr. Baechtold,

The Institute for Trade, Standards and Sustainable Development (ITSSD) is pleased to submit its comments concerning the WIPO SCP Report on Patent Exclusions, Exceptions & Limitations (Document SCP/13/3), which raises a number of important issues related to the WIPO Report on Standards and Patents (Document SCP/13/2).

The ITSSD appreciates the opportunity to contribute to the SCP's evolving work program, and hopes that this submission helps ensure that SCP members and observers do not overlook the critical and indispensable role long served by private property rights in spurring individual, company and group innovation and dissemination of knowledge nationally, regionally and globally.

Thank you once again for your serious and thoughtful consideration.

Sincerely,

Lawrence A. Kogan

Lawrence A. Kogan, Esq.

President / CEO

ITSSD Comments Concerning Document (SCP/13/3) Patent Exclusions, Exceptions & Limitations

(viii) Compulsory licenses and government use

Paragraphs 138-142 - Examples of European and Developing Country Compulsory Licensing Practices Questionably Sanctioned by the WIPO Paris Convention and the WTO TRIP Agreement

It is true that Article 5A(2) of the Paris Convention, as amended,¹ provides national governments with “the right to take legislative measures providing for the grant of compulsory licenses to prevent the *abuses* which might result from the exercise of the exclusive rights conferred by [a] patent”.² It is also true that Article 5A was incorporated by reference into the WTO TRIPS Agreement via Article 2(1) and the Preamble to Article 31 of said Agreement.³ And, it is true that within the laws of those member countries that adopted and implemented Article 5A, the “failure to work or insufficient working” of a patent continues to be considered as but only one example of such an ‘abuse’.⁴

It is true, furthermore, that European and certain developing country Member States believe they are free to define the expressions ‘abuses which might result from the exercise of the exclusive rights conferred by the patent’ or ‘failure to work’⁵ within the meaning of Article 5A(2).⁶ Consequently, creative member countries with paternalistic governments that regularly exercise expansive powers over citizens, have unilaterally defined at least four additional ‘abuses’ (i.e., grounds for determining that an abuse has occurred) worthy of being addressed via compulsory licensing. They include: 1) “the refusal [to] grant[] a license on reasonable terms and conditions”;⁷ 2) “the failure to supply the national market with sufficient quantities of the patent

¹ See Article 5A(2), Paris Convention for the Protection of Industrial Property of March 20 1883, as amended, at: http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html#P123_15283 .

² See Paul Champ and Amir Attaran, “Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute”, *supra* (emphasis added).

³ See Article 2(1), Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, WTO Agreement, Annex 1C.

⁴ See Article 5A(2), Paris Convention for the Protection of Industrial Property of March 20 1883, as amended.

⁵ See SCP/13/3, Paragraph 78 *supra*, citing “Actes de la conférence réunie à Londres, 1934”, p.174.

⁶ It appears that the importation of a patented invention manufactured in another treaty party into the country where the patent was granted would qualify as a ‘working’ of the patent, and thus, NOT as an abuse (i.e., as ‘a failure to work’), within the meaning of Article 5A(1), especially considering that “[w]orking in all countries is generally not economical...[and that]...it is generally recognized that immediate working in all countries is impossible.” See “The Paris Convention for the Protection of Industrial Property in WIPO Intellectual Property Handbook: Policy, Law and Use”, Chapter 5, Paragraph 5.46, at p. 247, (WIPO 2nd Edition ©2004) at:

<http://www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch5.pdf> ; <http://www.wipo.int/about-ip/en/iprm> .

⁷ See SCP/13/3, Paragraph 78 *supra*, citing Actes de la conférence réunie à La Haye, 1925, p.434.



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product”;⁸ 3) “demanding excessive prices for such product”;⁹ and 4) “anti-competitive behavior”.¹⁰

If a government ultimately determines that a patent ‘abuse’ has occurred on the grounds that the patent holder has failed to work the patent, or to work it sufficiently, it may issue a compulsory license only if it satisfies the conditions set forth in Article 5A(4).¹¹ First, a compulsory license based on such grounds cannot be granted “before the expiration of three years from the date of the grant of the patent or four years from the date the patent application was filed.”¹² Second, “[s]uch a compulsory license must be non-exclusive and non-transferable”¹³ to “sub-licensees that could potentially wield greater market power than would otherwise be available under the compulsory license.”¹⁴ And, third, the patent holder must be deemed unable to “justify his inaction by legitimate reasons.”¹⁵ At least one expert has concluded that “legitimate reasons may be legal, economic, or technical obstacles to exploitation.”¹⁶

Yet, it must be reemphasized, at this point, that “the Paris Convention only mentions compulsory licensing as a remedy for *abuses*. [It] is silent on compulsory licensing for [other reasons, including] *public interest* reasons.”¹⁷ In other words, some European and developing country commentators believe that “Article 5.A does not deal with compulsory licenses other than those

⁸ *Id.*

⁹ *Id.*

¹⁰ See Paul Champ and Amir Attaran, Paul Champ and Amir Attaran, “Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute” *supra* at p. 372.

¹¹ *Id.*, Article 5A(4).

¹² *Id.*; See Paul Champ and Amir Attaran, *supra* at p. 372.

¹³ *Id.*

¹⁴ See SCP/13/3, Paragraph 78 *supra*, citing G.H.C. Bodenhausen, “Guide to the Application of the Paris Convention for the Protection of Industrial Property”, WIPO Publication No.611. “5.49 The compulsory license for non-working or insufficient working must be a non-exclusive license and can only be transferred together with the part of the enterprise benefiting from the compulsory license. The patent owner must retain the right to grant other non-exclusive licenses and to work the invention himself. Moreover, as the compulsory license has been granted to a particular enterprise on the basis of its known capacities, it is bound to that enterprise and cannot be transferred separately from that enterprise. These limitations are intended to prevent a compulsory licensee from obtaining a stronger position on the market than is warranted by the purpose of the compulsory license, namely, to ensure sufficient working of the invention in the country.” See “WIPO Intellectual Property Handbook: Policy, Law and Use”, WIPO Publication No.489E (©WIPO 2004, Second Edition), Chap. 5, at p. 247 at: <http://www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch5.pdf>.

¹⁵ See Article 5A(4), Paris Convention for the Protection of Industrial Property of March 20 1883, as amended. See also Paul Champ and Amir Attaran, *supra* at p. 372, fn 47. (“Before compulsory licensing, a patent holder could similarly avoid forfeiture by justifying ‘his inaction.’) Washington Revision to Paris Convention (1911), *supra* note 14, art. 5(2), in Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law*, 35 OSGOODE HALL L. J. 243, 251-52 (1997) at 285. Under the Hague Revision to Paris Convention (1925), art. 5(4), the patent holder could avoid compulsory licensing if he or she proved ‘the existence of legitimate excuses.’ The ‘legitimate reasons’ language originated in the London Revision to Paris Convention (1934), Art. 5(A)(4).

¹⁶ See Paul Champ and Amir Attaran, *supra* at p. 372 citing G.H.C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY 71, 73 (1968).

¹⁷ *Id.*, at p. 373 (emphasis added).



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whose purpose it is to prevent *abuses* of a patentee. [In their opinion, this leaves] Member States...free to provide analogous or different measures under the applicable law.”¹⁸ Indeed, many such member countries have “proposed grounds beyond *abuses*...[i.e., “in cases where there is no abuse by the patent owner of his rights”¹⁹]...broadly categorized as being in the ‘public interest’”.²⁰ And these compulsory licensing grounds are *not* deemed subject to the restrictions set forth in Article 5A(4) that arise only in the failure to work and insufficient working scenarios.²¹

For example, European and certain developing countries have issued the following compulsory licenses “which can be grouped together under the general heading of compulsory licenses *in the public interest*”.²² They include compulsory licenses: 1) “in the fields of military security[;] or [2]...public health[;]”²³...[and 3] to protect the public interest in unhampered technological progress ...[as in the case of]... so-called *dependent patents*.”²⁴ Paragraph 138 of this Report exemplifies this thinking. It claims that the issuance of a compulsory license is justified on broad ‘public interest’ grounds, where the exercise or non-exercise of a patent impairs the ability of the “patent system [to] contribute to the promotion of innovation in a competitive environment and to the transfer and dissemination of technology”.

The American, European and developing country parties to the Paris Convention had long disagreed about the grounds for issuing compulsory licenses²⁵, and these debates carried into and

¹⁸ See SCP/13/3, Paragraph 80, *supra* (emphasis added).

¹⁹ See “The Paris Convention for the Protection of Industrial Property in WIPO Intellectual Property Handbook: Policy, Law and Use”, Chapter 5, Paragraph 5.51, at p. 247, *supra*.

²⁰ See SCP/13/3, Paragraph 80, *supra*. Commentators Champ and Attaran quote Bodenhausen as saying that “compulsory licensing on public interest grounds is permitted under the Paris Convention because the treaty is silent on the issue. He adds that this question was discussed by the parties in Lisbon in 1958, and the omission is meaningful. But since failure to work locally was already categorized as an abuse with a clear remedy (compulsory licensing), it is possible that this obviated the need to redefine local working in terms of the ‘public interest,’ whether in the Paris Convention or the later TRIPS Agreement.” See Paul Champ and Amir Attaran, *supra* at p. 373.

²¹ “5.50 All these special provisions for compulsory licenses in Article 5A(4) are only applicable to compulsory licenses for non-working or insufficient working. They are not applicable to the other types of compulsory licenses for which the national law is free to provide. Such other types may be granted to prevent other abuses, for example, excessive prices or unreasonable terms for contractual licenses or other restrictive measures which hamper industrial development.” See “The Paris Convention for the Protection of Industrial Property in WIPO Intellectual Property Handbook: Policy, Law and Use”, Chapter 5, Paragraph 5.50, at p. 247, *supra*.

²² *Id.*, at par. 5.53, p. 248. “National laws are not prevented by the Paris Convention from providing for such compulsory licenses, and they are not subject to the restrictions provided for in Article 5A. This means in particular that compulsory licenses in the public interest can be granted without waiting for the expiration of the time limits provided for compulsory licenses that relate to failure to work or insufficient working.” *Id.*

²³ *Id.*, at par. 5.51, p. 247.

²⁴ *Id.*, at par. 5.52, at pp. 247-248.

²⁵ For example, “until the early 1990s, almost every country in the world had local working requirements...In 1993, the vast majority of countries, industrialized and otherwise, required local working. A few countries, such as Australia, Hungary, South Korea, and Mexico, considered importation to satisfy this requirement. The United States and Canada were notable exceptions, though Canada did have a comprehensive compulsory licensing regime.” See Paul Champ and Amir Attaran, *supra* at p. 372.



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continued during the negotiations surrounding the TRIPS Agreement.²⁶ And, even though an unrecorded political compromise²⁷ was finally reached that ultimately resulted in Articles 2(1) and 31 of the WTO TRIPS Agreement incorporating by reference “more than 75 years of State... compulsory licensing practice... to regulate *abuses* of a foreign patentee’s exclusive rights under domestic law”,²⁸ many countries have still not been able to come to terms with the outcome. Fostering a better understanding of Article 31 could assist in this effort. For instance, how many WTO parties would agree that “The final text of Article 31 indirectly vindicated the public interest as a ground separate from the category of abuse [...]”?²⁹

While Document SCP/13/3 generally describes in accurate fashion the leading practices of compulsory licensing-inclined jurisdictions around the world, it raises certain issues. A more honest depiction of such practices would arguably attempt to draw a connection between the magnitude and frequency of government CL practices and the type of legal system in question. Such an analysis would likely show that a far greater number of CLs were issued in civil law *ex ante* preventive justice based legal systems than in *ex post* common law contentious justice-based legal systems or even blended legal systems.³⁰ It would also show that most of the former

²⁶ This disagreement was also evident during the TRIPS Agreement negotiations concerning the issue of compulsory licensing. “Not only did the U.S. Draft impose no obligation of local working on patentees, as developing countries sought, but it also totally barred compulsory licensing as a remedy for a patentee’s failure to work locally, which the E.C. proposal expressly allowed. In short, the United States was proposing that there be only two permissible grounds for compulsory licensing: anti-competition violations and declared national emergencies. By comparison, the E.C. Draft was quite different because it did not restrict the available grounds for issuing a compulsory license, but instead stipulated procedures and conditions for such issuance.” *Id.*, at p. 375.

²⁷ *Id.*, at p. 390.

²⁸ See “Statement of Jerome H. Reichman, Testimony Before National Institutes of Health, Public Hearing On March-In Rights Under the Bayh-Dole Act” (May 25, 2004), (emphasis added) at: <http://www.essentialinventions.org/drug/reichman05252004.doc>, citing G. H. C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY AS REVISED AT STOCKHOLM IN 1967 70-71 (1968). “A State’s ability to impose compulsory licenses to regulate abuses of a foreign patentee’s exclusive rights under domestic law has been regulated by article 5A of the Paris Convention for more than 75 years, and these provisions were incorporated into the TRIPS Agreement of 1994. The large body of state practice in implementing these norms over time was succinctly and authoritatively summarized by Bodenhausen in 1967, as follows: “[W]hen national legislation is aiming at preventing *the abuses which might result from the exercise of the exclusive rights conferred by the patents*, the rules given in paragraphs (3) and (4) [of article 5A, Paris Convention] are mandatory for the member states...[E]xamples of such abuses may exist in cases where the owner of the patent, although working the patent in the country concerned, refuses to grant licenses on reasonable terms and thereby hampers industrial development, or does not supply the national market with sufficient quantities of the patented product, or *demand excessive prices, for such products*. The member states are free to define these, and other abuses” (emphasis supplied) *Id.*

²⁹ See Jerome H. Reichman and Catherine Hasenzahl, “Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA”, *supra* at p.2.

³⁰ See e.g., Lawrence A. Kogan, *Effort to Expand ‘Authentic Acts’ in Europe Imperils Economic Freedom*, Washington Legal Foundation Backgrounder Vol. 24 No. 6 (Feb. 13, 2009) at: http://www.wlf.org/upload/2-13-09Kogan_LegalBackgrounder.pdf; Lawrence A. Kogan, *The Creeping Authenticity of Europe’s Intrusive Civil Law System*, Institute for Trade, Standards and Sustainable Development, NotaryTalk of England and Wales website (Feb. 18, 2009) at: http://www.notaries.org.uk/eu_authentic_acts/files/page52_4.pdf and http://www.notaries.org.uk/eu_authentic_acts/eu_authentic_acts.html.

are located on the European continent and in Latin America and Southeast Asia, while most of the latter are located in North America, Oceania and East Asia.

More troublesome, is this document's nuanced portrayal of only one perspective concerning this most controversial subject matter. The document essentially extols the proactive government issuance of CLs, while it simultaneously ignores the substantive and procedural due process concerns of governments undertaking much more limited CL practices. The SCP Secretariat should seek to broaden its information gathering efforts to ensure the objectivity of this document. This means jettisoning the unspoken presumption embedded within this document (likely sanctioned by well-funded progressive academicians and universal access to knowledge / healthcare activist groups), that European and developing country CL practices to date *are* the international 'gold standard' to be incorporated ultimately within a global Substantive Patent Law Treaty (SPLT). Rather than merely restate and compare the CL practices within and among only these countries, this document should reflect new information about those governments featuring more limited CL practices around the world, against which the former could then be compared. The ITSSD recommends that the Secretariat commission such a comparison *before* it undertakes any further activity that could be interpreted as moving towards the harmonization of national patent laws based predominantly on only *one* model of CL practice. Lastly, Document SCP/13/3 appears to relegate the private property aspect of patents to second-class status vis-à-vis an enlightened vision of the 'public interest', which effectively renders such patents intellectually vulnerable to the unchecked discretions of governments known for their paternalistic and market-intrusive proclivities. This must end.

A considered first-step in this direction would entail the Secretariat's acknowledgement that, although WTO Members may employ compulsory licensing practices pursuant to TRIPS Article 31, those practices are now circumscribed by a robust statutory framework that "imposes strict conditions and procedural requirements for such issuance."³¹

"Indeed, Article 31 does impose many new procedural or substantive conditions. Under the new rules, each grant of a compulsory license must be considered on a case-by-case basis. [Art. 31(a)] The government must first make efforts to obtain a voluntary license. [Art. 31(b)] The patent holder must receive "adequate remuneration." [Art. 31(h)] Production must be predominantly for the domestic market. [Art. 31(f)] The license must be non-exclusive. [Art. 31(d)] Judicial review must be afforded for any decisions related to the compulsory license. [Art. 31(i)] And finally, the "scope and duration" of the license must be "limited to the purpose for which it was authorised," and must be liable to termination if the reasons underlying that authorization cease to exist. [Arts. 31(c),(g)]...[T]hese

³¹ "According to one scholar, 'negotiators weighed both options and preferred to leave open the cases where compulsory licensing...may be allowed.'" See Paul Champ and Amir Attaran, *supra* at p. 368, fn 15, citing DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING ANALYSIS AND NEGOTIATING HISTORY 165 (1998).



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*new rules certainly narrow the opportunity for countries to grant compulsory licenses...*³²

Admittedly, these TRIPS procedural requirements are relaxed somewhat where a CL is issued to address a public interest concern. For instance, in the event of a “national emergency or other circumstances of extreme urgency”, prior efforts to license on reasonable commercial terms are not required.³³ And, where a CL is issued to address a judicially or administratively determined anticompetitive use of a patent, there is no need either to make a prior effort to license or to limit the license to domestic use.³⁴

Arguably, however, compulsory licensing has been restricted under TRIPS to this extent because it comports with one of the two primary objectives of the treaty – *the recognition that intellectual property rights are private rights*.³⁵ This key concept has been acknowledged by a growing number of developing countries, including India and³⁶ Qatar.³⁷ It also apparently, conflicts with and is in stark contrast to the “conventional wisdom in [other] Asian countries, including Thailand, regarding IP enforcement against infringers, where conducting police raids rather than civil court procedures, and treating intellectual property rights as ‘public’ rather than ‘private’ rights is the norm.”³⁸

According to at least one commentator, paragraph four of the Preamble of the TRIPS Agreement makes it abundantly clear that such “recognition...ultimately protects the owners of intellectual property against confiscation or diminution of their rights by arbitrary acts of government.”³⁹ It does so, in part, by guaranteeing that intellectual property owners are paid due compensation for their rights.

³² *Id.*, at p.385, supra (emphasis added)..

³³ See TRIPS Article 31(b).

³⁴ See TRIPS Article 31(k).

³⁵ See Nuno Pires de Carvalho, “The TRIPS Regime of Trademarks and Designs” (Kluwer Law International © 2006) at p. 43, at: http://books.google.com/books?id=WyNen7A0WUkC&pg=PA46&lpg=PA46&dq=TRIPS+Article+31+%2B+emin+ent+domain&source=bl&ots=dCuc7H-uk8&sig=F2WlEJJDHjx8tNC0rFnPnLC2M&hl=en&ei=kLPKsA-JIsyrtgeaqfjuCQ&sa=X&oi=book_result&resnum=2&ct=result#PPA46,M1.

³⁶ See “Item 8: The Relationship Between the TRIPS Agreement and the Convention on Biodiversity – Communication from India”, World Trade Organization Committee on Trade and Environment WT/CTE/W/65 (Sept. 29, 1997) at par. II.3, at: http://commerce.nic.in/wt_cte_W65.pdf (“The preamble of the TRIPS Agreement recognizes intellectual property rights (IPRs) to be private rights”)

³⁷ See “Responses from Qatar to the Questions Posed by Australia, Canada, the European Communities and their member States, Switzerland and the United States”, World Trade Organization Council for Trade-Related Aspects of Intellectual Property Rights IP/C/W/346 (June 5, 2002) at p. 17, accessible at: http://www.wtcenter.org.tw/SmartKMS/do/www/readDoc?document_id=30100&action=content.

³⁸ “Conventional wisdom in the enforcement of IPRs in most Asian countries, as well as in Thailand, has always been conducting police raids and treats IPRs as ‘public rights’.” See Vichai Ariyanuntaka [Judge of the Central Intellectual Property and International Trade Court, Bangkok Thailand], “Enforcement of Intellectual Property Rights under TRIPS: A Case Study of Thailand”, US-ASEAN Business Council IPR Study at p. 1, at: http://www.us-asean.org/us-thai-fta/IPR_study.pdf.

³⁹ See Nuno Pires de Carvalho, “The TRIPS Regime of Trademarks and Designs” supra at p. 43.

“This language was adopted having in view the concerns of some Parties that, in spite of the measures taken to empower intellectual property right owners to enforce their rights, governments might be charged of non-compliance in the event right owners failed to do so. The paragraph, therefore, clarifies that the role of governments is to pass legislation and create the institutions that enable private citizens to protect themselves against infringement, rather than enforcing private rights on behalf of citizens.⁴⁰

In addition, paragraph four of the Preamble also ensures intellectual property owners that their rights are not merely passive rights, but also affirmative rights entitled to due process of law.

“[The language of paragraph four of the Preamble does not simply state that governments are not accountable for the failure or the lack of care of private citizens in enforcing their rights. In addition to that, paragraph four makes it clear that the TRIPS Agreement considers intellectual property rights the subject of private property, which means that those rights may not be taken by governments without due compensation. [In effect,]...the fourth paragraph...entails the right of private citizens to protect their legitimate interests against governments.”⁴¹

The significance of this interpretation of paragraph 4 of the TRIPS Preamble was also clearly recognized by the Government of Qatar as it responded during 2002 to questions posed by the United States with respect to the CL provisions within Qatar’s national IP legislation implementing the TRIPS Agreement.⁴²

Furthermore, in this commentator’s considered opinion, the spirit of paragraph four of the TRIPS Preamble manifests itself within TRIPS Articles 31(h) and 44.2. First, Article 31(h) mandates that when a compulsory license is issued, the rights holder will be paid ‘adequate’ remuneration based on the facts and circumstances of the individual case, taking into account the ‘economic

⁴⁰ *Id.*, at p. 45, *citing* Daniel Gervais, “The TRIPS Agreement – Drafting History and Analysis”, at 37 (Sweet & Maxwell, 1998).

⁴¹ *Id.*

⁴² The United States requested the following information: “**Please describe any provisions for compulsory licensing of patents in Qatar's law and explain how Qatar ensures that each of the conditions in Article 31 of the TRIPS Agreement is met in relation to any compulsory licences. Please cite to the relevant provisions of law.**” And, Qatar provided the following response: “Compulsory licences under the GCC regulation may be granted for public interest, and in case of lack of or insufficient working in the GCC states. The first ground is in conformity with the TRIPS Agreement, which establishes that intellectual property rights are private rights (paragraph 4 of the preamble) but they are subject to public policy objections (paragraph 5 of the preamble) as well as to the public interest (Article 8-1). The requirement to work the patented invention in the GCC states is in conformity with Article 5-A(2) of the Paris Convention and is in line with the legislative practice of several WTO members... The conditions and the procedure for the grant of compulsory licences - which include the payment of a fair compensation (Article 11 and 18 of the GCC regulation) [...]” (boldfaced emphasis in original) *Id.* at p. 46, *citing* “Responses from Qatar to the Questions Posed by Australia, Canada, the European Communities and their member States, Switzerland and the United States”, *supra* .

value’ of the license.⁴³ Second, Article 44.2 “establishes that Article 31(h) shall apply where the unauthorized use of the patented invention is carried by the government or by a third party authorized by the government.”⁴⁴ This clearly supports the guarantee set forth in TRIPS Articles 31(i) and (j) that patent holders are entitled, *as of right*, to the “judicial or other independent review by a distinct higher authority” within an expropriating WTO Member State, of “the legal validity of any decision relating to the authorization of such use”,⁴⁵ as well as, any decision relating to the remuneration provided in respect of such use”.⁴⁶

Moreover, this same commentator has argued that the due process rights embedded within the TRIPS Preamble and operative provisions cited are not diminished in any substantive way by the 2001 Doha Declaration on TRIPS and Public Health.⁴⁷ “The Doha Declaration has not changed [the principle] that any measure that limits private property rights in intangible goods must be compensated.”⁴⁸ He has also reasoned that Paragraph 3 of the Decision of the General Council of August 30, 2003, on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health⁴⁹ “should not be interpreted as a waiver of Article 31(h)” since at least one compulsory license (either in the exporting country or the importing country) will be granted for a fee.⁵⁰ Likewise, the implementation of Paragraph 3 should not result in a waiver of Article 31(h) to the extent that the grant of “two compulsory licenses ha[s] a particular impact on the economic value of the license”. He believes, in such case, “that value [would need to] be reflected in the compensation paid to the patent owner”.⁵¹ And the same arguably applies as

⁴³ “[T]he rightholder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”. See TRIPS Article 31(h)

⁴⁴ See Nuno Pires de Carvalho, “The TRIPS Regime of Trademarks and Designs”, *supra* at p. 46; “...[P]rovided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31.” See TRIPS Article 44.2.

⁴⁵ See TRIPS Article 31(i).

⁴⁶ See TRIPS Article 31(j).

⁴⁷ See WTO Ministerial 2001, Declaration on the TRIPs agreement and public health, WT/MIN(01)/DEC/2 (Nov. 14, 2001), (“Doha Declaration”), available at <http://docsonline.wto.org/imrd/directdoc.asp?DDFDdocuments/t/WT/Min01/DEC2.doc>.

⁴⁸ “...The Doha Declaration of the TRIPS Agreement and Public Health has been announced by commentators as the most important international development in intellectual property law since the adoption of the TRIPS Agreement. But it is not. Actually, rather than a major development, the separate Doha Declaration had the purpose of appeasing fears of developing countries that were totally unreal and that stemmed essentially from an overall misunderstanding of the international patent system. As a matter of course, no one would believe that the patent system – or any system of protection of private rights – could prevent a government from taking measures in order to protect public health...[G]overnments have the right to expropriate patents (and any other property rights, for that matter) whenever they find it necessary to pursue the public good. What the TRIPS Agreement does in that context is to make it clear that any measure that limits private property rights in intangible goods must be compensated.” See Nuno Pires de Carvalho, “The TRIPS Regime of Trademarks and Designs”, *supra* at pp. 197-198.

⁴⁹ See Decision of the General Council of August 30, 2003, on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health [http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm].

⁵⁰ See Nuno Pires de Carvalho, “The TRIPS Regime of Trademarks and Designs”, *supra* at p. 198.

⁵¹ *Id.*

concerns new Article 31.2*bis* contained within the Annex to the Protocol Amending the TRIPS Agreement⁵² (which endeavors to prevent the issuance of more than one CL), when, and if, it goes into force.⁵³

Lastly, this commentator has argued that TRIPS Articles 31(k) and 62.4 together reflect the clear message of TRIPS Preamble, paragraph 4, namely, that intellectual property rights, in the end, are private rights.

“Compulsory licenses granted under Article 31(k) have an impact on the maintenance of patent rights (for a failed compulsory license can lead to the revocation of the licensed patent), the provisions of Article 62.4 also apply in that context. This means that administrative or judicial procedures leading to granting a compulsory license are subject to the rules of equity and fairness, **namely the rule of the due process of law**. Even where the procedure leading to a compulsory license aims at remedying anti-competitive practice that is deemed illegal *per se*, the principle of due process applies. The TRIPS Agreement (as well as the Constitution of a vast majority of WTO members) does not permit the automatic imposition of sanctions to remedy anti-competitive practices without giving the patent owner a right of defense...A *per se* illegal anti-competitive practice is unjustifiable. However, the industrial property owner must be given the opportunity of defending him or herself in the sense that arguments may exist either to disqualify the practice from illegal *per se* to a measure that is subject to the rule of reason[fn] or simply to clarify that the practice did not occur. The due process of law must be observed in all cases in accordance with Article 41.2 and 3.”⁵⁴

In effect, these provisions serve to offset the diminution of patent owner rights which would otherwise follow from the imposition of remedies/sanctions, including compulsory licenses, for judicially or administratively determined anti-competition (antitrust) violations.

At least one Asian legal commentator, a Judge of the Central Intellectual Property and International Trade Court of Bangkok, Thailand, has expressed how he, too, has seen the light. Specifically, he, discusses the significance of TRIPS Preamble paragraph 4, and its relationship

⁵² See Article 31.2*bis*, Annex to the Protocol Amending the TRIPS Agreement, at: http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

⁵³ See Decision of the General Council of December 6, 2005, on the Amendment of the TRIPS Agreement, at: http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm. The approved Amendment of the TRIPS Agreement will make permanent the waivers granted by WTO Member States pursuant to “the decision on patents and public health originally adopted in 2003 [only] when two-thirds of the WTO’s members have accepted the change. They originally set themselves until 1 December 2007 to do this. The deadline was extended to 31 December 2009 under a decision by the General Council on 18 December 2007.” See “TRIPS and Public Health: Members Accepting Amendment of the TRIPS Agreement”, World Trade Organization Website at: http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

⁵⁴ See Nuno Pires de Carvalho, “The TRIPS Regime of Trademarks and Designs”, *supra* at p. 203 (boldfaced emphasis added).

to the due process-based civil procedures which IP owners, and even infringers, are afforded in common law jurisdictions and under TRIPS in connection with IPR enforcement matters.

“TRIPS in its preamble recognizes that intellectual property rights are private rights. In Anglo-American jurisdiction, most claimants in the IPRs enforcement make use of civil process, partly because its technique and atmosphere are appropriate to the assertion of private property rights amongst businessmen, and partly because the types of remedy -- in particular the injunction (interlocutory and permanent) and damages – are more useful than punishment in the name of the state...Suppose one may...reconsider the philosophy of enforcement [and] examine[] the common law technique and the TRIPs mechanism of enforcement of IPRs...In the long run it is suggested that if the procedure for enforcement of IPRs as private rights is adequate and effective, the legal profession efficient and knowledgeable[,] the enforcement of IPRs by civil proceedings may be a good or even better alternative to criminal proceedings...Treating IPRs as private rights and encouraging right owners to institute private prosecutions or civil actions for injunction and damages might be an answer.”⁵⁵

Unfortunately, for every soul that becomes enlightened about the importance of patents as private economic assets⁵⁶ and as an incentive to promote innovations⁵⁷ that generate both private and public benefits, there are many others who, because of their inability to grasp reality, or due to some ideological predisposition or reticence, remain huddled in the dark mumbling amongst themselves, that the TRIPS Agreement “establish[ed] rules for the appropriation of intellectual assets and the control over the production and trade of products derived therefrom.”⁵⁸ Tragically, it is these individuals and organizations that are committing the greatest disservice to

⁵⁵ See Vichai Ariyanuntaka [, Bangkok Thailand], “Enforcement of Intellectual Property Rights under TRIPS: A Case Study of Thailand”, supra at pp. 2 and 13.

⁵⁶ See “ITSSD Comments on Annex III of the Report on the International Patent System” (SCP/12/3 Rev.2) (Feb. 24, 2009) at: http://www.wipo.int/export/sites/www/scp/en/meetings/session_13/pdf/itssd_annex3.pdf.

⁵⁷ “[U]nlike tangible property rights such as real estate that carry along with them the concept of a basic ‘dignity’ of ownership, patents provide their owners with a tool for creating wealth only. It is not abstract ownership of the right that is important in this relationship, but rather what that right can do for its owner. The possibility of monopoly rents induces invention that otherwise might not exist.” See Daniel R. Cahoy, *Confronting Myths and Myopia on the Road from Doha*, Georgia Law Review, Vol. 42, 2007-08 at p. 156, at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=989817, citing U.S. Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Ch. 1, at 9–12 (2003) (“[O]ne could ask whether the claimed invention would have emerged in roughly the same time frame ‘but for’ the prospect of a patent.”).

⁵⁸ See Carlos M. Correa, “Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement”, (Oxford University Press © 2007), at Preface, at: <http://fds.oup.com/www.oup.co.uk/pdf/0-19-927128-3.pdf>. “As in other WTO agreements and the WTO Agreement itself, the TRIPS Agreement contains a detailed Preamble where the negotiating parties expressed the objectives that they sought in adopting this component of the WTO system. While the provisions of the Preamble reflect, to some extent, the different positions that the negotiating parties brought to the negotiating table, they substantially respond to the protectionist paradigm advocated by the United States and other developed countries with regard to intellectual property.” *Id.*, at Chap. 1, p.1,



the public by mischaracterizing and/or misrepresenting legal terms of art and distorting the positive legal and socio-economic impacts that patents and other proprietary IP rights have had and are capable of having upon national innovation systems, economic development opportunities and public welfare around the world⁵⁹ For example, this kind of mischaracterization/misrepresentation has often involved the intentional conflation of the terms ‘compulsory license’ and ‘non-commercial governmental use’.

It is quite clear, however, that the language contained in TRIPS Article 31, “*other use without authorization of the right holder*,” distinguishes between the practice of issuing compulsory licenses and government noncommercial use.

“The agreement allows compulsory licensing as part of the agreement’s overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. But the term ‘compulsory licensing’ does not appear in the TRIPS Agreement. Instead, the phrase ‘**other use without authorization of the right holder**’ appears in the title of **Article 31**. Compulsory licensing is only part of this since “other use” includes use by governments for their own purposes. Compulsory licensing and government use of a patent without the authorization of its owner can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder”.⁶⁰

And, this distinction is quite important. “United States patent law has no general statutory provisions, like those in foreign countries, designed to displace the operation of the free market with government decision making.”⁶¹ Consequently, the “statutory compulsory licensing of patents in favour of third parties in the United States is ‘virtually non-existent’”.⁶²

There is significant reason for this and it is grounded in the U.S. Constitution. Every U.S. citizen possesses an exclusive inalienable right to his or her discoveries and inventions that is recognized by Article I, Section 8, Clause 8, of the U.S. Constitution. The founders understood that temporary exclusive rights granted in property served as an adequate incentive to encourage the research and innovation by inventors and creators needed to ‘propel [the United States] from

⁵⁹ For an accurate assessment of the impact that patents and strong patents protection can have on attracting knowledge-based foreign direct investment, human capital development and economic development, See “ITSSD Comments on Annex III of the Report on the International Patent System” *supra*.

⁶⁰ See “FACT SHEET: TRIPS AND PHARMACEUTICAL PATENTS, Obligations and exceptions”, World Trade Organization website (emphasis in original) at: http://www.wto.org/English/tratop_e/trips_e/factsheet_pharm02_e.htm#anticompetitive .

⁶¹ See Jay Dratler, “Licensing of Intellectual Property”, (Law Journal Press © 2006) §3.03[2] at p. 3-28, at: http://books.google.com/books?id=ibtRO4PqdDEC&pg=PP13&lpg=PP13&dq=Jay+Dratler,+Licensing+of+Intellectual+Property&source=bl&ots=1oWPVeS6Wk&sig=WBC3PDjNnUV_YpqmXfe9o1Z1zSg&hl=en&ei=BTMSaT_HAd7VIOeGprjCQ&sa=X&oi=book_result&resnum=1&ct=result#PRA1-PT184.M1

⁶² See Jerome H. Reichman and Catherine Hasenzahl, “Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA”, *supra* at p. 21.

a small, agrarian colony into an advanced and prosperous country.’ *Such progress would not have been possible had the U.S. Government appropriated or retained for itself the rights to own and use patented inventions without first obtaining inventor consent or providing them with an economic return for their efforts.*⁶³ And, this was first recognized by the U.S. Supreme Court back in 1881.

“It has been the general practice, when inventions have been made which are desirable for government use, either for the government to purchase them from the inventors, and use them as secrets of the proper department; or, if a patent is granted, to pay the patentee a fair compensation for their use. *The United States has no such prerogative as that which is claimed by the sovereigns of England, by which it can reserve to itself, either expressly or by implication, a superior dominion and use in that which it grants by letters-patent to those who entitle themselves to such grants. The government of the United States, as well as the citizen, is subject to the Constitution; and when it grants a patent the grantee is entitled to it as a matter of right, and does not receive it, as was originally supposed to be the case in England, as a matter of grace and favor.*”⁶⁴

Paragraphs 189-190 – Government Non-Commercial Use - *In the United States of America, a third party who uses a patented invention in the performance of a Government contract in effect obtains immunity to liability for patent infringement of the patent. This is based on 28 USC §1498(a)...This provision acts as a codification of a defense in litigation between private parties. Consequently, where an infringement action is found in the performance of a Government contract, the recourse for the patentee is limited to a recovery of reasonable compensation.*

The following analysis will show that in those rare instances where the US government actually (directly or indirectly) *uses* privately owned patents without the owners’ consent or authorization for a narrowly tailored public purpose that *use* is typically treated as a ‘takings’ under the Fifth Amendment to the U.S. Bill of Rights accompanying the US Constitution. This designation reflects the US government’s express assumption of a legal and equitable liability to ensure that the rights holder receives the just compensation to which he or she is constitutionally entitled. Such an obligation brings with it an acknowledgement that strict preconditions must be met before the government may legally engage in such *use*.

Indeed, the US government has employed government ‘use’ provisions sparingly because of the social costs necessarily associated with overuse or an overbroad application, which can deter foreign as well as domestic investors and licensing. If a ‘government use’ provision is overused or over-extended in scope, it is likely to certainly deter foreign investors and licensing, and it

⁶³ See Lawrence A .Kogan, Brazil’s IP Opportunism Threatens U.S. Private Property Rights, 38 U. Miami Inter-Am. L. Rev. 1, 104-105 (2006) at: [http://www.itssd.org/Publications/IAL105-II\(frompublisher\)%5B2%5D.pdf](http://www.itssd.org/Publications/IAL105-II(frompublisher)%5B2%5D.pdf) .

⁶⁴ James v. Campbell, 104 U.S. 356, 358 (1881) (emphasis added); *see also* Hollister v. Benedict, 113 U.S. 59, 67 (1885).

may deter local investors and innovators as well. “Agencies that invoke a government use provision should, therefore, know what the likely social costs will be, and they should take such action only if the government is prepared to pay those costs.”⁶⁵

Paragraphs 189-190 correctly characterize 28 USC 1498⁶⁶ as a ‘governmental use’ statute that may be invoked to prevent U.S. government business from grinding to a halt as the result of an injunction being issued during the course of patent litigation between the government’s contractors and third parties. However, discerning readers will find it interesting that the description of 28 USC 1498 in Paragraphs 189-190 as a ‘litigation/infringement immunity provision’ is intentionally limited. It is also quite similar to the mischaracterization of this statute contained within a letter dated December 12, 2006, addressed from KEI President James Love to former US Ambassador and Trade Representative Susan Schwab.⁶⁷ As that letter reveals, Mr. Love and fellow KEI activist Ralph Nader intentionally mischaracterized this provision (among others) as a widely used government compulsory licensing provision. Love alleged in the letter how, during 2001, DHHS Secretary Tommy Thompson held out the threat of breaking Bayer’s patents on the drug Cipro pursuant to 28 USC 1498 in order to ensure that lower priced generic versions of the drug could be secured in the event of a possible anthrax attack. But, the Love letter failed to mention that Secretary Thompson never had the intention of breaking the Cipro patent since it would not have saved any money given Cipro’s meager 8% share of the government’s intended purchase.⁶⁸

Apart from providing evidence of such inaccuracy, the ITSSD would like to share with the SCP and its members and observers some of its research about 28 USC 1498, in the hope that it might promote a greater understanding of the broader legislative purpose behind it.

First, legal commentators have come to the conclusion that it is more likely in the nature of a *government ‘non-commercial use’* statute which is distinct from a compulsory license.⁶⁹

⁶⁵ See Jerome H. Reichman, “Compulsory Licensing of Patented Inventions: Comparing United States Law and Practice with Options under the TRIPS Agreement”, *supra* at p. 7.

⁶⁶ 28 U.S.C. 1498, at: <http://www4.law.cornell.edu/uscode/28/1498.html> .

⁶⁷ See “December 12 Letter from Jamie Love to USTR on Compulsory Licensing”, Consumer Project on Technology, at: <http://www.cptech.org/ip/health/c/thailand/ustr12dec2006thailand.html> .

⁶⁸ “[Thompson] said that at present ‘there was no need’ to override Bayer’s Cipro patent. ‘We have plenty of Cipro right now,’ he said (Pear, *New York Times*, 10/20). Tony Jewell, an HHS spokesperson, said that agency officials ‘do not believe’ that breaking the patent is necessary, adding, ‘It would not save money to break the patent.’ Bayer supplies the government with Cipro at a discounted price of \$1.83 per tablet. Thompson said Saturday that he has negotiated with Bayer and other drug companies to purchase about 1.2 billion doses of antibiotics to treat 10 million Americans for 60 days in the event of an anthrax outbreak. Federal health officials last Friday said Cipro makes up only about 8% of the pills that the government plans to purchase. The remainder will be generic versions of other antibiotics such as penicillin and doxycycline (*Washington Post*, 10/20).” See “Thompson Negotiating With Drug Companies to Purchase Anthrax Antibiotics; Sees No Need to Override Cipro Patent”, Kaiser Daily Health Policy Report (Oct. 22, 2001) at: http://www.kaisernetwork.org/Daily_reports/rep_index.cfm?DR_ID=7586 .

⁶⁹ “A related matter – distinct from compulsory licensing but sometimes confused with it – provides special remedies for certain governmental uses of intellectual property that are found to infringe intellectual property rights.” See Ronald Cass, “Compulsory Licensing of Intellectual Property: The Exception That Ate the Rule?”, Washington Legal Foundation (Sept. 2007) at p. 10, <http://www.wlf.org/upload/casswpCover.pdf>.



“Overall, § 1498(a) is different from foreign [compulsory licensing] statutes in several ways, including its location within the overall structure of U.S. law [it is separate and independent from the U.S. Patent Act],⁷⁰ the entities allowed to enjoy immunity under it, the procedure by which a petition for immunity is made, the conditions under which the government may use the subject matter of a private patent, and the rights and remedies provided to the patentee.”⁷¹

Indeed, § 1498(a) is not a compulsory license provision. There is no government agency to oversee the exercise of § 1498(a) power by performing individual merit-based considerations, nor is the government required to engage in prior negotiation with the patentee. It is arguable, therefore, that § 1498(a) does not satisfy the mandatory licensure requirements of [TRIPS] article 30. Furthermore, because § 1498(a) places no restrictions on the government’s use, it arguably does not comply with [TRIPS] article 31(f), which restricts government use of the subject matter of a patent to the government’s domestic market”.⁷²

Such an interpretation is more or less consistent with the purpose of the statute, which is “to allow *important governmental functions* to proceed without fear of interruption through issuance of injunctions against the government or its contractors”.⁷³

The legislative history accompanying the precursor to this provision, as described by the U.S. Supreme Court in the case of *Richmond Screw Anchor Co., Inc. v. United States*,⁷⁴ reveals that it was enacted originally during World War I, as part of the Naval Appropriations Act of 1918⁷⁵ for military (Defense Department) purposes. Apparently, the then Acting Secretary of the Navy had written a letter to the chairman of the Senate Committee on Naval Affairs expressing his frustration about how manufacturers had been reluctant to take Navy contracts, because under the predecessor Act of 1910 (chapter 423, 36 Stat. 851 (35 USCA 68; Comp. St. 9465)),⁷⁶ they had remained “exposed to expensive [patent infringement] litigation, involving the possibilities of prohibitive injunction payment of royalties, rendering of accounts, and payment of punitive damages.” The Navy was genuinely concerned that unless an amendment to the 1910 Act was

⁷⁰ See, e.g., David R. Lipson, “We’re Not Under Title 35 Anymore: Patent Litigation Against the United States Under 28 U.S.C. 1498(A)”, 33 PUB. CONT. L.J. 243, 247 (Fall 2003).

⁷¹ See COMMENT, “A Comparison of 28 U.S.C. § 1498(A) and Foreign Statutes and An Analysis Of § 1498(A)’S Compliance With TRIPS”, 41 Houston Law Review 1659, 1670-71 (2005) at: http://www.houstonlawreview.org/archive/downloads/41-5_pdf/ren.pdf.

⁷² *Id.*, at p. 1683 (emphasis added).

⁷³ See Ronald Cass, “Compulsory Licensing of Intellectual Property: The Exception That Ate the Rule?”, *supra*, at p. 10(emphasis added); Cf. Daya Shanker, “Korea, Pharmaceutical Industry and Non-commercial use of Compulsory Licenses in TRIPS” University of Wolloongong (2003) at pp. 31, 36, at:

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=438880 (The author argues that the WTO TRIPS Agreement and 28 U.S.C. 1498 do not confine ‘public non-commercial use’ to governmental use only, and consequently does not restrict such use to ‘legitimate government functions’).

⁷⁴ *Richmond Screw Anchor Co., Inc. v. United States*, 275 U.S. 331 (1928), at: <http://caselaw.lp.findlaw.com/cgi-bin/getcase.pl?court=us&vol=275&invol=331>.

⁷⁵ *Id.*, cited in Danielle M. Conway, “One Step Outside the Country, One Step Back from Patent Infringement”, *The Army Lawyer* department of the Army Pamphlet 27-50-404 (Jan. 2007) at p. 138, at: http://www.loc.gov/rr/frd/Military_Law/pdf/01-2007.pdf.

⁷⁶ This Act was otherwise known as “An Act to Provide Additional Protection for Owners of Patents of the United States, and for Other Purposes.”

adopted to correct that situation, it would have resulted in a “serious disadvantage to the public interests” and would have “[unduly restrict[ed]]...vital activities of this department... at [a critical] time...”⁷⁷

The Navy’s preferred solution, as reflected in the amendment finally adopted, was

“to stimulate contractors and *furnish what was needed for the war*, without fear of becoming liable themselves for infringements to inventors or owners or assignees of patents... To accomplish *this governmental purpose*, Congress exercised the power to take away the right of the owner of the patent to recover from the contractor for infringements.”⁷⁸

Second, the legislative history accompanying the enactment of the predecessor 1910 Act⁷⁹ “indicates that Congress believed that the Fifth Amendment protected patents and that patent infringement by the government was an exercise of *eminent domain*” (emphasis added).⁸⁰

“...[T]he House Report that accompanied the [1910] bill described patent infringement by the government as a Fifth Amendment taking. ‘When the United States issues a patent to an inventor he takes an absolute and exclusive property right in that invention, which, under the Constitution, can no more be taken away from him without compensation than his house’...In the House debate, Members repeatedly described the remedy at issue in terms of providing just compensation for a taking, such as Representative Crumpacker’s statement that ‘the Constitution declares that there shall be property in inventions, and the Supreme Court . . . has held that they are as much property as any other species of property can be, and that property can not be taken without due process of law or without just compensation.’”⁸¹

Thus, the US Solicitor General and the Supreme Court had good reason to emphasize that what was then being sought in the 1918 amendment to the 1910 Act was “more than a waiver of immunity and *effect[ed] an assumption of liability by the government*”.⁸² It limited the patent owner and his assigns to recovery against the United States “of his reasonable and entire compensation for such use and manufacture. The word ‘entire’ emphasizes the exclusive and

⁷⁷ *Richmond Screw Anchor Co., Inc. v. United States*, 275 U.S. 331, 343.

⁷⁸ *Id.*, at 345. “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...” (emphasis added). *Id.*, at 344.

⁷⁹ Act of June 25, 1910, 36 Stat. 851 (1910).

⁸⁰ See Justin Torres, “The Government Giveth, and the Government Taketh Away: Patents, Takings, and 28 U.S.C. §1498”, NYU Annual Survey of American Law, Vol. 61, (2007), at pp. 12-13, at: <http://ssrn.com/abstract=970567>.

⁸¹ *Id.*, citing H.R. REP. No. 61-1288, at 1 (1910); 45 CONG. REC. 8756 (1910) (statement of Rep. Crumpacker); “(see also *id.* at 8771 (statement of Rep. Lenroot) (A patent “is a property right, and the government has no more right to take that invention from the inventor and use it for itself than it has to go and appropriate the home of any Member of this House, and when it does it ought to be compelled to compensate him for it.”). The fairness rationale that underlies the Fifth Amendment was also referenced repeatedly. See, e.g., *id.* at 8758 (statement of Rep. Graham) (“It is a bill to require the United States Government to live up to the eighth commandment, ‘Thou shalt not steal.’ What right have they to steal a man’s patent?”); *id.* at 8783 (statement of Rep. Burke) (Claiming that nothing “justif[ies] this great Government in leading in a practice of piracy in patents, in invading the rights and despoiling the property of genius.”)).

⁸² *Richmond Screw Anchor Co., Inc. v. United States*, 275 U.S. 331, 344.



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comprehensive character of the remedy.”⁸³ According to the Court, therefore, since an important component of the patent holder’s right of ‘exclusivity’ had been diminished, the Act triggered ‘takings’ obligations under the Fifth Amendment to the US Constitution which the US government was required to fulfill.

*“This is not a case of a mere declared immunity of the government from liability for its own torts. It is an attempt to take away from a private citizen his lawful claim for damage to his property by another private person, which but for this act he would have against the private wrongdoer. This result...would seem to raise a serious question as to the constitutionality of the act of 1918 under the Fifth Amendment to the Federal Constitution. We must presume that Congress in the passage of the act of 1918 intended to secure to the owner of the patent the exact equivalent of what it was taking away from him. It was taking away his assignable claims against the contractor for the latter's infringement of his patent. The assignability of such claims was an important element in their value and a matter to be taken into account in providing for their just equivalent”.*⁸⁴

Other legal commentators, as well, have agreed that such a “limitation on remedies rightly is viewed as a limitation on IP rights, as it reduces the property owners’ effective control over exclusive use – unless damage remedies are as threatening to infringers as injunctive remedies”.⁸⁵ This would comport with the Supreme Court’s understanding that whatever monetary remedy is provided must qualify as a ‘just equivalent’ to what has been ‘taken’. Thus, where the government provides less than equivalent value, it would remove most, if not all, indicia of ownership and control (dominion) over the patent.⁸⁶

Similarly, at least one commentator has characterized 28 U.S.C. 1498 as merely a *jurisdictional* statute that identifies “the Court of Federal Claims as the exclusive forum for adjudicating a class of [eminent domain]⁸⁷ claims for which the government *has already accrued liability under the*

⁸³ *Id.*

⁸⁴ *Id.*, at 345 (emphasis added). “Although an injunction is the normal remedy in a private patent infringement suit,25 under § 1498(a) a patentee cannot enjoin an infringer from using or making the subject matter of the patentee’s invention. The patentee’s sole remedy under § 1498(a) is reasonable compensation. Therefore § 1498(a) leaves very little in the patent owner’s bundle of rights—the only property right remaining is the right to collect reasonable compensation” (emphasis added). See COMMENT, “A Comparison of 28 U.S.C. § 1498(A) and Foreign Statutes and An Analysis Of § 1498(A)’S Compliance With TRIPS”, at pp. 1664-1665.

⁸⁵ See Ronald Cass, “Compulsory Licensing of Intellectual Property: The Exception That Ate the Rule?”, *supra* at p. 10.

⁸⁶ *Id.*

⁸⁷ See Justin Torres, “The Government Giveth, and the Government Taketh Away: Patents, Takings, and 28 U.S.C. § 1498”, *supra* at p. 19, (emphasis added) citing JAMES F. DAVIS, ED., U.S. COURT OF CLAIMS PATENT PRACTICE 25 (1970) (3d ed.) (“[U]nauthorized use of a patented invention by the Government is usually not considered a tort, but rather a taking of the patent property by eminent domain.”); David R. Lipson, *We’re Not Under Title 35 Anymore: Patent Litigation Against the United States Under § 1498(a)*, 33 PUB. CON. L. J. 243, 245 (2003) *supra*; (“Section 1498(a) cases thus are not truly ‘infringement’ cases, but rather actions to recover compensation Against the United States and Government Contractors Under 28 U.S.C. § 1498 in the United States Court of Federal Claims”), 2 J. INTELL. PROP. L. 389, 417 (1995) (“[S]uit under § 1498 in the United States Court of Federal Claims is an action in eminent domain.”); *Hughes Aircraft Co. v. United States*, 86 F.3d 1566, 1571 (Fed. Cir. 1996) (“The government’s unlicensed use of a patented invention is properly viewed as a taking of property under the Fifth Amendment through the government’s exercise of its power of eminent domain and the



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Fifth Amendment”. This commentator relies upon prior Supreme Court decisions under the Tucker Act,⁸⁸ which essentially serves an analogous function to that of 14 U.S.C. 1498 with respect to causes of action arising from unauthorized government use of private property *other than* patents or copyrights⁸⁹ (the infringement of which by private parties would ordinarily constitute a civil law ‘tort’).⁹⁰ He also relies on the informed and well-reasoned dissenting opinion of Senior Federal Circuit Court Judge Plager in the *Zoltek* case.⁹¹ Justice Plager challenged a divided Court’s seriously flawed holding in *Zoltek v. United States*,⁹² which held that patents were *not* ‘property’ within the meaning of the Fifth Amendment (the ‘takings’ clause) of the U.S. Constitution.⁹³

patent holder’s remedy for such use is prescribed by 28 U.S.C. § 1498(a)”); *Irving Air Chute Co. v. United States*, 93 F. Supp. 633, 635 (Ct. Cl. 1950) (Section 1498 “is in effect, an eminent domain statute, which entitles the Government to manufacture or use a patented article becoming liable to pay compensation to the owner of the patent.”); *Wright v. United States*, 53 Fed Cl. 466, 469 (2002) (“Compensation is premised on a Fifth Amendment taking of a nonexclusive license under the patent.”).

⁸⁸ See The Tucker Act, 28 U.S.C. 1491, “Claims against United States generally; actions involving Tennessee Valley Authority”, at: <http://www.law.cornell.edu/uscode/28/1491.html> . “The United States Claims Court shall have jurisdiction to render judgment upon any claim against the United States founded either upon the Constitution, or any Act of Congress or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases *not* sounding in tort.” 28 U.S.C. 1491(a).

⁸⁹ See, e.g., *Jacobs v. United States*, 290 U.S. 13, 16 (1933) (“[T]he Tucker Act is not a waiver of sovereign immunity for takings claims: ‘The suits were thus founded upon the Constitution of the United States’”); *United States v. Clarke*, 445 U.S. 253, 257 (1980) (describing the Fifth Amendment as self-executing...[and] ...requir[ing] a refinement in judicial understanding of the Tucker Act, which is now construed as a jurisdictional statute that creates no substantive right of recovery”); *United States v. Testan*, 424 U.S. 392, 398 (1976).

⁹⁰ “Infringement, whether direct or contributory, is essentially a tort, and implies invasion of some right of the patentee”. *Carbice Corp. of Am. v. American Patents Dev. Corp.*, 283 U.S. 27, 33, 51 S.Ct. 334, 336, 75 L.Ed. 819 (1931). The Government, unlike a private party, cannot commit the ‘tort’ of patent infringement. Rather, its unauthorized use of a patented invention is viewed as an eminent domain ‘taking’ of a license under the patent.

⁹¹ “There are two separate though related issues in this case, both matters of first impression. One is of major significance to our understanding of the constitutional obligations of the United States (“United States” or “Government”); both relate as well to important rights of patent owners. The first issue is, may an owner of a United States patent bring a cause of action under the Fifth Amendment to the Constitution against the United States for a ‘taking’ as all other owners of property rights may; or is a patent right somehow less of a property interest, not worthy of such constitutional protection? Until this case, this issue has never been addressed directly by this or any other court.” *Zoltek v. United States* 442 F.3d 1345, 1370-1371 (C.A.Fed. 2006).

⁹² *Zoltek v. United States* 442 F.3d 1345 (C.A.Fed. 2006).

⁹³ “A divided panel of the Federal Circuit has just ruled that patentees can not sue for the taking of a property interest under the Constitution, but only for compensation under a tort theory within the parameters of section 1498.” See Jerome H. Reichman, “Compulsory Licensing of Patented Inventions: Comparing United States Law and Practice with Options under the TRIPS Agreement”, presented to the AALS Mid-Year Workshop on Intellectual Property Vancouver, Canada (June 14-16, 2006) at p. 5, at: <http://www.aals.org/documents/2006intprop/JeromeReichmanOutline.pdf> . “The [Court of Federal Claims] CFC [had undertaken] an extensive review of the cases from th[e] U.S. Supreme] Court and others and concluded that patents are property rights and government activity that would otherwise infringe patent rights, but that is not covered by § 1498, constitutes a taking...subject to a claim under the Fifth Amendment.” *Zoltek v. United States*, 51 Fed. Cl. 829, (2002) at App. C17-C26. On appeal, “the Federal Circuit, *per curiam*...rejected the CFC’s discussion of the subsequent century of takings jurisprudence, arguing that patent rights were not ‘property’ protected by the Fifth Amendment, but rather were ‘creature of federal law’ protected only by such relief as the federal government saw fit to grant under § 1498.” *Zoltek v. United States* 442 F.3d 1345, 1352 (C.A.Fed. 2006).

According to at least one legal commentator, 28 USC 1498 serves another valuable purpose. This U.S. government non-commercial use statute arguably fulfills the TRIPS Article 31(h)⁹⁴ ‘adequate remuneration’ (‘but for’/ ‘made whole’) standard,⁹⁵ *as well as*, the U.S. Bill of Rights’ Fifth Amendment eminent domain/‘market value’-based ‘just compensation’ and ‘due process of law’ requirements.⁹⁶ And each comports with property-focused ‘market compensation theory’.

“The market compensation theory is essentially the one followed by the United States in determining the accountability of the federal government for unauthorized use of a patent invention. By virtue of 28 U.S.C. § 1498, a jurisdictional statute that waives sovereign immunity and permits patent owners to sue the government in the Court of Federal Claims, compensation may be obtained...[R]ecent appellate decisions have declared that full, infringement-like compensation may be appropriate in many instances. Specifically, the U.S. Court of Appeals for the Federal Circuit has held that lost profits compensation may be appropriate in some § 1498 cases. A reasonable royalty can be obtained in cases where the plaintiff cannot meet the lost profits criteria.”⁹⁷

This commentator believes that a threefold benefit would be derived from internationalizing 28 USC 1498 at the WTO TRIPS level. First, the ability of patent owners to fully exploit and profit from their inventions and to reap the rewards of disseminating valuable knowledge throughout

⁹⁴ TRIPS Article 31(h) requires that “the economic value of the authorization” be taken into account in determining compensation in order to approximate what amounts to ‘market value’.

⁹⁵ Market compensation theory generally provides a window through which to understand the economic impact of government expropriation of private property rights. “[T]he financial impact of reducing the right to exclude is an unanticipated burden imposed on the patent owner; the expected income that provided the investment incentive is retroactively reduced, and future investment may be viewed as a greater risk. Under [market compensation] theory, while powerless to enjoin the government’s act, the patent owner has a right to be insulated from the government’s decision to increase public access to the invention. To determine the appropriate remedy, one must assess what the patent owner has lost as a result of the compulsory license. To the extent a patent holder suffers a demonstrable loss of sales the compensation could reasonably constitute the profits that were lost as a result. Alternatively, if only a licensing opportunity was eliminated, the royalties that would have flowed from such an arrangement could provide the measure of remuneration. In the context of private patent litigation, a successful patent owner would be entitled to receive damages sufficient to place him in the financial position he would have occupied had the infringement not occurred.” See Daniel R. Cahoy, *Confronting Myths and Myopia on the Road from Doha*, Georgia Law Review, Vol. 42, 2007-08, *supra* at pp. 156-157.

⁹⁶ “The U.S. Supreme Court has defined the ‘just compensation’ requirement as ensuring payment that amounts to ‘full and adequate compensation’ or ‘a full and perfect equivalent for’ whatever interest in or share of real or personal property has been taken. It also ruled that the value of the property interest in question shall be determined “by refer[ring] to the uses for which the property is suitable, having regard to the existing business and wants of the community, or such as may be reasonably expected in the immediate future....” In other words, just compensation must reflect the fair market value of the property, or what a willing buyer would pay a willing seller. If circumstances render it difficult to calculate fair market value, or such value is not otherwise ascertainable, then other data must be utilized that will yield a fair compensation that reflects the true economic value of the asset taken. A similar standard, as applicable to patents, has since been codified into federal law...28 U.S.C. § 1498.” See Lawrence A. Kogan, “Brazil’s IP Opportunism Threatens U.S. Private Property Rights”, *supra* at pp. 107-108.

⁹⁷ *Id.*, at pp. 157-158.



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society would be preserved. Second, since licensing countries and their societies rather than private companies would bear the full market cost of obtaining inventions, there would be fewer compulsory licenses issued; countries would likely only issue a compulsory license when negotiation fails or the desired quantities could not be produced by the patent owner. Third, abusive product pricing would no longer be possible because of the patentee's inability to seek injunctive relief as the result of the government's waiver of sovereign immunity.⁹⁸

Arguably, such an approach would go a long way toward maintaining the delicate balance of public-private interests implicit within Article I, Section 8, Clause 8, of the U.S. Constitution (the 'inventors clause') and the Fifth Amendment of the U.S. Bill of Rights ('the taking clause'). After all, foreign governments must not overlook the important role the U.S. Supreme Court has played in this area of U.S. constitutional jurisprudence. It has held that the U.S. Government cannot act against, and must affirmatively protect, outside of the territory of the United States, any and all of the constitutional rights guaranteed to U.S. citizens by the U.S. Constitution and the Bill of Rights within the United States. The Fifth Amendment right against the taking of private property for public use without just compensation falls within this obligation. This has remained the law of the land for over 150 years.

In addition, foreign governments must also be aware of the U.S. constitutional 'separation of powers' questions that are likely to arise where their actions impair the constitutionally protected private IP rights of U.S. citizens. In particular, the obligation of the federal government to protect the private property rights held by U.S. citizens outside of U.S. borders against unlawful appropriation also extends to takings effectuated pursuant to treaties. While treaties and federal statutes constitute the "supreme law of the United States," and are effectively equal to one another in status, they are both inferior to the U.S. Constitution and the Bill of Rights. The U.S. Supreme Court recognized this hierarchy almost fifty years ago, in the case of *Reid v. Covert*. Thus, according to the Court, it is arguable that the President cannot execute and that Congress can neither ratify nor enact legislation implementing a treaty with another nation that effectively violates *any* of the Constitutional protections afforded U.S. citizens. Furthermore, "the records of the Virginia Ratifying Convention contain specific discussions of the scope of the treaty power. These discussions confirm that the Framers did in fact envision [constitutional] limitations on the treaty power."

⁹⁸ "The main benefit of the market compensation theory is that it preserves almost all of the reasons for having a property system for innovation in the first place. A patent owner has the ability to exploit and profit from the invention to the fullest, and to reap the rewards of providing the world with an important piece of biomedical information. The licensing country, on the other hand, must bear the full costs of obtaining the drug. By imposing the market cost as a compensation measure, countries will only issue a compulsory license when negotiation fails or the desired quantities cannot be produced by the patent owner. Such a system may create exactly the right kind of incentives. Instead of transposing the costs of a medical crisis on the drug manufacturer, society will bear them, preserving the initial investment incentive. *Price gouging or supramonopoly rents through holdout behavior will not be possible due to the elimination of injunctive relief as an option*" (emphasis added). See Daniel R. Cahoy, *Confronting Myths and Myopia on the Road from Doha*, Georgia Law Review, Vol. 42, 2007-08, *supra* at 159-160

Consequently, the President, in the exercise of his Article II powers, and the Congress, in the exercise of its Article I powers, would therefore be constitutionally precluded from executing *and implementing* a treaty the provisions of which did *not* adequately protect U.S. citizens against non- or poorly compensable takings of their intellectual property by a foreign treaty party's government. Indeed, this is perhaps why the U.S. Government has insisted that a takings clause be included within Article 31 of the TRIPS Agreement, Chapters 11 and 17 of the North American Free Trade Agreement (NAFTA), the Central American Free Trade Agreement (CAFTA), and the many free trade agreements and bilateral investment treaties it has consummated with other nations around the world. With this history and court precedent in mind, why should foreign governments be able to claim that *they* are entitled to the private IPRs of U.S. citizens that the U.S. Government can neither legally appropriate for itself for a public interest without paying just compensation, nor otherwise abandon at the expense of rights holders?⁹⁹ Perhaps, SCP members and observers should ponder this a bit before demanding the surrender of private U.S. IP rights at concession-rate prices.

Such a market compensation-based approach, furthermore, would help to reconcile the TRIPS Agreement's two primary public policy objectives: 1) "to reduce distortions and impediments to international trade"; and 2) to "recognize[] intellectual property rights...as private rights".¹⁰⁰ At least one commentator, who views compulsory licensing ultimately as a trade issue, has referenced these objectives in his discussion about how CL-related cross-border disagreements could be resolved in primarily economic terms through use of the WTO's well-oiled dispute settlement mechanism to determine 'adequate', 'just', 'full' compensation.¹⁰¹

"The analysis of TRIPS text offers a conception of 'adequate remuneration' that recognizes actual commercial opportunities foregone within the scope of an NVUA¹⁰²-putting the right holder in the position of a legitimate participant in commercial competition with clear and irreducible, if clearly bounded, entitlements. 'Adequate remuneration', then, is set at the level that ensures no prejudice to legitimate expectations of commercial opportunity. Legitimacy of opportunity is determined by the formal legal standards established within TRIPS as a general framework within which domestic legal and commercial systems should function to yield the social benefits of innovation and competition: a fundamental systemic interest shared by all trading nations."¹⁰³

⁹⁹ See Lawrence A. Kogan, "Brazil's IP Opportunism Threatens U.S. Private Property Rights", *supra* at pp. 114-116, 118.

¹⁰⁰ See Nuno Pires de Carvalho, "The TRIPS Regime of Trademarks and Designs" *supra* at p. 43.

¹⁰¹ See Antony Taubman, "Rethinking Trips: 'Adequate Remuneration' for Non-Voluntary Patent Licensing", *Journal of International Economic Law* (Dec. 2008).

¹⁰² "[N]on-voluntary use authorizations ('NVUAs')...are conscious interventions by an administrative or judicial authority, on the grounds of failure of effective competition or on other public interest grounds, that permit third parties or government agencies to make significant use of patented technology without the authorization of the patent holder, subject to remuneration." *Id.*, at p. 3. Despite their important legal distinctions, the author's definition of NVUAs refers collectively to both compulsory licenses and 'other authorizations' for discussion purposes.

¹⁰³ *Id.*, at p. 20.

Above and beyond 28 USC 1498, the Bayh-Dole Act (1980) (P.L. 96-517, Patent and Trademark Act Amendments of 1980) is another prime example of a U.S. governmental non-commercial use statute that may be employed only under the narrowest of circumstances. The Bayh-Dole Act's purpose was to trigger innovations and to stimulate the US economy by providing federal executive agencies with the means of shifting (transferring) legal title to federally funded ideas and patents from the government virtually free of cost to those private hands (approved universities, small businesses and non-profit organizations) most capable of securing the monies and expertise needed to commercialize them. The US Congress recognized that the public would benefit from a uniform patent policy that permitted universities and non-profits to elect ownership of legal title to federally-funded inventions and to work with companies to bring them to market. The Bayh-Dole Act encouraged universities and non-profits to become directly involved in the commercialization process by allowing them to *exclusively license* such R&D to private entities. This promoted innovation and technology transfer by creating economic incentives for university researchers to consider the practical applications of their discoveries and for universities to search out potential companies to develop them.

In effect, embedded within the Bayh-Dole Act was a societal compromise reached between Government, research institutions, industry, taxpayers and consumers. It aimed to spur research and bring new inventions to the market for the benefit of all. The US Government's part of the bargain consists of: "ensur[ing] that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise"; promot[ing] the commercialization and public availability of inventions made in the United States by United States industry and labor;" and "ensur[ing] that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions".¹⁰⁴

To fulfill its end of the bargain, the government was vested with a significant power to exercise 'march in' rights in the event the grantees of federally-funded R&D failed to fulfill *their* obligations, and as a result, frustrated the several purposes of the Act. This power, nonetheless, was circumscribed by strict limitations and conditions in order to avoid deterring the types of enabling investments and break-through innovations the Act sought to inspire. Furthermore, it was well recognized how the inclusion of an overly flexible 'march-in' rights provision (similar to those in foreign countries that practice 'compulsory licensing) "could potentially devastate [small] company[ies] that expect[] and need[] an exclusive license to technology". For this reason, "the government has *never* granted such a forced license, and has only received one compulsory license request."^{105 106}

¹⁰⁴ 18 U.S.C. 200 et seq.

¹⁰⁵ See Tamsen Valoir, "The Bayh-Dole Act: Eight Points that Every Technology Company Should Know" (published in Intellectual Property Today, at 36 -37 (Nov. 11, 2001)) at: <http://www.bakernet.com/NR/rdonlyres/A4DD2727-EE2C-431C-92CA-675AE5D0C71E/0/TheBayhDoleAct.pdf> . See also IPMG Working Document, "Detailed Overview of the Patent System of the United States of America", Center for Intellectual Property Policy at p. 9 at: <http://www.cipp.mcgill.ca/data/world/00000011.pdf> citing Donna Gitter, "International Conflicts over Patenting Human DNA Sequences in the United States and the European

Pursuant to 18 U.S.C. Sec. 203(1), “the Federal agency under whose funding agreement [an] invention was made shall have the right... to require the contractor,¹⁰⁷ an assignee, or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances”.¹⁰⁸ Furthermore, “if the contractor, assignee, or exclusive licensee refuses such request” the Federal agency shall have the right to step-in and “to grant such a license itself.”¹⁰⁹

One may justifiably argue that there is good reason for concern about the potential for abuse given the low or no-cost government knowledge (basic research and development) that companies receive as part of the grand Bayh-Dole bargain.

“Under normal conditions, the patentee assumes the full risk of his or her research and development expenditures, and in U.S. law, there are relatively few constraints on the licensing practices by means of which the patentee tries to recoup that investment and turn a profit. Under Bayh-Dole, however, the government will have funded a significant part of the patentee’s R&D costs and thus attenuated the risk.”¹¹⁰

However, even considering these risks, Congress clearly believed that the government must first determine that the exercise of its ‘march-in’ rights is absolutely necessary: 1) “because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve ‘practical application’¹¹¹ of the ‘subject invention’¹¹² in such field of use”; 2) “to

Union: An Argument for Compulsory Licensing and a Fair-Use Exemptions” (2001) 76 N.Y.U.L. Rev. 1623. (Although “[t]he *Bayh-Dole Act*, permits the federal government to require federally funded patentee to grant licenses under its patent to third-party applicants where the party holding title to the patent has failed to achieve sufficient practical application of the invention (35 U.S.C. 203(1)(a)(1994) or where action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee or their licensees (35 USC 203(1)(b). *The government has never actually exercised this right*”).

¹⁰⁶ “If research is supported by U.S. gov[ernmen]t grants, *then march-in rights theoretically exist but [are] almost impossible to trigger*. [M]arch-in rights allow gov[ernmen]t to force nonexclusive license under patent supported by gov[ernmen]t funding. [T]angential to the patent infringement action brought by CellPro against Hopkins, whose patents contained broad claims to antibodies for isolating stem cells & stem cells as products, were held valid and enforceable (CAFC 1998),] *CellPro petitioned NIH to exercise march-in rights as to Hopkins’ stem cell patents. NIH denied the CellPro petition*: The NIH has evaluated the administrative record with regard to two prongs of the statutory criteria, 35 U.S.C. § 203(1)(a) and (b). The NIH has examined whether, (1) Baxter has failed to take, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject inventions; and, (2) there exists a health or safety need which is not reasonably satisfied by Hopkins or Baxter. Based on these criteria and the available information, march-in is not warranted at this time” (emphasis added). See Stephen B. Maebius, “Patenting Stem Cell Research & Developments in Regenerative Medicine”, at pp. 6-8, at: http://www.foley.com/files/tbl_s31Publications/FileUpload137/889/maebius_stemcell.pdf.

¹⁰⁷ “The term ‘contractor’ means any person, small business firm, or nonprofit organization that is a party to a funding agreement”. 18 U.S.C. 201(c).

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ See Statement of Jerome H. Reichman, Testimony Before National Institutes for Health Public Hearing on March-In Rights Under the Bayh-Dole Act (May 25, 2004) supra, at p. 3.

¹¹¹ “The term ‘practical application’ means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such

alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees”; 3) “to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees”; or 4) “because the agreement required by section 204 [an agreement secured from the government to waive the requirement to manufacture the subject matter of the patent substantially within the US] has not been obtained and the condition has not otherwise been waived OR because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204”.¹¹³

Despite this reality, academicians and universal access to information/healthcare groups such as KEI have proceeded to attack this legislation on tenuous grounds focusing on the issues of unreasonable drug pricing¹¹⁴ and anti-competitive behavior which they allege the Act has spawned.¹¹⁵ It was apparently their goal to secure legislative reforms that would reserve a larger future role for US government intervention (permitting a broader exercise of ‘police powers’ to preserve the ‘public interest’) and market (price) controls, revise the societal compromise

conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.” 18 U.S.C. 201(f).

¹¹² “The term ‘subject invention’ means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement”. 18 U.S.C. 201(e).

¹¹³ 18 U.S.C. 203(1)(a)-(d).

¹¹⁴“In 2000, the House of Representatives considered an amendment by Rep. Sanders prohibiting the use of NIH funding to grant exclusive or partially exclusive patent licenses under Bayh-Dole except in accordance with the Bayh-Dole Act provision, 35 U.S.C. section 209, requiring that a federally owned invention and its benefits be made available to the public on reasonable terms. It was, in essence, an amendment that *called on NIH simply to enforce existing law*. The House debate on the amendment returned repeatedly to the Bayh-Dole requirement that medicines made with federal research dollars be sold on reasonable terms. Rep. Sanders told his colleagues: ‘Our amendment requires that the NIH abide by current law and ensure that a company that receives federally owned research or a federally owned drug provide that product to the American public on reasonable terms. This is not a new issue ...’ 146 Cong.Rec. H4291-93; 35 U.S.C. sections 209(c)(1)(A) (license granted only if ... the interests of the Federal Government and the public will best be served by the proposed license, in view of the applicant’s intentions, plans and ability to bring the invention to practical application or otherwise promote the invention’s utilization by the public.) and 201(f) (defining ‘practical application’ to include the ‘reasonable terms’ requirement).” See David Halperin, “The Bayh-Dole Act and March-In Rights” National Institute of Health Policy Meeting (May 2001) at p. 15, at: <http://www.ott.nih.gov/policy/meeting/David-Halperin-Attorney-Counselor.pdf>.

¹¹⁵“Apart from the legislative history, which is consistent with international practice, it cannot logically be doubted that the language in the Bayh-Dole Act requiring patented products to be made available to the public on reasonable terms encompasses the patentee’s pricing strategy. All unreasonable terms and conditions that rise to the level of actionable abuses have as their object the power, directly or indirectly, to increase the licensor’s prices beyond the level that competition would otherwise ensure and thus to enhance profits. When patentees impose ‘field of use’ or other licensing restrictions, when they engage in illegal tying, or as in the case at hand, they adopt a marketing strategy consistent with the practice known as “monopoly leveraging,” they are not conducting scientific or economic experiments for the sake of increasing academic knowledge. They pay their lawyers to devise contractual conditions that will enable them to raise prices and make more money..When the Bayh-Dole Act affirms that the resulting products must be made available to the public on reasonable terms, it can only mean that the underlying licensing agreements should not undersupply the market, unduly distort competition, or otherwise leverage the procurement of active ingredients in ways that boost the price to unreasonable ‘windfall’ levels that many users cannot afford.” See Statement of Jerome H. Reichman, Testimony Before National Institutes for Health Public Hearing on March-In Rights Under the Bayh-Dole Act (May 25, 2004) *supra*, at pp. 4-5.



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previously reached, and thus, bring US law into greater harmonization with the laws of foreign nations with more centrally-planned economies.^{116 117}

KEI has also attempted to misrepresent when the U.S. government has exercised its Bayh-Dole ‘march-in’ rights, for purposes of promoting the belief that U.S. government compulsory licensing practices are widespread. For example, KEI’s Love previously alleged that, during “2001, the Department of Health and Human Services used its authority to exercise [Bayh-Dole] March-In rights for patents on stem cell lines held by the Wisconsin Alumni [Research] Foundation [WARF] as leverage to secure an open [compulsory] license on those patents.”¹¹⁸ What is more likely to have occurred, rather, was that NIH had tried to reserve for itself an experimental government use exception, not unlike that already contained in the Hatch-Waxman Act.¹¹⁹ Such a use exception, no doubt, would be broader than that available under US federal jurisprudence, which historically has been very narrowly construed.¹²⁰

¹¹⁶ “The Bayh-Dole Act’s requirement that patented products be made available “to the public on reasonable terms” is one of the clearest examples of such a specialized enabling clause. It may be compared with a Canadian statute that authorized compulsory licenses for acts of abuse, which occur, *inter alia*, “if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms.” *Id.*, at p. 3. “While the Bayh-Dole ‘march-in’ provisions thus clearly contemplate practices that produce excessive prices—what Manbeck and others called “windfall profits”—and would make no sense if they did not, I hasten to add that the Act in no way implies a regime of price controls, like that adopted in Canada and many EU countries. Indeed, loose assertions about “price controls” merely create confusion and divert attention away from the real issues bearing on the patentee’s specific marketing strategies. Statutes that seek to prevent abuses or otherwise to protect the public interest, like the march-in provisions of the Bayh-Dole Act, normally leave patentees free to adopt the marketing strategies they deem suitable. They do not require regulatory approval of prices as would be the case under, say, Canada’s regulatory agency, the Patented Medicines Prices Review Board (PMPRB). By the same token, the marketing strategies that the patentee actually adopts, and their impact on the availability of the relevant products to the consumers on reasonable terms, is always open to public scrutiny and challenge on objective grounds of abuse. In the Bayh-Dole context, this would necessarily require attention to the taxpayers’ interests as well as those of the patentee, including the ability of purchasers to afford critical, life-saving medicines and not be charged prices that “create ... hardship for the overall public or for individual members of the public.” *Id.*, at 5.

¹¹⁷ “Generally speaking, with regard to government-funded research results that universities might otherwise patent; and there is also a built-in anti-abuse clause requiring products manufactured under the resulting patents to be made available to the public on reasonable terms and conditions, including affordable prices. *However, the National Institutes of Health (NIH) have so far declined to exercise these powers, even in a clamorous case of price gouging with regard to at least one HIV/AIDS drug, and the statute makes triggering these measures subject to cumbersome procedures at best. In contrast, Brazil has used public-interest compulsory licenses to manage its nationwide AIDS program with success.*” See Jerome H. Reichman, “Compulsory Licensing of Patented Inventions: Comparing United States Law and Practice with Options under the TRIPS Agreement”, *supra* at p. 4-5.

¹¹⁸ See “December 12 Letter from Jamie Love to USTR on Compulsory Licensing”, Consumer Project on Technology, *supra*.

¹¹⁹ 35 U.S.C. 271(e)(1), at: <http://www4.law.cornell.edu/uscode/35/271.html>. “[T]he most relevant, understanding of experimental use is the statutory *de minimis* infringement provision [contained within]...the Drug Price Competition and Patent Term Restoration Act of 1984” otherwise known as the Hatch-Waxman Act [Pub. L. 98-417, 98 Stat. 1585]. The Act “provided the first and only specific research-use exemption...‘Under a literal interpretation of patent law, it is clear that ‘research exemption’-type of activities are literal infringements’ [citing Lauren C. Bruzzone, *The Research Exemption: A Proposal*, 21 AIPLA Q. J. 52, 54 (1993)]. Congress explicitly exempted certain infringing activities from the scope of the patent protection for policy considerations. As Judge Nies observed, in *Eli Lilly & Co. v. Medtronic, Inc.*, [872 F.2d 402 (Fed. Cir. 1989), *aff’d*, 496 U.S. 661 (1990)], ‘section 271(e)(1) was added to overrule this court’s decision in *Roche*.’ In *Roche Products, Inc. v. Bolar Pharmaceuticals Co.*, 733 F.2d



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Love had seized upon a September 2001 announcement that a Memorandum of Understanding (MOU)¹²¹ had been executed between the National Institutes of Health [NIH] and the WiCell Research Institute, Inc. providing “for research use of WiCell’s existing five human embryonic stem cell lines that me[t] the criteria articulated by the President in his August 9, 2001”.¹²² Apparently, this MOU occurred one month following WARF’s commencement of litigation against Geron Corporation which had partially funded and previously obtained from WARF an exclusive license to commercialize six types of human cells derived from the stem cell technologies developed by WARF scientists. WARF possessed, through the Bayh-Dole Act, the

858 (Fed. Cir. 1984), the Federal Circuit held that experimental use did not encompass the use of a patented compound for federally mandated pre-marketing tests even if the new drug (here, the one marketed by Bolar) would not enter the market prior to patent expiration. The legislature agreed with the pharmaceutical company’s argument that patents will, under the *Roche* rule, be *de facto* extended if competitors must wait on mandatory bioequivalency tests until the patents expire.” See Peter Reuss, “Accepting Exceptions?: A Comparative Approach to Experimental Use in U.S. and German Patent Law”, 10 Marquette Intellectual Property Law Review 81, 90-91 (2006) at: <http://law.marquette.edu/ip/RuessArticle.pdf>.

¹²⁰The ‘experimental use exception’ is a judicially created doctrine that “exempts from patent liability anyone using a patented product ‘for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.’ While the doctrine could be expanded to exempt downstream researchers from patent infringement until and unless their research leads to a commercial product, the Federal Circuit revisited the experimental use doctrine as recently as 2000 and firmly held that it should be construed ‘very narrowly.’ Specifically, the court agreed with the limitation expressed in *Roche Products v. Bolar Pharmaceutical Co.* that ‘courts should not ‘construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of ‘scientific inquiry’ when that inquiry has definite, cognizable, and not insubstantial commercial purposes.’” It therefore seems very unlikely that the type of experimental use exception that would solve the upstream patent problem—namely, license-free use of patented inventions until such commercially driven research produces a marketable product—will be permitted by the federal courts.” See Amy Rachel Davis, Note “Patented Embryonic Stem Cells: The Quintessential ‘Essential Facility’?”, 94 Georgetown University Law Journal 205-246 (Nov. 2005) at: http://findarticles.com/p/articles/mi_qa3805/is_200511/ai_n16013122 ; Peter Reuss, “Accepting Exceptions?: A Comparative Approach to Experimental Use in U.S. and German Patent Law”, *supra* at pp. 87-89. See also Jennifer Miller, “Sealing the Coffin on the Experimental Use Exception”, 2003 Duke L. & Tech. Rev. 0012 (May 2003) at: <http://www.law.duke.edu/journals/dltr/articles/pdf/2003DLTR0012.pdf> (discussing the Federal Circuit’s decision in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002). “The CAFC held that the “very narrow and strictly limited experimental use defense” applies only if use of the patented invention is “solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry,” and that the defense does not apply if the use is “in furtherance of the alleged infringer’s legitimate business[.]” *Id.*, at 1362-63. This is true regardless of the “profit or non-profit” status of the user and “regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain[.]” *Id.*, at 1362.

¹²¹ See “Memorandum of Understanding between WiCell Research Institute, Inc. and Public Health Service U.S. Department of Health and Human Services (Sept. 5, 2001) at: http://stemcells.nih.gov/staticresources/research/registry/MTAs/Wicell_MOU.pdf .

¹²² “Pursuant to this MOU, scientists at the NIH will be able to access these cell lines to explore new avenues of research in this emerging field of technology. In compliance with NIH guidelines for the transfer of research materials, this agreement permits NIH scientists to freely publish the results of their research. The NIH will retain its ownership to any new intellectual property that might arise from the conduct of its research in this area. In addition, the MOU provides a ‘Simple Letter of Agreement’ to govern the transfer of cell lines to individual laboratories with minimal administrative burden.” See National Institutes of Health and WiCell Research Institute, Inc., Sign Stem Cell Research Agreement”, NIH News Release (Sept. 5, 2001) at: <http://www.nih.gov/news/pr/sep2001/od-05.htm> .



basic patents comprising claims on the methods to reproduce the stems cells.¹²³ WARF sued Geron¹²⁴ when it tried to exercise its option on commercial rights to an additional (12) cell types. WARF argued that Geron's option had already expired by the time it was exercised and was thus invalid, and that it was contrary to NIH guidelines.¹²⁵ Furthermore, WARF asserted its own right to sell and distribute the stem cells to researchers.¹²⁶ The suit was ultimately settled, with WiCell Research Institute, a WARF subsidiary, being granted the right to distribute existing [stem] cell lines to academic and governmental researchers royalty- and payment-free."¹²⁷

Paragraphs 167-179 – Compulsory Licensing ('Public Interest') - Many countries [other than the United States] allow the grant of compulsory licenses on broad grounds of public interest.

While this may be true, there are perhaps only two well known U.S. compulsory patent licensing statutes and both are circumscribed by strict due process conditions.

While the US government may be authorized, pursuant to Section 153 of the Atomic Energy Act¹²⁸, to use an inventor's privately held patent in performing its powers under the Act¹²⁹ it must first follow certain procedural guidelines and satisfy two substantive requirements. For example, the US Atomic Energy Commission (now incorporated within the Department of Energy) must provide the patent owner with the opportunity for a 'due process' hearing to contest the 'taking'. The Commission must then be able to substantiate that the patent is 'affected with the public interest'.¹³⁰ This requires a showing that: 1) "the invention or discovery covered by the patent 'is of primary importance' in the production or utilization of special nuclear material or atomic energy"; and 2) "the licensing of such invention or discovery...is of 'primary importance' to effectuate the policies and purposes of this chapter".¹³¹

If, and only if, a patent is found to be '*affected with a public interest*', may the government then consider issuing to an eligible third party applicant¹³², without the patent holder's authorization,

¹²³ See Lawrence B. Ebert, "WARF's US 5,843,780 on Stem Cells" IPBIZ (Nov. 14, 2004) at: <http://ipbiz.blogspot.com/2004/11/warfs-us-5843780-on-stem-cells.html> .

¹²⁴ See *WARF v. Geron*, Civ. No. 01-C-459-C (D. Wis. Aug. 2001).

¹²⁵ See Diane T. Duffy, "Background and Legal Issues Related to Stem Cell Research", Congressional Research Service (Updated June 12, 2002), at: http://www.policyalmanac.org/health/archive/crs_stem_cell.shtml.

¹²⁶ See Lawrence B. Ebert, "WARF's US 5,843,780 on Stem Cells", *supra*.

¹²⁷ And, "Geron received both exclusive and nonexclusive licenses to develop various therapeutic and diagnostic products derived from stem cells", [while] WARF/Geron agreed to grant research rights to academic and governmental researchers without royalties or fees." See Stephen B. Maebius, "Patenting Stem Cell Research & Developments in Regenerative Medicine" at: http://www.foley.com/files/tbl_s31Publications/FileUpload137/889/maebius_stemcell.pdf .

¹²⁸ See "Non-Military Utilization", 42 U.S.C. 2183, at: <http://www4.law.cornell.edu/uscode/42/2183.html> .

¹²⁹ 42 U.S.C. 2183(b)(1).

¹³⁰ The purpose of the Act is "[t]o encourage widespread participation in the development and utilization of atomic energy for peaceful purposes." 42 U.S.C. § 2013(d).

¹³¹ 42 U.S.C. 2183(a).

¹³² "Nor shall the Commission grant any patent license to any other applicant for a patent license on the same patent without an application being made by such applicant pursuant to subsection (c) of this section, and without separate



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a nonexclusive license for a specified, limited use¹³³ of the invention covered by that patent.¹³⁴ However, “no such...license has [actually] been issued in the more than 50 years since the legislation was enacted.”¹³⁵ The Commission may issue a license following a third party application hearing,¹³⁶ provided the applicant is able to satisfy, in addition to the first condition set forth above,¹³⁷ three further requirements. The applicant must be able to show also that: 1) the licensing of the invention or discovery is of primary importance to the conduct of the applicant’s proposed activities; 2) the proposed activities to be covered by the license “are of primary importance to the furtherance of policies and purposes of this chapter” of the Act; and 3) the applicant cannot otherwise obtain a license from the patent owner on terms deemed reasonable for the applicant’s intended use of the patent.¹³⁸

Lastly, the Commission must ensure that the terms under which the patent license is ultimately granted are “equitable...and generally not less fair than those granted by the patentee or by the Commission to similar licensees for comparable use.”¹³⁹ In any event, the patent owner is entitled to receive “a reasonable royalty fee from the licensee” for *any* use of the patented invention or discovery so licensed.¹⁴⁰

The U.S. government, furthermore, does not possess broad powers to ‘take’ private patents under the auspices of Section 308 of the federal Clean Air Act¹⁴¹ via mandatory court-ordered licensing ‘for *public* or commercial use’.¹⁴² Indeed, this has been a rarely, if ever used, mechanism.¹⁴³ In fact, the Attorney General of the United States, upon application by the Administrator of the Environmental Protection Agency, cannot petition a federal district court to issue a mandatory license on a patented invention under this provision *unless and until* he (she) can certify that ALL three of the following conditions have first been satisfied. The Attorney General must determine that: 1) “an otherwise unavailable patent is needed [by a third party] to accomplish the

notification and hearing as provided in subsection (d) of this section, and without a separate finding as provided in subsection (e) of this section.” 42 U.S.C. 2183(f).

¹³³ “The Commission shall not grant any patent license pursuant to subsection (e) of this section for any other purpose than that stated in the application.” 42 U.S.C. 2183(f).

¹³⁴ 42 U.S.C. 2183(b)(1);

¹³⁵ See Ronald Cass, “Compulsory Licensing of Intellectual Property: The Exception That Ate the Rule?”, Washington Legal Foundation (Sept. 2007) *supra* at p. 9.

¹³⁶ 42 U.S.C. 2183 (d).

¹³⁷ 42 U.S.C. 2183(e)(1).

¹³⁸ 42 U.S.C. 2183(e)(2)-(4).

¹³⁹ 42 U.S.C. 2183(e).

¹⁴⁰ 42 U.S.C. 2183(g).

¹⁴¹ See “Mandatory Licensing”, 42 U.S.C. Sec. 7608, at: http://www.law.cornell.edu/uscode/html/uscode42/usc_sec_42_00007608----000-.html.

¹⁴² “The purpose of this provision is to allow industries greater access to air pollution control devices, and to prevent companies from avoiding the use of superior inventions by claiming that they are not available. See Paul Gormley, Comment, *Compulsory Patent Licenses and Environmental Protection*, 7 TUL. ENVTL. L.J. 131, 141–42 (1993).

¹⁴³ “Section 308 of the Clean Air Act...provides a theoretical, but never-used, authorization for compulsory license of patents (withheld from a putative licensee) that are essential to accomplishing the environmental goals of the Act and for which no alternative technology exists.” See Ronald Cass, “Compulsory Licensing of Intellectual Property: The Exception That Ate the Rule?”, *supra* at p.9.



goals of the Clean Air Act”; 2) “no reasonable alternative methods exist that satisfy [the Act’s] goal”; and 3) the unavailability of such a license “may result in a substantial lessening of competition or monopoly conditions.”¹⁴⁴

Once these three substantive conditions have been met, the federal court must then ensure that the patent holder receives procedural due process, just as in the case of an ordinary government eminent domain (“takings”) proceeding. In other words, the patent holder is entitled to a court hearing for the specific purpose of arriving at a license based “on reasonable terms and conditions”.¹⁴⁵

In effect, a compulsory license can be issued under both the Atomic Energy Act and the Clean Air Act, *but* only for a “narrowly tailored” governmental public interest purpose¹⁴⁶ and “only if a reasonable alternative is [otherwise] unavailable.”¹⁴⁷

Paragraphs 191-192 - License of Right

The ITSSD requests that the SCP refer to its recently submitted comments concerning the SCP Report on Standards and Patents. Specifically, the ITSSD directs the SCP’s attention to ITSSD comments regarding Paragraph 143 of that Report.

¹⁴⁴ See William W. Beckett & Richard M. Merriman, *Will the Patent Provisions of the Atomic Energy Act of 1954 Promote Progress or Stifle Invention?*, 37 J. PAT. OFF. SOC’Y 38, 59 (1955) (citing H.R. REP. NO. 83-2181, at 99 (1954)). The compulsory licensing provisions generated considerable opposition in Congress. *Id.*, at note 28, pp. 43–45 (detailing attempts by the House to eliminate the compulsory licensing provision).

¹⁴⁵ 42 U.S.C. 7608.

¹⁴⁶ See Joseph A. Yosick, “Compulsory Patent Licensing for Efficient Use Inventions”, 5 Univ of Ill. L. Rev. 1275, 1279 (2001) at: <http://www.usebrinks.com/docs/publications/107.pdf> (“The author suggests implementing compulsory licensing into U.S. patent law by enacting legislation similar to the patent laws of other nations.”).

¹⁴⁷ See Carol M. Nielsen and Michael R. Samardzija, *Compulsory Patent Licensing: Is It a Viable Solution in the United States?*, 13 Mich. Telecomm. Tech. L. Rev. 509 (2007) at pp. 537-38, at: <http://www.mttlr.org/volthirteen/nielsen&samardzija.pdf> . “This raises the question of whether it would be practicable to design around the claimed invention or whether an alternative is reasonably available.” *Id.*