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THE TRANS-PACIFIC PARTNERSHIP: EXPERIMENTAL USE OF PATENTS ON THE INTERNATIONAL AGENDA

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As the secret negotiations of the Trans-Pacific Partnership Agreement ("TPP") between the United States and eleven other nations advance, the recent release of the draft Intellectual Property Chapter provides a timely opportunity to examine its content. Among the myriad issues addressed in the draft is experimental use of patents, a topic that has been the source of much discussion and debate in recent years. This Article analyzes the proposed Experimental Use Clause and evaluates it in light of the policy considerations underlying the patent system.

The analysis demonstrates that adoption of an international standard concerning experimental use of patents can have significant benefits in promoting uniformity and removing uncertainty. However, a close examination of the proposed Experimental Use Clause reveals that it falls short of attaining these goals due to a few notable shortcomings. First, the clause is drafted in a permissive manner, and thus, may end up having little impact on the laws of the member nations. Second, it does not provide guidance with respect to key doctrinal questions related to the application of the experimental use exception. Finally, the clause is drafted in too narrow a manner, and fails to include in its scope the important scenario of patented research tools used for the purpose of follow-

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on research and development. Thus, rather than facilitating the adoption of broad exceptions by member nations in an attempt to create a global legal environment supportive of cumulative research and development, the proposed Experimental Use Clause may actually have the opposite effect. The Article concludes with a proposal to revise the Experimental Use Clause in order to remedy its deficiencies.

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I. INTRODUCTION

On November 13, 2013, WikiLeaks released the newest draft of the Intellectual Property Rights Chapter (the "IP Chapter") of the Trans-Pacific Partnership Agreement ("TPP").[1] The TPP is a proposed regional free trade agreement negotiated in secrecy between Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam.[2] Touted as one of the largest free trade agreements in the history of the United States,[3] the TPP aims to achieve broad Asia-Pacific regional economic integration.[4]

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[1] *Secret Trans-Pacific Partnership Agreement (TPP) - IP Chapter*, WIKILEAKS (November 13, 2013), https://wikileaks.org/tpp/pressrelease.html [hereinafter WikiLeaks Release]. For the draft of the IP Chapter, see https://wikileaks.org/tpp/ [hereinafter IP Chapter].

[2] The TPP is essentially an expanded version of the 2005 Trans-Pacific Strategic Economic Partnership Agreement among Brunei, Chile, New Zealand and Singapore. IAN F. FERGUSSON & BRUCE VAUGHN, CONG. RESEARCH SERV., R40502, THE TRANS-PACIFIC PARTNERSHIP AGREEMENT 1 (Dec. 12, 2011), *available at* http://www.fas.org/sgp/crs/row/R40502.pdf.

[3] *See* BROCK R. WILLIAMS, CONG. RESEARCH SERV., R42322, TRANS-PACIFIC PARTNERSHIP (TPP) COUNTRIES: COMPARATIVE TRADE AND ECONOMIC ANALYSIS, (June 10, 2013), *available at* http://fas.org/sgp/crs/row/R42344.pdf ("The TPP would be the largest U.S. FTA to date by trade value."); Mireya Solís, *Endgame: Challenges for the United States in finalizing the TPP Negotiations*, 622 KOKUSAI MONDAI (INTERNATIONAL AFFAIRS) 1, (June 14, 2013), *available at* http://www2.jiia.or.jp/en/pdf/publication/2013-06_004-kokusaimondai.pdf (describing the TPP as "the single most important trade negotiation under way [sic] for the United States"); Mark Weisbrot, *The Trans-Pacific Partnership Treaty is the Complete Opposite of 'Free Trade'*, GUARDIAN, (Nov. 19, 2013), http://www.theguardian.com/commentisfree/2013/nov/19/trans-pacific-partnership-corporate-usurp-congress ("The proposed Trans-Pacific Partnership agreement [. . .] [is] one of the largest 'free trade' agreements in US history.").

[4] *The United States in the Trans-Pacific Partnership*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE (Nov. 2011), http://www.ustr.gov/about-us/press-office/fact-sheets/2011/november/united-states-trans-pacific-partnership; *see* Krista L. Cox, *The United States' Demands for Intellectual Property Enforcement in the Trans-Pacific Partnership Agreement and Impacts for Developing Countries* (Knowledge Ecology International Working Paper 2012), *available at* http://ssrn.com/abstract=2188029 ("The goal of the [TPP] agreement is to cover the entire APEC region, comprising [of] 40% of the worlds' population.").

Recently, the TPP has been the target of growing criticism focused on both the secret nature of the negotiations[5] and the content of certain controversial provisions in leaked drafts.[6]

The IP Chapter, in particular, became the source of much debate after an earlier release of the United States' proposal for such a chapter (the "U.S. Proposal"),[7] followed by the recent release of the current draft by WikiLeaks. The IP Chapter has been termed "the most controversial chapter of the TPP."[8] Overall, it has been criticized as providing an excessive intellectual property protection that goes well beyond the standards reflected in the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement")[9] and other international

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[5] *See*, *e.g.*, *Analysis of the Draft Intellectual Property Chapter of the Trans-Pacific Partnership*, CENTRE FOR LAW AND DEMOCRACY 2–6 (December 2013), http://www.law-democracy.org/live/wp-content/uploads/2013/12/TPP.IP-final.Dec13.pdf [hereinafter Centre for Law and Democracy Analysis] (criticizing the secret nature of the TPP negotiations). On May 23, 2012, United States Senator Ron Wyden introduced a bill to require the United States Trade Representative to disclose its TPP documents to all members of Congress. The bill was never enacted. Congressional Oversight Over Trade Negotiations Act, S. 3225, 112th Cong. (2012)

[6] *See* Connor Adams Sheets, *How to Fight the Trans-Pacific Partnership: Anti-TPP Petitions, Protests & Campaigns*, INTERNATIONAL BUSINESS TIMES (Nov. 18, 2013), http://www.ibtimes.com/how-fight-trans-pacific-partnership-anti-tpp-petitions-protests-campaigns-1475530 ("A number of petitions, protests and campaigns have been organized to let citizens voice their concerns about the agreement, and perhaps even stop it from moving forward as currently written."). Notably, among such problematic provisions is a clause granting foreign corporations the power to challenge legislation in a privately run international court. *See*, *e.g.*, Zach Carter, *Obama Faces Backlash Over New Corporate Powers in Secret Trade Deal*, HUFFINGTON POST, (Dec. 8, 2013), http://www.huffingtonpost.com/2013/12/08/tpp-trade-agreement_n_4409211.html (describing international criticism towards the political power given to foreign corporations in sovereign nations under the agreement to contest litigation in a privately-run international court).

[7] *Trans-Pacific Partnership Intellectual Property Rights Chapter Draft* (Feb. 10, 2011), http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf [hereinafter U.S. Proposal].

[8] WikiLeaks Release, *supra* note 1.

[9] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, 1869 U.N.T.S. 299 (1994) [hereinafter the TRIPS

instruments governing the IP arena.[10] In essence, the TPP is what is commonly termed a "TRIPS-plus" agreement.[11] Among other things, as currently drafted, the IP Chapter would require party nations to lengthen copyright terms;[12] make the availability of safe harbors for internet service providers contingent on their implementation of various measures beyond the standard notice-and-takedown regime;[13] bolster patent protection in various

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Agreement]. The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization.

[10] *See*, *e.g.*, Cox, *supra* note 4, at 2 (noting that certain proposed measures go well beyond the requirements of the TRIPS Agreement); *see also* Peter K. Yu, *The Non-Multilateral Approach to International Intellectual Property Normsetting* 2 (2013) (observing that economic partnership agreements and free trade agreements in the IP arena generally include IP standards that go beyond what is required by the TRIPS Agreement or other international agreements administered by WIPO), *reprinted in* RESEARCH HANDBOOK ON INTERNATIONAL INTELLECTUAL PROPERTY LAW (Daniel J. Gervais ed., forthcoming 2014), http://ssrn.com/abstract=2325766; Sean M. Flynn, Brook Baker, Margot Kaminski & Jimmy Koo, *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT'L L. REV 105, 119 (2012) (maintaining that the U.S. proposal for the IP Chapter, if adopted, "would heighten standards of protection for rights holders well beyond that which the best available evidence or inclusive democratic processes support").

[11] The term "TRIPS-plus" is used to describe international instruments that seek to impose legal standards for intellectual property rights protection that exceed the baseline requirements of the TRIPS Agreement. *See*, *e.g.*, Kenneth L. Port, *A Case Against the ACTA*, 33 CARDOZO L. REV. 1131, 1154–55 (2012); Yu, *supra* note 10, at 2 ("[T]he intellectual property provisions in these so-called 'TRIPS-plus agreements' often mandate protections in excess of the levels required by the TRIPS Agreement and other international intellectual property agreements.").

[12] Australia, Chile, Mexico, Peru, Singapore and the United States have proposed standardizing copyright protection terms to match their domestic standards (one hundred years after the death of the creator, under the Mexican proposal, and seventy years after the death of the creator, under the proposal supported by Australia, Chile, Peru, Singapore and the United States). IP Chapter, *supra* note 1, art. QQ.G.6. For a critical analysis of this proposed provision, see Centre for Law and Democracy, *supra* note 5, at 10–12.

[13] *See* IP Chapter, *supra* note 1, art. QQ.I.1. For a critical analysis of the proposed arrangements in this context, see Centre for Law and Democracy, *supra* note 5, at 6–8.

manners;[14] and strengthen enforcement mechanisms.[15] In light of the above, critics of the TPP have expressed concern that, if instated, the IP Chapter would result in decreasing access to low-cost medicine;[16] restricting certain basic uses of the internet;[17] and, more generally, shifting the balance between IP rights holders and the public far to the side of rights holders.[18] The provisions of the TPP are expected to be particularly harmful for developing countries.[19]

Without undermining the significance of the aforementioned critiques of the IP Chapter, this Article focuses on yet another proposed arrangement that so far has not gained any attention by academic scholars or other critics of the TPP: Article E.5*ter*, entitled "Experimental Use of a Patent" (the "Experimental Use Clause").[20] This Article conducts a thorough examination of the Experimental Use Clause against the relevant policy considerations. As detailed below, rather than criticizing the Experimental Use Clause, this Article views its inclusion in the IP Chapter of the TPP as a commendable opportunity to set a clear standard in this important context. Yet, this Article also recommends certain

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[14] *See* IP Chapter, *supra* note 1, § E. For a critical analysis of the arrangements proposed by the United States in this context, see Flynn et al., *supra* note 10, at 150–86.

[15] *See* IP Chapter, *supra* note 1, § H; Centre for Law and Democracy, *supra* note 5, at 12; Cox, *supra* note 4, at 45.

[16] *See*, *e.g.*, Flynn et al., *supra* note 10, at 153 (noting that the patent provisions proposed by the United States "would have predictable negative effects on the availability of affordable medicines in developing countries").

[17] *See*, *e.g.*, Centre for Law and Democracy, *supra* note 5, at 6–7.

[18] *See* Flynn et al., *supra* note 10, at 119 (noting that the IP Chapter, as proposed by the U.S., "contains insufficient balancing provisions for users, consumers, and the public interest"); Cox, *supra* note 4, at 45 (expressing concern that the enforcement provisions included in the draft may create an unbalanced intellectual property system).

[19] *See*, *e.g.*, Cox, *supra* note 4, at 3 ("The [proposed] provisions are [. . .] of particular concern for developing countries and those that are considered to be 'net-importers' of intellectual property."); Yu, *supra* note 10, at 2 ("[The] 'TRIPS plus agreements' [. . .] threaten to ignore the local needs, national interests, technological capacities, institutional capacities and public health conditions of many less developed countries."); Flynn et al., *supra* note 10, at 119–20.

[20] IP Chapter, *supra* note 1.

changes in the way the Experimental Use Clause is currently drafted in order for it to properly serve its purpose.

The Experimental Use Clause was not included in the original U.S. Proposal.[21] It was proposed at a later stage by New Zealand, Canada, Singapore, Chile, and Malaysia.[22] The Experimental Use Clause permits member states to adopt an exception from patent infringement liability that would cover certain experimental uses of a patented invention.[23] Notably, the TRIPS Agreement did not include a similar provision, but rather handled the topic of permitted exceptions to the rights of the patent holder in a more general manner by establishing a three-step test that any exception adopted by a member state must satisfy.[24] The Three-Step Test is repeated in the IP Chapter of the TPP,[25] but it is accompanied by

[21] *See generally* U.S. Proposal, *supra* note 7.

[22] *See* IP Chapter, *supra* note 1, art. QQ.E.5*ter*.

[23] For the proposed text of the Experimental Use Clause, see text accompanying *infra* note 81.

[24] *See* TRIPS Agreement, *supra* note 9, art. 30 ("Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."). Certain proposals made during the negotiations of the TRIPS Agreement included more specific provisions regarding permissible exceptions from the rights of the patent holder. *See, e.g.*, CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS – A COMMENTARY ON THE TRIPS AGREEMENT 303 (2007) (OXFORD COMMENTARIES ON GATT/WTO AGREEMENTS) (noting proposals made during the negotiations of the TRIPS Agreement, which contained specific provisions regarding permissible exceptions from the rights of the patent holder, such as the EEC submission contained in MTN.GNG/ NG11/W/26 of 7.7.88); DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 471 (4th ed. 2012) (citing the July 23, 1990 draft, which included specific exceptions, including one for "[a]cts done for experimental purposes"). However, such proposals were not included in the final text of the Trips Agreement due to the difficulty of the negotiating parties to agree upon them.

[25] *See* IP Chapter, *supra* note 1, art. E.5, which states that "[e]ach Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third

two additional clauses addressing two specific types of permissible exceptions: The Experimental Use Clause and a separate clause dealing with "regulatory review" exceptions.[26]

In contrast to other arrangements included in the IP Chapter, the Experimental Use Clause appears to operate to the benefit of users rather than patent holders, by allowing member nations to permit certain uses that would otherwise constitute infringement.[27] This may be particularly valuable in the context of the TPP in light of the seemingly IP maximalist agenda underlying the IP Chapter.[28] As demonstrated below, one of the main rationales undergirding the experimental use doctrine is the desire to enable follow-on inventors to build upon the work of their predecessors while making their own contribution. Setting an international norm concerning the freedom to experiment with patented inventions may thus have an important impact on promoting a global regime that encourages cumulative innovation.

Comparative legal analysis shows that various legal systems differ greatly in the manner in which they treat experimental use of patents.[29] While some countries have adopted relatively broad

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parties." Article E.5 was included in the original proposal of the United States. *See* Article 8(4) of the U.S. Proposal, *supra* note 7.

[26] *See* IP Chapter, *supra* note 1, at art. E.5bis. A placeholder for such provision, also titled "Bolar" provision, was already included in the U.S. Proposal. *See* Section 5 of the U.S. Proposal, *supra* note 7. However, the actual text of the provision was proposed later by New Zealand, Canada, Singapore, Chile and Malaysia. Pursuant to the proposed Article E.5bis:

> [E]ach Party may provide that a third person may do an act that would otherwise infringe a patent if the act is done for purposes connected with the collection and submission of data in order to comply with the regulatory requirements of that Party or another country, including for purposes connected with marketing or sanitary approval.

IP Chapter, *supra* note 1, at art. E.5bis. Another related provision in the IP Chapter is Article E.13.

[27] Clearly, an experimental use exception would still need to satisfy the Three-Step Test. For discussion, see *infra* notes 100–04 and accompanying text.

[28] *See generally supra* notes 7–19 and accompanying text.

[29] *See, e.g.*, Henrik Holzapfel & Joshua D. Sarnoff, *A Cross-Atlantic Dialog on Experimental Use and Research Tools*, 48 IDEA 123, 199 (2008) (discussing the differences between U.S. and European laws regarding experimental use of patents).

exceptions,[30] allowing the performance of a variety of experimental activities during the patent term, other countries have not followed suit.[31] In the United States, in particular, the scope of the experimental use exception is extremely narrow.[32] Even in countries that employ relatively broad experimental use exceptions, there are often significant uncertainties over the scope and application of such exceptions.[33] This reinforces the importance of adopting an international standard concerning experimental use of patents. Such a standard could have significant benefits in promoting uniformity and removing uncertainty regarding this important topic. Clearly, though, if a standard is to be set, it must be the right standard. This Article seeks to evaluate whether this is indeed the case in the context of the TPP.

The Article proceeds as follows: Part II discusses the general concept and the main policy considerations underlying the Experimental Use Clause. As a basis for the ensuing discussion, this Part demonstrates the essential role that an experimental use exception may play in attaining a properly balanced patent system that enables follow-on research and development based on patented inventions. In light of the importance of the matter, and considering the high level of uncertainty surrounding it, this Article demonstrates that adopting an international standard regarding experimental use of patents can be highly beneficial. In Part III, however, the analysis turns to take a close look at the actual text of the Experimental Use Clause, and this examination reveals that, as currently drafted, the clause fails to serve as an appropriate standard for the following reasons: First, the Experimental Use Clause does not mandate the member parties to adopt an experimental use exception but merely permits them to do so. Second, the clause fails to provide guidance regarding the applicability of the experimental use exception in commercial settings. And third,

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[30] Notable examples for countries that have adopted wide experimental use exceptions are Belgium and Israel. *See infra* notes 143–44 and accompanying text.

[31] An example for a country that does not have an experimental use exception at all is South Africa. *See infra* note 76.

[32] *See infra* notes 107–10 and accompanying text.

[33] *See*, *e.g.*, Holzapfel & Sarnoff, *supra* note 29, at 126–27.

the clause leaves outside its scope important scenarios of cumulative innovation, including the use of patented research tools for the purpose of developing a different invention. Based on this analysis, Part IV recommends certain revisions to the manner in which the Experimental Use Clause is currently drafted, in order to increase its chances to facilitate the creation of a global legal environment supportive of cumulative research and development.

II. THE POTENTIAL BENEFITS OF THE EXPERIMENTAL USE CLAUSE

Under the dominant utilitarian justification for the patent system,[34] patent law ought to reflect a balance of the benefits associated with patents in promoting technological progress against their adverse effects.[35] Among the costs associated with the patent system is the potential chilling effect of a patent on follow-on research and development.[36] Technological research and development is often conducted in a cumulative manner.[37] When the information

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[34] *See*, *e.g.*, A. Samuel Oddi, *Un-Unified Economic Theories of Patents – The Not-Quite-Holy Grail*, 71 NOTRE DAME L. REV. 267 (1996) (surveying the economic justifications for the patent system offered over the years).

[35] *See*, *e.g.*, Wendy J. Gordon, *Intellectual Property*, THE OXFORD HANDBOOK OF LEGAL STUDIES 617, 619 (Peter Cane & Mark Tushnet eds., 2003) (noting the view of patents as reflecting a balance between providing incentives to inventors and providing access to the members of the public).

[36] *See*, *e.g.*, Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 253 (1994).

[37] Cumulative innovation is far from being a new phenomenon. As early as 1675, Sir Isaac Newton noted: "If I have seen further[,] it is by standing on the shoulders of giants." Letter from Isaac Newton to Robert Hooke (Feb. 5, 1675), *reprinted in* ROBERT K. MERTON, ON THE SHOULDERS OF GIANTS: A SHANDEAN POSTSCRIPT, THE POST-ITALIANTE VERSION 1 (1993). For the prevalence of cumulative innovation in different technological fields, see, for example, Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990) (providing a general account of cumulative innovation in various industries); Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1691 (focusing on follow-on research involving patented DNA sequences); Clarisa Long, *Patent Law and Policy Symposium: Re-Engineering Patent Law: The Challenge of New Technologies: Part II: Judicial Issues: Patents and Cumulative Innovation*, 2 WASH. U. J.L. & POL'Y 229, 233–46

required in order to pursue a follow-on research and development project is covered by a patent, there is a potential conflict between the exclusive rights of the patent holder and the need to make use of her invention in order to make further developments. The patent system must take this potential conflict into consideration and ensure that the exclusive rights granted to the patent owner do not end up stifling technological research and development rather than promoting it.[38]

One of the primary potential measures that may assist in facilitating cumulative innovation is the adoption of an experimental use exception, allowing for certain experimental uses of the patented invention to take place during the patent term without the need to receive the patentee's advance permission.[39] Such experimental uses of the original invention may ultimately result in the development

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(2000) (discussing cumulative innovation biomedical research). For a detailed account of cumulative innovation, see Ofer Tur-Sinai, *Cumulative Innovation in Patent Law: Making Sense of Incentives*, 50 IDEA 723 (2010) [hereinafter Tur-Sinai, *Cumulative Innovation*].

[38] The discussion in this paragraph implicitly assumes that encouraging cumulative innovation is in society's best interest. A detailed analysis of this matter exceeds the scope of this Article. For relevant discussion, see Tur-Sinai, *Cumulative Innovation*, *supra* note 37, at 733–35.

[39] For a detailed explanation of the experimental use exception's role in facilitating cumulative innovation, see discussion *infra* notes 40–50 and accompanying text. For scholars advocating a wide experimental use exception in patent law, see generally Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research,* 97 YALE L.J. 177, 224–31 (1987) [hereinafter Eisenberg, *Rights*]; Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1078 (1989) [hereinafter Eisenberg, *Patents*]; Irving N. Feit, *Biotechnology Research and the Experimental Use Exception to Patent Infringement*, 71 J. PAT. & TRADEMARK OFF. SOC'Y 819, 839–41 (1989); Janice M. Mueller, *No "Dilettante Affair:" Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 66 (2001); Tom Saunders, *Case Comment: Renting Space on the Shoulders of Giants: Madey and the Future of the Experimental Use Doctrine*, 113 YALE L.J. 261, 268 (2003); Katherine J. Strandburg, *What Does the Public Get?: Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 119–52 (2004); Wendy Thai, *Toward Facilitating Access to Patented Research Tools*, 6 MINN. J.L. SCI. & TECH. 373, 390–97 (2004); Tur-Sinai, *Cumulative Innovation*, *supra* note 37, at 754–58.

of follow-on inventions. The importance of enabling potential inventors to conduct experiments without permission from patent owners stems, to a large extent, from the difficulty in relying on voluntary license agreements permitting such experiments to be executed in the free market.[40] There are various reasons why the chances for achieving such *ex ante* agreements are not high.[41] Among other things, at this point in time, before the relevant research project has even commenced, transaction costs are particularly high due to the great level of uncertainty surrounding the relevant parameters. Such parameters include, inter alia, the development costs of the follow-on invention, the risks associated with the project, and the expected value of the resulting innovation.[42] There is also the inherent difficulty of agreeing upon the relative contributions of sequential inventors.[43] Furthermore, having no exclusive legal rights to her prospective invention at this early stage, the follow-on inventor might hesitate to disclose confidential information about her research agenda to the original

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[40] For empirical evidence attesting to such difficulty, see *infra* note 46.

[41] *See generally*, with respect to the difficulties associated with bargaining in a cumulative innovation setting, Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1052–65 (1997); Merges & Nelson, *supra* note 37, at 874–75; Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1179 (2000). For the reasons specified in the text, when it comes to an *ex ante* agreement—i.e., an agreement which is concluded before the development of the second invention—the chances for the conclusion of an agreement are particularly low.

[42] *See* Tur-Sinai, *Cumulative Innovation*, *supra* note 37, at 753. *See also* Eisenberg, *Rights*, *supra* note 39, at 217 (discussing the difficulty of valuing the right to use a patented invention before the research project is completed); Timothy J. Engling, *Improvements in Patent Licensing*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 739, 741–42, 746 (1996) (maintaining that a future improvement cannot be valued upfront); Merges & Nelson, *supra* note 37, at 895 n.251 (pointing out that valuation problems in licensing transactions are difficult enough after an invention has been developed and are seemingly even more difficult prior to its development).

[43] This difficulty may exist even after the follow-on invention has been developed, "as each inventor may have an inflated idea of their own contribution or not understand the other's contribution." *See*, *e.g.*, Tur-Sinai, *Cumulative Innovation*, *supra* note 37, at 751; Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 89–91 (1994).

inventor, who may potentially use such information for the original inventor's own benefit in case the deal falls through.[44] Finally, in some situations, anti-competitive motives of the original patentee, who wishes to retain sole control of the market, may cause her to refuse licensing her invention to other inventors, in order to block them from improving on the invention or designing around it.[45] The concerns outlined above are not merely theoretical, but rather are backed by a number of empirical studies that provide evidence regarding delays or impediments to follow-on research projects as a result of various factors, including high transaction costs and licensing failures.[46]

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[44] *See* Howard F. Chang, *Patent Scope, Antitrust Policy, and Cumulative Innovation*, 26 RAND J. ECON. 34, 38 n.6 (1995) (noting that while the follow-on inventor may not be able to induce the original inventor to get into a deal without disclosing her idea, such disclosure may undermine her bargaining power). See generally Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 615–616 (Richard R. Nelson ed., 1962) (noting the quandary of disclosing information without legal rights to the invention).

[45] *See*, *e.g.*, Tur-Sinai, *Cumulative Innovation*, *supra* note 37, at 751.

[46] *See* studies cited by Holzapfel & Sarnoff, *supra* note 29, at 143–44 n.98; *Rebecca S. Eisenberg, Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1098 (2008) [hereinafter Eisenberg, *Noncompliance*] (describing studies suggesting that product development firms face a growing burden of transaction costs to identify and clear rights); Jay P. Kesan, *Transferring Innovation*, 77 FORDHAM L. REV. 2169, 2182–83 (2009) (describing empirical studies indicating, among other things, the slowdown of development in industry as university patenting has increased). *See also* James E. Bessen, *Holdup and Licensing of Cumulative Innovations with Private Information*, 82 ECON. LETTERS 321, 322 (2004) (demonstrating that *ex ante* licensing, in particular, is not a prevalent practice in industries characterized by cumulative innovation). *But see* John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) [hereinafter Walsh et al.] (providing survey results indicating that the patenting of research tools in the biomedical industry has generally not been viewed as having a substantial negative effect on further research in the field). The main explanation for the results, supplied in the study, is that firms and universities have been able to develop "working solutions" that allow their research to proceed, which one of them is, simply, "taking licenses." *Id*. at 286. The authors opine that "it is

In light of this potential market failure, certain experimental uses must be allowed to take place during the patent term even without the patent owner's consent. A properly designed experimental use exception can achieve exactly this result. Under such an exception, a follow-on inventor would be able to work on her project without the need to disclose the matter to the original patentee, and upon completion, may even register a patent on her invention.[47] Because the experimental use exception, by its nature, only applies to experimental activities carried on during the development stage, the follow-on inventor may still need a license from the original patentee in order to manufacture, use, or sell her follow-on invention.[48] However, the follow-on inventor would most likely find it easier to approach the original patentee at this later stage, particularly if she has already applied for patent protection on her invention.[49] All in all, the chances of concluding such an ex post agreement, under which the profits from the commercial exploitation of the follow-on invention would be

typically not that difficult to contract" and state that "[l]icensing is routine in the drug industry." *Id.* at 322. It should be noted, however, that the study of Walsh et al. focused primarily on the effects of patents on the research science community itself while paying relatively little attention to the effects of such patents on downstream product development. *See* Eisenberg, *Noncompliance*, *supra*, at 1076, 1098. In any event, even the authors of the study admit that there is "some evidence of delays associated with negotiating access to patented research tools, and there are areas . . . where access to foundational discoveries can be restricted." *See* Walsh et al., at 286. All in all, even if there are indeed cases where the parties can manage to come to an agreement despite the difficulties described above, there surely remain other cases where a voluntary agreement cannot be counted on.

[47] In such a scenario, the original patent and the follow-on patent are sometimes referred to as "blocking patents." *See, e.g.*, SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES 129 (2006); Lemley, *supra* note 41, at 1008–10; Merges & Nelson, *supra* note 37, at 860–62.

[48] It should be noted that the need for a license in order to exploit the follow-on invention only arises when such activity falls under the scope of the original patent. Indeed, in legal systems that employ a wide experimental use exception, it is particularly important to design the rules governing patent scope in such a manner in order to guarantee the original patentee's right to profit from follow-on inventions. *See infra* notes 72, 136–41 and accompanying text.

[49] *See supra* note 44 and accompanying text with respect to the difficulty of conducting negotiation with the original patentee absent legal protection.

divided between the parties, seem to be higher than the chances of agreeing on the matter *ex ante*.[50] Thus, the experimental use exception is an important tool in facilitating cumulative innovation.

An experimental use exception to the rights of the patent holder can be justified not only from economic efficiency considerations, but also from the perspective of certain non-utilitarian justifications for the patent system—particularly, the labor theory and the personality theory. Under the labor theory, every person has a right to the fruits of her labor.[51] The labor theory is one of the main theories for justifying rights in private property,[52] and it has been used for the justification and analysis of intellectual property rights as well.[53] One of the conditions for acquiring property, under the labor theory, is that "there is enough, and as good, left in common for others."[54] In other words, "[o]ne may prevent others from using her work products only if sufficient resources remain in the public domain to allow others to labor and acquire property as well."[55] In the context of patents, an experimental use exception may be necessary in order to satisfy this condition. If potential inventors are not allowed to use and incorporate previously

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[50] Admittedly, although *ex post* agreements are easier to negotiate than *ex ante* agreements, they too cannot be taken for granted. As a result, there may be a need to adopt liability rule doctrines in this context. For a detailed discussion, see Tur-Sinai, *Cumulative Innovation*, *supra* note 37, at 760–66. *See also infra* note 138.

[51] The labor theory is based on the work of John Locke. *See* JOHN LOCKE, TWO TREATISES OF GOVERNMENT 290–91 (Peter Laslett ed., Cambridge Univ. Press 1988) (1690).

[52] *See*, *e.g.*, J. W. HARRIS, PROPERTY AND JUSTICE 182–212 (1996); STEPHEN R. MUNZER, A THEORY OF PROPERTY 254–91 (1990); JEREMY WALDRON, THE RIGHT TO PRIVATE PROPERTY 137–252 (Brotherhood eds., Jerusalem 1988).

[53] *See, e.g.*, Lawrence C. Becker, *Deserving to Own Intellectual Property*, 68 CHI.-KENT L. REV. 609, 609–10 (1993); Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287, 296–305 (1988); Benjamin G. Damstedt, *Note, Limiting Locke: A Natural Law Justification for the Fair Use Doctrine*, 112 YALE L.J. 1179, 1180–83 (2003); Wendy J. Gordon, *A Property Right in Self Expression: Equality and Individualism in the Natural Law of Intellectual Property*, 102 YALE L.J. 1533, 1538 (1993).

[54] LOCKE, *supra* note 51, at 288.

[55] Ofer Tur-Sinai, *Beyond Incentives: Expanding the Theoretical Framework for Patent Law Analysis*, 45 AKRON L. REV. 243, 265 (2012) [hereinafter Tur-Sinai, *Beyond Incentives*].

patented inventions in their projects, they may not have a real opportunity to engage in research and development.[56]

A similar argument can be made under the personality theory of property,[57] according to which, private property is necessary as a means for developing and realizing one's personality.[58] The personality theory can provide justification for property rights in various types of assets,[59] including intellectual property assets. With respect to intellectual property, a personhood interest may result early on in certain cases from the fact that the product reflects the personality of the individual who developed it.[60] In other cases, a personality bond between the intellectual product and its owner may develop at a later stage.[61] In the cumulative innovation context discussed herein, the personality theory can bolster the arguments in favor of an experimental use exception in patent law. This is because entrusting control over experimental uses of an invention in the hands of the patent owner denies "other potential inventors an opportunity to develop follow-on inventions based on such invention, and thus, narrows their opportunities to engage in research and development and express their own personality through such activity."[62]

Beyond the role that an experimental use exception may serve in enabling follow-on research and innovation, an experimental use exception may have value in other contexts as well. Such an exception provides members of the public with the freedom to engage in experiments for the purpose of "gratifying a philosophical

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[56] *See id.* at 270 (arguing that the labor theory supports the adoption of an experimental use exception in patent law).

[57] This theory is based on the work of Hegel. *See generally* G.W.F. HEGEL, PHILOSOPHY OF RIGHT (S.W. Dyde trans., 1996) (1821). It has been further refined by Margaret Radin. *See generally* Margaret Jane Radin, *Property and Personhood*, 34 STAN. L. REV. 957 (1982).

[58] HEGEL, *supra* note 57, at 51–52.

[59] *See generally* Radin, *supra* note 57.

[60] *See* Tur-Sinai, *Beyond Incentives*, *supra* note 55, at 278–79. This is certainly the case with respect to many creative works of authorship, the subject matter of copyright protection. Yet, this may also be the case with respect to various technological properties.

[61] *See id.* at 279–80.

[62] *See id.* at 281–82.

taste, or curiosity, or for mere amusement."[63] Permitting experimental use of patented inventions may also be beneficial in facilitating the testing and evaluation of patents by third parties.[64] This may result in the nullification of invalid patents and the restoration of competition in the domains covered by such patents.[65] Furthermore, experiments are often necessary for the purpose of designing around the patent in an attempt to seek alternative solutions to the same technological problem.[66]

The main argument against the adoption of a broad experimental use exception is that it might undermine the value of patents by depriving patent owners of the license fees to which they might otherwise be entitled.[67] The experimental use exception may also, in certain circumstances, facilitate the generation of improvements that may serve as market substitutes for the original invention.[68] Therefore, an experimental use exception may ultimately result in reducing the incentives to make and disclose patentable inventions in the first place.[69] Whether such incentives would be reduced to a sub-optimal level is unclear.[70] In any event, in order to properly balance the considerations at stake, many scholars discussing the experimental use exception have suggested the exception be qualified in various manners to distinguish between

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[63] Poppenhausen v. Falke, 19 F. Cas. 1049, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

[64] *See* Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) (noting, in dictum, that "it could never have been the intention of the legislature to punish a man, who constructed a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects").

[65] *See*, *e.g.*, Holzapfel & Sarnoff, *supra* note 29, at 16619 F. Cas. 104968.

[66] For the importance of enabling competitors to design around patents, see, for example, Gordon, *supra* note 35, at 632. *See also* Westvaco Corp. v. Int'l Paper Co., 991 F.2d 735, 745 (Fed. Cir. 1993); Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n, 805 F.2d 1558, 1572 (Fed. Cir. 1986); Yarway Corp. v. Eur-Control USA, Inc., 775 F.2d 268, 277 (Fed. Cir. 1985).

[67] *See*, *e.g.*, Holzapfel & Sarnoff, *supra* note 29, at 165–66.

[68] *Id.*

[69] *See*, *e.g.*, Eisenberg, *Patents*, *supra* note 39, at 1033.

[70] *Cf. id.* at 1030 (noting that the incentive theories do not supply an answer to the empirical question of how much incentive is necessary for an optimal level of invention and disclosure).

permissible and non-permissible experiments.[71] Still, others have urged a non-qualified application of an experimental use exception, while proposing to compensate the original inventor for the use of her invention in other manners.[72] All in all, it seems fair to suggest that there is a wide consensus among scholars as to the necessity for an experimental use exception, albeit its potential costs.[73]

In light of the foregoing discussion, one might expect that a relatively wide experimental use exception would be an integral part of every patent system in the world. However, there is a gap between this policy ideal and reality. While many countries have indeed adopted some sort of an experimental use exception, by statute[74] or case law,[75] an experimental use exception does not exist

[71] For example, one parameter that has been suggested in the literature is to apply the exception only where the likelihood for agreement between the parties is evidently low. *See* DAVID GILAT, *Experimental Use and Patents*, 16 IIC STUD. 1, 39–42 (1995). Another suggested distinction is between users motivated by profit and users with other motivations. *See*, *e.g.*, Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC'Y 357 (1957). *Cf.* Gitter, *supra* note 37, at 1628, 1679 (proposing to apply different rules with respect to commercially driven research and other research). Finally, some commentators have suggested distinguishing between research users who compete with the patent owner in the same market and research users who are "regular consumers" of the invention. *See*, *e.g.*, Eisenberg, *Patents*, *supra* note 39, at 1074–78; Eisenberg, *Rights*, *supra* note 39, at 225; GILAT, *supra*, at 44–45. A detailed discussion of such proposals is outside the scope of this Article.

[72] *See*, *e.g.*, Tur-Sinai, *Cumulative Innovation*, *supra* note 37, at 743 (maintaining that the commercial exploitation of a follow-on invention must be included in the scope of the original patent, in order to ensure that the first inventor is always allocated a portion of the profits).

[73] *But see* Jordan P. Karp, *Note: Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991) (arguing against a broad experimental use exception); Alan Devlin, *Restricting Experimental Use*, 32 HARV. J.L. & PUB. POL'Y 599 (2009) (supporting the current narrow construction of the experimental use exception in the United States).

[74] *See*, *e.g.*, Patentgesetz [Patent Law], 16 December 1980, BUNDESGESETZBLATT, Teil I [BGBL. I] at 14 § 11.2, last amended by Gesetz [G], Oct. 19, 2013, BGBL. I at 3380, art. I (Ger.), *translated in* BUSINESS TRANSACTIONS IN GERMANY app. 11 (Bernd Ruster ed., Matthew Bender 2014); Patent Act, 1977, c. 37 § 60(5)(b) (U.K.); Lei da Propriedade Industrial [Industrial Patent Law], 14 de maio de 1996, DIÁRIO OFICIAL DA UNIÃO [D.O.U.] de 9.279 § 43, *available at* http://www.wipo.int/wipolex/en/details.jsp?id=515 (Braz.); Patent Law (promulgated by the Standing Comm. Nat'l. People's Cong., Mar. 12, 1984, effective April 1,

at all in other countries.[76] Among the legal systems that employ an experimental use exception, there are extensive differences regarding its breadth.[77] In some jurisdictions, including the United States, the scope of the experimental use exception is so limited, that it is fair to say that the exception is practically non-existent.[78] In general, there is a considerable amount of uncertainty regarding the scope of the exception.[79]

1985) (amended 2008), 2008 STANDING COMM. NAT'L PEOPLE'S CONG. GAZ. § 69(2), *available at* http://www.wipo.int/wipolex/en/text.jsp?file_id=178664 (China); The Patents Act, No. 39 of 1970 § 47(3), INDIA CODE (2013), *available at* http://indiacode.nic.in; Patent Act, Law No. 121 of 1959, art. 69, para. 1, http://www.cas.go.jp/jp/ seisaku/hourei/data/PA.pdf (Japan).

[75] This is the case, for example, in Canada. *See* Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp., [1972] S.C.R. 506; Merck & Co. v. Apotex Inc., [2007] 3 F.C.R. 588, para. 109. This is also the case in the United States, where the origin of the exception is commonly traced to Whittemore v. Cutter, 20 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600). Notably, alongside the common law exception, a separate statutory exception exempts uses reasonably related to the development and submission of information needed for a regulatory approval to manufacture, use, or sell generic drugs or veterinary biological products after the expiration of the patent. This exception was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C. (1984)).

[76] This is the case, for example, in South Africa. *See Questionnaire on Exceptions and Limitations to Patent Rights*, WIPO: EXCEPTIONS (Sept. 1, 2014) http://www.wipo.int/scp/en/exceptions. In Australia, after a long period of uncertainty regarding the matter, an explicit experimental use exception was enacted in 2012. *See Australian Patents Act* 1990 (Cth) s. 119 (c).

[77] For a detailed comparison between the exceptions employed in various legal systems, see RICHARD GOLD & YANN JOLY, THE PATENT SYSTEM AND RESEARCH FREEDOM: A COMPARATIVE STUDY 1, 40–42 (2010), http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex6.pdf [hereinafter GOLD & JOLY]; WIPO, EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: EXPERIMENTAL USE AND/OR SCIENTIFIC RESEARCH (2013), http://www.wipo.int/edocs/mdocs/patent_policy/en/scp_20/scp_20_4.pdf.

[78] For the use of the term "evanescent" to describe the U.S. exception, see Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917 (2004). *See also infra* notes 107–10 and accompanying text.

[79] *See generally* GOLD & JOLY, *supra* note 77, at 42 (noting, for example, that in many cases, it is not even clear what constitutes an "experiment").

Against this background, the potential benefits of adopting an international standard regarding experimental use of patents are apparent. A properly crafted experimental use clause in an international instrument could promote uniformity among countries regarding the existence and scope of the experimental use exception and reduce the uncertainties regarding the applicability of the exception in various circumstances. This may be particularly important in our current era of globalization, where innovation is often conducted by multi-national enterprises with R&D facilities in numerous jurisdictions. Harmonization of patent laws with respect to the freedom to experiment with patented inventions will alleviate the burden, which may otherwise be placed on such enterprises to understand diverse patent laws and take them into consideration in devising their R&D strategy. As to the content of such harmonized global standard, the discussion above clearly supports the adoption of a relatively broad experimental use exception.

Beyond the direct potential effects of adopting an experimental use clause as part of an international instrument governing the IP field, such step may also indicate, in a more general manner, a commitment by the international community to the public interest dimension of intellectual property law. This is particularly important considering the general tendency of international instruments dealing with IP to focus on an owners' rights perspective while failing to safeguard user rights and other public interests.[80] As noted above, the current draft of the TPP's IP Chapter, in particular, leans heavily towards the interest of IP rights holders.

[80] It is interesting to note, in this context, the Washington Declaration on Intellectual Property and the Public Interest issued on August 2011 by a group of over 180 experts from 32 countries and 6 continents, who convened to re-articulate the public interest dimension in intellectual property law and policy. THE GLOBAL CONGRESS ON INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST, THE WASHINGTON DECLARATION ON INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST (2011), http://infojustice.org/wp-content/uploads/2011/09/Washington-Declaration.pdf [hereinafter Washington Declaration]. Among other things, the Washington Declaration notes that limitations and exceptions to intellectual property rights are under threat, as a result of "efforts to recast international law as a constraint on the exercise of flexibilities in domestic legislation" and calls for "the development of binding international agreements providing for mandatory minimum limitations and exceptions."

Therefore, having a provision in the IP Chapter designed to protect user rights may serve an important balancing function. Needless to say, the declaratory value of an experimental use clause included in a plurilateral trade agreement may have an impact outside the immediate circle of the member nations. Eventually, such a norm may be adopted as part of a more inclusive international instrument. Yet, in order for the Experimental Use Clause to have such beneficial effects, it must be properly crafted. Part III takes a close look at the way the Experimental Use Clause is currently drafted in order to evaluate whether this is indeed the case.

III. A CRITICAL ANALYSIS OF THE EXPERIMENTAL USE CLAUSE

The Experimental Use Clause currently reads as follows:

> 1. Consistent with [Article QQ.E.5 (Exceptions)], each Party may provide that a third person may do an act that would otherwise infringe a patent if the act is done for experimental purposes relating to the subject matter of a patented invention.
> 2. For the purposes of this Article, experimental purposes may include, but need not be limited to, determining how the invention works, determining the scope of the invention, determining the validity of the claims, or seeking an improvement of the invention (for example, determining new properties, or new uses, of the invention).[81]

As demonstrated below, the proposed Experimental Use Clause has a few notable shortcomings: (a) the use of permissive language; (b) a lack of guidance regarding the applicability of the experimental use exception in commercial settings; and (c) a narrow scope resulting in important scenarios of cumulative innovation being left out.

A. *Permissive Language*

The Experimental Use Clause provides that member parties "may" adopt an experimental use exception but does not mandate that they do so.[82] The use of permissive language, thus, leaves the matter at the discretion of each member party. Such discretionary authority may not be sufficient in encouraging countries that do not

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[81] *See* IP Chapter, *supra* note 1, art. QQ.E.5*ter*.
[82] *Id.*

currently have an effective experimental use exception to amend their patent laws in order to create such an exception or broaden an existing one.[83] In developed countries, in particular, any attempt to enact legislation that may be perceived, justifiably or not, as weakening patent protection would most likely encounter strong objection on behalf of various interest groups.[84] Thus, without mandatory restraints that would be imposed by the international regime, the Experimental Use Clause is not likely to have a significant influence in pushing member nations' patent laws in the right direction.[85] Hence, the benefits of having a harmonized global standard regarding the matter may not be attained. This is a major weakness of the Experimental Use Clause as currently drafted.

Most importantly, adhering to the model of "mandatory rights" and "permissive exceptions and limitations," which has dominated international instruments in the IP arena for many years,[86] reinforces the rights-centric approach characterizing the global intellectual property regime, while leaving user privileges at the

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[83] *Cf.* Ruth L. Okediji, *The International Copyright System: Limitations, Exceptions and Public Interest Considerations for Developing Countries*, 15 UNCTAD-ICTSD PROJECT ON IPRS AND SUSTAINABLE DEV. 1, 12 (2006) (noting, in connection with exceptions to copyright, that "within the highly contested space of negotiating domestic policy priorities, the evidence over the last decade firmly establishes the insufficiency of discretionary power in both developed and developing countries").

[84] *See*, *e.g.*, Christopher M. Holman, *Biotechnology's Prescription for Patent Reform*, 5 J. MARSHALL REV. INTELL. PROP. L. 318, 325 (2006) (noting that the biotechnological industry is against virtually all of the major proposed reforms to patent law that would weaken patents or restrict the rights of patent holders); Jay P. Kesan & Andres A. Gallo, *The Political Economy of the Patent System*, 87 N.C. L. REV. 1341, 1353, 1359–61 (2009) (discussing the lobbying efforts on behalf of pharmaceutical companies in order to maintain a strong patent system).

[85] *Cf.* Washington Declaration, *supra* note 80 (supporting the development of binding international agreements providing for mandatory minimum limitations and exceptions to intellectual property rights).

[86] *See* Okediji, *supra* note 83, at 9 (describing this as the prevailing model in international instruments). This model goes back to the Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, *as revised* July 24, 1971, and *as amended* Sept. 28, 1979, 102 Stat. 2853, 1161 U.N.T.S. 3 (entered into force in the United States Mar. 1, 1989).

margin.[87] Such approach does not sufficiently take into account existing practices and norms that have evolved in different countries since the execution of the TRIPS Agreement in 1994.[88] Moreover, it does not fit within the modern-day innovation landscape, where the paradigm of cumulative innovation is prevalent and user innovation is a robust phenomenon.[89] Ultimately, the rights-centric approach fails to reflect the growing understanding of scholars and policy makers that in order for intellectual property law to fulfill its ultimate goal of promoting creativity and innovation, it must enable the public to engage in a wide range of activities otherwise covered by IP rights.[90]

Yet, despite this critique of the permissive structure of the Experimental Use Clause, it is not realistic to expect a current revision of the Experimental Use Clause that would transform it into a mandatory provision. This is so, exactly because of the fact that exceptions and limitations to IP rights have been traditionally addressed in a permissive manner in international instruments governing the field, including the TRIPS Agreement. Deviating from this standard structure would be a disruption of a long-standing status quo, and it is highly unlikely that the negotiating members of the TPP would opt for it. Among other reasons, the United States, which has only a very narrow experimental use exception in place, is a negotiating party to the

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[87] *Cf.* Okediji, *supra* note 83, at 12 (noting, with respect to copyright law, that the "absence of mandatory minimum limitations and exceptions reinforces the dominant ethos of the international copyright system as primarily author-centric").

[88] As stated above, many countries have adopted experimental use exceptions as part of their patent laws. *See supra* notes 74–75 and accompanying text. *Cf.* Okediji, *supra* note 83, at 12 (noting, in the context of copyright law, that "[i]f the historic development of international copyright regulation has reflected both the principles and the practices of member states, then there is no reason why only the rights-oriented side of such practices should be integrated as mandatory norms of the international order").

[89] For the robustness of user innovation, see ERIC VON HIPPEL, DEMOCRATIZING INNOVATION (2005); Katherine J. Strandburg, *Users as Innovators: Implications for Patent Doctrine*, 79 U. COLO. L. REV. 467 (2008); William W. Fisher III, *The Implication for Law of User Innovation*, 94 MINN. L. REV. 1417 (2010).

[90] *See*, *e.g.*, Washington Declaration, *supra* note 80.

TPP.[91] One can expect, both in the United States and in other developed countries, a strong objection on behalf of various interest groups against the adoption of a standard that mandates the implementation of a more robust exception.[92] Thus, albeit not optimal, a permissive provision regarding experimental use seems to be the most that one can hope for currently.[93]

In truth, despite its weakness relative to a mandatory standard, a permissive provision may still serve as a "nudge" for countries to adopt an experimental use exception or broaden the scope of an existing exception.[94] Such a "nudge" may be most potent with respect to developing countries, which may otherwise be subject to pressure from the outside world that might circumvent any attempts to weaken IP rights. In fact, a wide experimental use may be particularly beneficial for such developing countries, which tend to be net importers of intellectual property, in facilitating knowledge spillovers from developed countries and enabling the local technological community to engage in follow-on innovation

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[91] For the narrow scope of the experimental use exception in the United States, see *infra* note 78 and accompanying text.

[92] *See infra* note 84 and accompanying text.

[93] Surely, a permissive provision can become mandatory at some point in the future because of later revision acts. As an example for a provision in an IP international instrument that was originally designed as an optional provision and became mandatory in future negotiations, see Berne Convention for the Protection of Literary and Artistic Works, art. 7 (Sept. 9, 1886) *available at* http://www.law.cornell.edu/treaties/berne/overview.html. Article 7 originally set a copyright term of life plus fifty but allowed contracting states with shorter terms to retain these terms. Yet, in 1948, the life plus fifty term became mandatory for all contracting states. *See* STEF VAN GOMPEL, FORMALITIES IN COPYRIGHT LAW: AN ANALYSIS OF THEIR HISTORY, RATIONALES AND POSSIBLE FUTURE 104 n. 368 (2011).

[94] *Cf.* RICHARD H. THALER & CASS R. SUNSTEIN, NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS (2008). As an example for a treaty provision which has been gradually adopted by member nation despite its permissive language, consider the *droit de-suite* case. While the Berne Convention provides that the implementation of *droit de-suite* is optional, more than seventy countries so far have introduced *droit de-suite* for visual artists in their legislation. *See* UNITED STATES COPYRIGHT OFFICE: RESALE ROYALTIES: AN UPDATED ANALYSIS (December 2013), http://www.copyright.gov/docs/resaleroyalty/usco-resaleroyalty.pdf, p. 8 and Appendix A.

and in attempts to design around patented technologies.[95] This is predominantly true with respect to developing countries that nevertheless demonstrate strong technological capabilities such as Brazil, India, and China, as these countries have a better potential to utilize the exception and benefit from it.[96]

Another reason why a wide experimental use exception may be predominantly advantageous for developing countries is the possibility that such an exception would be a factor in the decision of foreign enterprises to offshore their R&D to such developing countries.[97] Yet, this potential effect of the experimental use exception should also serve as a catalyst for developed countries to adopt the doctrine, in order to motivate local enterprises to keep their R&D facilities in the country.[98] In addition, by facilitating the development of improvements and alternatives to a patented invention, the adoption of an experimental use exception may increase domestic rivalry, which constitutes an important determinant of competitive advantage of one country over other countries.[99] Therefore, developing countries may benefit as well from the

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[95] *See* Shamnad Basheer & Prashant Reddy, *The "Experimental Use" Exception Through a Developmental Lens*, 50 IDEA 831, 842–43 (2010) (discussing the link between an experimental use exception and the prospect of knowledge spillovers through patents).

[96] *See id.* at 843–44 (providing the example of the Indian pharmaceutical industry, which has developed a strong set of skills in the field of incremental innovation).

[97] *See*, *e.g.*, Pamela Samuelson, *Intellectual Property Arbitrage: How Foreign Rules Can Affect Domestic Protections*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY – UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 635, 640 n.25 (Keith E. Maskus & Jerome H. Reichman eds., 2005) (noting that follow-on inventors may prefer to establish R&D facilities in countries that employ experimental use exceptions); Basheer & Reddy, *supra* note 95, at 846 (suggesting that "India must actively leverage the existence of its rather wide research exception to attract more research from the United States").

[98] *See*, *e.g.*, William Hubbard, *The Competitive Advantage of Weak Patents*, 54 B.C. L. REV. 1909, 1957 (2013) (noting that "in the absence of a robust experimental use defense in U.S. patent law, some U.S. companies may be forced to locate research facilities outside of the United States").

[99] *See id.* at 1953, 1957 (maintaining that "[b]ecause the experimental use defense is weaker in the United States than in other jurisdictions, U.S. patent law limits domestic competition more than foreign patent law restricts foreign competition, thereby reducing the competitive advantage of U.S. firms").

adoption of an experimental use exception, and an international norm may add certain weight in this direction against the expected pressure from interest groups.

Furthermore, a significant role that even a permissive clause in an international instrument may play is providing assurance to countries that wish to adopt or enhance a relevant provision regarding their compliance with the international legal framework. As explained above, the TRIPS Agreement does not specifically address experimental use of patents, but rather establishes a general Three-Step Test as the governing framework for exceptions to the rights of the patent holder.[100] While it is reasonable to assume that an experimental use clause would normally satisfy the Three-Step Test,[101] an explicit clarification to this effect can remove any remaining uncertainty and provide valuable guidance as to the legitimate scope of the exception.[102] Admittedly, though, as the TPP does not supersede the TRIPS Agreement, but merely supplements it for its twelve member parties, an experimental use exception can still run afoul of the Three-Step Test. This is made clear in the Experimental Use Clause itself, which includes the qualifying phrase: "Consistent with [Article E.5 (Exceptions)]." Article E.5 essentially reiterates the TRIPS Agreement's Three-Step Test.[103] Implementing an experimental use exception by any member party in reliance on the TPP's permissive language thus would not necessarily shield it from a finding that it violates its

[100] *See supra* note 24 and accompanying text.

[101] *See*, *e.g.*, GERVAIS, *supra* note 24, at 473 (maintaining that the type of exceptions that a member party may wish to introduce based on the Three-Step Test established by Article 30 of the TRIPS Agreement could include, among other things, experimental use exceptions); CORREA, *supra* note 24, at 303 (noting that "[i]n the light of current comparative patent law and on other proposals made on the subject . . . using the invention for research and experimentation" is among the exceptions that may be deemed legitimate within the scope of Article 30). A detailed discussion of this question exceeds the scope of this Article.

[102] *See generally* Canada – Patent Protection of Pharmaceutical Products (WT/DS114/R), http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf (demonstrating the uncertainty surrounding the scope of permitted exceptions under Article 30 of the TRIPS Agreement).

[103] *See supra* note 25 and accompanying text.

obligations under the TRIPS Agreement. From this perspective, the only thing that could provide real comfort regarding the freedom to adopt an experimental use exception in patent law seems to be an amendment of the TRIPS Agreement itself that would address this in a definitive manner.[104]

Finally, a permissive standard may have one advantage over a mandatory one. A mandatory provision, if adopted, would have to reflect a balance between the demands of all member parties, and as a result, may be drafted in a very general manner without providing the necessary clarifications with respect to various doctrinal questions related to the scope and application of the experimental use exception. It is actually quite possible that such a mandatory provision would conform to the "lowest common denominator," and thus allow the enactment of very narrow exceptions, along the lines of the current United States' experimental use doctrine. Under such an international regime, the member nations may not even have flexibility to adopt broader experimental use exceptions, inasmuch as the mandatory clause is construed as exhaustive. Conversely, under a permissive provision, while strong harmonization cannot be achieved, it should presumably be easier to negotiate a more elaborate provision that would set guidance to the member parties regarding the scope of the exceptions that they may legitimately implement as part of their patent laws. The next sub-parts consider whether the Experimental Use Clause, as currently drafted, provides such guidance. Unfortunately, as demonstrated below, this does not seem to be the case.

B. *No Guidance Regarding the Exception's Applicability in Commercial Settings*

One of the potential benefits of having a treaty provision addressing the experimental use exception is providing clear guidelines to countries regarding the proper construction of the doctrine. Yet, the Experimental Use Clause does not appear likely to have a significant impact if it remains as currently drafted.

[104] For early proposals for more specific provisions made during the negotiations of the TRIPS Agreement, see *supra* note 24.

Beyond the limitations of a permissive provision, which, by its nature, cannot guarantee uniformity among member states, the current version of the Experimental Use Clause is not detailed enough to clear the fog around various aspects related to the application of the experimental use doctrine.

One such important question that the Experimental Use Clause does not address is whether the exception may apply to experimental acts done for commercial purposes. This is one area where extensive differences exist between various legal systems regarding the scope of the doctrine. In some jurisdictions, the fact that a commercial purpose underlies the experimental activity does not preclude an application of the exception.[105] Yet, in other jurisdictions the exception only encompasses non-commercial research.[106] One such jurisdiction is the United States, where courts have consistently maintained that a commercial motive as the basis of the experimental use negates application of the exception, even if the commercial activity is meant to commence only after the patent has expired.[107] Under recent case law, the commercial connection barring the application of the exception could be very remote. In *Madey v. Duke University*,[108] the United States Court of Appeals for the Federal Circuit refused to apply the exception even in the context of basic research conducted by scientists in a non-profit research university, stating that:

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[105] *See*, *e.g.*, Patentgesetz [Patent Law], 16 December 1980, BUNDESGESETZBLATT, Teil I [BGBL. I] at 14, § 11.2, last amended by Gesetz [G], Oct. 19, 2013, BGBL. I at 3380, art. I (Ger.), *translated in* BUSINESS TRANSACTIONS IN GERMANY app. 11 (Bernd Ruster ed., Matthew Bender 2014); Patent Act, 1977, c. 37 § 60(5)(b) (U.K.).

[106] *See*, *e.g.*, Industrial Property Law of Mexico, art. 22 and Argentine Law 24.481, art. 36.

[107] *See*, *e.g.*, Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000) (stating the narrow construction of the experimental use exception); Ares-Serono, Inc. v. Organon Int'l B.V., 862 F. Supp. 603, 608 (D. Mass. 1994) (clarifying that "[t]he experimental use exception does not protect experiments or tests which have a commercial purpose"); Pfizer, Inc. v. Int'l Rectifier Corp., No. 73-58, 1982 U.S. Dist. LEXIS 17411, at *12 (C.D. Cal. July 20, 1982) (holding that experimental use "cannot be invoked for the protection of one who uses a patented invention commercially").

[108] 307 F.3d 1351 (Fed. Cir. 2002). The Supreme Court declined to hear the case on review. *See* 539 U.S. 958 (2003).

> [R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.[109]

In finding infringement, the Federal Circuit maintained that research projects conducted in a university setting "unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects," and that such projects "also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty."[110]

In order for the experimental use exception to enable cumulative innovation in a variety of settings, the exception must be available to follow-on inventors even if they are motivated by the prospect of commercial success. In current days, most inventors can be assumed to be at least partially motivated by the prospect of commercial success.[111] In light of the high level of uncertainty and lack of uniformity among different legal systems surrounding this specific question, it would be optimal if the Experimental Use Clause explicitly addressed it.[112] Even under the current permissive design of the clause, it can be clarified that member parties may choose to apply their experimental use exceptions in commercial settings as well. Such treatment of this aspect in a manner that leaves discretion to the member parties

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[109] 307 F.3d 1351, 1362 (Fed. Cir. 2002).

[110] *Id.*

[111] *See*, *e.g.*, Eisenberg, *Patents*, *supra* note 39, at 1023 (stating that even academic research is often motivated at least in part by commercial interests); Peter Ruess, *Accepting Exceptions?: A Comparative Approach to Experimental Use in U.S. and German Patent Law*, 10 MARQ. INTELL. PROP. L. REV. 81, 89 (2006) (noting that "universities are very much in the business of research, and many are generating substantial revenues for experiments or earning considerable royalties from patents in the commercial sector").

[112] Again, this would not guarantee that an exception adopted by a member party would pass muster under the Three-Step Test. However, there is good reason to believe that an exception covering commercial activities would be considered legitimate under the TRIPS Agreement. *See supra* note 101 and accompanying text.

should not trigger objection on behalf of countries that currently employ narrower exceptions, including the United States. Eventually, a treaty provision that includes a clarification to this effect may have impact on decision makers that consider the matter even in such jurisdictions.

C. *Narrow Scope of the Exception Allowed by the Experimental Use Clause*

There is another important aspect that is not sufficiently taken care of in the current draft of the Experimental Use Clause. In prescribing what may be the scope of experimental use exceptions adopted by the member parties, the Experimental Use Clause is drafted too narrowly. Under the clause, an exception may apply only to acts done for "experimental purposes relating to the subject matter of a patented invention."[113] This phrase is in use by various countries that have adopted an experimental use exception,[114] and is commonly interpreted as limiting the exception to experiments *on* an invention, as distinguished from experiments *with* an invention.[115] Thus, an exception designed in this manner does not cover experimental use of the invention that aims at researching or developing a different subject matter. Accordingly, while clearly covering the scenario of improvements to a patented invention,[116] it

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[113] *See* IP Chapter, *supra* note 1, art. QQ.E5*ter*.

[114] This language is used, for example, in Article 27 of the Community Patent Convention (Luxembourg Convention for the European Patent for the Common Market, Dec. 15, 1975, as amended by the Agreement Relating to Community Patents, Dec. 15, 1989, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:41989A0695(01):EN:HTML). Many European countries have adopted similar language in their national laws. *See*, *e.g.*, UK Patents Act, 1977, c. 37, § 60(5)(b), *available at* http://www.ipo.gov.uk/patentsact1977.pdf; Intellectual Property Code, CODE DE LA PROPRIÉTÉ INTELLECTUELLE, Aug. 1, 2003, art. L613–5(b) (Fr.), *available at* www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/pdf/france_e/e_chiteki_zaisan.pdf; Patents Act, 1992 (Act No. 1/1992) § 42(b) (Ir.), *available at* http://www.irish statutebook.ie/1992/en/act/pub/0001/index.html.

[115] *See*, *e.g.*, GOLD & JOLY, *supra* note 77, at 41.

[116] The proposed Article E.5ter (2) explicitly addresses this scenario, while providing that "experimental purposes may include . . . seeking an improvement of the invention (for example, determining new properties, or new uses, of the invention)." IP Chapter, *supra* note 1, art. QQ.E.5*ter*(2).

does not encompass other significant scenarios of cumulative innovation, including, most importantly, the use of patented research tools for purposes of follow-on innovation.[117] Research tools are essentially "products or processes used in research to investigate subjects other than the tools themselves."[118] To illustrate, in the biomedical field, research tools encompass "cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines."[119] The use of a patented research tool for purposes of investigating a subject matter that is not the tool itself is, by definition, not an experiment "relating to the subject matter of a patented invention," and thus it is outside the scope of the Experimental Use Clause, as currently drafted. Another scenario of cumulative innovation that may not be covered under the Experimental Use Clause is the use of a basic technology for purposes of developing applications in various technological fields.[120] Here again, such experimental use may not count as "relating to the subject matter" of the patented technology.

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[117] With respect to the research tools scenario, see generally Tur-Sinai, *Cumulative Innovation*, *supra* note 37, at 732.

[118] Holzapfel & Sarnoff, *supra* note 29, at 124–25. For other possible definitions of the term "research tools," see, Joshua D. Sarnoff & Christopher M. Holman, *Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents*, 23 BERKELEY TECH. L.J. 1299, 1302 (2008). *See also* Mueller, *supra* note 39, at 4, 14 (defining research tools in the biomedical industry as "the many varied resources used by scientists to conduct research and development of new drugs, therapies, diagnostic methods, and other therapeutic products").

[119] Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72092 n.1 (U.S. Dep't of Health and Human Services Dec. 23, 1999), *available at* https://grants.nih.gov/grants/intell-property_64FR72090.pdf.

[120] *See generally* SCOTCHMER, *supra* note 47, at 127–29, 132 (using the laser technology as an example for this important scenario of cumulative innovation); Carmen Matutes et al., *Optimal Patent Design and the Diffusion of Innovations*, 27 RAND J. ECON. 60, 60–61 (1996) (surveying other examples of basic technologies with a variety of applications).

Admittedly, the case for allowing experimental use *with* (rather than *on*) a patented invention is not clear-cut. The main concern is that providing an exception for users in such cases would deprive the patent owner of a meaningful opportunity to profit from her invention. The concern is heightened with respect to patented inventions that are intended from the outset to serve as research tools, and hence, their owners hold legitimate expectations to receive commercial rewards from their use in research. Exempting experimental uses in such cases may significantly reduce the commercial value of the patent and decrease the incentive to develop new research tools.[121] Another argument against allowing experiments with patented research tools is that when the invention serves as a means for conducting experiments that are not related to the subject matter of the invention, there is no competition between the patent owner and the research user. In such case, then, there is arguably no reason to assume that the patent owner would not grant a license to the research user.[122]

On the other hand, there are several strong arguments supporting the expansion of the experimental use exception to cover experiments for purposes not related to the subject matter of the invention, as in the research tools scenario.[123] In general, all the reasons outlined above in support of the experimental use exception are applicable in such cases as well. The risk associated with the need to disclose information that is not protected by exclusive legal rights may deter potential users of research tools from approaching the patent owner in an attempt to receive a

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[121] *See* Eisenberg, *Patents*, *supra* note 39, at 1035. *See also* Holzapfel & Sarnoff, *supra* note 29, at 247 (noting that the commercial rewards from research markets for patented inventions intended as research tools are not incidental to patent holder expectations, and are likely to be significant).

[122] *See* Eisenberg, *Patents*, *supra* note 39, at 1074, 1078; Eisenberg, *Rights*, *supra* note 39, at 225; GILAT, *supra* note 71, at 44.

[123] For other commentators supporting the application of an experimental use exception in settings involving research tools, see, for example, Gitter, *supra* note 37, at 1684–85 (proposing the application of the experimental use exception with respect to noncommercial research in DNA sequences); Thai, *supra* note 39, at 393–97 (suggesting the exemption of certain uses of research tools in university research).

license to use the tool.[124] Such risk exists even if the patent owner herself is not directly involved in the same technological field as the research user because she may pass along the information to others. Even if the user gets over this initial hurdle and tries to negotiate a voluntary license, the patent holder may be simply unwilling to make the invention available on reasonable terms.[125] Furthermore, high transaction costs may prevent the parties from closing a deal, even if the parties are not competing against each other. Among other things, the parties may find it difficult to reach an agreement on various aspects of the transaction, including the division of profits from the follow-on invention and the payments due in case the project fails.[126] These aspects may be particularly problematic when the follow-on inventor must use multiple patented research tools in order to develop her invention.[127] In such a setting, a "tragedy of the anticommons" might emerge,[128] and obtaining all required licenses may not be feasible.[129]

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[124] *See* discussion *supra* note 44 and accompanying text.

[125] *See* Holzapfel & Sarnoff, *supra* note 29, at 180.

[126] *See* Mueller, *supra* note 39, at 40 (noting that because of these difficulties research users do not constitute "ordinary consumers" of the invention).

[127] For an example, see SCOTCHMER, *supra* note 47, at 132 (discussing the case of a bioengineered crop seed which may require for its development input of multiple genes that code for various traits as well as research tools that facilitate insertion of the genes into the germplasm).

[128] The term "tragedy of the anticommons" refers to the problem that may arise "when multiple owners each have a right to exclude others from a scarce resource, and no one has an effective privilege of use." *See* Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 624 (1998).

[129] *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998) (exploring the potential anticommons problem in biomedical research); Ron A. Bouchard, *Balancing Public and Private Interests in the Commercialization of Publicly Funded Medical Research: Is There a Role for Compulsory Government Royalty Fees?*, 13 B.U. J. SCI. & TECH. L. l. 120, 144 (2007) (noting that "there is significant evidence to suggest that the scientific commons is eroding and that there is at least the potential for development of an anticommons"). *See also* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 INNOVATION POLICY AND THE ECONOMY 119 (Adam B. Jaffe et al. eds, 2001) (discussing the problem of "patent thickets," which occurs when "an overlapping set of patent rights

As to the concern that exempting research uses may decrease the ability of the patent owner to profit off her invention, it is first important to note that the reduction in revenues would not necessarily be significant in every case. For instance, when the relevant research tool is a product that is offered for sale through an anonymous market transaction—as, for example, in the case of patented chemical reagents sold via catalogues—researchers may choose to purchase the tool rather than make it themselves.[130] Certain users may simply prefer to avoid the time and costs of production or wish to obtain benefits of standardized production,[131] while others may choose to enjoy warranties and support and maintenance services offered by the seller of the tool, when relevant. In addition, certain patented inventions that serve as research tools in individual cases may still have other non-experimental uses that require a license even under a broad experimental use exception.[132] Beyond that, even if some reduction in the revenues for owners of patented research tools can be expected because of the application of a broad experimental use exception, it is not clear whether this would actually decrease the incentives to develop new research tools to a sub-optimal level.[133] Many research tools are invented by university or other non-profit innovators, who are not motivated by the prospect of commercializing the tools, but rather by their own needs as

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requires that those seeking to commercialize new technology obtain license from multiple patentees").

[130] In fact, with respect to such research tools that are readily available in the market, the reasoning described above for the application of the experimental use exception may not be applicable at all. For a detailed discussion, see Tur-Sinai, *Cumulative Innovation*, supra note 37, at 757–58. In any event, even if the experimental use exception covers such research tools, which means that users are free to manufacture it on their own, many users may prefer to buy the tool for the various reasons outlined in the text.

[131] *See* Holzapfel & Sarnoff, *supra* note 29, at 181.

[132] For example, some of the biomedical research tools listed in the text accompanying *supra* note 119 have uses in medical treatment and diagnostics.

[133] *See, e.g.*, Holzapfel & Sarnoff, *supra* note 29, at 181. *See also supra* notes 69–70 and accompanying text.

researchers.[134] In other cases, non-market incentives for producing research tools may exist, including government funding.[135]

Furthermore, while under an exception covering experimental use of research tools, the patent owner does not get compensated for the mere research use of her invention, it may still be possible to ensure her adequate compensation by allowing her to participate in the profits made off the second-generation product. The challenging aspect of this proposal is that a research tool is often not embedded in the final version of such second-generation product, albeit having been used in the process of its development.[136] Therefore, commercialization of the second-generation product would not normally constitute an exploitation of the original invention and, thus, would not require the consent of the original patentee. Yet, this can be resolved by adjusting patent scope rules, so that the exploitation of any invention developed while using the patented invention would be considered within the scope of the original patent.[137] Under such a rule, if the

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[134] *See* Strandburg, *supra* note 89, at 473–74 (arguing that in light of the prevalence of user innovation of research tool inventions, "[r]esearchers would very often continue to invent tools and methods for performing their own research even if they could not prevent others from later using those inventions") and 508 ("Many research tools are invented by non-profit researcher innovators, such as university faculty, postdoctoral researchers, and graduate students.").

[135] *See, e.g.*, Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 838 (2001) (noting that "even narrow patent rights on upstream research may create sufficient incentives for producing this research, either because the research is relatively inexpensive or because it is, at least in part, publicly funded").

[136] *See* HAROLD EINHORN & ERIC E. BENSEN, PATENT LICENSING TRANSACTIONS (updated through October 2013), 6A-20 (noting that research tools by definition form no part of the resulting product); Tur-Sinai, *Cumulative Innovation*, *supra* note 37, at 732 (describing this feature as the defining characteristic of the research tools scenario, as distinguished from other cumulative innovation settings). *But see* SCOTCHMER, *supra* note 47, at 132 (demonstrating that some research tools may end up embodied in the second-generation product).

[137] For comparison, in copyright law, a "derivative work" is defined as any "work *based upon* one or more preexisting works . . . ." 17 U.S.C. § 101 (2006)

research use results in the successful development of a commercial product, the research user would have to request a license in order to market such product, and the fees payable in return for such license would serve as the means to pass a share of the profits to the hands of the original patentee.[138] Undeniably, proving that the follow-on product was developed by using the patented invention may not be easy. But the difficulty of detecting and proving infringement exists under the alternative no-experimental-use regime as well.[139] Notably, the difficulty to prove infringement resulting from the hidden nature of the use exists, in general, in connection with the broad category of process patents.[140] One mechanism that may mitigate this difficulty to some extent is the application of a legal presumption of infringement in certain cases where features of the final product or other circumstances indicate a strong likelihood of use of the patented research tool.[141]

In light of all the above, it seems that an application of the experimental use exception to the research tools scenario is something that should be given serious consideration by legal systems. Embracing such legal regime may serve an important role

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(emphasis added). For a suggestion to adopt such "Absolute Scope Principle," see Tur-Sinai, *Cumulative Innovation*, *supra* note 37, at 743.

[138] In this context, it may be advisable to adopt liability rule doctrines—e.g., a compulsory license regime—to be applied in case the parties fail to conclude a voluntary agreement allowing for the commercial exploitation of the follow-on product, while dividing the profit between the parties in a manner ensuring their respective incentives. A detailed cost-benefit evaluation of such regime exceeds the scope of this Article.

[139] *See* EINHORN & BENSEN, *supra* note 136, at 6A-20 (noting that the owners of research tool patents may find it hard to meet their burden of proving infringement, as they typically have no ability to ascertain whether certain research activities resulting in commercial products involved use of their patents); Eisenberg, *Patents*, *supra* note 39, at 1071–72 ("Making and using a patented invention within a research laboratory is not very conspicuous and thus may never come to the attention of the patent holder."); Walsh et al., *supra* note 46, at 324 (noting that infringement of research tool patents is often hard to detect).

[140] *See generally* Alan Wright, *The North American Free Trade Agreement (NAFTA) and Process Patent Protection*, 43 AM. U. L. REV. 603, 607 (1994) (describing the inherent difficulty of proving infringement of a process patent).

[141] *Cf.* 35 U.S.C. § 295 (2006) (a presumption to prove that a product was made by a patented process).

in preserving a proper balance between the rights of the patent holder and the need to minimize the potential chilling effect of patents on follow-on research and development. Certain patented research tools constitute essential building blocks for further developments in their respective technological fields, and the importance of ensuring broad access to such tools is apparent.[142] Indeed, a few countries, for example, Belgium[143] and Israel,[144] already employ a broad experimental use exception that encompasses experiments *with* an invention.

Yet, this is clearly not a "one size fits all" solution. While a meaningful experimental use exception must form an integral part of each and every patent system, the applicability of such an exception to the research tools scenario should ultimately be left to the discretion of each country, as it chooses the particular point of equilibrium amongst the competing considerations at stake. Such a decision would also necessarily be dependent on other features of the local patent system, including: (1) patentability requirements that may affect the possibility of registering patents on research tools in the first place;[145] (2) patent scope rules, which, directly affect the possibility of the research tool patent owner to profit from the markets for products developed while using the tool;[146] and (3) the availability of other means to incentivize development of research tools, including direct governmental support for such

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[142] *See, e.g.*, E. Richard Gold, Yann Joly & Timothy Caulfield, *Genetic Research Tools, the Research Exception and Open Science* 3:2 GENEDIT 1, 1–2 (2005) ("Some of the most important genetic research tools are fundamental research platforms that open up new and uncharted areas of investigation."). *See also* Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 603–04 (2005) (noting the existence of patents that cover the building blocks of the emerging field of nanotechnology).

[143] Loi sur les brevets d'invention [Patent Act] du 28 mars 1984, Moniteur Belge [M.B.] [Official Gazette of Belgium], art. 28(1)(b). For commentary, see generally Geertrui Van Overwalle & Esther van Zimmeren, *Reshaping Belgian Patent Law: The Revision of the Research Exemption and the Introduction of a Compulsory License for Public Health*, 64 IIP FORUM 42 (2006).

[144] Patents Law, 5727-1967, SH § 1 (Isr.).

[145] *See*, *e.g.*, Rai, *supra* note 135, at 838–44 (discussing the possibility of keeping upstream research outside the bounds of patentability).

[146] *See* discussion *supra* notes 136–41 and accompanying text.

activity.[147] In respect to this particular question, then, a permissive international regime delegating discretion to the member parties is probably the most appropriate one.[148]

However, the Experimental Use Clause, as currently drafted, does not even refer to an exception covering the use of research tools as an option. As stated above, the Experimental Use Clause stipulates that each Party may exempt acts that are done "for experimental purposes relating to the subject matter of a patented invention."[149] Accordingly, an experimental use provision that exempts experiments *with* patented inventions for the purpose of developing a different invention is not covered by the Experimental Use Clause. In theory, a member state could still choose to adopt a broader experimental use exception under the framework of Article E.5—the general authority to provide exceptions to patent rights—provided that such exception meets the general Three-Step Test restated therein.[150] Yet, the narrow manner in which the Experimental Use Clause is currently drafted may have a deterring effect on member parties that would consider doing so. Indeed, in light of the fact that the Experimental Use Clause is dedicated to experimental use of patents, one could plausibly argue that in this particular domain, such specific clause overrides the general authority to enact exceptions, and therefore, any enactment or revision of an experimental use exception by a member state must be made within its contours. As a result, rather than encouraging member states to consider adopting broad experimental use exceptions, the Experimental Use Clause may actually have the opposite effect. In order to remedy this

[147] *See supra* note 135 and accompanying text.

[148] Surely, even if the Experimental Use Clause as a whole is drafted in a mandatory manner, this particular aspect may be left to the discretion of the member parties.

[149] The Experimental Use Clause goes on, in its second part, to state that "experimental purposes may include, but need to be limited to" various acts, including seeking an improvement of the invention. However, this "open list" is merely an illustration of the general stipulation included in the first part of the clause, and thus—cannot be used as the basis for enacting an experimental use exception that deviates from such general stipulation. *See* IP Chapter, *supra* note 1, art. QQ.E.5*ter*.

[150] *See supra* note 25 and accompanying text.

shortcoming, the Experimental Use Clause must be amended so that it provides member states with discretion to enact exceptions that cover experiments *with* patented inventions alongside experiments relating to the subject matter of the invention.[151]

IV. CONCLUSION

The release of the draft IP Chapter of the TPP by WikiLeaks provides a timely opportunity to review its content, as the TPP negotiations advance.[152] This Article provided a critical analysis of one clause that is included in the draft: The Experimental Use Clause. As the analysis above shows, an experimental use exception should be regarded as an essential component of every patent system that seeks to mitigate the potential chilling effect of patents on follow-on research and development. Yet, despite the strong policy considerations supporting an experimental use exception, it has not been adopted by all countries. Even among the jurisdictions that employ such exception, there is no uniformity regarding its scope and a great deal of uncertainty surrounds the matter. Against this background, this Article highlights the opportunity that the TPP presents, in its potential to facilitate the adoption of broad experimental use exceptions by the member states in order to create a global legal environment supportive of cumulative research and development.

Yet, taking a close look at the actual text of the proposed Experimental Use Clause reveals certain shortcomings in the way it is currently drafted. First, by using permissive language, rather than mandatory language, the Experimental Use Clause leaves the matter to the discretion of the member parties. Without mandatory restraints imposed by the international regime, the clause is not

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[151] Clearly, such exceptions would still need to meet the Three-Step Test. In this particular context, in order to evaluate whether a specific exception is legitimate, other features of the relevant patent system may need to be taken into account. *See supra* notes 145–47 and accompanying text.

[152] *See, e.g.*, Solís, *supra* note 3, at 1 (noting that the talks have reached a crucial phase); Joshua Rosenfield, *Listen: Former Ambassador Urges U.S. Action on TPP Negotiations* (Feb. 27, 2014), *available at* http://asiasociety.org/blog/asia/listen-former-ambassador-urges-us-action-tpp-negotiations (indicating that the negotiations are in their final stretch).

likely to have a significant weight in local policy discussions regarding the matter. Second, the Experimental Use Clause does not prescribe clear guidelines to the member parties regarding various aspects related to the scope of the experimental use exception. Most notably, it does not clarify whether the exception may apply to experimental acts done for commercial purposes. Finally, while allowing member nations to make an exception for experimental acts relating to the subject matter of a patented invention, the Experimental Use Clause fails to address "experiments *with* an invention" aimed at developing a different invention. The clause, thus, leaves outside of its permissive scope important scenarios of cumulative innovation, including the use of patented research tools in the process of developing a follow-on invention.

The analysis made herein, thus, calls for an amendment of the Experimental Use Clause. Ideally, the clause should mandate the member nations to adopt an experimental use exception. However, as explained above, this is not likely to happen. Assuming that the Experimental Use Clause remains drafted in a permissive manner, it should at least provide extensive guidance to the member parties regarding the scope of the experimental use exceptions that may be legitimately implemented. Among other things, the Experimental Use Clause should clarify that a country may choose to adopt an experimental use exception that applies in commercial settings as well, and that such exception may cover experiments *with* an invention and not only experiments *on* an invention, as long it meets the Three-Step Test.

As noted above, including a detailed experimental use clause in an international instrument governing the IP field is valuable not only in itself, but also as a more general indication for a growing commitment of the international community to user rights in patent law. The rights-centric approach, which has dominated international instruments in the IP field for many years, does not sufficiently take into account existing practices and norms in various countries and does not fit modern-day innovation landscape, where innovation is often conducted in cumulative manner. In the context of the TPP, as the current draft of the IP Chapter includes various provisions that strengthen the rights of IP owners well beyond the

standards reflected in existing international instruments, a properly crafted Experimental Use Clause may serve a particularly important balancing function.