Over 5 Billion *Not* Served: The TRIPS Compulsory Licensing Export Restriction

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DISEASE AND ENVIRONMENTAL DESTRUCTION are two of the most pressing issues facing humankind in the twenty-first century. We rely on technological innovation and its widespread diffusion, to meet these global challenges. But as breakthrough technologies emerge on these fronts, the TRIPS Agreement frustrates product diffusion by prohibiting compulsory licensing to export markets (article 31(f)). The contribution of this article to the literature on TRIPS compulsory licensing is twofold. First, an economic analysis is employed to argue that article 31(f) is contrary to the patent and trade rationales embodied in the TRIPS Agreement. Specifically, TRIPS expresses a liability rule that balances the incentive to innovate with trade promotion and technological transfer rationales that justify compulsory licensing in situations of international patent abuse. Provided the incentive to innovate is maintained, serious product diffusion shortfalls in export markets can and should be remedied by compulsory licensing. Second, the article probes specific incentive- and diffusion-based factors that should be relevant to export market compulsory licensing. Business reasons for failing to sell or license on reasonable commercial terms are assessed for legitimacy from an incentive promotion perspective. At the same time, product demand must be assessed to gauge the magnitude of product diffusion-based problems in developing country markets. The article concludes by examining exhaustion rules and trade diversion concerns that would be central to a regime of international compulsory licensing.

LES MALADIES ET LA DESTRUCTION ENVIRONNEMENTALE sont les deux fléaux les plus urgents auxquels l'humanité fait face en ce début de 21e siècle. Nous comptons sur les progrès technologiques et leur vaste dissémination pour nous aider à relever ces défis à l'échelle mondiale. Cependant, tandis que les technologies de pointe font leur apparition sur ces fronts, l'Accord sur les ADPIC freine la diffusion des produits en interdisant l'octroi de licences obligatoires pour les marchés d'exportation (alinéa 31(f)). L'apport de cet article à la littérature relative à l'octroi de licences obligatoires en vertu de l'Accord sur les ADPIC est de deux ordres. D'une part, il renferme une analyse économique qui vient étayer la thèse selon laquelle cet alinéa 31(f) contredit les fondements relatifs aux brevets et au commerce de l'Accord sur les ADPIC. En particulier, l'ADPIC contient une règle en matière de responsabilité qui combine les incitatifs à innover en matière d'échanges commerciaux avec les raisons d'être du transfert technologique qui justifient l'octroi de licences obligatoires dans des situations d'abus de brevet international. Si l'on conserve l'incitatif à innover, il faudrait alors remédier aux graves problèmes de diffusion des produits dans les marchés d'exportation au moyen des licences obligatoires. D'autre part, l'article passe en revue les facteurs spécifiques à l'incitation et à la diffusion qui devraient être pertinents pour l'octroi de licences obligatoires aux marchés d'exportation. Les raisons commerciales expliquant l'échec à vendre ou à octroyer une licence à des conditions commerciales raisonnables sont analysées pour en déterminer la légitimité selon une perspective de promotion. En même temps, la demande pour les produits doit être évaluée de façon à jauger l'ampleur des problèmes liés à la diffusion des produits dans les marchés des pays en développement. L'article conclut en examinant les règles relatives à l'épuisement et les préoccupations liées au détournement des échanges cruciales pour un régime d'octroi de licences obligatoires à l'échelle internationale.

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1. INTRODUCTION

WE RELY ON TECHNOLOGICAL INNOVATION, and its widespread diffusion, to combat the pressing global threats of the 21st century including deadly disease and catastrophic climate change. But as breakthrough technologies emerge to help mitigate such problems, international patent law can frustrate global dissemination of innovative products and processes. In recent years, access to life-saving AIDS medicines and to environmentally sound technologies has been unreasonably denied to willing (even desperate) buyers in developing world countries. International compulsory licensing, i.e. forcing the licensing of needed technologies to competitors in the *developed* world to supply *developing* world markets, is an important way of addressing North-South dissemination problems. However, the World Trade Organization's (WTO) *Agreement on Trade-Related Aspects of Intellectual Property* (TRIPS)[1] restrictions on compulsory licensing—in particular, the article 31(f) export restriction—closes off this route of technological diffusion. While much fanfare has surrounded the recent amendment to the TRIPS compulsory licensing provision (TRIPS Amendment),[2] which makes it easier for generic manufacturers to export reasonably priced pharmaceuticals to the developing world, this new regime applies only to essential medicines and, even then, is overly restrictive.

The purpose of this paper is to argue for the repeal of article 31(f), which currently allows only compulsory licensing primarily for domestic markets. I argue that states should be free to implement compulsory licensing legislation to supply developing country export markets under certain specified and appropriately stringent circumstances. The starting point of my argument is to accept, rather than challenge, international trade law and patent law purposes as reflected in TRIPS

1. *Marrakesh Agreement Establishing the World Trade Organization, Annex IC: Agreement on Trade-Related Aspects of Intellectual Property Rights*, (15 April 1994), <http://www.wto.org/english/docs_e/legal_e/27-trips.doc>, 1869 *United Nations Treaty Series* 299 [TRIPS].
2. *Amendment of the TRIPS Agreement*, WT/L/641, World Trade Organization: General Council (6 December 2005) (adopted, not yet in force), <http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> [TRIPS Amendment].

and, further, to suggest that the export restriction contravenes these rationales. The purpose of TRIPS is both to promote technological innovation through the incentive of patent protection *and*, as an anticipated consequence of this protection, to facilitate the transfer and dissemination of patented technologies through international trade. TRIPS envisions dynamic gains in the innovative capacity of developing country markets through a global regime of strong patent rights; compulsory licensing for export markets (CLEM) is entirely consistent with this rationale. Furthermore, the concept of patent abuse, as conceived in TRIPS, suggests that the patent right to exclude is not absolute but may be conditioned by competing goals of technological transfer and dissemination. In the language of Calabresi and Melamed, TRIPS expresses patent rights as a liability rule, as opposed to a property rule, for which CLEM may (and should) be a vehicle to accomplish technological diffusion.[3]

Determining the exact threshold at which "international" patent abuse has occurred, thus justifying CLEM, is a difficult and inexact exercise. Courts and tribunals entrusted to assess these applications should employ a two-tiered analysis. First, they should strive to uncover and evaluate, from a patent incentive perspective, the legitimacy of business rationales for under-servicing export markets in respect of technological end products. The *ex ante* incentives to invent are preserved when courts uphold the right to exclude to allow businesses a reasonable period of time to develop and market an invention or to negotiate a licensing arrangement, to reap monopoly profits, or to gain competitive advantage in the marketplace. These business reasons for excluding competitors are legitimate and thus compulsory licensing applications should accordingly be denied unless the magnitude of demand in developing country markets is extremely high. However, there may be illegitimate business reasons, such as defensive patenting or refusing to license in markets in which the patent holder is not competing, where a compulsory license should issue even though demand for the product is less compelling. The second tier of analysis would assess the level of unmet demand for the technological end products and processes in export markets on a sliding scale based on the legitimacy or illegitimacy of the business reason for failing to license or trade on reasonable commercial terms.

Embarking on a discussion of the TRIPS Agreement or the HIV/AIDS pharmaceutical controversy invites considerations that I do not raise in this paper. The political dynamics of state and private actor interests concerning the international regime of intellectual property rights has been well documented.[4] The issue of access to AIDS/HIV drugs could easily include a discussion of the

3. Guido Calabresi and A. Douglas Melamed, "Property Rules, Liability Rules and Inalienability: One View of the Cathedral," (1971-1972) 85:6 *Harvard Law Review* 1089–1128.
4. For a contemporary treatment of the issue, see Keith E. Maskus and Jerome H. Reichman, "The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods," in Keith E. Maskus and Jerome H. Reichman, eds., *International Public Goods and the Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press, 2005), <http://eprints.law.duke.edu/archive/00001195/01/7_JIEL_279_(2004).pdf> at p. 3.

international law of human rights, technology transfer and/or development.[5] Finally, the concept of patent abuse (or in the US, the law of patent misuse) could be expanded into an analysis of relevant doctrine in competition law and policy.[6] I prefer, however, to pitch my arguments within the scope of TRIPS, and its underlying rationales. This paper is an attempt to offer a sustained analysis of the incongruous nature of TRIPS based on its own rationales of technological innovation, diffusion, and trade enhancement as well as to explore the relevant considerations that should be taken into account by national courts in determining whether to grant CLEM.

It is appropriate at the outset to clarify the use of terminology in the paper in connection with technology "transfer" and "dissemination," both of which appear as objectives of TRIPS. While there is no bright line distinction between these terms, it is arguable that "dissemination" is a broader term than "transfer." Technological dissemination may include disclosure of a patented invention, such as revealing to the world how a technology works, as well as dissemination of the actual product or process that embodies the invention. Technology transfer, on the other hand, refers to myriad activities involved in the successful transfer of hard equipment and soft know-how into developing countries.[7] As part of an international trade agreement, it is a reasonable inference that either or both of these terms imply the dissemination of patented end products or processes. I have adopted the term "technological diffusion" to specify the narrow focus of this paper, being a market-based method of meeting the demand in developing countries for technological end products or processes.[8]

The components of the discussion break down as follows. Part 2 provides an overview of TRIPS including its provisions on patent abuse (the wrong) and compulsory licensing (the remedy); as well, the TRIPS Amendment for essential medicines is briefly described and analyzed. Part 3 examines the patent and trade rationales for TRIPS and finds that the export restriction is contrary to the justifying aims of the treaty. In Part 4, the concept of patent abuse in TRIPS is discussed, and the part concludes that states should have discretion to undertake the necessary balancing between incentive-based as well as diffusion-based

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5. For international human rights law, see Philippe Cullet, "Patents and Medicines: The Relationship Between TRIPS and the Human Right to Health," (2003) 79:1 *International Affairs* 139–160, <http://www.ielrc.org/research_intellectual_property.php>. On the issue of international technology transfer, see Cameron Hutchison, "Does TRIPS Facilitate or Impede Climate Change Technology Transfer into Developing Countries?" (2006) 3:2 *University of Ottawa Law and Technology Journal* 517–537, <http://www.uoltj.ca/articles/vol3.2/2006.3.2.uoltj.Hutchison.517-537.pdf>. On the nexus between intellectual property and development, see Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development* (London, 2002), <http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf>.
6. See Canadian Competition Bureau, *Intellectual Property Enforcement Guidelines*, <http://www.competitionbureau.gc.ca/internet/index.cfm?itemID=1286&lg=e>. See discussion of patent misuse below at note 80 and accompanying text.
7. The term "technology transfer" has been defined in the context of climate change as "a broad set of processes covering the flows of know-how, experience and equipment for mitigating and adapting to climate change amongst different stakeholders such as governments, private sector entities, financial institutions, NGOs and research/education institutions." Intergovernmental Panel on Climate Change, *Methodological and Technological Issues in Technology Transfer* (Cambridge University Press, 2000), <http://www.grida.no/climate/ipcc/tectran/index.htm> at p. 3.
8. I borrow this term from the United Nations Framework Convention of Climate Change, *Summary of the Senior-Level Round-Table Discussion on Enabling Environments for Technology Transfer, held at The Ninth Session of the Conference of the Parties*, FCCC/SBSTA/2004/2 (5 April 2004) (United Nations Office at Geneva, 2004), <http://unfccc.int/resource/docs/2004/sbsta/02.pdf> at para. 9: business representatives at the round table preferred the term "diffusion" as a "demand-pull concept which is how the majority of technologies are transferred."

concerns to determine whether a patent abuse has occurred for which a CLEM should issue. Finally, in Part 5, I allay concerns that the availability of CLEM will reduce the incentive to innovate, increase the attractiveness of trade secrecy as an alternative form of intellectual property protection, or undermine patent holder rights in world markets through trade diversion.

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2. THE TRIPS PATENT REGIME AND DEVELOPING COUNTRIES

THE DIFFUSION OF INNOVATIVE TECHNOLOGIES to the developing world has been a stated, even if largely unrealized, goal of international law since the Second World War. In many ways, TRIPS follows this tradition by extolling the ideal of international technology diffusion in principle while, by its strong patent protection terms, restricting the ability of the international community to achieve this purpose.[9] This part proceeds as follows: part 2.1 provides a very brief overview of TRIPS; 2.2 introduces the reader to the concepts of "patent abuse" and "compulsory licensing" as understood in TRIPS; and 2.3 offers a brief overview and analysis of the TRIPS Amendment which ostensibly facilitates the export of affordable essential medicines to developing countries.

2.1. TRIPS Overview

An invention qualifies for patent protection when it is novel, non-obvious to a person skilled in the art, and has utility. A patent grant offers rights of exclusive use, manufacture and sale to the owner of an invention for a time-limited period, and provides legal recourse against infringement of these rights. The TRIPS Agreement sets minimum standards of patent protection in WTO Member countries (Members),[10] including:

- Exclusive patent rights with respect to making, using, selling or importing of the technology (article 28)
- 20-year term of protection from patent filing date (article 33)
- Patents to be provided without discrimination as to place of invention, field of technology, or whether imported or locally produced (article 27)
- National treatment such that patent protection of non-nationals is to be no less favorable than for nationals (article 3)

These provisions mean that Members are obliged to grant 20-year monopoly rights to all patent holders and are prevented from affording preferential treatment to foster domestic innovation industries.

Certain exceptions and exclusions to patent rights are stipulated in TRIPS that permit Members to legislate:

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9. Hutchison, "Does TRIPS Facilitate or Impede Climate Change Technology Transfer into Developing Countries?" *supra* note 5.
10. Least developed countries remain exempt from patent protection obligations until 2013, and in respect of pharmaceuticals until 2016: *Least-Developed Country Members—Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products,* WT/L/478, World Trade Organization: General Council (8 July 2002), <http://www.wto.org/english/tratop_e/trips_e/art70_9_e.htm>.

- Limited exclusions to patentable subject matter (article 27.2)[11]
- Exceptions to exclusive rights conferred by patents based on the legitimate interests of patent owner and those of third parties (article 30)[12]
- The adoption of measures to prevent and control licensing practices or conditions that may have adverse effects on trade and may impede the transfer and dissemination of technology, including exclusive grant back conditions, conditions preventing challenges to validity and coercive packaging licensing (article 40)[13]
- Patent abuse and compulsory licensing (articles 8.2 and 31)

2.2. Patent Abuse and Compulsory Licensing

Patent abuse may be conceived as the use of a patent for an improper, unintended or malicious purpose.[14] Compulsory licensing, i.e., authorization by the state "permitting a third party to make, use, or sell a patented invention without the patent owner's consent,"[15] is the usual remedy for a wrong of patent abuse. An applicant for a compulsory license is typically a competitor of the patent holder. Under article 8.2 of TRIPS, exclusive patent rights may be modified, in accordance with the terms of the treaty, where the owner commits a patent abuse that unreasonably limits trade or harms the international transfer or dissemination of technology:

> Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.[16]

This article leaves intact "broad authority to define what may constitute an abusive unilateral exercise of intellectual property rights,"[17] provided the grounds are consistent with the terms of TRIPS. Typical grounds of patent abuse

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11. Named exclusions are: those that are necessary to protect *ordre public* or morality, including the protection of human, animal or plant life or to avoid serious prejudice to the environment.
12. Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Kluwer, 2001) at pp. 314–315: "Most commentators agree that the limited exceptions are those recognized in most patent laws: private and non-commercial use, use for research, experimental or academic purposes, use in the direct preparation of individual medicines by pharmacies[…]." But see *Canada—Patent Protection of Pharmaceutical Products: Report of the Panel,* WT/DS114/R, World Trade Organization (17 March 2000), <http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf >, which interpreted the article 30 exceptions narrowly.
13. Carlos M. Correa, "Can the TRIPS Agreement foster Technology Transfer to Developing Countries," in Keith Maskus and Jerome Reichman, eds., *International Public Goods and Transfer of Technology* (Cambridge University Press, 2005) 227–256 at p. 238. Correa describes these licensing practices as: "1) exclusive grantback provisions, i.e. those that oblige the licensee to transfer the improvement made on the technology exclusively to the licensor; 2) obligations imposed on the licensee not to challenge the validity of licensed rights and 3) coercive package licensing, i.e. the obligation for the licensee to acquire from the licensor other technologies or inputs he does not need or desire."
14. See the discussion below at note 76 and accompanying text.
15. Colleen Chien, "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?" (2003) 18:3 *Berkeley Technology Law Journal* 853–908, <http://www.law.berkeley.edu/journals/btlj/articles/vol18/Chien.web.pdf > at pp. 857–858.
16. TRIPS, *supra* note 1 at art. 8.2.
17. Hanns Ullrich, "Expansionist Intellectual Property Protection and Reductionist Competition Rules: A TRIPS Perspective," in Keith Maskus and Jerome Reichmann, eds., *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge University Press, 2005) 726–757, <http://www.iue.it/PUB/law04-3.pdf> at p. 733.

found in national legislation include failure to work a patent locally, or refusal to license (trade) the patent to a willing buyer on reasonable commercial terms. For example, under Canadian patent legislation, it is an abuse of a patent to refuse to license a patent on reasonable commercial terms when it results in a corresponding unmet demand for the technology.[18]

In the international trade context, this connection between refusal to meaningfully supply export markets (or to license to competitors *for* those markets), on the one hand, and the demand for the technology not being adequately met on reasonable terms in an export market, on the other, may take on a North-South dimension. Indeed, we even presume that by the terms of article 8.2 above, the exercise of patent rights to the serious detriment of global technological diffusion or as an unreasonable restraint of trade may constitute patent abuse. The presumption would be strengthened by an examination of the very *purpose* of TRIPS set out in article 7:

> The protection and enforcement of intellectual property rights should contribute to the *promotion of technological innovation and to the transfer and dissemination of technology*, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[19]

We see in article 7 that the dual purpose of TRIPS is both to promote innovation through patent protection as well as to diffuse the fruits of innovation on an international basis. From a reading of articles 7 and 8.2, we might say that states retain a high degree of autonomy to accomplish these competing goals in respect of both domestic and export markets. Where TRIPS helps frustrate the goal of technological diffusion on an international scale is in the compulsory licensing restrictions contained in article 31. Specifically, the unambiguous terms of the treaty prohibit compulsory licensing of patented goods destined exclusively for export markets—a provision I argue here should be revoked.[20]

Compulsory licensing is a court-imposed license to a third party applicant

18. See discussion below at note 76 and accompanying text. Kurt M. Saunders, "Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression," (2002) 15:2 *Harvard Journal of Law and Technology* (2002) 389–452, <http://jolt.law.harvard.edu/articles/pdf/v15/15HarvJLTech389.pdf> at pp. 438–439: "[T]he overwhelming majority of countries that belong to the World Trade Organization have enacted compulsory licensing provisions as part of their patent laws. The three most common compulsory licensing provisions apply where a dependent or improvement patent is being blocked, where a patent is not being worked, and where an invention relates to food or medicine."
19. TRIPS, *supra* note 1 at art. 7. See also *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, World Trade Organization: Ministerial Conference (14 November 2001), <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf> [The Doha Public Health Declaration] (emphasis added). The Doha Public Health Declaration reaffirms that "*each provision* of the TRIPS Agreement shall be read in light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles" at para. 5(a) (my emphasis). TRIPS article 8 principles allow Members to adopt provisions to "protect public health and nutrition" and "promote the public interest in sectors of vital importance to their socio-economic and technological development" provided the measures are consistent with TRIPS: see TRIPS, *supra* note 1 at art. 8.1. The goals of IP protection and trade enhancement are further reinforced by the first recital of the preamble to the TRIPS Agreement: "*Desiring* to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;" TRIPS, *supra* note 1 at preamble.
20. As such, there is little need to undertake a formal treaty interpretation analysis of TRIPS. The point to be emphasized by looking at the language of TRIPS is that the actual terms of the treaty in connection with compulsory licensing appear to undermine its stated objectives of technology trade and diffusion to developing world markets. TRIPS, *supra* note 1 at art. 31.

in situations where a patent holder and applicant are unable to voluntarily come to terms on the sale of the technology. According to article 31, Members may, in their discretion and taking account of and balancing their rights and obligations, set the grounds for compulsory licensing in their national legislation.[21] These grounds would typically include patent abuse or some identified public interest imperative.[22] Article 31 of TRIPS restricts compulsory licensing by imposing stringent conditions:

1. Licenses are to be given on their individual merits: (paragraph (a))
2. The proposed user first attempts to obtain authorization from the patent holder on reasonable commercial terms and conditions, and such efforts are unsuccessful within a reasonable period of time: (paragraph (b))
3. Scope and duration of use is limited to the purpose for which the license is authorized; authorization is to be terminated when the circumstances that led to the license "cease to exist and are unlikely to occur": (paragraphs (c) and (g))
4. Use is to be non-exclusive and non-assignable: (paragraphs (d) and (e))
5. Use shall be authorized "predominantly for supply of the domestic market of the Member authorizing such use:" (paragraph (f))
6. Right holder is to be paid adequate remuneration taking into account the economic value of the authorization, and subject to judicial review: (paragraphs (h) and (j))
7. More permissive rules for authorization as a remedy for anti-competitive practice as determined by a judicial or administrative process: (paragraph (k))

Cumulatively, the restrictions pertaining to duration, non-exclusivity, and export markets (numbers 3, 4 and 5) leave little incentive for a competitor to apply for a compulsory license whether for domestic or (even more so) export markets. First, the requirement that the license be non-exclusive does not prevent the patent holder from competing in the same market with a brand name advantage.[23] Second, the limited duration of the compulsory license presents as a practical economic disincentive to pursue a compulsory license since applicants may be discouraged by the uncertain and potentially time-limited nature of the license. A licensee must be allowed to recoup its investment in production, and this

21. The Doha Public Health Declaration, *supra* note 19 at paras. 5(a) and 5(b). See also Watal, *Intellectual Property Rights*, *supra* note 12 at p. 319. Though there is reference to some grounds in arts. 7, 8 and 30, these are not the only grounds.
22. See for example, former art. 41(3) of the *Patent Act*, (1970) *Revised Statutes of Canada* ch. P–4, <http://laws.justice.gc.ca/en/P-4/index.html> [*Patent Act 1970*], which allowed generic manufacturers to obtain a compulsory license for food or medicine unless there was "good reason to the contrary" not to grant such a license. This is not a ground of patent abuse but rather a modification of patent rights taken in the public interest, i.e. public access to cheaper food and medicines.
23. Correa, "Can the TRIPS Agreement Foster Technology Transfer to Developing Countries," *supra* note 13 at p. 249.

may require the life of the patent,[24] or at least a predictable period of time.[25] Third, and most importantly for our purposes, the compulsory license can only be granted if it is to predominantly serve the domestic market (article 31(f)).[26] Accordingly, states can serve export markets through a compulsory license only as an incident of supplying domestic markets.

In light of this export restriction, one solution to technology diffusion problems in cases of patent abuse is for the host state to grant a compulsory

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24. Carlos Correa, "Patent Rights," in Carlos Correa and Abdulqawi Yusuf, eds., *Intellectual Property and International Trade: The TRIPS Agreement* (Kluwer, 1998) 189 at p. 214.
25. Maxwell Morgan, "Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment," (2006) 64:1 *University of Toronto Faculty of Law Review* 45–112, <http://www.law.utoronto.ca/accesstodrugs/documents/TRIPS%20morgan%20original.doc> at pp. 82-83: "In any strategy to promote generic production, it is crucial to understand that generic companies, like other business entities, make investment decisions based on future market prospects. [...]Vigorous generic entry is far more likely where prospective markets are large and where sufficient sales can be anticipated to defray up-front investment."
26. The various drafts that led up to the 1994 TRIPS Agreement stemmed from the Uruguay Round of Multilateral Trade Negotiations, which began in 1986 through to November 22, 1990. One of the first drafts which arose from the negotiations was produced on July 23, 1990, and was called the Anell draft (after the Chairman of the TRIPS Negotiating Group, Lars E.R. Anell). It provided two alternative options for proposals; each provision was identified either as an "A" proposal or a "B" proposal, which differed on the stance of what the TRIPS agreement should encompass. Based on consultations, the "A" proposals tended to be supported by developed nations, while the "B" proposed provisions were generally supported by developing nations. The provision that is most analogous to article 31(f) of TRIPS was under the "Patents" section (section 5) of the draft and was an "A" type proposal; it read as follows:

    > 5A.3 Where the law of a PARTY allows for the grant of compulsory licences, [such licences shall be granted in a manner which minimises distortions of trade. To this end] the following provisions shall be respected: [...]
    >
    > 5A.3.5 Compulsory licenses shall be granted to permit manufacture for the local market only.

    See *Status of Work in the Negotiating Group on Trade Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods: Chairman's Report to the General Negotiating Group* MTN.GNG/NG11/W/76 (23 July 1990), <http://www.wto.org/gatt_docs/English/SULPDF/92110034.pdf>. See also The United Nations Conference on Trade and Development and the International Centre for Trade and Sustainable Development, *Resource Book on TRIPS & Development* (Cambridge University Press, 2005), <http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm>; Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (Sweet & Maxwell, 1998) at pp. 159–167.

    It would seem then that this was a fairly acceptable provision by the parties, since a very similar provision was found in the subsequent draft. The *Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, MTN.TNC/W/35/Rev.1 (3 December 1990) submitted to the Brussels Ministerial Conference in December of 1990. This draft was also prepared by Chairman Anell and can be found in the Ministerial Text of December 1990. The text of article 34(f) from this Brussels Draft can be read below:

    Brussels Draft:

    > 34 Where the law of a PARTY allows for other use[1] of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government, the following provisions shall be respected:
    >
    > ...
    >
    > (f) Any such use shall be authorised predominantly for the supply of the domestic market of the PARTY authorising such use.
    >
    > [1 "Other use" refers to use other than that allowed under article 33.]

    This draft was basically adopted in an almost unchanged form, which can be seen through a comparison with the final text of the 1994 TRIPS Agreement, included below. Article 31(f) from the TRIPS agreement was accepted from the Dunkel Draft, which was also a Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations; however, it was prepared by GATT Director-General Arthur Dunkel and it was proposed on December 20, 1991.

    > 31 Where the law of a Member allows for other use[2] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
    >
    > ...
    >
    > (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
    >
    > [2 "other use" refers to use other than that allowed under article 30]

    Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, MTN.TNC/W/FA (20 December 1991). See also TRIPS, *supra* note 1 at art. 31. See *Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations* MTN/FA (15 December 1993); TRIPS Amendment, *supra* note 2.

license where the patent has been filed in that country.[27] However, developing country firms may lack the expertise or even the basic infrastructure to develop technologies without more than just the blueprint that a patent discloses.[28] Indeed, the TRIPS Amendment for the compulsory licensing of pharmaceuticals for export markets is premised on the lack of manufacturing capacity in many developing countries to produce generic versions of essential medicines. Thus, an unmet need for a patent may arise in places where the ability to manufacture the technology simply does not exist. The consequences can be tragic, as we know from the sad saga of over-priced pharmaceuticals and the HIV/AIDS epidemic in Africa.[29]

Another kind of problem involves developed world patent holders refusing to deal important technologies to *developing* world firms for fear of competition from those firms. For example, in the 1990s, patent holders of environmentally friendly non-ozone depleting substances refused to license to firms in both India and Korea for this very reason.[30] As we will see, failing to serve export markets that a patent holder is unwilling to participate in is an illegitimate business reason, under a patent incentive rationale, and should be amenable to compulsory licensing either in the host country (currently permitted) or from a country of export. We should wonder whether, when technological advances occur to reduce greenhouse gas emissions through the development of biofuels or the carbon capture of coal , developed country innovators will not also prevent the global dissemination of such technologies that help mitigate climate change. The diffusion effects are aggravated in situations such as ozone depletion (and possibly climate change) where the patent involves a breakthrough technology that is not easily "invented around" or subject to competitive price pressures in the short term.[31] By restricting the ability of competitors to step in and supply export markets on reasonable terms, TRIPS fails to offer a market-based diffusion remedy in these types of situations.

2.3. TRIPS and Essential Medicines for Developing Countries

The article 31(f) restriction on supplying export markets posed an enormous hurdle to the transfer of essential medicines to developing countries. At the 2005

27. This is a strategy employed by some of the more developed developing countries such as Brazil and Thailand that have issued compulsory licenses for AIDS/HIV drugs: see "The Americas: A Conflict of Goals: Brazil's AIDS Programme," (12 May 2007) 383:8528 *The Economist* 57, <http://www.economist.com/world/la/displaystory.cfm?story_id=9154222>.
28. In particular, compulsory licensing (nor patent law in general) does not oblige the patent holder to transfer know how. At most, article 29 TRIPS requires sufficiently clear and complete disclosure and best mode of the invention to the skilled addressee in the art.
29. See Hans Henrik Lidgard & Jeffrey Atik, "Facilitating Compulsory Licensing Under TRIPS in Response to the AIDS Crisis in Developing Countries," (2005) *Loyola— Los Angeles: Legal Studies Paper No. 2005-18*, <http://ssrn.com/abstract=794228> at p. 3. But see Amir Attaran and Lee Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" (2001) 286:15 *Journal of the American Medical Association* 1886–1892, <http://www.iipi.org/articles/Antiretroviral_Article.pdf>, which argues that patent protection is not the main problem preventing access to these drugs in Africa. While this may or may not be the case, the argument of this paper is to suggest that patent protection under TRIPS can pose a barrier to access and, in such cases, compulsory licensing could be a solution.
30. Watal, *Intellectual Property Rights in the WTO and Developing Countries*, *supra* note 12 at p. 389; IPCC, *Methodological and Technological Issues in Technology Transfer*, *supra* note 7 at p. 98.
31. Patented technologies will often face competition thus having a downward effect on cost. But when there is not competition, and the invention is unique and in demand, the market relinquishes any control on unreasonable licensing practices: see Simone A. Rose, "On Purple Pills, Stem Cells, and Other Market Failures: A Case for a Limited Compulsory Licensing Scheme for Patent Property," (2005) 48:2 *Howard Law Journal* 579–628, <http://www.law.howard.edu/dictator/media/229/how_48_2.pdf> at p. 600.

Hong Kong ministerial conference, the WTO adopted an amendment to the TRIPS agreement that formalized a waiver of article 31(f) passed two years earlier permitting compulsory licensing of essential medicines (including treatments for HIV/AIDS) into developing country export markets.[32] Developing countries can now solicit the export of these medicines under set conditions, the main ones being: notification by the developing country of insufficient or non-existent manufacturing capacity in the pharmaceutical sector for the product (automatic for least developed countries); and specification of name and expected quantities of product(s) needed. At the supply end, compulsory licenses to generic manufacturers may be granted provided adequate remuneration is made to the patent holder (taking into account the economic value to the importing Member); the license covers only quantities needed to meet the needs of importing member(s); and these quantities and any distinguishing guises are posted on the designated website. Though a limited exception is made for countries that are part of a regional trading agreement (at least half of the members of which are least developed countries), the system follows a single-supplier single-market model, i.e. one generic supplier serving individual developing country markets.

The amendment to TRIPS is a positive development for the dissemination of life-saving pharmaceuticals to developing countries, though it fails to go far enough.[33] It is unclear whether generic manufacturers will have incentive to apply for compulsory licenses under the new regime. Potential licensees are limited to single country markets and are not able to take advantage of economies of scale by serving all potential export markets. Furthermore, restrictions are placed on quantities produced for these single markets thus further limiting incentive. And, if Canada's legislation, which sets a two-year duration on compulsory licenses is any indication, national implementing regimes may limit terms even more strictly than that provided in the adopted TRIPS amendment.[34] Indications are that very few countries have implemented legislation to allow compulsory licensing for essential medicines destined for developing countries.[35] Even then, my research has uncovered only one case of a generic pharmaceutical company that has applied

32. TRIPS Amendment, *supra* note 2. These essential medicines are for the treatment of HIV/AIDS, malaria, tuberculosis and other epidemics: see Doha Public Health Declaration, *supra* note 19 at para. 1. On the legal status of the Doha Declaration on Public Health prior to the adoption of the formal amendment, see Carmen Otero García-Castrillón, "An Approach To The WTO Ministerial Declaration on the TRIPS Agreement and Public Health," (2002) 5:1 *Journal of International Economic Law* 212–219 at p. 212, viewing the Doha Declaration as a supplementary means of interpretation under the Vienna Convention on the Law of Treaties art. 32.
33. One view is that the new regime "imposes several procedural hurdles that may ultimately render it ineffective": Morgan, "Medicines for the Developing World," *supra* note 25 at p. 65, footnote 98 and accompanying text.
34. *Patent Act*, (1985) *Revised Statutes of Canada* ch. P-4, <http://laws.justice.gc.ca/en/showtdm/cs/P-4?noCookie> at s. 21.09. A renewal for a further period of two years is possible: at s. 21.12.
35. Jeffrey Atik and Hans Henrik Lidgard, "Embracing Price Discrimination: TRIPS and the Suppression of Parallel Trade in Pharmaceuticals," (2006) 27:4 *University of Pennsylvania Journal of International Economic Law* 1043–1076, <http://<ssrn.com/abstract=956682> at p. 1044 , "virtually no countries have resorted to compulsory licensing" despite the TRIPS amendment and the provisional rule in place since 2003. This appears in fact to be an overstatement. According to <http://www.cptech.org/ip/health/cl/cl-export-legislation.html>, China, India, Korea, Norway, the Netherlands, Switzerland, the European Union have adopted amendments to their laws or issued policy directives to allow for compulsory licensing of pharmaceuticals destined for export markets.

for a compulsory license under the new legislation.[36] The most meaningful effect of the TRIPS Amendment may be that it has forced pharmaceutical companies to reduce their prices for essential medicines in developing markets so as to avoid competition from generic manufacturers.[37]

The argument of this paper is that the export restriction imposed in article 31 should be abolished *entirely* for *all* technologies. Some may counter that CLEM is either unnecessary, since the pharmaceutical access problem in the developing world has improved considerably, or is unwarranted, owing to the paucity of documented cases. On the first point, I would argue that the *threat* of compulsory licensing instituted under the TRIPS amendment has had the effect of forcing pharmaceuticals to reduce their prices in the developing world to ward off generic competition. We can now only imagine how much pain and suffering would have been avoided had this competitive pressure been felt by pharmaceutical companies when the large-scale demand first arose years earlier. Secondly, examples of unmet developing country demand of needed technologies are hard to uncover since there has been no systematic study of the issue.[38] The cases mentioned above are either high profile or based on anecdotal evidence. Still, the *promise* of article 31(f)'s repeal lies in the ability of competitors to exploit markets effectively abandoned by patent holders. The twofold effect of the repeal should be that patent holders will be more vigilant in supplying export markets on reasonable commercial terms and, if they do not, competitors will step in to exploit those market opportunities.

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3. PATENT AND TRADE RATIONALES DO NOT SUPPORT AN EXPORT RESTRICTION

ONE SHOULD HAVE NO ILLUSIONS ABOUT TREATY-MAKING—it is essentially a bargaining process between blocs of nations advocating opposing interests. As one author has commented, "[i]nstead of being based on sound economic principles, the conclusion of TRIPS is better understood as the product of global political forces."[39] It should come as no surprise, then, that the terms of TRIPS conflict with the stated purposes of the treaty. This is the case with the relationship between the goal of international technological diffusion, on the one hand, and the compulsory licensing export restriction, on the other. In this part, I propose to attack the export restriction on the basis that it frustrates diffusion goals (which modify) and trade promotion rationales (which justify) the TRIPS regime of strong patent protection rights.

36. Three years after coming into force, there is only one case of a generic company using the amendments to Canada's Patent Act to supply AIDS medication to an African country: Lisa Priest, "Canadian Companies Agree to Share Generic AIDS Drugs with Rwanda", (9 August 2007) *Globe & Mail*, available at <http://www.canadapharmacynews.com/labels/AIDS.html>.
37. Atik and Lidgard, "Embracing Price Discrimination," *supra* note 35 at p. 1044.
38. Hutchison, "Does TRIPS Facilitate or Impede Climate Change Technology Transfer into Developing Countries?" *supra* note 5.
39. Morgan, "Medicines for the Developing World," *supra* note 25 at p. 59 and footnote 54.

3.1. Patent Rationale

Patent protection may be justified on natural rights[40] or utilitarian rationales. Article 7 of TRIPS discloses a utilitarian rationale for patent protection, namely that "intellectual property rights should contribute to the promotion of technological innovation." Patent rights then are instrumental to promoting the objective of technological innovation on the basis of generally accepted *ex ante* incentives, discussed below. But patent rights are also conditioned on the secondary objective of promoting "the transfer and dissemination of technology."[41] Through CLEM, these secondary purposes can be accommodated while preserving *ex ante* incentives to promote innovation provided appropriately stringent thresholds are in place.

Utilitarian arguments for patent protection are premised on both the desirability of technological innovation and the perceived need for *ex ante* economic incentive to accomplish this objective. The grant of exclusive rights by way of patent is a necessary legal construct since the ideas behind inventions are non-excludable and non-rivalrous: i.e. without legal protection, I can not exclude others from using my idea nor can use of the idea be depleted by multiple users. This "public goods" nature of ideas means that, without legal intervention, the market will undersupply these goods. Without the promise of a patent monopoly, in other words, inventors would have no incentive to invent and technological progress would suffer. Thus a patent imposes artificial scarcity to fence off the idea from otherwise free-riding appropriation through copying.

But what is the nature of this economic incentive that propels innovation? There are two conventional answers. First, the "exchange for secrets" or disclosure rationale holds that inventors will keep their creations secret unless they are offered legal protection against free-riders who will copy or imitate their ideas; in order to induce disclosure of the invention upon which to base further scientific progress, society offers patent protection. In other words, a notional "contract" is formed wherein the inventor agrees to disclose the patent in exchange for exclusive rights during a limited term.[42] The inducement to disclose an invention in exchange for patent protection is, in no small measure, contingent upon rights afforded under trade secrecy law. As Landes and Posner point out, trade secrecy is not afforded property-like protection in the vein of patents and copyrights. There is no infringement by a competitor who uses a trade secret that is lost through, for example, breach of contract or reverse engineering.[43] A major consideration

40. John Locke is often cited in support of natural rights justification that a person has a property interest in any idea or work of his or her creation: "Though the earth and all inferior creatures be common to all men, yet every man has 'property' in his own 'person'. This nobody has a right to but himself. The 'labour' of his body and the 'work' of his hands, we may say, are properly his. Whatsoever, then, he removes out of the state that Nature hath provided and left it in, he hath mixed his labour with it, and joined to it something that is his own, and thereby makes it his property": John Locke, "Two Treatises on Government," <http://www.gutenberg.org/catalog/world/readfile?fk_files=28217&pageno=7>. A second natural rights rationale is that a person is entitled to receive "reward for his [or her] services in proportion as these services are useful to society": Edith Tilton Penrose, *The Economics of the International Patent System* (John Hopkins Press, 1951) at p. 6. However, these moral justifications based on an inherent right to one's ideas, or fairness considerations, do not find explicit expression in TRIPS.
41. TRIPS, *supra* note 1 at arts. 7 and 8.2: patent abuse includes the unreasonable restraint of trade or technology transfer thus affirming this dual rationale.
42. Penrose, *Economics of the International Patent System*, *supra* note 40 at pp. 31–32.
43. William M. Landes and Richard A. Posner, *The Economic Structure of Intellectual Property Law* (The Belknap Press of Harvard University Press, 2003) at p. 355.

in the choice between patenting and trade secrecy is whether or not an owner is confident that a competitor will develop the same invention within a prospective patent term.[44] If not, then trade secrecy becomes an attractive alternative to patent protection.[45]

Second, the "incentive to invent and to innovate" rationale holds that innovation will not be maximized unless inventors (and investors) have hopes of recouping their research and development costs, together with reasonable profits, upon fruition of an innovation. Strictly speaking, invention pertains to the ingenuity of the idea behind a patent whereas innovation refers to actual commercialization of the invention, though these quite separate activities are not distinguished in the classical formulation of this rationale. While much literature has since elaborated upon the *ex post* (to innovate) rationale of patent protection,[46] the classical formulation of the incentive to invent and innovate was premised on the public goods nature of inventive ideas discussed above, i.e. without property rights in ideas as non-rival and non-excludable goods, the market would undersupply invention.

But are these two *ex ante* rationales for patent protection compatible or are they in tension? Strandburg seems correct in concluding that, though these rationales are in tension, they are directed toward different kinds of inventive activity.[47] Whereas the incentive to invent applies to self-disclosing inventions susceptible to reverse engineering—such as pharmaceuticals—the incentive to disclose is germane to another category of invention altogether, the non self-disclosing kind. Either rationale is consistent with the abrogation of exclusive patent rights in exceptional cases inasmuch as economic incentive may be preserved within a regime of compulsory licensing.[48] Research and development

44. Landes and Posner, *The Economic Structure of Intellectual Property Law*, *supra* note 43 at p. 357. When that is the case, disincentives to patent include giving a competitor the basis for inventing around your innovation through disclosure; and exposing yourself to costly litigation to enforce a patent and to the risk that the patent will be found invalid.
45. Landes and Posner, *The Economic Structure of Intellectual Property Law*, *supra* note 43 at pp. 328–331, argue that the strongest economic arguments for the patent system comprise the following: 1) without patent protection, inventive activity would be biased towards inventions that could be kept secret; 2) innovators may not be the most efficient manufacturers of inventions and patents facilitate this exchange; 3) similarly, efficiency is enhanced by patents since disclosure enhances the ability of manufacturers in various sectors to use the same invention to make better products; and 4) without disclosure, market entry of potential competitors would be impeded by secret innovations thus leading to a tendency toward monopolistic market organization.
46. See Edmund Kitch, "The Nature and Function of the Patent System," (1977) 20:2 *The Journal of Law and Economics* 265–290 at p. 273, who analogizes patents to prospect claims signaling to others in the marketplace to shift their research and development resources to other activities.
47. Katherine J. Strandburg, "What Does the Public Get? Experimental Use and the Patent Bargain," (2004) 1 *Wisconsin Law Review* 81–156, <http://works.bepress.com/cgi/viewcontent.cgi?article=1003&context=katherine_strandburg> at pp. 105–106:

> The 'incentive to invent' theory assumes that inventions are self-disclosing—that is, that competitors can immediately appropriate inventive ideas and begin commercial competition almost as soon as an inventor brings a patented product to market. [… Thus], the patent disclosure can add little to a society's store of technical knowledge […]." On the other hand, the incentive to disclose is relevant "to another category of inventions—those for which trade secret protection is a viable option. […] The free-rider 'incentive to invent' theory *does not apply* to non-self-disclosing invention. Because these inventions could have been maintained as trade secrets for a sufficient time after commercialization to recoup the costs of their development, an exclusive patent grant is not necessary to stimulate invention.

48. It is probably the case that the disclosure rationale is compromised more inasmuch as the risk of compulsory licensing factors against patent protection (and in favor of trade secrecy) for non self-disclosing inventions; whereas, for self-disclosing inventions, there is no choice as to the kind of intellectual property protection. Having said that, appropriately high thresholds for compulsory licensing should negate much of the patent protection disadvantage for non self-disclosing inventions. Furthermore, the kinds of patent abuse addressed in this paper—the failure to supply markets otherwise not served by the patent holder directly—would have no negative impact on the patent holder's profits.

costs can be recovered, and profits reaped, within a period that falls far short of a 20-year term; incentive to disclose is preserved on the same basis and, in addition, there is no reason why the notional contract between society and inventor cannot be "conditional" on expectations that the patent will not be abused.[49]

Under either rationale, patents rights would ideally last just long enough to provide the appropriate incentive on a per invention basis. Of course, such a system would be difficult and costly to administer. The one-size-fits-all approach, i.e. a 20-year term of exclusive rights for *all* inventions, creates economic inefficiency by, in some instances, maximizing monopoly rents to innovators and inhibiting dissemination of the invention at competitive prices beyond an optimal period, i.e. beyond what is required to preserve the incentive to disclose or the incentive to innovate.[50] In other words, there can be a loss in static efficiency (optimal use of existing resources at the lowest possible cost) that is not offset by a gain in dynamic efficiency (optimal introduction of new or better products and processes and eventually lower prices).[51] Compulsory licensing can remedy inefficiency by balancing dynamic (incentive-based) and static (diffusion-based) concerns in individual cases of patent abuse.

It is possible that not all patent systems allow for compulsory licensing even for their domestic markets.[52] Such patent systems, where they exist, may grant absolute exclusive rights during the life of the patent.

Calabresi and Melamed would characterize models of absolute and conditional patent grants as, respectively, a property rule and a liability rule. According to a property rule, the state favours the entitlement of one entity over the other; if the latter entity wishes to gain the entitlement she "must buy it from him in a voluntary transaction in which the value of the entitlement is agreed upon

49. In one Canadian case, the court characterized the failure of the patent holder to locally work the patent (a now deposed ground of patent abuse) as "disregard[ing] the conditions on which the patent had been granted": *Sarco Co. v Sarco Canada Ltd* (CAN Ex Ct, 1969), 1969:2 *Canada Law Reports: Exchequer Court* 190, 57 *Canadian Patent Reporter* 193 at para. 21.

50. Conversely, it is possible that a 20-year term may be an insufficient reward to compensate the patent holder for investing in the innovation. As we are concerned here with the end product for which there is an unmet demand, we can presume that such technologies are successful to the point of providing adequate reward within the patent term.

51. Joseph E. Stiglitz, "Knowledge as a Global Public Good," in Inge Kaul, Isabelle Grunberg, and Marc A. Stern, eds., *Global Public Goods: International Cooperation in the 21st Century* (Oxford University Press, 1999) 308–325, <http://www2.gsb.columbia.edu/faculty/jstiglitz/download/Knowledge_as_Global_Public_Good.pdf> at p. 311; Carlos M. Correa, "Managing the Provision of Knowledge: The Design of Intellectual Property Laws," in Inge Kaul, ed., *Providing Global Public Goods: Managing Globalization* (Oxford University Press, 2003) 410–434, <http://www.netamericas.net/Researchpapers/Documents/Ccorrea/Correa5.pdf> at pp. 411–412.

52. I am not aware of legal system that does not permit *some* form of compulsory licensing. Though the US *Patent Code* does not *per se* permit compulsory licensing, other titles in the US Code do. Furthermore, it should be acknowledged that US patent law limits the anti-competitive exercise of patent rights under the doctrine of patent misuse though this is not the same as patent abuse leading to a remedy of compulsory licensing. The doctrine of patent misuse is a defense to patent infringement that renders the patent unenforceable where the patent holder makes "an impermissible attempt to extend the time or scope of the patent grant" through such behaviors as licensing tie-ins with unpatented products. The doctrine has been narrowed in recent years by a requirement that patent misuse also have anticompetitive effects. The doctrine of misuse, even in its expanded form, is different than the kind of patent abuse under consideration here—a failure to sell or license on reasonable commercial terms leading to a significant unmet demand—for which compulsory licensing (and not merely as a defense to patent infringement) is a remedy. Interestingly, though, Feldman makes the normative argument that misuse of a patent should be conceived in terms of whether or not the holder is frustrating the goals of the patent system (i.e. the progress of science), through behaviors like patent blocking. His argument is similar to the argument made in this paper concerning the first prong of analysis as to whether patent abuse has occurred. See Robin C. Feldman, "The Insufficiency of Antitrust Analysis for Patent Abuse," (2003–2004) 55:2 *Hastings Law Journal* 399–450, quotation at p. 403, <http://library.uchastings.edu/library/Library%20Collections/Faculty%20Publications/feldman_insufficiency.pdf >.

by the seller."[53] A liability rule, on the other hand, permits an initial entitlement to be destroyed where the competing party "is willing to determine an objectively determined value for it."[54] Another dimension to the distinction is that a property rule allows the holder of the right to set the price *ex ante* while a liability rule may extinguish the right with a determination of appropriate compensation by a tribunal *ex post*.[55] The choice of rule reflects the entitlement the state favours between competing entities, based on rationales of administrative and economic efficiency. If the state is indifferent between conflicting entitlements, then it may grant a property rule to the party whose entitlement is cheapest to enforce for administrative efficiency.[56] However, the choice of patent law regime is rarely indifferent to the entitlements it offers; rather, entitlements are chosen to further the policy goals of innovation and, not infrequently, product diffusion at a certain threshold.

The greater concern is economic efficiency, i.e. setting entitlements so that an optimal allocation of resources is achieved. Optimal efficiency is possible in the absence of transaction costs (e.g. negotiation and valuation impediments),[57] in which case a property rule would typically be the most efficient rule: the parties could determine a reasonable royalty and terms of use (or not) within a range of true values offered by the parties. However, "[o]ften the cost of establishing the value of an initial entitlement by negotiation is so great that even though a transfer of the entitlement would benefit all concerned, such a transfer will not occur."[58] Sellers will hold out for as much as they think a buyer will pay; buyers will similarly lowball what they are willing to pay. In other words, "there is no reason to believe that a market, a decentralized system of valuing, will cause people to express their true valuations and hence yield results which all would *in fact* agree are desirable."[59] Where transaction costs are high, lawmakers may choose a liability rule to facilitate an efficient allocation or transfer of entitlements. But this also has problems: objectively determined value of the entitlement may lead to gross over- or under-valuations of the actual worth of the entitlement to the holder.

For patent law, a property rule might be desirable if a state chooses to maximize the incentive for innovation to the exclusion of other considerations or believes that transaction costs are not endemic enough to the process to justify the creation of a liability rule that will be more costly for the state to administer. A liability rule, on the other hand, may be chosen to impose an objective value on a patent through compulsory licensing (i.e. the setting of a court-imposed royalty rate) in situations of high transaction costs.[60] In the US context, Merges argues that, since negotiations over the licensing of intellectual property usually involve a small number of parties, transaction costs are low (or at least can be

53. Calabresi and Melamed, "Property Rules, Liability Rules, and Inalienability," *supra* note 3 at p. 1092.
54. Calabresi and Melamed, "Property Rules, Liability Rules, and Inalienability," *supra* note 3.
55. Robert P. Merges, "Of Property Rules, Coase, and Intellectual Property," (1994) 94:8 *Columbia Law Review* 2655–2673 at p. 2655.
56. Calabresi and Melamed, "Property Rules, Liability Rules, and Inalienability," *supra* note 3 at p. 1093.
57. Calabresi and Melamed, "Property Rules, Liability Rules, and Inalienability," *supra* note 3 at pp. 1094–1095: "In such a frictionless society, transactions would occur until no one could be made better off as a result of further transactions without making someone else worse off," *supra* note 3 at p. 1095. The authors note however that efficiency is also influenced by distribution of wealth, *supra* note 3 at p. 1096.
58. Calabresi and Melamed, "Property Rules, Liability Rules, and Inalienability," *supra* note 3 at p. 1106.
59. Calabresi and Melamed, "Property Rules, Liability Rules, and Inalienability," *supra* note 3 at p. 1107.
60. A requirement (such as found in TRIPS) that the parties first attempt to reach agreement on reasonable commercial terms within a reasonable time as a precondition to an applicant applying for a compulsory license represents a modest effort to reduce transaction costs. See TRIPS, *supra* note 1 at art. 31(b) and *Patent Act*, *supra* note 34 at s. 65(2)(c).

low through institutional arrangements such as patent pools), and courts are ill-suited to determine value (the objectively determined value problem), a property rule for intellectual property is most appropriate.[61] Merges may be correct in arguing that multiple party transaction costs are typically absent from intellectual property negotiations.[62] However, significant transaction cost problems remain in most licensing negotiations, notably disputes concerning the true value of the intellectual property, holdout problems of the kind described above, even the desire to undermine (or at least not favor) competitors.[63] Moreover, these transaction costs may not be amenable to mitigation by institutional arrangements such as patent pools. For example, there are unlikely to be patents that generic companies can cross-license or pool with pharmaceutical patent holders.

The proposal advanced in this paper does not suggest that compulsory licenses should issue where negotiation and transaction cost problems prevent agreement in the short term. Rather protracted problems on this front—particularly those occasioned by illegitimate business reasons on the part of the patent holder that have negative or at least neutral effects on the incentive to innovate—together with a significant unmet demand in the export market would trigger compulsory licensing. Due to a lack of institutional or market based arrangements that would offset significant transaction cost problems between competitors vis-à-vis export markets, it follows that compulsory licensing, as a liability rule, maintains a cogent theoretical basis for the purposes of North-South technological diffusion.

By recognizing the wrong of patent abuse and the remedy of compulsory licensing, TRIPS sets patent entitlements according to a liability rule that is informed by purposes identified in the treaty. These purposes as revealed in article 7 are economic incentives (to disclose, or to innovate) to promote innovation as well as technological diffusion. In principle, the incentive to innovate, or to disclose, may be preserved within a regime of export market compulsory licensing. There is no basis, on classical patent rationales, for precluding the possibility of a compulsory license to serve export markets when patent abuse occurs. We can expect that incentive and diffusion objectives can both be promoted through a compulsory licensing regime that appropriately balances these objectives. As we will see in the next part, the trade rationale for strong international patent protection holds that *both* objectives can and should be achieved.

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61. Merges, "Of Property Rules, Coase and Intellectual Property," *supra* note 55 at pp. 2664–2665. He further contends that high transaction costs, where they do arise, give incentive for the creation of institutional arrangements to minimize those costs, e.g. collective societies in the copyright context.
62. Admittedly, Calebresi and Melamed, "Property Rules, Liability Rules, and Inalienability," *supra* note 3, analyze property and liability rules from the perspective of high transaction costs arising from multiple stakeholders negotiating for the entitlement.
63. "Transaction costs are those tangible costs and intangible costs associated with implementing the transfer of property rights. These costs are as simple and tangible as the costs involved in locating the property's source/owner, negotiating price and other terms, the physical transfer of the property, and the future enforcement of property rights obtained […] each party's valuation of its property, the economic or other goals of the parties, personalities of the parties […], and concreteness of the existing market for the goods and services": Rose, "On Purple Pills, Stem Cells, and Other Market Failures," *supra* note 31 at p. 598. Transaction cost problems are magnified when the innovation sought requires multiple licenses from different patent holders: Ashish Arora, Andrea Fosfuri, and Alfonso Gambardella, *Markets for Technology: The Economics of Innovation and Corporate Strategy* (MIT Press, 2001) at pp. 265–266.

3.2. Trade Rationale

The appearance of an intellectual property protection regime within a multilateral free trade agreement strikes one as odd. Is not the rationale of international trade to have countries compete on the basis of comparative advantage, i.e. specializing in the production of goods in which a country has a natural or productive advantage, leading to decreased prices for consumers, increased trade for all countries to their mutual gain and the maximization of global wealth?[64] Where do monopoly rights, which restrict competition, raise prices, and reduce the diffusion of goods fit into such a theory? One answer is to say that patent protection has no place in comparative advantage: technological innovation operates solely at the level of reducing the costs of production thus contributing to comparative advantage and lowered prices.[65]

This approach, however, negates the incentive rationale for the creation of patent rights, treating innovation as a factor of production that does not need to be encouraged through the incentive of exclusive rights. If we accept the incentive rationale (and TRIPS does), we must also accept that the ideas behind innovation have commodified economic value that can only be captured through patent protection.[66] In other words, innovation in itself is a factor of comparative advantage that is realized through the patent regime. Within developed country regimes of strong patent protection, innovators remain able to recoup their investment and make profits in countries with intellectual property protection, albeit on a smaller scale than if all countries (i.e. all markets) had strong patent regimes. We should expect that greater access to markets with vigorous patent protection would increase overall innovation given the potentially higher global rate of return. However, since poorer countries' intellectual property markets are weak and do not often provide added incentive to invent and, at the same, these countries are unable to exploit their comparative advantage in imitation, global allocative efficiency is decreased: there is neither added incentive to invent nor the ability to develop poor economies through imitation.[67]

The implication of the foregoing is that imitator and innovator economies will value intellectual property rights differently. As was the case pre-TRIPS, countries whose comparative advantage was imitation (many developing countries) will choose weak intellectual property regimes, while innovation based economies (the developed countries) will want strong intellectual property protection.[68] The problem TRIPS poses from a comparative advantage perspective is that, while liberalization of trade in goods improves both domestic

64. For more on comparative advantage, see Michael J. Trebilcock and Robert Howse, *The Regulation of International Trade*, 3d ed., (Routledge, 2005) at pp. 3–4.
65. Described as the neoclassical economic view in Erik S. Reinert, "Competitiveness and its predecessors—A 500-Year Cross-National Perspective," (1995) 6:1 *Structural Change and Economic Dynamics* 23–42, <http://www.step.no/reports.asp?idAut=116> at p. 27. See also F.M. Scherer, *New Perspectives on Economic Growth and Technological Innovation* (Brookings Institution Press, 1999) at pp. 7–22 for a summary of the thoughts of Adam Smith, David Ricardo, and Thomas Malthus on the role of technology in relation to economic growth.
66. Economists view innovation as crucial to economic well-being in terms of productivity growth, i.e. the growth rate of output per labour hour. For a summary of leading economic views on the critical importance of innovation to economic growth see Scherer, *New Perspectives on Economic Growth and Technological Innovation*, *supra* note 65 at pp. 25–48. See also Reinert, "Competitiveness and its predecessors," *supra* note 65 at p. 27: innovation has value in terms of higher profits, higher wages and more taxable income.
67. Trebilcock and Howse, *The Regulation of International Trade*, *supra* note 64 at p. 401 citing Alan Deardorff.
68. Trebilcock and Howse, *The Regulation of International Trade*, *supra* note 64 at p. 400.

and global economic welfare, strong patent standards "in at least some sectors, could increase economic welfare in some countries, while reducing it in others," depending on whether a domestic sector is innovation or imitation oriented.[69] Moreover, countries that are strong in imitation industries but weak on innovation are not able to play to their strength but are forced to switch to innovation thus undermining their comparative advantage.

For the many developing world economies that are weak on innovation, strong patent protection makes no sense from a static perspective of comparative advantage. [70] The remaining rationale for TRIPS is dynamic in that innovation will disseminate into developing countries through the investment and trade gains that result from strong patent protection, thus eventually resulting in a comparative advantage in innovation. According to this line of thought, rigorous patent protection facilitates trade in goods and foreign investment by assuring technology exporters that there are remedies for infringement when imitators illegally copy or reverse engineer patented technologies.[71] Innovators will be more willing to invest in[72] and more willing to trade with[73] countries that institute strong patent regimes. The sole viable rationale for strong patent protection in imitator countries, then, is gains in trade and investment from the developing world that are assured through vigorous patent protection and enforcement. According to this rationale, there remains no reason why patent abuse should not be remedied through compulsory licensing to serve developing country

69. Trebilcock and Howse, *The Regulation of International Trade*, *supra* note 64 at p. 401.
70. Admittedly, this binary analysis does not have universal application. Some countries, such as China and India, may be predominantly imitation economies that are beginning to also be centres of innovation. Even for those advanced developing economies with emerging innovation industries, there may be insufficient capacity to marshal the resources to manufacture a given technology that is in demand. Under a trade promotion rationale, CLEM should be available in these situations.
71. The willingness of firms to trade in intellectual property rights may be affected by the effectiveness of the legal security afforded to the protection of their rights: Nicolas S. Gikkas, "International Licensing of Intellectual Property: The Promise and the Peril," (1996) 1:1 *Journal of Technology Law and Policy*, <http://grove.ufl.edu/~techlaw/vol1/gikkas.html> at para. 49. According to one study, however, increased intellectual property protection facilitates trade flows of patented goods into middle-income and large developing countries (where there is an imitation threat) whereas trade flows to poor countries "are not responsive to patent rights": Bernard M. Hoekman, Keith E. Maskus & Kamal Saggi, "Transfer of Technology to Developing Countries: Unilateral and Multilateral Policy Options," (2004) *World Bank Policy Research Working Paper 3332*, <http://go.worldbank.org/UYKYJBPR50> at p. 15.
72. Carlos A. Primo Braga, Carsten Fink and Claudia Paz Sepulveda, "Intellectual Property Rights and Economic Development," in Keith E. Maskus, ed., *The WTO, Intellectual Property Rights and the Knowledge Economy* (Edward Elgar, 2004) 245–291, <http://go.worldbank.org/24FQNNEOJ0> at pp. 270–271. However, there is evidence that strong intellectual property rights protection is not a determinative consideration for investment decisions by transnational corporations and thus relatively few developing countries have benefited from it, i.e. those that benefit have favourable investment conditions *and* intellectual property rights protection: IPCC, *Methodological and Technological Issues in Technology Transfer*, *supra* note 7 at p. 6. See also Arvind Panagariya, "TRIPS and the WTO: An Uneasy Marriage," in Keith E. Maskus, ed., *The WTO, Intellectual Property Rights and the Knowledge Economy* (Edward Elgar, 2004) 42–53, <http://www.columbia.edu/~ap2231/Policy%20Papers/TRIPSWTO2.pdf> at p. 46: The success of FDI in China, in the absence of strong patent protection, may support this view. See also Duncan Matthews, *Globalising Intellectual Property Rights: The TRIPs Agreement* (Routledge, 2002) at p. 112: Countries that appeared on the USTR watch list for worst violators of intellectual property rights were ones to receive some of the most significant inflows of FDI including Argentina, Brazil and PR China. And at p. 109: Even if IP laws do encourage technology transfer in individual cases, it is clear that FDI has tended to concentrate in a few countries, such as China, Mexico, Malaysia, and Brazil, rather than developing countries generally.
73. Maskus and Reichman, "The Globalization of Private Knowledge Goods," *supra* note 4 at p. 11. Guifang (Lynn) Yang and Keith E. Maskus, "Intellectual Property Rights and Licensing: An Econometric Investigation," in Carsten Fink and Keith E. Maskus, eds., *Intellectual Property and Development: Lessons from Recent Economic Research* (World Bank Publications, 2005) 111–132, <http://www.colorado.edu/Economics/CEA/papers98/wp98-34.pdf> at p. 112 refers to one study which indicated that US multinational enterprises "were less likely to transfer advanced technologies to unaffiliated firms in countries with weak patent laws." Furthermore, at p. 113, the degree of patent protection may influence whether a firm licenses the technology (strong patent laws) or invests directly (weak patent laws).

markets. In fact, there is reason to argue the opposite. The assurance of patent protection in developing countries should be ample reason to encourage trade in those countries either by a patent holder or, if it is unwilling or unable, its competitor. Patent protection remains the same in those countries regardless of who supplies the market, and trade into developing countries should not in principle be impeded by the unwillingness of a patent holder to supply an export market when a competitor is willing to do so.

While the terms of TRIPS have been suspended for least developed countries until 2013,[74] a lack of patent protection in these countries should not pose a serious problem for the CLEM proposal. Trade of end product technologies into countries where there is little or no capacity to imitate, much less innovate, should not present free-riding or competition concerns for patent holders.[75] Moreover, these markets are not lucrative in any event. For these same reasons, trade with these countries should not have the effect of undermining the *ex ante* patent incentives.

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4. SERVING EXPORT MARKETS: INTERNATIONAL PATENT ABUSE & COMPULSORY LICENSING

TO BRIEFLY RECAP, THE TRIPS PATENT REGIME embodies a liability rule—entitlements granted to the patent holder are incentive-driven and modified by goals of technological diffusion. The trade rationale for TRIPS is supportable only on the basis of encouraging trade (and investment) in technology through the legal security afforded by patent protection in developing countries. Together, these rationales remain firmly rooted in patent protection as a means of providing incentives both *to innovate* and *to trade* technologies; when this is frustrated by patent abuse, compulsory licensing is an available option that should not be limited by export restrictions. If all of this is true, then the question becomes what are the conditions of patent abuse that would justify a compulsory license to supply export markets? In view of articles 7 and 8.2 discussed above, the foundational elements of an international wrong of patent abuse must consider both incentive- and diffusion-based concerns. But, how should such a ground of patent abuse be formulated? Moreover, what is meant by "abuse" of the patent?

There are a few recognized grounds of patent abuse, though here we are only concerned with one that is rooted in incentive- and diffusion-based concerns. In the history of Canadian legislation, for example, patent abuse has taken many forms, including the failure to commercially "work" the patent in Canada and failure to license the technology on reasonable terms with the result either that demand for the technology is unmet to an adequate extent or there is harm to industry or trade.[76] All of these types of patent abuse potentially inhibit the diffusion of technology. The type of patent abuse most germane to the discussion here is the failure to license a technology on reasonable commercial

74. See *Least-Developed Country Members*, *supra* note 10.
75. While least developed countries do not have to follow TRIPS, developed countries still do; thus the CLEM restriction remains in full force and effect with the exception of the essential medicines amendment.
76. For current compulsory licensing provisions, see *Patent Act*, *supra* note 34 at s. 65(2).

terms and a corresponding unmet demand for that technology.[77] This ground of patent abuse is set out in section 65(2)(c) of Canada's *Patent Act*: "If the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms." The balance here is between the incentive to invent or disclose (implicit) and the stated objective of diffusion. With appropriate modifications, section 65(2) (c) is a useful template upon which to base a formulation of patent abuse that results in serious diffusion effects in developing country markets.

The relationship between the two objectives of incentive and diffusion in TRIPS can be explained with reference to the legal terminology of "abuse." In international law, for example, the doctrine of abuse of right has developed to control the unrestrained exercise of state rights. Abuse of right is a corollary of the principle of good faith in relation to the exercise of state rights. It has been variously interpreted as the exercise of a right with malicious intent to injure another party; for a contrary purpose than that for which the right was intended; or the unreasonable exercise of a right.[78] The most recent international law articulation of abuse of right occurred in the WTO *Shrimp-Turtles* Appellate Body decision which favored the latter approach:

> [T]he application widely known as the doctrine of *abus de droit*, prohibits the abusive exercise of a state's rights and enjoins that whenever the assertion of a right [quoting Bin Cheng] 'impinges on the field covered by [a] treaty obligation, it must be exercised bona fide, that is to say, reasonably.' An abusive exercise by a Member of its own treaty right thus results in a breach of the treaty rights of the other Members and, as well, a violation of the treaty obligation of the Member so acting.[79]

Concepts such as reasonableness or malicious intent imply the existence of an extraneous interest that suffers harm as a result of an unwarranted exercise of the right. Using a right improperly for a purpose contrary to that which was intended suggests that the purpose of a right is somehow discernible and the right should be exercised only within defined confines.

While perhaps meaningful in other contexts, these different formulations lead to the same interpretive result in the case of TRIPS. According to the above

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77. Since the failure to work a patent locally is not a trade-based solution to technological diffusion dependent on developed country export, I choose not to deal with this ground of patent abuse. The legality of compulsory licensing for failure to work a patent remains controversial and unclear under the TRIPS agreement. Article 5(A)(2) of the *Paris Convention for the Protection of Industrial Property* (of March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and as amended on September 28, 1979), <http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html>, (entry into force April 26 or May 19, 1970) permitting compulsory licensing for local working of the patent is incorporated by reference in article 2 of TRIPS. However, TRIPS article 27.1 prohibits discrimination against patents "whether products are imported or locally produced." The requirement to work a patent locally is antithetical to the theory of comparative advantage in that industry should set up in environments where production advantages are greatest. For a discussion of the legality of local working under TRIPS see Michael Halewood, "Regulating Patent Holders: Local Working Requirements and Compulsory Licensing at International Law," (1997) 35:2 *Osgoode Hall Law Journal* 243–287, <http://www.ohlj.ca/archive/articles/35_2_halewood.pdf>.

78. See also Bin Cheng, *General Principles of Law as Applied by International Courts and Tribunals* (Stevens & Sons, 1953) at pp. 122, 130. See also Henry Campbell Black, Joseph R Nolan, and Jacqueline M Nolan-Haley, *Black's Law Dictionary*, 6th ed. (West, 1990) at p. 10 defining abuse as, "[d]eparture from reasonable use; immoderate or improper use."

79. *United States—Import Prohibitions of Certain Shrimp and Shrimp Products* (Appellate Body, 1998), WT/DS58/AB/R, <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds58_e.htm> at para. 158.

formulations, patent abuse may be conceived as the exercise of exclusive rights that unreasonably impact on the legitimate interests of others, or beyond the scope of the defined purpose of a patent. In either sense, TRIPS sets diffusion through trade as a purpose (or legitimate interest) by which the exercise of patent rights (premised on the incentive to innovate and disclose) is to be measured. Where the exercise of patent rights results in significant diffusion problems arising from a failure to license or trade the technology, then an "abuse" may have occurred.

Arguably, a purposive approach to patent law also lies behind the US doctrine of patent misuse. Patent misuse is a defense to infringement in situations where the holder improperly attempts to expand the patent grant by *inter alia* contracting *de facto* term extensions or tie-in arrangements with unpatented products.[80] Bemoaning the current application of antitrust law analysis to this doctrine in the US, Feldman argues that a patent can be misused in ways that undermine its very purpose, being the inducement to create and disclose inventions instrumental to the progress of science. Examples of behaviours that impede technological development would include *inter alia* refusing to license the patent without intention to bring the invention to market or efforts to obtain a blocking patent to undermine competitors.[81] This conception of patent misuse as purposive of the *ex ante* incentives to invent and disclose finds resonance with the doctrine of patent abuse.

Thus, we must be mindful of the purposes of global patent protection in assessing patent abuse, which are to preserve the *ex ante* patent incentives *and* to promote trade and technological diffusion. Acting beyond the scope of a purpose, e.g. to use a patent in a way that frustrates or does not further the incentive to invent, and which has the effect of undermining a competing purpose, e.g. a corresponding and significant unmet demand for a technology, should alert us to the potential of a patent abuse. In other words, an appropriate balance between incentive and diffusion goals must be struck.

4.1. Preserving Incentive

As discussed in Part 3, a main purpose of TRIPS is to provide incentive for technological innovation. The incentives that a patent system offers must not be tampered with lightly, whether through compulsory licensing or otherwise. In other words, the prospect of exclusive rights must remain real to inventors otherwise they may eschew the patent system as a viable or worthwhile means of intellectual property protection. Accordingly, abuse of a patent must reach a high threshold as a condition to granting a compulsory license. In this part, incentive will be assessed in connection with a variety of business reasons for not selling or licensing a technology on reasonable commercial terms, or to a competitor, for an export market.

We should not presume that patented technologies are always so closely guarded. There are, in fact, many reasons why a patent holder may *want* to license

80. Feldman, "Insufficiency of Antitrust Analysis for Patent Abuse," *supra* note 52.
81. Feldman, "Insufficiency of Antitrust Analysis for Patent Abuse," *supra* note 52.

their technology in export markets.[82] However, a firm may choose not to trade their technology for business reasons that are legitimate or illegitimate according to the prevailing patent rationales discussed above. A legitimate reason is one that promotes the patent incentive while illegitimate business reasons have a negative or neutral impact on *ex ante* incentives to invent. Courts entrusted to judge CLEM should evaluate these reasons as a first stage of analysis; a second stage, to be discussed later, should gauge the magnitude of the diffusion problems in the subject markets.

4.1.1. Legitimate Business Reasons

There are many legitimate reasons for refusing to license a technology. I have categorized these reasons under headings of "competitive advantage," "transitional," "transaction costs" and "profit maximization" reasons.

4.1.1.1. Competitive Advantage

One genus of reasons for not selling a technology is the effect that dealing might have on a firm's competitive advantage. Competitive advantage is part of the incentive to invent or disclose and should be given due consideration by courts. Thus, in the Canadian case of *E.C. Walker & Sons Ltd. v. Lever Bias Machine Corporation*,[83] the applicant manufacturer was the only known source of demand for a patented process. Without a compulsory license, the competitor would be denied a more efficient and thus profitable means of producing the product; but this was not enough to force a license on grounds of injury to trade or industry. The court expressed the fear of treading on exclusive rights thereby undermining the competitive advantage of the patent holder:

> The owner of a particularly successful patent could work his patent and sell the product thereof cheaper than his competitor and in such case the competitor would be able to prove prejudice to his trade and obtain a licence. […] Competitors would wait until a product was well established on the market and then they would secure a compulsory license and reap the benefit of any pioneering work done by others.[84]

While the legal basis of patent abuse in this case is different than that under consideration, the point made in *EC Walker* is well taken. The ability of a patent holder to produce better products more efficiently is at the heart of a competition-driven economy. Thus, competitors should not be permitted, under guise of

82. See Gikkas, "International Licensing of Intellectual Property," *supra* note 71 at paras. 6–14: Developed country firms may be in position to exploit markets that the patent holder is unable to serve. Thus, for example, small innovator firms may not have the resources to fully exploit the market for their technology, or firms may not have the resources to exploit their patents through related products, or the technology may sell better as part of a larger package of products. Licensing may also be advantageous to a patent holder as barter for access to technologies it would also have to pay for (cross-licensing), e.g. dependent patents for improvements. Licensing of major technologies may give some control over the direction of the industry in terms of setting the industry standard. Licensing to a developing country's firm may also be advantageous where the latter is able to adapt the technology to local needs and take advantage of local distribution channels.
83. *E.C. Walker & Sons Ltd. v Lever Bias Machine Corp.* (Commissioner of Patents, 1953), 20 *Canadian Patent Reporter* 61, 43 *Fox's Patent, Trade Mark, Design and Copyright Cases* 98 [cited to *Canadian Patent Reporter*]
84. *Walker & Sons v Lever Bias Machine Corp. supra* note 83 at p. 65.

compulsory licensing, to unfairly access innovation, as well as product and market development in the absence of compelling demand for a technology abroad.

4.1.1.2. Transitional

As first-to-file monopolies, patent systems encourage the early disclosure of inventions. For this reason, patents may be filed for inventions that are not yet commercially viable because production costs are prohibitive or there is a lack of commercial demand.[85] Even if viable, the patent holder may not have the immediate capability to bring the invention to market. As well, a patent holder may be unwilling to bring the innovation to market for fear that it will compete with its existing products.[86] These kinds of transitional reasons i.e. reasons pertaining to the normal gap between invention and innovation should be treated as legitimate.

The lead time needed to commercialize or adjust production and markets to exploit the innovation are reasons behind legislation in many countries prescribing an exclusionary period of three to five years during which time a compulsory license may not be granted.[87] In order to accommodate these legitimate reasons, a property right should be in place during an exclusionary period in order to allow firms an opportunity to develop the patent or adjust production and marketing strategies. An added advantage of an exclusionary rule is that it assures a short-term monopoly period and thus will encourage innovators to disclose their invention rather than keep it secret pending commercial development or business adjustments. Transitional reasons may still hold some legitimacy after the exclusionary period but, one would think, only in exceptional cases. Indeed, if others are able to bring a product to market (or a particular market) when a patent holder is unwilling or unable to do so after the exclusionary period, the *prima facie* case for compulsory licensing would seem strong.[88]

4.1.1.3. Transaction Costs

Transaction costs reasons pertain to negotiation impediments associated with the licensing transfers, as discussed in Part 3.[89] These impediments may arise even when the parties are negotiating in good faith, e.g. disagreements as to the true value of the patent, with the result that a voluntary license is not

85. Saunders, "Patent Nonuse," *supra* note 18 at pp. 390–392, 420–421.
86. Saunders, "Patent Nonuse," *supra* note 18 at p. 418: new technologies sometimes compete with older, cheaper products or processes (of which the patent holder is a producer) meaning that immediate commercialization of the patent would cannibalize existing markets.
87. *Patent Act*, *supra* note 34 at s. 65 (2): setting a 3-year exclusionary period.
88. Mark Lemley, "Ex Ante Versus Ex Post Justifications for Intellectual Property," University of California-Berkley Public Law and Legal Theory Research Paper Series No. 144, <http://ssrn.com/abstract=494424> at p. 7: "The [idea] that a single company is better positioned than the market to make efficient use of an idea should strike us as jarringly counterintuitive in a market economy" (in response to Edmund Kitch's prospect theory of patent law).
89. For example, patent holders may refuse to license in situations where they seek to hold out for a cross license or patent pooling arrangement with other patent holders in related technologies. Saunders, "Patent Nonuse," *supra* note 18 at pp. 417–418.

achieved.[90] Calabresi and Melamed highlight such difficulties as impediments to an optimal allocation of resources which might justify the adoption of a liability rule such as compulsory licensing. Negotiations over intellectual property assets can be time-consuming and difficult. Businesses should be able to rely on a legitimate expectation that courts will not lightly intervene to quickly impose a license on patent holder, particularly if the applicant has not itself negotiated in good faith.[91] A rule permitting a compulsory licensing application after a brief period of failed negotiations would encourage potential licensors not to bargain in good faith or to prematurely resort to compulsory licensing. Failure to reach agreement on licensing on reasonable commercial terms within a reasonable period of time is a pre-condition for a compulsory license under TRIPS but should not, in the absence of large scale demand, be grounds for patent abuse.

4.1.1.4. Profit Maximization

Profit maximization, of course, lies at the heart of both *ex ante* incentive rationales. A patent holder may choose to exploit the market herself by extracting more lucrative monopoly profits rather than licensing revenues. On an incentive rationale, there can be no objection to this; however, problems arise when the terms of sale (usually high cost) create diffusion problems. As we shall see, the matter is complicated by the fact that monopoly pricing is based on undersupplying markets. As this issue is intimately tied with unmet demand, more will be said on this in the next part. Suffice to say at this point that tiered pricing of patented goods in different markets, to reflect elasticities of demand within those markets (meaning that developed world markets pay higher prices than developing world markets), is entirely consistent with maintaining an incentive rationale, while maximizing diffusion. A patent holder may also refuse to market the product on reasonable terms (or at all) for fear that direct sales to developing markets will be diverted, whether through parallel importation or illegally, into third country or home markets. Without proper legal and product safeguards in place, this cutting into profits may be real. However, it is suggested in Part 4 that appropriate safeguards can be put in place to deal with these concerns.

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90. See discussion above at note 63 and accompanying text. A concrete example is that of patent blocking where a first patentee holds the original patent and a second patentee owns an improvement on the original invention and the parties are unable to come to a licensing agreement resulting in the improvement not being used. While it may generally be in the mutual interest of both to cross license, agreement may be elusive due to inaccurate valuation of either or both invention or conflicting perceptions of the profitability of the improvement: Joseph A. Yosick, "Compulsory Patent Licensing for Efficient Use of Inventions," 2001:5 *University of Illinois Law Review* 1275–1304, <http://www.usebrinks.com/publication.cfm?publication_id=107>, at pp. 1293–1294, 1297.

91. *Sarco Co. v Sarco Canada Ltd.*, *supra* note 49 at para. 48; the Canadian owner of a dependent patent was found to have abused the patent by failing to work it in Canada. However, this failure was directly the result of threats by the US improvement patent holder to cut off other supplies if it *did* work the patent locally. The court stated:

> If, in such a case, a licence is granted to the person who in its own interest has been attempting to prevent manufacture in Canada it seems to me that the result will be to lend encouragement to those who wish to serve the Canadian market for patented articles, but prefer to do so, so long as they can, with goods of foreign manufacture, to proceed as the appellant has done. The granting of relief in such a case would, as I see it, be a reward for promoting the abuse of a patent and would tend to encourage those who seek to avoid or prevent manufacture of patented articles in Canada.

This case demonstrates that apparent patent abuse can be attributable, in whole or in part, to the unreasonable and bad faith conduct of the compulsory licensee applicant.

4.1.2. Illegitimate Business Reasons

There are some kinds of refusal to license situations that *prima facie* are illegitimate since they frustrate production and diffusion of the technology while having negative or neutral effects on innovation. When this is the case, a main purpose of patent protection, namely to encourage the creation and disclosure of invention, is undermined, thus indicating an abuse of the patent.

4.1.2.1. Defensive Patenting

A refusal to license may simply be an effort to undermine a competitor with no intention of ever developing the patent.[92] For example, a dependent patent holder (i.e. owner of an original patent) may wish to undermine its competitor by refusing to license to a patent holder of an improvement to the original.[93] A major theme in patent law literature tries to resolve this very problem of maintaining incentive for original inventions while not impeding follow-on improvements to the original in cases where both are competing in the development of similar products or processes. The debate is less problematic, however, when the original holder has no intention to commercially develop the invention. While a firm may theoretically have incentive to invent solely to frustrate rivals from developing the same or similar patent, but without any intention to develop it, this activity has negative incentive effects for innovators in the same field. Competitors in the same field will have less incentive to pursue research if they know that their prospective invention may be blocked by a dependent patent holder. In addition, innovative progress toward the creation of the best technologies is impeded by this practice.

4.1.2.2. Undermining Export Market Competition

A second *prima facie* illegitimate reason, and one that is particularly germane to the discussion here, is to refuse to trade or license in order to undermine a competitor in an export market for which there is no intention of the patent holder to supply on reasonable commercial terms. As happened in the ozone regime,[94] mentioned earlier, the competitive threat may be perceived to be in the export market itself. This basis for refusing to license has obvious negative diffusion effects while having a neutral effect on the incentive to innovate. Indeed, inventions are not pursued and realized in the hope of frustrating competitors who might be interested in supplying markets that you are not willing to supply. This reason for refusing to license is not the same as preserving competitive advantage in a market in which you are both competing. Refusing to deal in the latter scenario is legitimate since a competitor should not be able to step in and free ride on an invention under guise of compulsory licensing and, in so doing, undermine the patent holder's market share. However, where a competitor is serving a market that a patent holder has abandoned, there is no market share to be lost.

92. Landes and Posner, *The Economic Structure, supra* note 43 at p. 321 also known as defensive patenting.
93. Landes and Posner, *The Economic Structure, supra* note 43 at p. 320. See also TRIPS, *supra* note 1 at art. 31(l): stipulates special conditions for dependent/improvement patent situations.
94. Watal, *Intellectual Property Rights*, *supra* note 12 at p. 389. See also IPCC, *Methodological and Technological Issues*, *supra* note 7 at p. 98.

These reasons are not intended to be an exhaustive list. Instead, they are meant to be illustrative of the kinds of reasons that can be justified (or not) according to *ex ante* incentive rationales. Moreover, courts may uncover legitimate and illegitimate business reasons for refusing to license or trade and will, accordingly, have to determine whether or not *ex ante* incentives are threatened by a compulsory license. The second tier of analysis for patent abuse justifying compulsory licensing is to determine whether a significant unmet consumer demand for the patented product can be demonstrated in developing country market(s).

4.2. Dissemination: Unmet Demand to an Adequate Extent

The language of "unmet demand to an adequate extent on reasonable terms" in section 65(2)(c) of Canada's *Patent Act* raises difficult questions. First, since the consequences of a monopoly include reduced quantity and higher prices for consumers,[95] the market for a patented product will invariably be undersupplied. In other words, the demand for a product at monopoly prices will never meet the demand that arises as a result of competitive prices.[96] Furthermore, how do we determine what is a failure to license on reasonable terms when, after all, we are dealing with monopoly pricing that will far exceed competitive prices?[97] In light of this, demand or reasonable terms should not be assessed at the level of competitive prices since this would defeat the patent incentive.

Problems of assessing unmet demand are somewhat mitigated when segregated export markets on a global scale are at issue. In such cases, price discrimination allows a firm to "charge more in those markets where consumer demand is inelastic, and charge less in those markets where demand is elastic (relatively more responsive to changes in price)."[98] Differential pricing in segregated markets increases overall social welfare insofar as some groups are made better off while no group is made worse off.[99] Thus, patent holders stand to gain by charging monopoly prices in developed world markets while selling at more competitive prices in developing world markets. Consequently, patent incentives are preserved while diffusion is maximized. Despite this, patent holders may choose not to pursue differential pricing since there may be leakage between segregated markets in the form of arbitrage (illegal diversion of low priced goods into developed world markets) or parallel importation (legal importation into markets that have adopted international rules of exhaustion).[100] Both of these issues will be discussed at the end of this article, though in my view, neither are serious hurdles for patent holders to serve segregated markets on a differential pricing basis.

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95. Trebilcock and Howse, *The Regulation of International Trade*, *supra* note 64 at p. 589.
96. Cole M. Fauver, "Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come," (1988) 8 *Northwestern Journal of International Law and Business* 666–685 at p. 669.
97. Not all innovations, of course, enjoy monopoly pricing: e.g. there may be competing products on the market that force prices below this level. Having said that, high demand for an under-supplied product in a marketplace will usually involve technologies that are not subject to substitution in the marketplace, and thus are amenable to monopolistic pricing.
98. Peter J. Hammer, "Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health," (2002) 5 *Journal of International Economic Law* 883–912 at p. 885.
99. Hammer, "Differential Pricing of Essential AIDS Drugs," *supra* note 98 at p. 889. This is known as a Pareto improvement.
100. Morgan, "Medicines for the Developing World," *supra* note 25 at p. 79: defines arbitrage as "the migration of low prices offered in poor countries into developed world pharmaceutical markets"

More than pricing concerns, the concept of demand is malleable—are we talking about demonstrable demand, i.e. I can show you that X number of this product is needed in marketplace Y?[101] And if that is the measure, how does one gauge this kind of demand if unreasonable terms set by the patent holder have quelled interest in the patent,[102] or the patent is not sold in that market? Alternatively, demand may be understood as the potential for demand, i.e. there is no present demand but I have a plan to develop and market product X in market Y? Courts will of course need to determine the veracity of claims by applicants that a demand is not being met to an adequate extent based on the evidence before them. In some cases, the demand for the patent will be obvious, e.g. life-saving drugs in epidemic situations, while in other cases modest demand may not meet the threshold if coupled with a legitimate business reason for not dealing. Courts should, as a general rule, be more lenient in setting a demand threshold when there is evidence that the refusal to deal is based on illegitimate business reasons and more stringent with respect to legitimate business reasons.

4.3. Proposal

If the TRIPS export restriction is repealed, states may wish to promote the goals of technological diffusion by amending domestic legislation. States would do well to model their legislation on the terminology of section 65(2)(c) of Canada's *Patent Act* (with appropriate modifications for the inclusion of export markets). This provision reflects the incentive-diffusion balance that must be struck in ensuring that the purposes of international patent law are met. In general terms, a remedy of compulsory licensing must also strike a balance between permissiveness and inaccessibility. If the regime is too lax, competitors will seek out a compulsory license prior to exhausting negotiation efforts; furthermore, compulsory licensing will act as a disincentive for competitors to develop new technologies since they can opt for a compulsory license. If the regime is too strict, the patent holder has little incentive to deal in cases where significant demand is not being met. We should expect, furthermore, that courts will be reluctant to undermine domestic innovation industries by too easily granting compulsory licenses for export markets. The primary goal of the regime should be to provide incentive for patent holders to diffuse technologies into developing countries, and for firms negotiating licensing terms to do so in good faith.[103]

The elements of a regime that would strike the appropriate balance would include a short exclusionary period during which a compulsory license

101. This appears to be the approach taken by the Canadian Federal Court in the case of *Brantford Chemicals Inc. v Canada (Commissioner of Patents)*, 2006 FC 1341, <http://decisions.fct-cf.gc.ca/en/2006/2006fc1341/2006fc1341.html>, 2006 *Federal Court Reporter* 1341, 54 *Canadian Patent Reporter, 4th ser.* 158 at para. 86: which interpreted unmet "demand" in s. 65(2)(c); para. 86: "demand of the public at large, and not that of a single trader"; para. 96 "the *existing* demands of the market in this country […]"; para. 103 "the 'demand' for a patented article does not include a potential demand for a cheaper version of the article being sold."

102. Paul Torremans, "Compulsory Licensing of Pharmaceutical Products in Canada," (1996) 27 *International Review of Industrial Property and Copyright Law* 316 at pp. 326–327.

103. Rose, "On Purple Pills, Stem Cells, and Other Market Failures," *supra* note 31 at p. 622: "the mere presence of a compulsory licensing provision should have the aforementioned 'wings effect' of motivating the parties to work through their bargaining and valuation issues, rather than face the cost and uncertain outcome of governmental intervention." This kind of result seems to have occurred with the TRIPS amendment, with pharmaceutical companies supplying developing country markets with essential medicines at affordable prices. See also Atik and Lidgard, "Embracing Price Discrimination," *supra* note 35.

is not an available remedy. Beyond this exclusionary period, however, courts should consider myriad factors, always in the context of balancing incentive- and diffusion-based considerations. The business reasons for not selling or developing the patent needs to be measured against the yardstick of whether it promotes, diminishes or is neutral toward the incentive rationales. The legitimacy or illegitimacy of the business reason is only the first prong of the analysis. The second prong is to assess whether there is a significant demand for the patented product or process. In cases where the demand reflects the high social value of the patent, this aspect of the test should be more easily satisfied. In other cases, the demand analysis should be more or less stringent in correlation to the legitimacy of the business reason for refusing to deal. If the motivation is only to undermine competitors in foreign markets, courts may be more forgiving in interpreting demand; by the same token, if the reason is *bona fide*, then more concrete evidence of substantial, present demand may be required.

There will, no doubt, be hard cases where diffusion- and incentive-based concerns are more or less equally balanced. In such cases, one answer may be to set a royalty rate commensurate with research and development expenses plus a reasonable profit, where possible.[104] With respect to inventions of high social value, such as life-saving or life-prolonging medicines, maximum diffusion becomes desirable but with the possible consequence of research money being diverted away from inventions that might more easily be subject to compulsory licensing. However, appropriately stringent thresholds for compulsory licensing together with anti-diversion measures (discussed below) should ensure that the incentive to innovate is maintained while diffusion is maximized as much as possible.

Prior to ordering a compulsory license, courts should consider whether there is manufacturing and technical capacity to produce the invention by local industry in the export market. If so, it would be reasonable to expect that the invention could be produced, or a compulsory license obtained, in the local jurisdiction. As well, the exporting country should heed national exhaustion rules (discussed below) that are in play for a local patentee in the targeted state. In other words, if a patent is registered in the target country according to a legal regime of national exhaustion, a compulsory license should not be issued. In reality, these last two considerations have little relevance to most developing country markets.

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5. IMPLICATIONS OF PROPOSAL

ONE ARGUMENT AGAINST COMPULSORY LICENSING, in general, is that it enhances the attractiveness of trade secrecy (undermining the exchange for secrets rationale) and diminishes incentives to invent and innovate vis-à-vis a regime of compromised patent rights. A second concern is that CLEM would in practice

104. *Parke, Davis & Co. v Fine Chemicals of Canada Ltd.* (CAN SC, 1959), 1959 *Supreme Court Reports* 219, 30 *Canadian Patent Reporter* 59, at para. 6: in the context of compulsory licensing for medicines, the Supreme Court said "the royalty [should be] commensurate with the maintenance of the research incentive." See also Fauver, "Compulsory Patent Licensing in the United States," *supra* note 96 at p. 677; "The United Kingdom scheme considers several factors before [a] rate is set, including research costs, profit margin, and administrative and advertising expenses."

violate the integrity of segregated markets through trade diversion, i.e. reimportation of the compulsory licensed goods into the exporting state at cheaper prices. I will deal with each of these arguments in turn.

5.1. Diminished Incentives?

One argument against compulsory licensing posits that innovators, facing diminished rights under a patent regime, will choose to keep innovations secret. Some general statements may be postulated to counter this argument. First, trade secrecy does not prevent competitors from copying the technology; thus, industries prone to reverse engineering, e.g. pharmaceutical and chemicals or other discrete products (as opposed to complex products or processes), rely extensively on patent protection.[105] In this regard, the non-proprietary nature of trade secrecy law should be preserved.[106] Second, competitors that are knowingly involved in the race, i.e. working towards development of the same or similar technology, will still seek to file a patent at the earliest possible time. Finally, it is not clear that strong patent rights always induce patent disclosure in any event. One classic study shows that, in high technology sectors, secrecy and learning advantages are perceived by firms to play a stronger role than patents in protecting innovation from competitors (even without compulsory licensing).[107] There remain strong incentives for innovators to patent their creations under a compulsory licensing regime with appropriately high thresholds; conversely, even inviolable property rights associated with a patent grant may not be enough to induce patent disclosure in some cases. In situations where an invention would not otherwise be disclosed for "transitional" reasons, an exclusionary period should make patenting more attractive.[108]

The availability of compulsory licensing, according to another line of thought, will reduce the incentive to invent and to innovate. Since the economic value of the patent is diminished by a possible compulsory license, less money and effort will go towards the research and development of new technologies. The empirical evidence of this claim suggests, if anything, that compulsory licensing has no impact on research and development expenditures in innovation.[109] As well, the royalty rate set by courts could be used to compensate innovators for research and other costs plus profits. Most importantly, the issuing of a compulsory license will occur in circumstances where the patent holder has failed to supply an export market for which there is significant unmet demand and for which a

105. Katrina Hussinger, "Is Silence Golden? Patents versus Secrecy at the Firm Level," (2006) 15:8 *Economics of Innovation and New Technology* 735–752, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=825426>, at pp.740–741.
106. See discussion above note 43 and accompanying text.
107. Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson and Sidney G. Winter, "Appropriating the Returns from Industrial Research and Development," in Martin Neil Baily and Clifford Winston, eds., *Brookings Papers on Economic Activity 3: Special Issue on Microeconomics* (The Brookings Institution, 1988) 783–831. See also Hussinger, "Is Silence Golden," *supra* note 105 at p. 759. A recent empirical study of German firms seems to suggest that patents tend to be used to protect valuable inventions that are ready to market in the short-term whereas secrecy is applied to inventions that will enter the market at a later period.
108. An exclusionary period affords the patent holder a head start advantage (not to mention brand name advantage): Fauver, "Compulsory Patent Licensing in the United States," *supra* note 96 at p. 676. See also Yosick, "Compulsory Patent Licensing for Efficient Use of Inventions," *supra* note 90 at p. 1292.
109. Saunders, "Patent Nonuse," *supra* note 18 at p. 440; Yosick, "Compulsory Patent Licensing for Efficient Use of Inventions," *supra* note 90 at p. 1293; Chien, "Cheap Drugs," *supra* note 15 at p. 873. Compulsory licensing for export markets is, in most cases, only feasible through a system of differential pricing between developed and developing country markets.

competitor has attempted to negotiate a license over a reasonable period of time. Patent holders, in such cases, will have adequate warning to either supply the market or voluntarily negotiate a license. Consequently, the issuing of a compulsory licensing will be the result of their failure to respond to these signals. A compulsory licensing regime with appropriately high thresholds should neither discourage patenting nor decrease expenditures in research and development.

5.2. Parallel Imports and Trade Diversion

CLEM is, in most cases, only feasible through a system of differential pricing between developed and developing country markets. Differential pricing in turn relies upon the effective segregation of these markets, on both a legal and practical basis. The effective segregation of markets can be achieved through legal rules of national exhaustion, which prevent cheaper parallel imports from coming into lucrative markets, and anti-trade diversion measures which help ensure that illegal imports do not frustrate national exhaustion rules.

Patent rights under the TRIPS Agreement are territorial in nature. Patent holders must register their patents in each country for which they seek to protect their rights in an invention. Furthermore, TRIPS allows Members to set rules of national or international exhaustion as they see fit.[110] Exhaustion "defines the territorial rights of intellectual property owners after the first sale of their protected products."[111] A rule of national exhaustion permits a patent holder of one country to prevent the parallel importation from the owner or authorized dealer of the same patented product of another country;[112] in other words, national exhaustion permits the patent owner to exploit the domestic market for a patent free from outside competition. Under a rule of international exhaustion, parallel imports of the product are allowed upon first sale of the product regardless of where it occurs.[113]

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110. TRIPS, *supra* note 1 at art. 6: "[N]othing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." TRIPS, *supra* note 1, art. 28(1), which mandates required patent rights, conditions the right of import to art. 6, i.e. rules of exhaustion set by a state. Paragraph 5(d) of The Doha Public Health Declaration, *supra* note 19 explicitly leaves it for each state to establish its own exhaustion rules.
111. Carsten Fink, "Entering the Jungle of Intellectual Property Rights Exhaustion and Parallel Importation," 171 in Carsten Fink and Keith E. Maskus, eds., *Intellectual Property and Development: Lessons from Recent Economic Research* (World Bank/OUP, 2005) at p. 171. See also Nick Gallus, "The Mystery of Pharmaceutical Parallel Trade and Developing Countries," (2004) 7:2 *Journal of World Intellectual Property* 169–173 at p. 170: "A system of national exhaustion prohibits parallel trade because it deems that the company's right is only exhausted in the nation in which they have first sold the good."
112. A doctrine of national exhaustion (favoured by most developing countries) acts as a non-tariff barrier and thus is contrary to free and open trade based on comparative advantage: Fink, "Entering the Jungle," *supra* note 111 at pp. 175–176; Fink offers four advantages to national exhaustion doctrine: first, it prevents free riding of marketing and goodwill established by the local patent owner; second, it protects consumers from deception as to the origin of the goods; third, it encourages licensing in export markets knowing that the licensee will not compete in the home or third-country markets; and fourth, it does not necessitate the uniform pricing of products and thus developing countries may reap the advantages of lowered differential pricing: Fink, "Entering the Jungle," *supra* note 111 at pp. 179–180, 184. These reasons, however, appear unconvincing where significant demand for a patented product is not met on reasonable terms and thus developing countries are wise to maintain rules of international exhaustion. The third and fourth advantages do not appear applicable to this kind of situation: licensing and differential pricing arrangements are presumptively unsatisfactory if demand for the patented product is not being met to a reasonable extent. Loss of good will and deception as to source may be more legitimate concerns but seem to pale in comparison with negative dissemination effects of refusing to deal on reasonable terms.
113. Notwithstanding the fact that an importing country has adopted an international exhaustion regime licensing contracting can achieve the same ends of limiting sales in export markets: Fink, "Entering the Jungle," *supra* note 111 at p. 172.

While the concepts of national and international exhaustion are simple enough, exhaustion rules can be complex. There are many rights (some overlapping) associated with a patent grant (e.g. to make, use, sell) which begs the question—what is the effect of a sale of a patented product on the purchaser's right to re-sell the product to consumers in another country? There are two main theoretical approaches to the problem. Kohler conceived of the first sale of a product as an inherent transfer of all rights associated with that good. His approach was premised on the view that patent law entitled the patentee to a reward of her invention but that the rights granted were "intrinsically linked" with one another. [114] Thus, the patentee is entitled to one reward for each product and once sold, she is no longer entitled to residual patent rights in the specific product.[115] Anglo-American law, on the other hand, has dealt with this issue through the doctrine of implied license, meaning that the law will imply the transfer of rights of use and re-sale but leaves the possibility of the patentee to withhold rights by contract.[116] In essence, the difference between the two is that Kohler views the transfer as absolute while the Anglo-American approach offers the patentee the ability to expressly contract restrictive terms at the time of initial sale.

US patent law, for example, has adopted a national exhaustion rule as well as the doctrine of implied license when a patented item is first sold. The Federal Circuit in *Jazz Photo Corporation v. International Trade Commission* applied these principles to an infringement action involving the refurbishment of single use cameras, some of which were first sold in the US and some of which were first sold abroad. The court's holding on national exhaustion is unmistakable: "United States patent rights are not exhausted by products of foreign provenance. To invoke protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent."[117] But what of the cameras that were first sold in the US, exported, and then re-imported into the US? Here, the court seems to extend the implied license doctrine to not just use, repair and re-sale but also the right of re-import (as opposed to import in the first instance): "The unrestricted sale of a patented article, by or with the authority of patentee, 'exhausts' the patentee's right to control further sale and use of that article by enforcing the patent under which it was first sold."[118] The underlying question, continued the Court, was whether the patentee had received reward for the use of the article.[119]

Under US law, then, the right of import is protected by national exhaustion though the right of re-import (after first sale in the US) is not. The underlying rationale here is whether the patentee has received her reward *in that market* pursuant to the sale of the goods. If so, then the ancillary rights associated with the patent are exhausted in respect of the product. To allow imports (as opposed

114. Christopher Heath, "Legal Concepts of Exhaustion and Parallel Imports," in Christopher Heath, ed., *Parallel Imports in Asia* (Kluwer Law International, 2004) at pp. 14–15.
115. Heath, "Legal Concepts of Exhaustion and Parallel Imports," *supra* note 114.
116. Robert L. Harmon, *Patents and the Federal Circuit* (Bureau of National Affairs, 2005) at p. 411. As a rule, the purchaser of a patented product is entitled to use, sell, and repair the product under an implied license. But a sale made under licensing conditions not to re-sell will not exhaust the rights in that product. Implied licenses may arise by operation of law based on the conduct and mutual expectations of the parties, though the burden is on the party asserting the defense.
117. *Jazz Photo Corporation v International Trade Commission* (USA Fed Circ, 2001), 264 *Federal Reporter, 3d ser.* 1094 at para. 1105.
118. *Jazz Photo Corporation v International Trade Commission*, *supra* note 117 at para. 1105.
119. *Jazz Photo Corporation v International Trade Commission*, *supra* note 117 at para. 1105.

to re-import) from sales abroad would compromise territorial market rights by undermining the higher prices set for the goods in the importing country. TRIPS allows for the right of import of products—and products made from processes—and states may rightly prevent parallel imports in these circumstances through national exhaustion rules.[120]

Since most developed countries have national exhaustion regimes that legally segregate and protect high returns in these markets, while developing countries generally have international exhaustion rules that permit imports (including from developed country markets), [121] differential pricing is both possible and desirable for all involved, provided that trade diversion is minimized. A system of tiered or differential pricing of patented goods in different markets, to reflect elasticities of demand within those markets (meaning that developed world markets pay higher prices than developing world markets), is entirely consistent with maintaining an incentive rationale, while maximizing diffusion. Within developed country markets with national exhaustion rules, patent owners are able to maximize their profits. To set product prices in poorer countries at developed country levels, which few can afford, results in a deadweight loss, i.e. lower returns for the patent holder than at a cheaper price. Setting prices much lower in developing countries results in less return but still more so than if the product were marketed at developed country levels. While sensible in theory, the reason pharmaceutical companies in particular do not price differentiate is because they fear trade diversion of cheaply priced medicines into lucrative developed country markets.

Irrespective of exhaustion rules that may be in place, there remains the risk of trade diversion of patented products that are intended for sale in developing country markets made under a compulsory license but which are illegally (re)imported into developed country markets. Trade diversion into developed countries is a practical problem to compulsory licensing that threatens high profits within lucrative markets and therefore the patent incentive rationales. However, there are mechanisms that may be employed to minimize the occurrence of trade diversion. For example, Morgan observes that mechanisms can be effectively employed to maintain the integrity of segregated markets for pharmaceuticals, such as differential branding and packaging, customs controls, supply chain management, strong contractual arrangements with procurement agencies, as well as rules against parallel imports.[122]

The December 2005 amendment to TRIPS reflects the concern given to the issue by requiring export market countries to take diversion measures and ensuring that generic pharmaceuticals embody distinguishing guises and different labeling from the patented originals. Specifically, the amendment requires that eligible importing countries notify the TRIPS Council of both their identity and the

120. While TRIPS is neutral as to the exhaustion rights of products, it is explicit in giving states the right of import to products *made directly from patented processes*: TRIPS, *supra* note 1 at art. 28(1)(b).
121. Robert J. Tomkowicz and Elizabeth F. Judge, "The Right to Exclusive Access: Misusing Copyright to Expand the Patent Monopoly," (2006) 19:2 *Intellectual Property Journal* 351–391, <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=819109> at para. 41: with the exception of copyright, Canada has international rules of exhaustion for intellectual property.
122. Morgan, "Medicines for the Developing World," *supra* note 25 at p. 79.

needed quantities of essential medicine products.[123] Further, when a compulsory license is issued, mandatory conditions are imposed including: limiting quantities to the amount necessary to meet the needs of importing countries as per their requested amount(s); and distinct labeling of packages and colouring/shapes of pills from the patented originals; and website notification by the licensee of the quantities supplied, destination and distinguishing guises.[124] Importing countries are also required to take "reasonable measures" to avert trade diversion.[125] Notification measures assist in the detection of illegal imports by custom officials, while the limitation of quantities ensures that any trade diversion is limited in its effects. While the threat of trade diversion is real, these kinds of measures show that such problems are manageable through appropriate safeguards that may be imposed as conditions to the grant of a CLEM. If anti-diversion measures can be devised for pharmaceuticals, which are relatively difficult to detect due to their small size and common features, there is no reason that safeguards cannot be found for other technological products.

Process patents pose unique problems from an import perspective. In terms of detection, upon viewing an end product, it may be impossible to distinguish products made from a patent-protected process from products made from a non-patented process. Further, a product may be made from various processes of which only one or some are under patent. Article 28(1)(b) TRIPS deals with the latter problem by limiting protection only for those products "obtained directly" by a patented process.[126] In terms of the detection problem, one solution is to create a statutory presumption that new products are deemed to be made by a patented process, unless the contrary can be proven.[127] Placing this kind of legal onus on an alleged infringer can go some way toward detecting illegal imports of products made from patent protected processes in the importing jurisdiction. In any event, process patent infringement issues are not unique problems to international trade in general or to trade from developing countries in particular.

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6. CONCLUSION

THE OSTENSIBLE PURPOSE OF TRIPS IS TO PROMOTE technological innovation through the financial incentive of meaningful patent protection while, at the same time and on the same basis, encouraging diffusion of technology through international trade. But the Article 31(f) export restriction presents a barrier to diffusion in cases where a patent holder refuses to sell her invention on reasonable commercial terms in developing country export markets. My

123. TRIPS Amendment, *supra* note 2 at 1(b), 2(a)(i).
124. TRIPS Amendment, *supra* note 2 at 2(b).
125. TRIPS Amendment, *supra* note 2 at 3.
126. TRIPS, *supra* note 1 at art. 28: "A patent shall confer on its owner the following exclusive rights: […] (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process." Further, this rule is followed in: *Patent Act*, 35 United States Code, s. 271(g), <http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf>.
127. *Patent Act*, *supra* note 34 at s. 55.1 (in respect of "new products").

recommendation is to repeal article 31(f) to allow states to implement compulsory licensing legislation to remedy patent abuse with serious product diffusion effects in developing countries. Such national legislation should:

1. Provide for an exclusionary period of 3 to 5 years;
2. Preserve patent rationales of incentive to invent and to innovate, and to disclose, by examining the legitimacy of a refusal to license on reasonable commercial terms;
3. Consistent with #2, maximize diffusion where there is demonstrated high demand for the technology and a lack of manufacturing and technical capacity to produce the technology in a developing country market;
4. Respect rules of national exhaustion in developing country export markets; and
5. Require appropriate safeguards against trade diversion.

The main point of this paper has been to show that the incentive and diffusion objectives of TRIPS are conceived as mutually supportive goals: both can be accomplished without unduly diminishing the other. The most dramatic and timely example of this is the developing country export market for pharmaceuticals. Differential pricing within effectively segregated markets can preserve both the incentive to innovate and disclose while maximizing diffusion of technology. Furthermore, abolishing article 31(f) would likely have the desirable effect of reducing transaction costs by encouraging patent holders to supply export markets under threat of a compulsory license. As global threats to public health and the environment gather, international compulsory licensing seems an important market-based solution to unreasonable failures to disseminate needed technologies in developing countries.