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## One View of Compulsory Licensing: Comparative Perspectives From India and Canada

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# ONE VIEW OF COMPULSORY LICENSING: COMPARATIVE PERSPECTIVES FROM INDIA AND CANADA

PADMANABHA RAMANUJAM AND YUGANK GOYAL\*

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## I. BY WAY OF A PROLOGUE

Lockean property rights theory<sup>1</sup> establishes that a creation belongs naturally to its creator. There is little disagreement that property and property rights are born simultaneously. Information is an intangible property and is produced through the labour of intellect. Again, invoking Locke,<sup>2</sup> this information should then be private property of the labourer.<sup>3</sup> But information is a non-excludable and non-rival good.<sup>4</sup> Hence, a (legal) framework to grant (a) *exclusive right* for (b) a *limited period* helps sequentially<sup>5</sup> balance (a) incentive (for labourer) to produce the information, and (b) access (for society) to make use of the information. This framework is intellectual property.

So as to favour accessibility of intellectual property thus created, society needs a transaction system whereby the benefits of creation (legally said, property right) can be shared amongst all those who value it. This system is naturally based on some sort of market transactions. The buyer of the right pays some money for it. The seller of the right takes that money as compensation for having made a socially beneficial creation. Where demand meets the supply, price is determined. We achieve an equilibrium.

However, this may be a difficult equilibrium to achieve because of the inherent non-rival and non-excludable nature of the information good<sup>6</sup>—once the intellectual property has been divulged to another person it becomes a public good.<sup>7</sup> Such characteristics allow free-riders to take access without

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1. JOHN LOCKE, TREATISE OF CIVIL GOVERNMENT AND A LETTER CONCERNING TOLERATION 19–21 (Charles L. Sherman ed. 1937) (1690).

2. *Id.*

3. *Id.*

4. See Kenneth J. Arrow, *Economic Welfare and Allocation of Resources for Inventions*, in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS, 609 (National Bureau of Economic Research ed. 1962) (for illustration of this problem).

5. The sequence is as follows: initially, with exclusive rights, the information becomes excludable. Thereafter, when work passes into public domain, it becomes free for the consumers.

6. Information good/service is any commodity/service whose value is determined by the information it contains. The nature of material does not matter, but only arrangement of material matters. Common examples are CD, computer file, book, invention formula, and so on. See JAMES BOYLE, SHAMANS, SOFTWARE AND SPLEENS: LAW AND CONSTRUCTION OF INFORMATION SOCIETY (1996).

7. A public good in economics is considered to be non-rival, meaning goods/services where increasing consumption of that good/service does not reduce its availability to other users; and also non-excludable, which are those goods where it may be impossible to prevent people who have not paid for that good/service. Imagine national defense, or air in the environment. These are public goods. See Joseph E. Stiglitz, *Knowledge as a Global Public Good*, in GLOBAL PUBLIC GOODS 308, 308 (Inge Kaul, Isabelle Grunberg & Marc A. Stern eds., 1999) (for theoretical treatment of knowledge as public good); FRANÇOIS LÉVÊQUE & YANN MÉNIÈRE, THE ECONOMICS OF PATENTS AND COPYRIGHTS 7–9 (2004) (for an excellent understanding of non-rivalry and non-excludability in intellectual property rights).



paying.<sup>8</sup> Therefore, society needs an artificial mechanism that excludes non-payers, lest the market generates insufficient revenues to compensate the creator for his efforts and dilute his incentives to create that property in the first place. This artificial mechanism is provided by an exclusionary right, called IPR. So while IPR accords temporary monopoly power on the right holder, it results in a deadweight loss in the form of excluding buyers for who the good has become unaffordable.<sup>9</sup> The upside is, IPR framework incentivizes people to innovate and it also propels diffusion on knowledge, thereby helping development of cumulative innovations. Designing an optimal IPR framework therefore demands a compromise between the costs and benefits at both public and private realms.

As the normative and structural strands of legal theory suggest, IP laws are fundamentally located in the skeleton of property rule. However, given the public good nature of the information product, temporary monopoly imposes huge public costs. Take for example, pharmaceutical innovation. A life-saving drug, when granted a patent, will be sold at a cost unaffordable to a large chunk of population thereby increasing social costs. For such externality that germinates in intellectual property laws, incorporation of liability rules has emerged as a reactionary solution. In this paper, we will attempt to show that proponents of liability rules carry a heavy theoretical burden that needs to be spelt out.<sup>10</sup>

The paper is an attempt to excavate silences of property-liability framework in a cacophony of compulsory licensing. The remainder of the paper is divided as follows. In Part I, we illustrate the legal framework of compulsory licensing as a mechanism by way of which the right holder of the intellectual property (IP) will *have to* license the use of her/his rights to another party, at the behest of the government. Part II explores the relationship between compulsory licensing and property-liability framework. We highlight here, that compulsory licensing is a liability-based approach, and its imposition on a foundational

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8. See Arrow, *supra* note 4; TOM D. CROUCH, *THE BISHOPS BOYS: A LIFE OF WILBUR AND ORVILLE WRIGHT* (for a classic example. In this biography, the author described the Wright brothers' dilemma when, prior to filing for a patent on their airplane design, they were approached by the government to reveal their invention; they proposed a large up-front payment to solve the problem); see also William M. Landes & Richard A. Posner, *An Economic Analysis of Copyright Law*, 18 J. LEGAL STUD. 325 (1989); Stanley M. Besen & Leo J. Raskind, *An Introduction to Law and Economics of Intellectual Property*, 5 J. OF ECON. PERSPS. 3 (1991).

9. A deadweight loss is reduction in transactions by throwing out those buyers who now find it unaffordable to pay. Landes & Posner, *supra* note 8.

10. Roberto Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate* 27 RES. POL'Y 273 (1998) (the paper shows that the conventional astuteness amongst economists, lawyers, and many public officials is heavily weighted towards the proposition that "patent rights are conducive to economic progress").

property rights based approach on which IP laws are based, needs to attract academic principles that guide this approach. We expect to surface the institutional, conceptual, and theoretical feasibility inherent in the marriage of property and liability based approach for compulsory licensing, through building an analytical narrative. In Part III, IPR regimes of India and Canada are compared with a focus on patents for medicines. In the case of Canada, we look at the institution of compulsory licensing from the view of the Doha Declaration,<sup>11</sup> by way of which relevant clauses that favour implementation of compulsory licensing provisions were incorporated into the text of Trade Related Intellectual Property Rights (TRIPS).<sup>12</sup> The case of India is however, hinged on the regular flexibility in TRIPS, as incorporated in the Indian Patents Act 2005. Conclusion follows in Part IV.

## II. COMPULSORY LICENSING: CONCEPT AND SHORT HISTORY

The term “compulsory license” is often used as an umbrella term for many types of non-voluntary authorizations by the State (or any of the State’s machinery) to exercise a patentee’s rights without his or her authorisation, such as ex officio licenses, government use, crown (or government) use, licenses to remedy anti-competitive practices, mandatory licenses, and statutory licenses.<sup>13</sup> Compulsory licenses can be given for any kind of intellectual property, and it can take various names. In general, compulsory licensing is used to address anti-competitive issues of IPR.<sup>14</sup> The extensive survey taken by World Intellectual Property Organisation (WIPO) between 2009-11 exposed a wide variety of usages of the term compulsory licensing,<sup>15</sup> which included invoking on account of national or public interest; public health; compulsory cross-

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11. World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) (The basic idea was to carve out flexibilities in TRIPS particularly for circumventing patent rights for ensuring that access to essential medicines is not adversely affected in (mainly) developing regions of the world. Paragraphs 6 of Doha Declaration states: “We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.” This paragraph was implemented in amending the TRIPS Agreement by the Ministerial Declaration taken on 30 August 2003).

12. Other Use Without Authorization of the Right Holder art. 31, Jun. 1, 1995, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 300, 313 (Article 31 of TRIPS is a result of Doha Declaration) [hereinafter Marrakesh Agreement].

13. Coenraad Visser, *Patent Exceptions and Limitations in the Health Context*, at 10, U.N. Doc. SCP/15/3 (Sep. 2, 2010).

14. WIPO Secretariat, *Survey on Compulsory Licenses Granted by WIPO Member States to Address Anti-Competitive Uses of Intellectual Property Rights*, U.N. Doc. CDIP/4/4 REV./STUDY/INF/5 [hereinafter *Survey on Compulsory Licenses*].

15. *Id.*

licensing; failure to work; non-exploitation of IP rights for a period of time; patent-dependency; necessity to supply markets; exporting patented drugs; *inter alia*.<sup>16</sup> The concept can also take various nomenclatures. For example, in the European Union (and also in the United States), in the case of a single dominant company, the concept is called the 'essential facilities doctrine.' An essential facilities doctrine specifies when the owner(s) of an essential or bottleneck facility is mandated to provide access to that facility at a reasonable price.<sup>17</sup> The term essential facilities doctrine originated in commentary on United States antitrust case law and now has multiple meanings, each having to do with mandating access to something by those who do not otherwise get access.<sup>18</sup> Over time however, the doctrine is more closely associated with anti trust cases, and its application in IP is rather rare.<sup>19</sup> Compulsory licensing is fairly important and frequent however, in copyright statutes. For example, the Copyright Act of 1909 and 1976 in USA, both have compulsory licensing provisions.<sup>20</sup>

But in no other domain has compulsory licensing been more debated, contextualized and argued over, as in the case of pharmaceutical patents. Health improvements stimulate economic development<sup>21</sup> and so does innovation. If there is a trade-off between the two, it is a difficult choice. Compulsory licensing seems to tip the needle in favour of health, and therefore, has been the source of unending controversies, socio-political maneuvering by interest groups, and schism between industry and civil society. On one hand, industry supporters argue that doling out compulsory licenses reduces incentives to innovate, while on the other, civil society and public health advocates vociferously narrate the perils associated with giving monopoly rights on life saving drugs. Our paper deals with the subject of compulsory licensing, solely on the application of compulsory licenses on pharmaceutical patents.

It may be worthwhile to have a quick glance at how the global political machinery developed the framework of compulsory licensing.<sup>22</sup> Compulsory

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16. *Id.* at 7–8.

17. OECD, *Policy Roundtables The Essential Facilities Concept* (1996), <http://www.oecd.org/dataoecd/34/20/1920021.pdf>.

18. *Id.* at 7.

19. *Survey on Compulsory Licenses*, *supra* note 16.

20. See Robert Stephen Lee, *An Economic Analysis of Compulsory Licensing in Copyright Law*, 5 W. NEW ENG. L. R. 203, 204 (1982).

21. David E. Bloom & David Canning, *The Health and Wealth of Nations*, 287 SCIENCE 1207, 1209 (2000).

22. See JEROME H. REICHMAN & CATHERINE HASENZAH, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS: HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS, AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE USA ISSUE PAPER NO. 5 13 (2003) at

Licensing has been an integral part of the patent regime since its inception and at least one hundred countries make compulsory licenses available in one form or another.<sup>23</sup> The introduction of patents in Venice in the fifteenth century was accompanied by a broad set of rules, which included the state's right to issue a compulsory license.<sup>24</sup> Article 5A(2) of the Paris Convention of 1883 also provides for the liability rule.<sup>25</sup> And ever since 1883, this tool has become a fixture in patent systems around the world, and has perpetually been a topic of controversy.<sup>26</sup> Even during the World Wars, compulsory licensing was resorted to for the sharing of aviation technology and the manufacture of penicillin.<sup>27</sup>

It may be important to briefly dwell on emergence of compulsory licensing in the international framework as it stands today. With the decline of American manufacturing and growth of technology-led firms, the United States began raising the public perception of the importance of IPR.<sup>28</sup> The result was the linking of IP with trade and seeking global protection.<sup>29</sup> This attracted a lot of resistance, particularly by developing countries like India.<sup>30</sup> However, with the intense political maneuvering and bargaining power that America had over trade with India and other countries, coupled with pressure groups of pharmaceutical companies, developing nations succumbed. A comprehensive agreement was tabled and negotiated at the end of the Uruguay Round of the

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[http://ictsd.net/downloads/2008/06/cs\\_reichman\\_hasenzahl.pdf](http://ictsd.net/downloads/2008/06/cs_reichman_hasenzahl.pdf).

23. Carlos M. Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, 4, 24 (Ctr. for Advanced Studies at the Univ. of Buenos Aires, Arg., Working Paper 1999).

24. CHRISTOPHER MAY & SUSAN K. SELL, *INTELLECTUAL PROPERTY RIGHTS: A CRITICAL HISTORY* 58–59 (2006).

25. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, England–France–Sweden–United States, art. 5, available at [http://www.wipo.int/treaties/en/ip/paris/trtdocs\\_wo020.html](http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html) (last visited Feb. 7, 2014) (“Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.”) [hereinafter Paris Convention].

26. Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 *BERKELEY TECH. L.J.* 853, 859 (2003).

27. DEPARTMENT OF INDUSTRIAL POLICY & PROMOTION, *DISCUSSION PAPER ON COMPULSORY LICENSING* (2011) available at <http://thebigredbiotechblog.typepad.com/files/dipp-cl-draftdiscussion1.doc>.

28. Peter M. Gerhart, *Reflections: Beyond Compliance Theory—TRIPS as a Substantive Issue*, 32 *CASE W. RES. J. INT'L L.* 357, 367 (2000).

29. It is well illustrated how senior management of Pfizer was responsible for creating this link, by bringing together various other interested corporations and making IP privileges the most important priority of the United States in the 1980s. See JOHN BRAITHWAITE & PETER DRAHOS, *GLOBAL BUSINESS REGULATION* 61–62 (2000).

30. Elizabeth Chien-Hale, *Asserting U.S. Intellectual Property Rights in China: Expansion of Extraterritorial Jurisdiction?*, 44 *J. COPR. SOC'Y* 198, 226; see also ROBERT C. BIRD, *Defending Intellectual Property Rights in the BRIC Economies*, 43 *AM. BUS. L.J.* 317, 328–29 (2006).

General Agreement on Tariffs and Trade in 1994, called Agreement on Trade Related Aspects of Intellectual Property Rights<sup>31</sup> (TRIPS). Essentially, countries embracing TRIPS were required to fulfill greater IP protection, with the patent period fixed at twenty years, and in return got access to foreign markets and a safety net from whims of unilateral sanctions from their governments.<sup>32</sup> TRIPS was a revolution in the world of intellectual property with pharmaceutical companies emerging as major winners.<sup>33</sup> To be a member of WTO, countries had to sign TRIPS (although their signing was deferred until later, by when they were thought to develop sufficient expertise to be able to withstand competitive forces from the industrialized world).<sup>34</sup>

What the developing countries achieved through the TRIPS negotiations was the tool of compulsory licensing expressed in Article 31.<sup>35</sup> In short, referring to “use without the authorization of the right holder,” article 31 explicitly permits member states to issue compulsory licenses under three circumstances: (1) after efforts to obtain a license from the patent holder on “reasonable commercial terms and conditions” have failed, (2) in the case of “national emergency or other circumstances of extreme urgency” and (3) for public non-commercial use. Although the usage of this tool came with certain preconditions, they were waived off in cases of national emergency.<sup>36</sup> One of the conditions however, was to employ the use of compulsory licensing predominantly for domestic markets,<sup>37</sup> and many of the concerned markets had no ability or capacity to manufacture the generic version of the patented drug in question. This constraint was removed through the Multilateral Trade Negotiations, now known as Doha Round, where developing nations firmly resolved to participate only if their demands were met. Finally, Ministerial

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31. See Marrakesh Agreement, Annex 1C, *supra* note 12 at 311–15; Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154.

32. See Marrakesh Agreement, Annex 2, *supra* note 12 at art. 418.

33. Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247, 247 (2009).

34. Countries like India, China, Brazil were given time until 2005, while other countries, particularly the LDCs were offered a delay of few more years (patents until 2013 and pharmaceutical patents until 2016). See Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 for Least-Developed Country Members*, IP/C/40 (Nov. 30, 2005); Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, IP/C/25 (July 1, 2002).

35. See Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, *supra* note 12; JAYASHREE WATAL, *INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES* 24 (2002) (Noting that Indian delegation was instrumental in getting the article incorporated).

36. Marrakesh Agreement, *supra* note 12.

37. *Id.*

Declaration on the TRIPS Agreement and Public Health of 2001 affirmed that TRIPS can be interpreted to promote access to medicines for all<sup>38</sup> and later expressly declared the legitimacy for importing the drug from countries that are willing to do so.<sup>39</sup> This waiver is also called the Decision of 30 August 2003.<sup>40</sup>

### III. PROPERTY RULES, LIABILITY RULES AND *THEIR COEXISTENCE IN IPR*: ONE VIEW OF THE MODEL

In the four sub-sections that follow, we propose to argue that countries having weak property rights framework will (and should) attract liability regimes and those that are characterized by strong property rights framework do not need to invoke liability structures. In other words, compulsory licensing is justified if IP regimes of countries are weak and not when they are strong. The sections methodically show how: (a) choice of property or liability rests on transaction costs, (b) licensing mode (compulsory or voluntary) depends on transaction costs, (c) low transaction costs favour strong IPR regimes and high costs prefer weak IPR frameworks. In the last sub-section we link these findings to show that compulsory licensing regimes will be successful in weak IPR regimes.

#### *A. Transaction Costs as Determinant of Choice of Legal Rule*

The dichotomy between property rules and liability rules was set in the most illustrative manner in Calabresi-Melamed's seminal paper (hereinafter referred to as Cathedral Paper) published in 1972.<sup>41</sup> This was an interesting and convincing analytical tool stimulating scholars in various disciplines—most notably in law and economics—to cross-navigate beyond established terminology to appreciate functional and formal differences/congruence between two different areas of law—property and liability.<sup>42</sup> The property-

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38. See World Trade Organization, Declaration on the TRIPS Agreement and Public Health, ¶4, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2001).

39. *Id.* at ¶6.

40. This waiver however, has only been used once by Canada in exporting the drug to Rwanda, owing to procedural inefficiencies. See Paige E. Goodwin, *Right Idea, Wrong Result—Canada's Access to Medicines Regime*, 34 AM. J.L. & MED. 567 (2008); note that the following countries agreed not to use the Paragraph 6 provisions as importing members: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America. *Id.*

41. Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules and Inalienability: One View of a Cathedral*, 85 HARV. L. REV. 1089 (1972).

42. It was because of this article, along with his other seminal work in tort law that he is considered to be a founder of law and economics movement, along with Ronald Coase and Richard Posner. Under his influence (he was the Dean of Yale Law School) Yale Law School became one of the leading centre for economics influenced legal scholarship.

liability rule framework has inspired a range of scholarship in issues related to legal protection of information goods<sup>43</sup>, and has been extremely useful in understanding copyright collectives<sup>44</sup>, determining appropriate protection of incentives to innovate<sup>45</sup> and explaining relationship between several IP regimes.<sup>46</sup>

Cathedral Paper puts forth what are property rules and how do they differ from liability regime:

An entitlement is protected by a property rule to the extent that someone who wishes to remove the entitlement from its holder must buy it from him in a voluntary transaction in which the value of the entitlement is agreed upon by the seller. It is the form of entitlement which gives rise to the least amount of state intervention: once the original entitlement is decided upon, the state does not try to decide its value. It lets each of the parties say how much the entitlement is worth to him, and gives the seller a veto if the buyer does not offer enough. . . . Whenever someone may destroy the initial entitlement if he is willing to pay an objectively determined value for it, an entitlement is protected by a liability rule. . . . Obviously, liability rules involve an additional stage of state intervention: not only are entitlements protected, but their transfer or destruction is allowed on the basis of a value determined by some organ of the state rather than by the parties themselves.<sup>47</sup>

Hence, a property rule is a legal entitlement that can be bought only after bargaining with the entitlement holder and the price for the transaction is mutually decided by the buyer (holder) and seller of the right. On the other hand, under a liability rule, a tribunal (third party) will determine the appropriate compensation in an ex post proceeding. Cathedral Paper's argument establishes that transaction cost<sup>48</sup> is the primary determinant of the

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43. See Roger D. Blair & Thomas F. Cotter, *An Economic Analysis of Damage Rules in Intellectual Property Law*, 39 WM. & MARY L. REV. 1585, 1693 (demonstrating how Cathedral Paper should be decided for baseline recovery in cases of IP infringement—plaintiff's damages or defendant's profits accrued from infringement); see also Dan L. Burk, *The Trouble with Trespass*, 4 J. SMALL & EMERGING BUS. L. 27 (2000) (for a critical argument utilizing Cathedral paper in favour of injunctive relief in internet context); Alex Kozinsky & Christopher Newman, *What's so Fair about Fair Use?*, 46 J. COPYRIGHT SOC'Y 513 (1999) (in the context of copyright law).

44. Robert P. Merges, *Contracting Into Liability Rules: Intellectual Property Rights and Collective Rights Organization*, 84 CALIF. L. REV. 1293

45. Mark Schankerman & Suzanne Scotchmer, *Damages and Injunctions in Protecting Intellectual Property*, 32 J. INDUS. ECON. 199, 202 (2001).

46. J.H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 COLUM. L. REV. 2558 (1994).

47. Calabresi, *supra* note 41 at 1092 (footnote omitted)

48. Simply put, transaction costs in terms of law and economics are those costs that are incurred

choice for property rule or liability rule. Whenever market transaction costs are low, property rules are preferred; while liability rules are favoured when the transaction costs are high.<sup>49</sup> The argument for such factorization is simple. Whether parties can negotiate for the transaction of the right is a direct function of how costly the bargaining process is. In other words, transaction costs will determine whether price discovery will be a result of negotiation or whether a third party will impose prices it has determined on the basis of (so-called) objective criteria. The doctrine asserts that low transaction costs favour negotiation and reaching a Coasian bargain,<sup>50</sup> while high transaction costs will impede any Coasian solution to be achieved.<sup>51</sup> Therefore in the case of high transaction costs, parties will not be able to come to a mutually agreeable solution, and will need a tribunal (third party) which can declare the damage quantum and ensure the same. This is a crucial starting point for hinging our discussion against.

Low market transaction costs facilitate negotiation and adjustments, so there is no need of a third party to enforce a bargain. The parties themselves can contract mutually. However, when institutional design of voluntary negotiation is ineffective due to high transaction costs, liability rule (third party enforcement) suits best. Remember that employing property rule is possible only when transaction costs are low. This in turn means that (a) parties to a transaction are easily identifiable to each other, (b) costs of transaction between the parties is low, “and ([c]) a court setting the terms of the exchange would have a difficult time doing so quickly and cheaply, given the specialized nature of the assets and the varied and complex business environments in which the assets are deployed.”<sup>52</sup> Hence parties make their own deal. This approach generally builds the argument that property rules are better suited to protect IP as opposed to liability rules in case of low transaction cost. Liability rules always come with an efficiency loss and their application in presence of low

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in making an economic exchange. These may include search and information costs, bargaining costs, enforcement costs, contracting costs, negotiation costs. Transaction cost economics has led to a series of development in law and economics scholarship. See R. H. Coase, *The Nature of the Firm*, 4 *ECONOMICA* 386 (1937) (for first theoretical reference); see also Oliver E. Williamson, *The Economics of Organisation: The Transaction Cost Approach*, 87 *AM. J. SOC.* 548 (1981).

49. Calabresi, *supra* note 41.

50. Coase in his seminal article suggested that if initial entitlements are clear, they don't matter in absence of transaction costs. Efficient solution will always be reached no matter who has the entitlement. This is famously called Coase Theorem. He proposed that if transaction costs are negligible, parties can effectively negotiate and contract to buy the right. Whoever values it more will get it, and that in fact is efficient solution. See R. H. Coase, *The Problem of Social Cost*, 3 *J.L. & ECON.* 1 (1960) [hereinafter Coase, *Social Cost*].

51. Calabresi, *supra* note 41 at 1106-8.

52. Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 *TENN. L. REV.* 75, 78 (1994).



transaction costs does not make sense since the objective can be achieved at a lesser cost. One can imagine such efficiency losses in costs imposed by incomplete information of the third party, inefficient fixation of price, diminished utility of the parties, procedural delays and constraints, administrative expenses, flaws in institutional design, generation of perverse incentives, possibilities of errors, political economy factors, psychological costs or perhaps, the transaction not taking place at all (which happens to be the case many a times). On the other hand, in presence of high transaction costs, liability rules are employed to avoid the danger of adopting a suboptimal solution, a result that flows naturally if we modify the Coase theorem and view it from a non-zero transaction cost perspective.<sup>53</sup> The costs of incorporating liability rule in a property rule set-up is offset by the exercise of the transaction which should yield a higher optimal outcome.

The Cathedral Paper therefore states, among other things, that the choice of property or liability rule depends on transaction costs. Property rules are achieved in low transaction costs, while liability rules are used when transaction costs are high. This can further be explained to understand that property rule is applied when negotiation is possible because transactions costs are lower, whereas liability rule is applied when negotiation is not possible in the face of high transaction costs.

### *B. Licensing*

Licensing activity refers to the grant of creator's rights (IP right) to non-creator at a price called licensing fee. Low market transaction cost facilitates negotiated licensing transaction between the right holder and the one who is seeking the license for using and sharing the right holder's invention (if it is a patent, say). When market transaction costs are low, it lets the parties negotiate and reach a mutually amicable price for the license. On the other hand, if the market is faced with a high transaction cost, it is difficult to bargain the license. Therefore, in those circumstances, government/a court acts as a third party and intervenes through 'non-voluntary' contract between the creator and the non-creator. The crucial assumption—which we are not disputing—is that for public interest, it is indeed important that the license be given. In the absence of a third party, and in presence of high transaction costs, the license will never be doled out, which is not the desirable solution. The solution comes in the form of an involuntary contract enforced by a third party. This intervention comes in the form of compulsory licensing (for the purpose of this article, in patents). The government authorizes itself to allow third parties to use the subject matter of a patent without the authorization of the right holder or a mandated

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53. See Coase, *Social Cost*, *supra* note 50.

authorization of the right holder. In these cases, the public interest in broader access to the invention is considered more important than the private interest of the right holder to fully exploit his exclusive rights.<sup>54</sup>

Compulsory licensing for pharmaceutical products aims at ensuring that everyone has an access to essential medicines at affordable prices. While recognizing a nation's right to protect the public health of its people, even at the expense of not honoring intellectual property rights, TRIPS was flexibilized through incorporation of clauses concerning compulsory licensing, and nations securing their desire to amend their national laws to conform to the *flexible* TRIPS in the manner it suits best to the nations. In addition, the Inter-Ministerial Conference of the World Trade Organization initiated the Doha Agenda. The objective of granting compulsory licenses is to prevent the abuse of monopoly granted by the patent, and to safeguard the public welfare and health care issues prevailing in the nations. In the present context, the exercise is sought to obtain permission to manufacture the generic versions of the patented drug. Compulsory license is generally made "available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems."<sup>55</sup>

It is notable that the very logic behind providing the flexibility is to fulfill the normative frameworks of public health, at the cost of rights-based framework. Compulsory licensing therefore portrays liability framework because the rights holders are protected by a "liability rule" (royalty set by the government) instead of a "property rule" (receipt of an injunction with the rights-holder then negotiating the price out with potential buyers).<sup>56</sup> Hence, while compulsory licensing stands as a true liability rule, property rule is invoked whenever licenses are given on voluntary licensing. Whether property rule (voluntary licensing) or liability rule (involuntary licensing) should be preferred is a discussion we will come back to a little later. With little reason, it stands clear that voluntary licensing will take place if the transaction costs are low, while compulsory licensing will be preferred in high transaction costs (negotiation for licensing without involving a third party is easy if bargaining costs are low, while for higher bargaining costs, negotiations will fail or not take place at all—a clear case for third party intervention).

The above discussion *demonstrates that voluntary licensing is possible at*

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54. REICHMANN & HASENZAH, *supra* note 22.

55. Swarup Kumar, *Compulsory Licensing under Trips: A Study of Roche v. Natco Case in India vis-à-vis the Applicability of the Principle of Audi Alteram Partem*, 7 SCRIPTED 135, 149 (2010) available at <http://www.law.ed.ac.uk/ahrc/script-ed/vol7-1/kumar.asp>.

56. Calabresi, *supra* note 41.

*low transaction costs, whereas high transaction costs disfavour voluntary licensing. This also means that compulsory licensing emerges in the foreground when transaction costs in the picture are higher.*

### *C. Licensing and IPR Strength*

Trade in licensing is a natural consequence. A license is a commercial contract between licensor and licensee. Primarily, it specifies two basic features—the subject material which has an intellectual property and functional use of the subject material. The licensee compensates the licensor for use of licensed subject by a flat fee (lump-sum) and/or through royalties based on income earned by the licensee. The royalty rate can be fixed at a varying percentage of licensee's value of output, units of output, profits, or sales.<sup>57</sup> Licensees save the expense of independent research and development for the licensee and licensors derive fees and royalties, as well as capitalize on licensees' local reputation and knowledge. There are a number of other advantages of licensing for both the parties, thereby achieving Pareto optimal<sup>58</sup> solutions:

- a) Some companies may not have sufficient investment capacity to operationalise Foreign Direct Investment and penetrate the market on their own. These small companies therefore can then use licenses to test a market before making huge investments.
- b) Licensing creates an easy entry and exit from the pharmaceutical market, which is otherwise characterized by high fixed costs and therefore rigid and few exit options.<sup>59</sup>
- c) Licensors can earn fixed revenue much quicker from the license and therefore get an early return on their research and development (R&D) efforts.<sup>60</sup>

Our contention is that when costs of enforcing contracts (transaction costs)

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57. See ALAN S. GUTTERMAN, *THE LAW OF DOMESTIC AND INTERNATIONAL STRATEGIC ALLIANCES: A SURVEY FOR CORPORATE MANAGEMENT* (1995); see also Bharat N. Anand and Tarun Khanna, *The Structure of Licensing Contracts*, 48 J. INDUS. ECON. 103, 130 (2000).

58. Pareto Optimality is due to Vilfredo Pareto, an Italian economist whose thesis had that optimality is achieved when there is at least one person better off with no one worse off. See VILFREDO PARETO, *COURS D'ECONOMIE POLITIQUE* (vol. II 1897); JULES L. COLEMAN, *MARKETS, MORALS AND THE LAW* 67–132 (1988) (for discussion about Pareto efficiency in detail).

59. Author believes that FDI may be very costly exercise. Also export sales may face tariff and non-tariff barriers.

60. This is an important point. It was raised at the *High-Level Workshop on IPR and Economic Development in China: Meeting Challenges and Opportunities Following WTO Entry*, Beijing, April 2004, organised by OECD in collaboration with State IP Office and Development Research Centre of State Council, China.

are low, this may be because of strong IPR regimes. Strong IPR regimes can be characterized by clearly defined rights and identifiable boundaries, rights holder-favouring regime, emphasis on innovation and incentives structure, strong enforcement mechanisms, and certainty. And interestingly, certainty reduces market transaction costs. The certainty of entitlement of the right reduces costs associated with identification, information, and bargaining. In addition, certainty also crystallizes the boundaries of patents. It creates strong enforcement mechanisms, thereby making infringement impossible and licensing the only alternative for access to technology. Thus stronger IPRs will facilitate expanded licensing regimes and may confer excess market power thereby lifting up license fee and discouraging prospective licensees. However, if the license fee is worth the investment, it will result in license being issued, and if it is not, then compelled by market forces (under our assumption of low market transaction costs), the license fee will reduce. Either ways, an efficient solution will be achieved. On the other hand, if the IPR regime is weak, the right holder may still want to license his right to a local producer to have the latter safeguard him against possible infringement.

There have been several studies taking different approaches that have gotten more or less similar results. In 1984, Farok Contractor attempted to correlate patent protection and licensing using cross-sectional data, which explained the determinants of the ratio of receipts in the United States of royalties and licensing fees from unaffiliated sources to various measures of direct investment activity.<sup>61</sup> The study defined patent intensity of a nation by flows of new patents in force. Technology transfer on the other hand was used as proxy for licensing. The study found that patent intensity indeed did attract licensing. The argument behind this observation is that patent protection increases the income extractable from licensing. In another well-cited study, Edwin Mansfield established<sup>62</sup> that multinationals are less likely to engage in technology transfer (licensing) with firms of countries where IP protection is weak.<sup>63</sup> In yet another study, Pamela Smith infers<sup>64</sup> that the effect of stronger IPRs on international licensing depends on the imitative capabilities of host countries, by drawing on cross-sectional data on US multinationals' licensing

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61. Farok J. Contractor, *Choosing Between Direct Investment and Licensing: Theoretical Considerations and Empirical Tests*, 15 J. INT'L BUS. STUD. 167 (1984).

62. Edwin Mansfield, *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer*, INT'L FIN. CORP. Discussion Paper No. 19, (1994).

63. However, this finding depends on the industry or nature of the technology. U.S. firms in the chemicals and electronics industries appeared to place a greater emphasis on intellectual property protection, whereas firms in the metals and transportation industries were seen to be less reliant on it. *See id.*

64. Pamela Smith, *How Do Foreign Patent Rights Affect U.S. Exports, Affiliate Sales, and Licenses?*, 48 J. INT'L ECON. 151 (2001).

activities in 50 countries.<sup>65</sup>

Later studies extended the scope and methodology of the general finding, that strong patent rights and licensing activities are positively correlated. Yang and Maskus extended the analysis of US foreign licensing to a panel data set covering three time periods (1985, 1990, and 1995) and twenty-three partner countries, of which approximately ten are developing or emerging market economies. They found that countries with stronger patent rights attract larger volumes of licensed technology.<sup>66</sup> More recently, Michael Nicholson finds that R&D intensive firms are more apt to license when patent protection is strong.<sup>67</sup> His approach is to focus on count data rather than value data. It was a cross-sectional empirical analysis and it pools together data for 1995 from forty-nine destination countries and eighty-two industries.

While previous studies were using Bureau of Economic Analysis aggregated industry or national level data, Branstetter, Fisman, and Foley conducted a study using Bureau of Economic Analysis *micro-data*. A key finding was that IPR reforms—signifying strength of patent protection—stimulate US firms to license abroad to affiliated parties.<sup>68</sup>

Anand and Khanna attempted to explore how much licensing is dependent on IPR protection levels. The study employed data on international licensing contracts from the *Joint Ventures and Strategic Alliances* database of the Securities Data Company.<sup>69</sup> The authors found that licensing in the pharmaceutical and chemical sectors is dependent on patent protection, while licensing in the semiconductor industry is relatively less dependent on it. In their hypothesis, the authors suggested that this could be due to the fact that contents and boundaries of knowledge are relatively easy to ascertain for products in pharmaceutical and chemical industry, but for products in semiconductors (circuit-layout etc.), knowledge boundaries are blurred so patent protection cannot be substantial enough to encourage licensing.

Another study, one that has empirically arrived at conflicting result, is that of Andrea Fosfuri in 2003.<sup>70</sup> It established weak effects of IPRs on

65. In situations where imitative risk is low, stronger IPRs serve primarily to raise rents to rights holders. In countries where imitative capabilities are high, stronger patent rights stimulate licensing to unaffiliated foreign firms. See Besen & Raskind, *supra* note 8.

66. Guifang Yang & Keith E. Maskus, *Intellectual Property Rights and Licensing: An Econometric Investigation*, 137 WELTWIRTSCHAFTLICHES ARCHIV 58 (2001).

67. Michael Nicholson (2003) "The Impact of Industry Characteristics on International Technology Transfer", *Bureau of Economics, Federal Trade Commission Working Paper*.

68. Lee G. Branstetter, Raymond Fisman & C. Fritz Foley, *Do Stronger Intellectual Property Rights Increase International Technology Transfer?*, (Columbia Business School Working Paper No. 20, 2002).

69. Anand & Khanna, *supra* note 57, at 105.

70. Andrea Fosfuri, *Country Risk and the International Flows of Technology: Evidence from*

international licensing and found that patent rights have an insignificant or negative effect on licensing. It used firm-level data for the world chemical industry. However, this study was focusing only on firms with process innovations. And for such innovations, patents may not be the most effective mechanism. In fact, it has been noted that biotechnology—a standard process innovation—firms prefer trade secrecy to patent protection.<sup>71</sup> Process innovations are harder to enforce compared to product innovations. In other words, as explained in the next section, process patents are equivalent to weak IP protection, and a move from process to product patents is a move towards stronger IP protection. Hence, this finding does not in any way undermine the results found in other papers.

One study, conducted by OECD, deserves our special attention because of its elaborate methodology and effective control variables.<sup>72</sup> This study undertakes a regression analysis to estimate the relationship between indicators for licensing and IPR strength in developing countries, while controlling for other factors. This study attempts to make an empirical contribution to one of the main channels of technology transfer—licensing. It considered the relationship between strengthening of IPR and licensing activities, particularly in the 1990s. It employed a regression analysis to draw on an international data set to consider the relationship over time between changes in the host-country patent regime and changes in the number of licensing transactions between developed and developing countries. The strength of IPR was measured by different IP index, like patent rights,<sup>73</sup> copyrights<sup>74</sup> and trademarks,<sup>75</sup> and finally the fourth index examines enforcement effectiveness.<sup>76</sup>

This study is conducted first using aggregate data, then the firm-level data.

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the Chemical Industry (July 2003) (Universidad Carlos III de Madrid, Working Paper).

71. Nikolaus Thumm, *Research and Patenting in Biotechnology: A Survey in Switzerland*, SWISS FEDERAL INSTITUTE OF INTELLECTUAL PROPERTY, [https://www.ige.ch/fileadmin/user\\_upload/Juristische\\_Infos/e/j10005e.pdf](https://www.ige.ch/fileadmin/user_upload/Juristische_Infos/e/j10005e.pdf) 1 (2003), [https://www.ige.ch/fileadmin/user\\_upload/Juristische\\_Infos/e/j10005e.pdf](https://www.ige.ch/fileadmin/user_upload/Juristische_Infos/e/j10005e.pdf).

72. Walter G. Park & Douglas Lippoldt, *The Impact of Trade Related Intellectual Property Rights on trade and Foreign Direct Investment in Developing Countries*, 3 ORG. FOR ECON. CO-OPERATION AND DEV. PAPERS (SPECIAL ISSUE ON TRADE POLICY) Paper No. 294 (2003).

73. Juan C. Ginarte & Walter G. Park, *Determinants of Patent Rights: A Cross National Study*, 26 RES. POL'Y 283; Walter G. Park & Smita Wagh, *Index of Patent Rights*, in ECONOMIC FREEDOM OF THE WORLD ANNUAL REPORT 2002 (James Gwartney et al. eds., 2002).

74. Taylor William Reynolds, *Quantifying the Evolution of Copyright and Trademark Law* (2004) (Doctoral dissertation paper).

75. *Id.*

76. See Office of the United States Trade Representative, [http://www.ustr.gov/Document\\_Library/Reports\\_Publications/Section\\_Index.html](http://www.ustr.gov/Document_Library/Reports_Publications/Section_Index.html) (last visited 20 Oct. 2010) (No formal study has been done to measure enforcement effectiveness, but some information collected by Park and Lippoldt comes from reports filed with US Trade Representatives.)

Variables that needed controlling were, gross productivity, corruption, tariff rates, and country risks for example. The study finds general support for the proposition that strengthening of IPRs has a net positive effect on technology transfer via licensing. This result is perhaps synchronous with our first prediction that strong IPRs (effective enforcement and certainty in bargaining) make it attractive for right holders to appropriate the returns to innovation by increasing the licensing efforts. It is interesting to note that licensing fees and royalties were found to vary positively with stronger patent rights and more effective enforcement.<sup>77</sup> A country can stimulate innovation more effectively only with a given strengthening of patent rights. This is because patents generate deadweight loss in the country that affords protection and accordingly provides for dynamic efficiency. Scholars have constructed an index of patent rights and have shown that the index is highly correlated with per capita GDP, accordingly Global North (producers of innovation) typically provide stronger patent protection than their counterparts in the Global South (consumers of innovation).<sup>78</sup>

It was also indicated in the statistical study that a critical level of patent protection is needed before firms have an incentive to engage in licensing. This is the reason, perhaps, as to why developing nations even after their 'reforms,' do not attract voluntary negotiations for licensing and have to resort to the compulsory nature of licensing. The study also showed, surprisingly, that with weak IPRs, firms may be compelled to undertake FDIs and not licensing, for obvious reasons.<sup>79</sup> But as soon as the IPRs become strong, licensing is chosen over FDIs.<sup>80</sup>

Intuitively, it is not difficult to understand why licensing thrives in strong IP regimes.<sup>81</sup> If IP rights are not strong, prospective licensees will have sufficient incentives to imitate and use the product without paying any license. This theoretical thread binds all empirical studies too.

*This sub-section explains that voluntary licensing is prominent and effective in strong IPR regimes and compulsory licensing in weak IPR regimes.*

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77. Copyrights and trademarks rights were found to exercise comparatively weak influences. This may be due to a number of factors, which don't merit our attention here, except that there needs to be due appreciation of diverse nature of these intellectual properties and therefore one must understand that they deserve to be treated differently. See Landes & Posner, *supra* note 8.

78. Ginarte & Park, *supra* note 73.

79. Ignatius Horstmann & James R. Markusen, *Licensing Versus Direct Investment: A Model of Internalization by the Multinational Enterprise*, 20 Can. J. Econ. 464, 471-74 (1987). See also Yang & Maskus (2001), *supra* note 66.

80. *Id.*

81. See Nancy T. Gallini, *Patent Policy and Costly Imitation*, 23 RAND J. ECON. 52 (1984) (for elaborate theoretical discussion).

#### *D. Connecting the Dots*

The three strands of discussion above can be connected analytically. We attempt to do this here. As discussed, whether liability or property rule be applied, is the outcome of the level at which transaction costs exist. Property rules are achieved in low transaction costs, while liability rules are used when transaction costs are high. Furthermore, voluntary licenses' negotiations arrive at successful conclusions when transaction costs are low and compulsory licenses are invoked when transaction costs are high. Therefore, when transaction costs are low, IPR regimes are property rule based, and are therefore strong. On the other hand, liability regimes develop in IPR regimes, which are weak in nature. Hence, it makes sense to install the framework of compulsory licensing in jurisdictions that are characterized by weak IPR regimes. This is the pivotal result that we arrive at for the purpose of our analysis. Analytically:

SINCE,

*Property rules  $\approx$  low transaction costs*

*Liability rules  $\approx$  high transaction costs*

AND

*Low transaction costs  $\approx$  negotiation  $\approx$  voluntary licensing*

*High transaction costs  $\approx$  no negotiation  $\approx$  compulsory licensing*

THEREFORE,

*Property rules  $\approx$  voluntary licensing*

*Liability rules  $\approx$  compulsory licensing*

#### IV. IPR REGIMES OF CANADA AND INDIA

The choice of comparative analysis of Canada with India stems from a shared priority that the countries have in their policies of access to medicines and their relative locations with respect to access to medicines and public health concerns. Both countries have had their own tryst with implementing flexibilities in TRIPS (Canada employing the para. 6 decision of Doha Declaration and India invoking the domestic regulation clause for compulsory licensing), while located in different income group countries.

In 2005 India shifted to implement the new Patent Act, with strong clauses in favour of inventors (for example, product patents replacing earlier process patents), and also implemented TRIPS with its flexibilities. India has positioned itself as one of the global leaders in manufacturing of generic medicines. India today, has assumed a pivotal responsibility of being regarded as what Médecins Sans Frontières (MSF) calls, *Pharmacy of the Developing World*.<sup>82</sup> 85% of the HIV/AIDS patients that MSF treats in over thirty countries

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82. Leena Menghaney, *Patent Dispute: Delhi High Court Gives a Boost to Access to Affordable*



depend on generics from India. MSF buys more than twenty-five per cent of the drugs for malaria, TB, and antibiotics from India. Moreover, approximately fifty per cent of essential medicines that UNICEF distributes in developing countries come from India, “while 75-80% of medicines distributed by International Dispensary Association are made in India.”<sup>83</sup> India has become the dispensary for the poor of the world. Since the 1970s, India has become a drug producer for the developing world, revolutionizing the treatment of diseases like AIDS, tuberculosis, and malaria with low-cost generics. “It now makes one-fifth of the world’s generics.”<sup>84</sup> Indeed, it is because of competition from Indian generics that the cost of HIV/AIDS treatment has come down from \$10,000-\$15,000 to \$150 per patient per year, since the 1990s.<sup>85</sup> This is a result of tremendous growth of pharmaceutical industry in India since 1960s, encouraged by government policies, the enterprising nature of post-independence born Indians,<sup>86</sup> and the Patent Act 1970. This Act changed in 2005, and TRIPS flexibilities were introduced. The reason this merits our attention is because such policy changes have had, and will have, far reaching consequences in India’s pharmaceutical industry, which is the world’s third largest by volume<sup>87</sup> and is poised to grow even further. In addition, it will also have a bearing on India’s access to medicine situation. India also has the largest population of people who are living without any adequate access to basic medicine. 65% of the Indian population lives below the *access to medicine line*.<sup>88</sup> The government expenditure on health is only 17.9% while private expenditure is 82.1% reports the National Health Accounts of India and this happens when drugs accounts for about 70% of the total expenditure on health. Lack of purchasing power is one of the main reasons behind poor access to

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*Medicines*, 7 INDIAN J. MED. ETHICS 97, 100 n.2 (2010).

83. Priyanka Golikeri, *EU Firm on Strong IP Provisions in Free Trade*, DAILY NEWS AND ANALYSIS, 8 June 2010.

84. Erika Kinetz, *Europe Trade Deal Could Hit Indian Generic Drugs*, ASSOCIATED PRESS, April 26, 2010.

85. Latha Jishnu, *Vicious Sting in the Tail of FTAs*, BUSINESS STANDARD (June 24, 2009), [http://www.business-standard.com/article/opinion/latha-jishnu-vicious-sting-in-the-tail-of-ftas-109062400080\\_1.html](http://www.business-standard.com/article/opinion/latha-jishnu-vicious-sting-in-the-tail-of-ftas-109062400080_1.html).

86. See, e.g., AMLANJYOTI GOSWAMI, NAMITA DALMIA, & MEGHA PRADHAN, ENTREPRENEURSHIP IN INDIA (2008) (discusses in detail a primary survey conducted on Indian entrepreneurial aspects); R. Gopalakrishnan, “Prosperity Beyond Our Cities by Spreading Enterprise,” AD Shroff Memorial Lecture, October 17, 2007; see also TARUN KHANNA, BILLIONS OF ENTREPRENEURS: HOW CHINA AND INDIA ARE RESHAPING THEIR FUTURE AND YOURS (2007); PAVAN VERMA, BEING INDIAN (2005).

87. M.V. Ramsurya, *Pharma, Engineering to Topple IT as Big Paymaster*, ECONOMIC TIMES, June 8, 2010.

88. Andrew Creese, Nadine Gasman & Mamadou Mariko, *The World Medicines Situation* (2004), <http://www.ops.org.bo/textocompleto/ime23901.pdf>.

essential medicines in India.

During almost the same time that India moved towards new patent laws—Canada made noticeable efforts too. It is the only country in the world to employ the August 30 decision to export essential medicines to countries that do not have capacities to manufacture them. Canada has been able to do it successfully (although we will later see, it has its own implementation fallacies) and stands out in patiently carrying out the procedures in a multilateral level. Indian and Canadian experiences are very few of those that encapsulate implementation of TRIPS' flexibilities for compulsory licensing<sup>89</sup> and a comparative analysis will throw light on what these countries have to learn from each other and indeed, what other nations may need to follow from there.

That said, the authors recognize the relatively differential economic and social locations of the two countries, and strongly note that our analysis is insulated from these natural concerns. Even though the economies of the two countries are markedly different from each other, the issue of access to medicines, which this article primarily concerns with, is viewed from supply side economy. Our analytical framework dissects institutions at the level of manufacturing and patenting. As long as the countries have manufacturing abilities, different economic growth rates and relevant indicators do not call for the need of employing GDP deflator or purchasing power parity parameters. These instruments would be crucial if we are to study the market demand institutions. The existence of competitive manufacturing ability, coupled with similar-spirited legal framework that governs supply side makes the comparative case immune to divergent economies and societies. Hence, even though Canada and India are dissimilar in multiple respects, one of the few converging legal frameworks exists in the case of pharmaceutical industry—which is something we intend to explore.

#### *A. Access to Medicine Regime in Canada*

Canada introduced the Patent Act in 1923, and developed aggressive policy on compulsory licenses on pharmaceutical products.<sup>90</sup> The only problem was the requirement to manufacture key ingredients in Canada. Since the Canadian market was strong, producers did not have incentives to produce generic drugs making use of the compulsory licensing using expensive labour and the

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89. See Yugank Goyal, *Economic and Procedural Constraints of Compulsory Licenses for Medicines*, in *COMPULSORY LICENSING—PRACTICAL EXPERIENCES AND WAYS FORWARD* (Reto Hilty & Kung-Chung Liu eds., forthcoming 2014) (For detailed analysis of compulsory licenses granted since Doha); see also Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLOS MED. 1 (2012).

90. See Paris Convention, *supra* note 25 at art. 5A (perhaps the only restriction was the prescribed minimum period of time before a compulsory license could be applied for).

technology of Canada.<sup>91</sup> This became a crisis<sup>92</sup>, and in 1969, Canadian Parliament amended the Act to allow for import of active ingredient and medicines. This reform had drastic results. In the two decades following the 1969 Amendment, 1030 applications were filed for compulsory licenses and 613 licenses were granted as against forty-nine applications received (of which twenty-two patents granted) since 1923 until 1969.<sup>93</sup>

In late the 1980s, pressurized from diplomatic corners and North American Free Trade Agreement, Canada was, for lack of a better term, *forced* to amend its compulsory licensing policies.<sup>94</sup> In 1993, Canada abolished the compulsory license regime. Canada however, designed new ways of promoting generics, using different 'term of protection,' 'early working patents,' and 'stockpiling options.' These created a lot of stir amongst U.S. and E.U. pharmaceutical lobbies and they dragged Canada to World Trade Organisation (WTO) dispute resolution. It appears that Canada was so dissuaded by external pressures trying to control its Patent Act that as soon as the 30 August 2003 WTO decision on the eve of Cancun Ministerial Conference (after Doha Development Round) was declared, in less than a month, Canada announced its intention to implement the same. Canada was the first country to employ compulsory licensing using Decision of 30 August for importing an HIV drug to Rwanda.

### B. Pharmaceutical Patents in India

In India, pharmaceutical patents were first introduced by the British, during colonial rule, when they passed first patent law in 1856, just before formal beginning of British Raj.<sup>95</sup> By 1970, India had realized that it has been hit by the influence of foreign firms (which controlled 70% of the Indian market)<sup>96</sup>,

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91. See Donald McFetridge, *Intellectual Property, Technology Diffusion, and Growth in Canadian Economy*, in COMPETITION POLICY AND INTELLECTUAL PROPERTY IN KNOWLEDGE BASED ECONOMY 65 (Robert Anderson & Nancy Gallini eds., 1998).

92. The drug prices in Canada reached amongst the highest in the world, and Canadian provinces began to nationalize their medical services and pay for pharmaceuticals to cushion people's burden. See DEPARTMENT OF JUSTICE OTTAWA RESTRICTIVE TRADES AND PRACTICES COMMISSION, REPORT CONCERNING THE MANUFACTURE, DISTRIBUTION AND SALE OF DRUGS (1963); see also Canada (1966), House of Commons, Special Committee on Drug Costs and Prices: *Report of the Standing Committee on Drugs Costs and Prices*, Ottawa: Queen's Printer.

93. See HARRY C. EASTMAN, THE REPORT OF COMMISSION OF THE COMMISSION OF INQUIRY ON THE PHARMACEUTICAL INDUSTRY (1985).

94. For political details about the amendment, see Joel Lexchin, *Globalisation, Trade Deals and Drugs: Heads, the Industry Wins; Tails, Canada Loses*, 2 CAN. CENTRE POL'Y ALTERNATIVES (2001).

95. See P. NARAYANAN, PATENT LAW 5-6 (4th ed. 2006).

96. P.K. Ramachandran and B.V. Rangarao, *The Pharmaceutical Industry in India*, 7 ECON. & POL. WKLY. M-27 (1972).

and high drug prices.<sup>97</sup> India therefore, passed a law on patents that prohibited product patent on medicines. The Indian Patents Act of 1970 acted as the main thrust to India's pharmaceutical industry.<sup>98</sup> This led to a steep fall in the number of patents granted.<sup>99</sup> Although the law permitted process patents on medicines<sup>100</sup>, it was rarely sought and had limited scope.<sup>101</sup> This therefore, gave rise to a number of local pharmaceutical firms increasing their share of the market.<sup>102</sup> Indian pharmaceutical firms became larger and more sophisticated. They employed reverse engineering methods to develop new processes for the drugs. Over the next three decades, the Indian pharmaceutical industry became extremely competitive and diverse<sup>103</sup> and by the 1990s, India started producing the most inexpensive medicines in the world.<sup>104</sup>

In 1995, WTO introduced TRIPS. TRIPS set up minimum standards of IP regulation<sup>105</sup> specifying enforcement mechanisms, dispute resolution features, and remedies. India opposed TRIPS initially,<sup>106</sup> but finally acceded to the Agreement, since staying out of WTO framework was a difficult choice. However, India bought time until 2005 to comply with TRIPS. By this time,

97. S. REP. NO. 87-448, at 43-44 (1961) (Which showed India with the highest prices of the seventeen countries surveyed, which included the United States); see Daniel D. Adams and William E. Nelson, *The Drug Amendments of 1962*, 38 N.Y.U. L. REV. 1082 (1963) (For report and other aspects of the sub-committee).

98. Jean Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of Poor and Suffering* 3-4 (Nat'l Bureau of Econ. Research, Working Paper No. 6366, 1998).

99. *Id.* at 4.

100. See The Patents Act, 1970, No. 39, § 53(1) Acts of Parliament (2013) available at [http://ipindia.nic.in/ipr/patent/patent\\_Act\\_1970\\_28012013\\_book.pdf](http://ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf). For example, such patents only lasted for the shorter of five years from the date of grant or seven years from the date the patent was filed.

101. H. Ashok Chandra Prasad & Shripad Bhat, *Strengthening India's Patent System: Implications for Pharmaceutical Sector*, 28 ECON. & POL. WKLY. 1037, 1057 (1993).

102. This was accompanied by other regulatory and policy measures that the government took to encourage building local markets against foreign firms. See *id.*

103. See SUDIP CHAUDHURI, *THE WTO AND INDIA'S PHARMACEUTICAL INDUSTRY: PATENT PROTECTION, TRIPS AND DEVELOPING COUNTRIES* (2005) (For an overview of how pharmaceutical industry developed after patent law was enacted); Aradhna Aggarwal, *Strategic Approach to Strengthening the International Competitiveness in Knowledge Based Industries: The Indian Pharmaceutical Industry*, RIS, Discussion Paper No. 80 (2004) [http://ris.org.in/images/RIS\\_images/pdf/Dp80\\_pap.pdf](http://ris.org.in/images/RIS_images/pdf/Dp80_pap.pdf).

104. See CHAUDHURI, *supra* note 103, at 46-58.

105. TRIPS contains requirements that nations' laws must meet for copyright rights, including the rights of performers, producers of sound recordings and broadcasting organizations; geographical indications, including appellations of origin; industrial designs; integrated circuit layout-designs; patents; monopolies for the developers of new plant varieties; trademarks; trade dress; and undisclosed or confidential information. See *id.* See also Aggarwal, *supra* note 103.

106. George K. Foster, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and its Aftermath* 3 UCLA J. INT'L L. & FOREIGN AFF. 283.

Doha Development Agenda had been carved out as well. In 2005, India adopted TRIPS, and thereby institutionalized *product patent* regime in the pharmaceutical sector, supplanting the earlier *process patent* approach in pharmaceutical industry in the Patents Act 2005.

The distinction between *product* and *process* patents is important to be emphasized. India had only *process patents* since 1970. In pharmaceutical industry, a process patent inherently makes it easier for generic manufacturers to adopt a different process and produce the same product by reverse engineering. Since the marginal cost of making a drug is negligible, process patents enables generic manufacturers to manufacture a drug at a substantially cheap prices and consequently, market it at cheap price. This way, from patent policy's perspective, access to medicines was not a concern<sup>107</sup>—meaning Patent Act 1970 has produced a favoured system for access to medicine in India.<sup>108</sup> Therefore, India never needed compulsory license. In other words, even if compulsory licensing was allowed, there were other less expensive means to produce generic drugs, so it would have been useless legislation.

In 2005, India adopted TRIPS and consequently, *product patents*, thereby strengthening the IPR regime. Since TRIPS in its pristine form was highly unfavourable to developing countries' concerns regarding access, the flexibilities implanted in TRIPS by Doha Declaration, were also quickly adopted by India. One of the flexibilities was compulsory licensing.

## V. LOCATING CANADA AND INDIA IN THE MODEL

Our hypothesis emerging out of the above discussion is that while Canada exhibits a strong IPR regime, India does not. Canada is characterized by (a) product patents, (b) TRIPS-compliant laws, (c) R&D investments in

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107. See Biswajit Dhar & Niranjana Rao, *Transfer of Technology for Successful Integration into the Global Economy: A Case Study of the Pharmaceutical Industry in India*, UNCTAD/UNDP Programme on Globalisation, Liberalisation and Sustainable Development, New Delhi U.N. Doc. UNCTAD/ITE/IPC/Misc.22 (For the role of patents in the evolution of the Indian pharmaceutical industry); see also, CHAUDHURI, *supra* note 103.

108. Access to medicines has been a primary concern from the perspectives of affordability though, and largely so. India is overburdened by communicable and infectious diseases alongside an emerging epidemic of non-communicable diseases. But public health spending constitutes around 0.9% of Gross Domestic Product. Government expenditure of health in India is 17.9% of the total health expenditure and remaining 82.1% is private in nature. See Central Bureau of Health Intelligence, *National Health Profile 2005*, CENTRAL BUREAU OF HEALTH INTELLIGENCE, NATIONAL HEALTH PROFILE 77–79 (2005); see also MINISTRY OF HEALTH AND FAMILY WELFARE, NATIONAL HEALTH ACCOUNTS OF INDIA 2001–2002 (2005) (For the details of health financing in India). The World Health Organisation's *World Medicine Situation Report* based 1999 data state that out of (the then) 998 million people in India, only 17% has the access to medicine. For an overview, see K. M. Gopakumar, *Product Patents and Access to Medicines in India: Critical Review of Implementation of TRIPS Patent Regime*, 3 L. & DEV. REV. 325 (2010).

pharmaceuticals, and (d) strict enforcement laws in place. Upon carefully viewing the *de facto* patterns of patent rights intensity there, there is little doubt that Canada possesses very high strength in IPR regimes. India on the other hand, has only recently amended its weak patent laws to make itself TRIPS-compliant and create a framework for product patents. Even after the *de jure* change, the situation in India remains bleak as far as strength of IP rights are concerned. *De facto* piracy and IP infringement is very high in India, and even after amending the patent laws India has a long way to go before it can remotely be called as a country driven by strong IP rights.

We showed that strong property regimes favour voluntary licensing, while weak regimes attract compulsory licensing. This is because negotiations fail in case of weak property rights, and so government has to intervene and create a liability rule, in the form of compulsory licensing. In strong property rights regimes, voluntary licensing can work *and* compulsory licensing is suitable for weak property rights regime only. This means, Canada is suited for a strong property rights framework and India for a liability approach. In other words, compulsory licensing creates a reverse spiral and pulls strong property rights towards transformation into weak property rights structure. Strong IP laws are viewed to make information readily available, crystallizing boundaries and ensuring certainty of rules and institutions. In such a situation, players are free to transact with each other, negotiate, renegotiate, and buy/sell licenses. This system is supposed to work through a property rights framework. Just when a liability rule approach is impregnated into the system, it develops cracks to weaken the existing property rights structure and strong IP framework.

#### *A. Compulsory Licensing and its Impact on Strength of IP Regime*

Compulsory licensing is an old idea, first adopted by the 1883 Paris Convention, and fossilized into the pharmaceutical debate with respect to access to medicines.<sup>109</sup> For a variety of reasons, it has been noted as a ‘destructive’<sup>110</sup> approach. This is largely due to its potential to erode exclusivity of right and therefore disrupt an expected future profit from a patented medicine,<sup>111</sup> which demands heavy investment in the first place.<sup>112</sup> It

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109. See Chien, *supra* note 26.

110. We borrow this phrase from Jamie Feldman, *Compulsory Licenses: The Dangers Behind the Current Practice*, 8 J. INT’L BUS. & L. 137, 139 (2009).

111. Janna Greve, *Healthcare in Developing Countries and the Role of Business: A Global Governance Framework to Enhance the Accountability of Pharmaceutical Companies*, 8 CORP. GOVERNANCE: INT’L J. OF BUS. IN SOC’Y 490 (2008).

112. According to one estimate made three years ago, on an average, pharmaceutical industries spend upto \$288 billion on R&D. See, e.g., Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLOS MED. 29, 30 (2008), [http://medicine.plosjournals.org/archive/1549-1676/5/1/pdf/10.1371\\_journal.pmed.](http://medicine.plosjournals.org/archive/1549-1676/5/1/pdf/10.1371_journal.pmed.)

is important to understand that most pharmaceutical research does not conclude in a patented medicine but instead renders many unsuccessful results. Hence these companies must secure earnings that cover both R&D costs as well as cost of such futile research.<sup>113</sup> Any decrease in such *risky* research will hurt medical innovation. Compulsory licensing dilutes these incentives, and therefore can be counterproductive.<sup>114</sup> Compulsory licensing acts as expropriation of IP and therefore sends a chilling effect to attractiveness of undertaking risky research on diseases that affect the developing world.

Yet, empirically, the correlation between investments in R&D and patent protection is not very convincing. Few studies have shown that perhaps the only industry, in which there exists a positive correlation between patent protection and investments in R&D, is that of pharmaceutical industry.<sup>115</sup> Fisch has tried to establish that compulsory licensing reduces investments into research<sup>116</sup> by comparing innovation activities in Canada and the United States in a period when the former was going through intense programme of compulsory licensing, and when Canada had much lower investment on research during this period. Yet, as Eastman Commission reveals, if compared to other small, developed countries, compulsory licensing did not significantly erode the innovation in Canada.<sup>117</sup> This was largely because Canada's market was rather insignificant to the worldwide market for pharmaceuticals.<sup>118</sup> In a classic study of 700 companies (various industries, including pharmaceutical), forty-two of which were subject to compulsory licensing, Scherer notes that these forty-two companies actually spent more on R&D.<sup>119</sup> A very interesting study by Moser and Voena uses an exogenous event of compulsory licensing after World War I, under the 'Trading With the Enemy Act' to examine the

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113. Greve, *supra* note 111.

114. One of the good arguments that disfavour overuse of compulsory licenses is Kevin Outterson, *Fair Followers: Expanding Access to Generic Pharmaceuticals for Low-income Populations*, 7 (2008), <http://www.cptech.org/ip/health/prizefund/files/outtersonaaccess-to-generics.pdf>.

115. See JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK* (2008).

116. Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unreasonable Problem*, 34 JURIMETRICS J. 295, 313 (1994).

117. Donald G. McFetridge, *Intellectual Property, Technology Diffusion, and Growth in the Canadian Economy*, in COMPETITION POLICY AND INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE BASED ECONOMY 65 (Robert D. Anderson & Nancy T. Gallini eds., 1998).

118. *Id.* McFetridge reports that with the exception of Merck, 1994 Canadian R&D expenditures as a percentage of worldwide expenditures were less than 2%; e.g. 1.3% for Glaxo, 1.0% for Hoffman LaRoche, 0.7% for Pfizer, 1.2% for Sandoz, 1.4% for Ciba, 1.7% for Eli Lilly, and 6.1% for Merck. *Id.* at 84, n.24.

119. FREDERIC M. SCHERER, *THE ECONOMIC EFFECTS OF COMPULSORY PATENT LICENSING* 67–75 (New York University Monograph Series in Finance and Economics, 1977).

effect of compulsory licensing on domestic innovation.<sup>120</sup> Analyzing around 130,000 chemical inventions, Moser and Voena conclude compulsory licensing increased innovation by about 20%.<sup>121</sup> There is, therefore, hardly any conclusive correlation that compulsory licensing hurts incentives to innovation.

However, the fact that pharmaceutical companies will have weakened incentives to invest in drugs for those diseases that are prevalent in countries having strong compulsory licensing, cannot be ignored. Indeed, firms often invest in life-style drugs rather than life saving drugs like for malaria, since the latter breaks into countries that have little affordability, and therefore higher instances of compulsory licensing.<sup>122</sup> The impression of the strength of the IP regime in a country could therefore be measured by how frequent and readily available compulsory licenses are in that country. The costs of compulsory licensing will be high in countries that have weak IPR, because these very countries will also have weak IPR regimes. In a way, this gives rise to a vicious cycle.

India presents a case of weak IP rights. In India, there was no product patent for a long time since 1970. This developed Indian pharmaceutical company into an imitating giant—thereby obviating any need of licensing structure. However, since the mid-1990s, when India decided to be a part of TRIPS, the strategy started shifting. One of the most notable features was increasing thrust in R&D.<sup>123</sup> India had no inclination to join TRIPS and had vociferously argued against joining the treaty,<sup>124</sup> but given that negotiations were being done from the WTO, she finally acceded. However, India was given until 2005 to comply with TRIPS. This transition period had immense impact on the mindset of the pharmaceutical industry and that of policy makers in India.<sup>125</sup> TRIPS propelled the Indian pharmaceutical industry to identify existing markets outside India and started looking to export, thereby intensifying their R&D efforts. It has become one of the largest suppliers of pharmaceutical formulations in the world by volume<sup>126</sup> and leading Indian pharmaceutical firms earn more of their

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120. Petra Moser & Alessandra Voena, *Compulsory Licensing: Evidence from the Trading with the Enemy Act*, 102 AM. ECON. REV. 396 (2012).

121. *Id.* at 396.

122. Joseph Stiglitz, *Trade Agreements and Health in Developing Countries*, 373 LANCET 363, 364 (2009).

123. Mainak Mazumdar & Meenakshi Rajeev, *Comparing Efficiency of Indian Pharmaceutical Firms*, 57 INDIAN ECON. J. 60, 61 (2010).

124. Foster, *supra* note 106.

125. For example, India took other steps towards complying with TRIPS requirements in 2002, when it extended a twenty-year term to all patents, reversed the burden of proof in process infringement cases, and introduced for the first time a definition of “inventive step.” The Patents Act, 1970, No. 39, §§ 2(ja), 53, 104(a) Acts of Parliament, 2013.

126. See, e.g., Shubham Chaudhuri, Pinelopi K. Goldberg, & Panle Jia, *Estimating the Effects*



revenue through exports than through domestic market.<sup>127</sup> Empowered, currently domestic companies control 80% of the domestic market when in 1970 the share of Indian companies was only 20%.<sup>128</sup> The exports of drugs and pharmaceuticals by the Indian pharmaceutical industry are around 5.3 billion dollars.<sup>129</sup> Indian players regard globalization and IP as one of the strongest driving forces for this change.

But even then, many of the biggest generic pharmaceutical product firms opened in India and they exported drugs to countries that have no patent protection, or those for which patents have expired. Today, India's pharmaceutical industry is not hinged on R&D, unlike many developed countries. Although high barriers to entry in developed world market discouraged Indian pharmaceutical players to enter in that market, from the mid-1990s, Indian companies started making some serious efforts and slowly gained expertise in producing generic drugs in compliance with highly regulated pharmaceutical industry abroad. Yet, the industry remained under the umbrella of weak patent rights.<sup>130</sup> This only builds a case for compulsory licensing to be implemented in India.

#### *B. Procedural Problems with Compulsory Licensing in Canada and India*

Canada's Access to Medicines Regime (CAMR) was the first domestic statute to implement WTO's 30 August decision in the world.<sup>131</sup> CAMR provides a system for pharmaceutical manufacturers to export generic drugs to least developed countries (LDCs) and developing nations through compulsory licensing. However, shortcomings of compulsory licensing are visible once we dissect the chronology of first (and only) case of compulsory licensing—export of Apo TriAvir, an antiviral cocktail medication used for treatment of HIV/AIDS, by Apotex (a Canadian generic pharmaceutical manufacturer) to Rwanda.

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*of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India*, 96 AM. ECON. REV. 1477, 1479 (2006).

127. For example, more than 80 percent of the sales of the leading firm Ranbaxy occur outside of India. Ranbaxy Labs. Ltd., *Key Markets Review*, ANN. REP., 2007, at 12–14 <http://www.ranbaxy.com/wp-content/uploads/2012/ar2007.pdf>.

128. See Gopakumar, *supra* note 108, at 329; see also Reji K. Joseph, *India's Trade in Drugs and Pharmaceuticals: Emerging Trends, Opportunities and Challenges*, RIS, Discussion Paper No.159 (2009).

129. See Joseph, *supra* note 128.

130. Aaron Smith, *India's Elephant in the Room: Weak Patent Laws*, CNN MONEY (May 4, 2007), [http://money.cnn.com/2007/05/04/news/companies/india\\_biotech/](http://money.cnn.com/2007/05/04/news/companies/india_biotech/); see also Economic and Political Weekly, *A Confusing Patent Law for India*, 40 ECON. & POL. WKLY. 1576, 1576 (2005).

131. See Richard Elliot, *Pledges and Pitfalls: Canada's Access to Compulsory Licensing of Pharmaceutical for Export*, 1 INT'L J. INTELL. PROP. MGMT. 94 (2006).

The same year when Canada amended its patent laws to incorporate WTO's August 30 decision to give birth to CAMR, Apotex committed to and began developing *fixed dose* combination of the HIV/AIDS antiviral drugs<sup>132</sup>, which were still under patent protection.<sup>133</sup> The cost differential was substantial.<sup>134</sup> Apotex then had to amend the CAMR to include "combination" drugs in its scope. This approval came from all sources in August 2006. Then started the process of voluntary negotiations with patent holders (this is an essential criteria whereby all possibilities of voluntary negotiations have to be exhausted before applying for compulsory licensing) to buy the license. Until September 2007, these negotiations had not been concluded.<sup>135</sup> Meanwhile in July 2007, the Rwandan government had notified WTO of its plan to import the drug from Canada. This notification from Canada went to WTO in October 2007. Apotex won the tender in Rwanda by May 2008, and the first package was shipped to Rwanda in September 2008. It took more than one year for the shipment to reach the actual beneficiaries. Overall, it took five years for one compulsory license structure to be effectively invoked and employed using the 30 August 2003 WTO Decision—no wonder there have been none ever since.<sup>136</sup>

In India, TRIPS/Doha style compulsory licenses have been incorporated in the amended Patents Act of 2005.<sup>137</sup> Under Section 84, any person can make an application for a grant of compulsory license for a patent after three years from date of grant of the patent.<sup>138</sup> Section 92A enables export of pharmaceutical products to any country having insufficient or no manufacturing capacity in pharmaceutical sector. Note that Canada does not have a counterpart provision of Section 84, but only 92A.

132. Holger Hestermeyer, *Canadian-made Drugs for Rwanda: The First Application of WTO Waiver on Patents and Medicines*, 11 ASIL INSIGHT (Dec. 10, 2007), <http://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and>.

133. The patents were held by Glaxo-SmithKline, and Shire and Boehringer Ingelheim. *See id.*

134. Apo TrivAvir costed forty cents per pill, while patented medicine was priced at twenty dollars. *See* Christina Cotter, *The Implications of Rwanda's Paragraph 6 Agreement with Canada for Other Developing Countries*, 5 CHINA INT'L L. REV. 177, 185 (2008).

135. As we will see later, negotiations involving voluntary negotiations cannot remain unprejudiced if scope for compulsory licensing remains. *See id.*

136. *See* George Tsai, *Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes under the WTO Doha Declaration*, 49 VA. J. INT'L L. 1063, 1079 (2009) (for a brief chronology of events).

137. The Patents Act, 1970, No. 39, Acts of Parliament, 2013 (dedicated Chapter XVI to the "Working of Patents, Compulsory Licenses and Revocation" and clarifies the ambit of compulsory licensing).

138. *Id.* at §84 (The grounds that may be vouched to apply for the same include: "(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India.").

India's first ever—and only one as yet—compulsory license application was made by Natco Pharma to allow it to manufacture Roche's patented drug Erlonitib (its trade name is Tarceva) for export to Nepal.<sup>139</sup> This case was then digressed to another relevant though procedural matter, when Natco Pharma filed an interlocutory petition asserting that patentees be disallowed to participate in compulsory license hearings that takes place between the Patent Office and Natco.<sup>140</sup> The petition was dismissed. However, in March 2012, the Controller of Patents granted the first ever compulsory license in India to Natco.<sup>141</sup>

Even the process of granting the first ever compulsory license was not free of its own complexity.<sup>142</sup> This labyrinth of meandering structure of compulsory license has shown that it is not an easy medicine to administer.<sup>143</sup> Yet, the costs of the procedure are worth the efforts in countries where IP regime is weak. It is in these countries that inter-firm bargaining may not help nations achieve access to medicines, if left unto themselves. Government needs to step in, invest in procedural costs and administrative delays, and ensure that people have access to life saving drugs.

### *C. Voluntary Licensing Works Alone but Cannot Co-Exist with Compulsory Licensing*

Voluntary licensing works in low market transaction cost, which in turn creates fertile breeding ground for strong IP laws and their sustenance. Indeed, voluntary licensing has been working in most parts of the world where IP laws

139. Following this, another application was also filed by Natco to obtain a license for Pfizer's Sutent, also an anti-cancer drug. See Peter Ollier, *India Holds Drugs Hearings*, 182 MANAGING INTELL. PROP. 62 (2008).

140. The issue in interlocutory petition was of *audi alteram partem* (hear the other side). This was purely a procedural issue from standpoint of this paper, hence we are not discussing it at all. For those interested, see Kumar, *supra* note 55.

141. Natco Pharma Limited v. Bayer Corporation, Compulsory Licence Application No 1/2011. See J. J. Nedumpara & P. Misra, *NATCO v. BAYER: Indian Patent Authority Grants Its First Ever Compulsory License on Pharmaceutical Products*, 7 GLOBAL TRADE & CUSTOMS J. 326 (2012); Shamnad Basheer, *India's first compulsory license: Patents v. public health*, IP OSGOOD (2012), available at <http://www.iposgoode.ca/2012/04/india%E2%80%99s-first-compulsory-license-patents-vs-public-health/>.

142. For details into the entire application process and case, see <http://spicyip.com/2012/03/breaking-news-indias-first-compulsory.html> and <http://spicyip.com/2011/09/anatomy-of-natcos-compulsory-license.html> and relevant hyperlinks therein.

143. By way of information, recently in January this year, Natco Pharma has sought a voluntary license from Pfizer to manufacture and sell the latter's drug *Maraviroc* (sold as *Celsentri*) for HIV positive patients. This drug is expensive and Natco's claim is to manufacture the same drug at very cheap prices. It is expected that Pfizer is going to deny the license (it has six months to reply), owing to high cost in R&D that went behind the drug. Consequently, we may expect a legal battle again. See Khomba Singh, *Natco Seeks Pfizer Nod for Drug Clone*, ECON. TIMES, Jan. 5, 2011.

are strong. Oseltamivir, a drug marketed under the brand name Tamiflu, was developed to fight influenza and has been instrumental in treating millions of patients of bird flu, swine flu, and the like.<sup>144</sup> This drug is sold by Roche, but it was developed by Gilead Sciences (which still holds the patent) and licensed to Roche. In fact, Gilead has twelve drugs patented under its name, and eight of them have been licensed to other players at a fee decided mutually between the two parties.<sup>145</sup> Roche sub-licensed the Tamiflu drug to Hetero Drugs in India to speed up availability.<sup>146</sup> Last year, Santarus bought the license to make a diabetes drug marketed under the name of Cycloset tablet, from S2 Therapeutics and VeroScience, at five million dollars.<sup>147</sup> Structure for such voluntary licensing is very straightforward and works like any other license negotiation process, entirely voluntary. In fact, it is fairly common to observe laboratories discovering the drug, and then licensing it to other manufacturers who can better market them. Imagine a singer, who sings and licenses the songs to record company. If property rights are strong, and (consequently) transaction costs are low, such bargains can emerge. We must recognize that for companies there is no difference between drugs and audio CDs, no matter how much of difference it is for the consumers. And any activity to tame inherent incentive game will only hurt the consumers more. This is a strong statement, but the sooner we realize its poignant truth, the better we can structure the system.

Our contention is that when compulsory licensing exists in the market, it erodes all possibilities of a voluntary licensing between manufacturer and generic manufacturer to exist. If the licensee knows that after certain a period of time, she will get a compulsory license, at a fixed known rate of royalty, she will never accept a license higher than that rate. On the other side of the table, the licensor will never reach any figure lower than that fixed rate. Hence, the bargain will never reach, and if it reaches, it will always arrive at the rate fixed by government for license fee. India and Canada are good examples. Royalty of both countries is fixed (Canada used a more sophisticated method to calculate it, and India uses crude averages). Hence, both in Apotex (Canada) and Natco's cases (India), the parties could never have voluntarily contracted in the first place.<sup>148</sup>

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144. See *Weekly Virological Update on 05 August 2010*, WHO (2010), [http://www.who.int/csr/disease/swineflu/laboratory06\\_08\\_2010/en](http://www.who.int/csr/disease/swineflu/laboratory06_08_2010/en).

145. Gilead, ANN. REP., 20 (2009), [http://www.allejaarverslagen.nl/reports/508\\_2009.pdf](http://www.allejaarverslagen.nl/reports/508_2009.pdf).

146. *Roche Grants Tamiflu Sub-license to India's Hetero Drugs to Make Flu Medicines for India and Developing Countries*, MED. NEWS TODAY (Dec. 23, 2005, 5:00 PM PST) available at <http://www.medicalnewstoday.com/articles/35342.php>.

147. *Update 1-Santarus Buys License to Make Diabetes Drug for \$5 mln*, REUTERS, Sep. 8, 2010, available at <http://www.reuters.com/article/idUSSGE6870KN20100908>.

148. Canada and India are not alone. Efavirenz (commercially sold as Storcrin) was the highest used antiretroviral drug in Brazil. Brazil wanted to pursue a compulsory licensing approach to the

It would be a highly optimistic picture if we propose that voluntary licensing will always succeed in the absence of compulsory licensing. This is because research in patent activities of a drug can be highly uncertain and it is hard to predict inventions and value them *ex ante*.<sup>149</sup> Such uncertainty in the discovery process (of both the drug and its value) is bound to create divergence in both parties' expectations and may stall the negotiation process.<sup>150</sup> Such uncertainty also gives rise to strategic behavior during the contracting process.<sup>151</sup> Therefore, voluntary licensing is not expected to always work. However, there is no reason to believe (infact more so on the contrary) that compulsory licensing is better suited.

In addition, it is imperative to note that (a) courts may not effectively identify hold-up situations, justifying liability rules, (b) even if courts can identify the true scenarios, they are ill-suited to develop a liability rule framework.<sup>152</sup> The would-be purchasers of property right would invariably prefer liability rules and use them as an opportunity for government rent-seeking. Parties see courts as administrative agencies overseeing liability rules as providing 'cheap option' which means a better deal than they could obtain in a marketplace arrangement. As noted long ago, by F.M. Sherer, "All in all, the substantial amount of evidence now available suggests that compulsory patent licensing, judiciously confined to cases in which patent-based monopoly power has been abused . . . would have little or no adverse impact on the rate of technological progress."<sup>153</sup>

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drug. But this had prejudiced the negotiations on the side of Brazil. The voluntary negotiations brought Merck (the manufacturer) to propose that it will ensure the technology transfer to pharmaceutical manufacturer Farmanguinhos, in time. In addition, there will be two percent certain price reduction and Farmanguinhos can purchase the drug supply and perform packaging and labeling activities. But this negotiation did not reach any end, owing to the final recourse of CL available in the hands of Brazilian government. And that's exactly what happened. See Beatrice Sterner, *Compulsory Licensing of Efavirenz in Brazil*, ACCESS TO PHARMACEUTICALS (Feb. 23, 2010) available at <http://www.accesstopharmaceuticals.org/case-studies-in-global-health/efavirenz-brazil/>.

149. See Mark A. Lamey, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989; David J. Teece, *Profiting from Technological Innovation: Implication for Integration, Collaboration, Licensing and Public Policy*, 15 RES. POL'Y 285 (1986).

150. See Robert Cooter, *The Cost of Coase*, 11 J. LEGAL STUD. 1 (1982) (on dynamics of bargain breakdown).

151. Ben Depoorter, *Property Rules, Liability Rules and Patent Market Failure*, 1 ERASMUS L. REV. 59, 72 (2008).

152. See Richard A. Epstein, *A Clear View of the Cathedral: The Dominance of Property Rules*, 106 YALE L.J. 2091 (1997).

153. FREDERIC M. SHERER, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 456-57 (2d ed., 1980).

## VI. BY WAY OF AN EPILOGUE

Research on patents and intellectual property through the framework of property-liability has achieved only some attention from IP scholars, in varying dimensions.<sup>154</sup> What we have tried to accomplish in this paper is to locate the strength of IP regimes in the property-liability framework as proposed to classic law and economics literature. We derived from Cathedral Paper that societies must structure themselves on property rules when transaction costs are low and liability rule when transaction costs are high. Voluntary licensing is an element of property rule while compulsory licensing falls under the liability rule approach. Hence, low transaction cost dictate voluntary licensing and high transaction costs attract compulsory licensing. Empirical results show that indeed strong IPR regimes favour voluntary licensing and weak regimes attract compulsory licensing. This, when compared with previous results shows that property rules are the best mode of reliance when we have strong IPR regimes like Canada, and liability rules suit weak regimes like India.

This paper in no way makes an argument towards completeness of the model, in explaining factors on which characteristics of compulsory licensing depends. Indeed, a host of other factors determine a grant of compulsory license, including royalty fee, duration, scope, legal framework, international obligation, expected hit in FDI, relative bargaining position of the countries, market potential, public funds towards innovation, and the like. This paper attempts to create a discourse on one of the fundamental grounds of compulsory licensing, which is, the strength of IPR regimes.

In addition, like any analytical framework, our methodology does come with its inherent limitations. The model crucially rests on property-liability framework elucidated in Cathedral Paper. That model, in turn pivots on transaction cost economics. A lot of work has been done since then in categorization, structural layering, and re-inventing the concepts of transaction costs. The contextual application of transaction cost economics is therefore very important. While our model does highlight the impact of such an analysis on compulsory IP regimes of the countries, it would also largely depend on the value of the transaction costs. These values are difficult to collate, and hence most studies do not go deep into classifications of transaction costs, it does merit the question of what happens if the transaction costs vary greatly in a country from across regulations affecting the same industry. In addition,

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154. A more general paper on such a framework is by Robert P. Merges, *Of Property Rules, Coase and Intellectual Property*, 94 COLUM. L. REV. 2655 (1994); see also Jerome H. Reichman & Tracy Lewis, *Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 337 (Keith E. Maskus & Jerome H. Reichman eds., 2005).

although extremely comprehensive, existence of only two categories—low and high transaction costs—obscures subtle nuances in mid-level transaction costs. Our model would suggest that for those transaction costs, only procedural concerns in compulsory licensing will matter, but this cannot be conclusively ascertained.

In addition, our approach seems to ignore intra-country differential structures of the pharmaceutical industry. Firstly, note that compulsory licensing does not make any sense in a country, which has no manufacturing ability. Secondly, even with those countries that have sufficient manufacturing capacity to warrant the use of liability approach, there may exist multiple industry structures and heterogeneous manufacturing patterns in form of big corporations and small and mid-sized enterprises and each one of these different patterns demand different institutional processes for their efficiency. However, we feel, the impact of such differential industry structure may not alter the conclusions significantly.

In a society with strong IP rights, our critical approach to compulsory licensing would seem to have developed an oversight to public interest concerns. This view is by no means myopic, since our purpose has not been to deliberately ignore this important issue. Let us address this possible concern at two levels. Firstly, our stand is clear as far as medical emergency, epidemic or drugs/diseases posing severe public health concerns and is sought to be dealt with immediately—and that is to invoke compulsory license right away. Such scenarios are untouched and safely insulated from the implications arising out of our study. The research question that has been posed in the paper is attempting to look at the institution of compulsory licensing in matters that are business-as-usual. In other words, a general adoption of compulsory licensing is discouraged, but not exceptional. Secondly, if the general discouragement of compulsory licensing appears to come at the cost of public interest, then such direct causal relationship needs to be rectified. The apportioned contribution of present structure of compulsory licensing to achieve public interest goals is highly overstated, something glaringly apparent in the two cases in Canada and India. Compulsory licensing has been too much of a victim of procedures and poor implementation. Hence, agency does not bear the entire blame or merit. And these procedures are not easily rectifiable because they stem from the nature of institution itself and its framework. Hence, compulsory licensing is itself incapable of achieving public interest goals in the first place, at least not to the levels expected. So we may need to find alternative solutions. Public interest is important but amorphous policies that have no theoretical grounding will do more harm than good.

We intend to propose two policy solutions that have increased merit as compared to compulsory licensing for countries characterized by strong IP

regimes. Elaborating these proposals is beyond the scope of the paper, but given their success in separate institutional frameworks begs us to briefly examine other alternatives. These two policy outlines are therefore merely suggestive and require extensive study to test their efficacy. None of these proposals can rectify informational problems vested in letting a third party decide upon the license fee/price. However, they do not tamper with IP regimes and let their structure stay strong.

- a) One possible solution is competition law. Compulsory licensing may not be justified because competition law can possibly benefit at a relatively lesser cost compared to compulsory licensing that imposes a huge cost on legal institutions. Using competition law, similar to the model of Essential Facilities Doctrine (as is adopted in EU) can help us do away with the perils of compulsory licensing, yet achieve similar (intended) results. It is the abuse of dominant position that patent accords to a company/product which must be attacked.<sup>155</sup> This idea is to view high prices as abuse of dominant position, and let courts decide on appropriate prices, or let licenses be given on that account. It is important to appreciate that even if licenses come from competition law, they denote a structural and functional divergence from compulsory licensing. Incentives to innovate may not be diluted in the former case, because it has to be proved in the court of law/competition commission that an abuse had indeed happened. With India constituting competition law in 2005, and Canada's Competition Act surfacing through Competition Commission and Competition Bureau respectively, it should be preferred in conjunction with strong IPR regimes.
- b) The second possible alternative—a more specific and effective strategy for India—would be to do what Canada has done. The uniqueness lies in the federal government's direct price control regulation. This is done by an independent, quasi-judicial board, called Patented Medicine Price Review Board (PMPRB).<sup>156</sup> Whenever the Board feels that the price of a drug is excessive, it intervenes and sets the optimum price. This is decided based on several criteria. Particular attention is given to the median price for this drug in seven comparable countries: France, Germany, Italy, Sweden, Switzerland, the UK, and the US. If the drug contains a

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155. For an impressive illustration, see John Temple Lang, *The Application of the Essential Facility Doctrine to Intellectual Property Rights under European Competition Law*, in ANTITRUST, PATENTS AND COPYRIGHT 56 (François Lévêque & Howard Shelanski eds., 2005).

156. Valérie Paris & Elizabeth Docteur, *Pharmaceutical Pricing and Reimbursement Policies in Canada*, OECD HEALTH WORKING PAPERS 12-3 (2006) <http://www.oecd.org/dataoecd/21/40/37868186.pdf>.



small improvement to already existing drugs, the board will first compare its price with one of the drugs in the same therapeutic class. This price comparison system is, in fact, very similar to those used in other countries, such as in France, Spain, or Greece, when determining what brand-name drug (patented or not, in this case) can be listed on drug formularies.<sup>157</sup> Another interesting thing is that according to the *Patent Act* (sections 79ss), patented drug prices cannot, in any case, exceed changes in the *Consumer Price Index*. This has had a great effect on prices of the drugs. We discussed above, that post 1987, towards a restricted compulsory license regime, R&D investments have increased in Canada. It must be mentioned that in the same time, patented drug prices reduced considerably and became, on an average, below the international median price.<sup>158</sup> A chilling effect of such price review board (although there is lack of enough empirical data), cannot be denied, yet there is hardly any reason to believe that compulsory licensing stifles access-to-medicine-policies any less.

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157. See Melanie Bourassa Forcier & Jean-Frédéric Morin, *Canadian Pharmaceutical Patent Policy: International Constrains and Domestic Priorities*, in AN EMERGING INTELLECTUAL PROPERTY PARADIGM: PERSPECTIVES FROM CANADA 81, 87–89 (Ysolde Gendreau ed., 2009).

158. See Paris & Docteur, *supra* note 156.