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## N O R T H W E S T E R N JOURNAL OF TECHNOLOGY AND INTELLECTUAL PROPERTY

### **Questioning the Justifiability of Innovation Protection in Antimicrobial Drugs: A Law and Economics Perspective**

Ankur Sood & Vardaan Ahluwalia



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## Questioning the Justifiability of Innovation Protection in Antimicrobial Drugs: A Law and Economics Perspective

### By Ankur Sood\* & Vardaan Ahluwalia\*\*

### INTRODUCTION

History has proven that the property rights<sup>1</sup> regime has a significant part to play in shaping the destiny of a nation.<sup>2</sup> Scholars and jurists have suggested that property rights are essential for freedom to be enjoyed in its truest sense.<sup>3</sup> Perhaps, therefore, laws protecting property rights have been hailed as "the noblest triumph of humanity over itself."<sup>4</sup> Institutions protecting property rights are a consequence of the technological advancement and evolution of society.<sup>5</sup> It comes as no surprise, therefore, that they have

<sup>1</sup> See, e.g., ARMEN A. ALCHIAN, ECONOMIC FORCES AT WORK 130 (1977) ("A property right for me means some protection against other people's choosing against my will one of the uses of resources, said to be 'mine."").

<sup>2</sup> See, e.g., Gerald P. O'Driscoll Jr. & Lee Hoskins, *Property Rights: The Key to Economic Development*, 482 LAW & ECON DEV. 1, 2 (2006) (discussing why there was such disparity in the economic condition of various countries despite having similar cultures, resources, and history); Allan H. Meltzer, The Irving Kristol Lecture of the American Enterprise Institute: Leadership and Progress (Feb. 26, 2003) (transcript available at http://www2.tepper.cmu.edu/afs/andrew/gsia/meltzer/US\_leader\_progress.doc) ("In each of these comparisons, culture, language, and traditions are the same. Outcomes are markedly different. The countries with capitalist institutions and market system grew richer; the others faltered or went backwards.").

<sup>3</sup> See Timothy B. Lewis, Constitutional Freedom Foundation, Property Rights (June 6, 2004), http://www.constitutionalfreedomfoundation.org/Articles/constitutional\_primer\_7.htm ("The first and chief design of every system of government is to maintain justice: to prevent the members of society from encroaching on one another's property, or seizing what is not their own. The design here is to give each one the secure and peaceable possession of his own property."); FRIEDRICH A. HAYEK, THE ROAD TO SERFDOM 103-04 (1944) ("The system of private property is the most important guaranty of freedom, not only for those who do not. It is only because the control of production is divided among many people acting independently that nobody has complete power over us, that we as individuals can decide what to do with ourselves. If all the means of production were vested in a single hand, whether it be nominally that of 'society' as a whole or that of a dictator, whoever exercises this control has complete power over us.").

<sup>4</sup> O'Driscoll & Hoskins, *supra* note 2, at 19 ("Jeremy Bentham who disagreed with Blackstone on various accounts, agreed with the jurist on property, saying that the law securing property is 'the noblest triumph of humanity over itself." (citing TOM BETHELL, THE NOBLEST TRIUMPH: PROPERTY AND PROSPERITY THROUGH THE AGES 19, 100 (1998))); *see also* WILLIAM BLACKSTONE, EHRLICH'S BLACKSTONE 113 (J. W. Ehrlich ed., 1959).

<sup>5</sup> Boudewijn Bouckaert, *Original Assignment of Private Property*, in 2 ENCYCLOPEDIA OF LAW AND ECONOMICS 2 (Boudewijn Bouckaert & Gerrit de Geest eds., 2000) (suggesting that property rights are a consequence of the evolutionary process involving a transition from an institutionless and ruleless open

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been around for centuries in one form or another.<sup>6</sup> Economic theory indicates that early property rights existed in the form of "common property" and it was later that private property rights emerged.<sup>7</sup> The majority of economists consider private property rights as an essential "ingredient in economic development."<sup>8</sup> They argue that a clearly defined private property right reduces the incentive to free ride and ensures that the costs<sup>9</sup> and benefits arising from the exercise of that right accrue solely to the owner.<sup>10</sup> Moreover, economists with reasonable success have established that the degree of investment in a particular asset is strongly related to the degree of protection of that asset.<sup>11</sup> Economists have likewise established that the resources available for investment and their allocation eventually determine the wealth generated by an individual or an enterprise.<sup>12</sup> A

http://socserv2.socsci.mcmaster.ca/~econ/ugcm/3ll3/maine/anclaw/chap06 (relying on both his research in India and the work of European scholars on primitive societal setups as well as the conceptual origins of property to suggest that it originated from joint, not separate, ownership); RICHARD STROUP, *Free-Market Environmentalism*, in THE CONCISE ENCYCLOPEDIA OF ECONOMICS, *available at* 

http://www.econlib.org/library/Enc/EnvironmentalismFreeMarket.html; Terry Anderson and Peter J. Hill, *The Race for Property Rights*, 33 J.L & ECON. 177, 177-98 (1990) (highlighting the fact that the plains in America lost their status as commons and eventually were privatized); STEVEN SHAVELL, *Economic Analysis of Property Law*, CH. 7, at 11 Harvard Law School, Discussion Paper No. 399 (2002), *available at* http://www.law.harvard.edu/programs/olin\_center/papers/pdf/399.pdf.

<sup>6</sup> See RICHARD PIPES, PROPERTY AND FREEDOM 65 (1999) (discussing the manner in which institutions protecting property rights evolved from ancient times to the emergence of the state); See generally Martin. J. Bailey, Property Rights in Aboriginal Societies, in THE NEW PALGRAVE DICTIONARY OF ECONOMICS AND THE LAW 155-57 (Peter Newman ed., 1998); Robert M. Netting, What Alpine Peasants Have in Common: Observations on Communal Tenure in a Swiss Village, 4(2) HUMAN ECOLOGY 135-146 (1976) (suggesting that the attribution of resources often determines the kind of property rights regime regulating their use and citing the example of communities in Switzerland where peasants followed separate ownership property rights model for agricultural land compared to a communal property model for alpine hillside grazing grounds); see also Elinor Ostrom, Private and Common Property Rights, in 2 ENCYCLOPEDIA OF LAW AND ECONOMICS 332, 346 (Boudewijn Bouckaert and Gerrit de Geest eds., 2000) (recognizing that similar systems have existed in Norway for centuries.).

<sup>7</sup> See MAINE, supra note 5, Ostrom, supra note 6; See generally Robert C. Ellickson, Property in Land, 102 YALE L.J. 1315 (1993) (highlighting that property rights often emerge out of a need for efficient resource allocation or to minimize risks).

<sup>8</sup> Ostrom, *supra* note 6, at 334.

<sup>9</sup> Harold Demstez, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347, 350 (1967) (asserting that in absence of a property rights regime all costs incurred by society in production of a good may not be internalized in the price of the good produced).

<sup>10</sup> See Ostrom, supra note 6, at 334.

<sup>11</sup> See Thomas J. Miceli, *Property, in* THE ELGAR COMPANION TO LAW AND ECONOMICS 121 (Enrico Colombatto ed., 2005) ("[T]he economic approach to property rights emphasizes its role in promoting efficient allocation of resources. Accomplishing this goal generally involves creation and protection of individual rights in property so as to encourage exchange and investment . . . ."); *see also* Simon Johnson et al., *Property Rights and Finance*, 92 AM. ECON. REV. 1335 (2002) (using some post-communist countries as examples that secure property rights are essential for investment); *see generally* Timothy Besley, *Property Rights and Investment Incentives: Theory and Evidence from Ghana*, 103 J. POL. ECON. 903 (1995) (relating property rights to investment incentives and discussing land ownership by farmers in Ghana).

<sup>12</sup> See Stijn Claessens & Luc Laeven, *Financial Development, Property Rights, and Growth 4-32* (World Bank Fin. Sector Strategy and Pol. Dep't, Pol'y Res. Working Paper No. 2924, 2002).

access situation towards an ordered and complex system involving administrative, policing and adjudicative institutions system of rights); *see also* O'Driscoll & Hoskins, *supra* note 2, at 445 ("It is a mistake to assume that the task of assigning, defining and protecting property rights is the exclusive job of the state. Property developed from traditions and customs long before we had nations."); *see generally* HENRY SUMMER MAINE, ANCIENT LAW; IN CONNECTION WITH THE EARLY HISTORY OF SOCIETY AND ITS RELATION TO MODERN IDEAS (1963), *available at* 

corollary of this suggests that in the absence of an efficient property rights regime, an individual or enterprise may be forced to invest in practices which are less productive than others.<sup>13</sup> In application of these principles, property rights can be understood as rules that determine how individuals or enterprises gain access to resources, the manner in which they utilize them, and the net benefit that can be expected out of them. Hence, it can be concluded that allocation of property rights leads to the creation of incentives, which encourages efficient resource exploitation.<sup>14</sup>

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Furthermore, another factor that influences resource allocation is the nature of goods.<sup>15</sup> Studies have indicated that in the absence of a property rights regime, firms tend to invest in tangible goods rather than intangible goods because it is easier for a firm to protect the former compared to the latter.<sup>16</sup> Hence, property rights matter more for protection of intangible goods as compared to tangible goods.<sup>17</sup> Drawing from above, it is evident that in the case of extremely weak<sup>18</sup> or a complete lack of protection of intellectual property (IP), firms would refrain from investing in research and development of IP, thereby, considerably reducing the rate of growth in IP.<sup>19</sup>

<sup>15</sup> Edwin Mansfield, *Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer* (Int'l Fin. Corp. & World Bank, Discussion Paper No. 19, 1994) (indicating a relationship between property rights and resource allocation in intangible and tangible assets) [hereinafter *Intellectual Property Protection*]; Edwin Mansfield, *Unauthorized Use of Intellectual Property: Effects on Investment, Technology Transfer, and Innovation, in* GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY 107, 145 (Mitchel B. Wallerstein et al. eds., 1993) (highlighting the effect of a weak IPR regime in Latin American countries).

<sup>16</sup> One of the reasons is that "intangible goods" can be copied and reproduced at a very low cost. Claessens & Laeven, *supra* note 12, at 4-6. *See also Intellectual Property Protection, supra* note 15.

<sup>17</sup> See Claessens & Laeven, *supra* note 12, at 6 (indicating that one of the factors resulting in low degree of investment in intangible goods may be a weak property rights regime.). See also Intellectual Property Protection, supra note 15.

<sup>18</sup> By a weak protection we imply that the legal regime provides a narrow scope and short duration of protection. For instance, a regime grants monopoly rights only for process patents or which grants product patent for an extremely short duration of time. For comments and analysis of strong and weak patent regimes in India, see for example, Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491 (2007); Carsten Fink, *How Stronger Patent Protection in India might affect the Behavior of Transnational Pharmaceutical Industries* (The World Bank Development Research Group, Working Paper No. 2352, 2000), *available at* 

http://wbln0018.worldbank.org/Research/workpapers.nsf/bd04ac9da150d30385256815005076ce/5d9b67dfa0777405852568e80065f3c4/\$FILE/wps2352.pdf.

<sup>19</sup> Model I: Y > 0, X > Y, B > A (since the duration of monopoly in the market would be longer). A is the profit accruing due to the monopoly enjoyed due to the time taken by competitors to copy the innovation. B is the profit due to protection which would vary with the scope and duration of the intellectual property regime.

Nature of Regime	Cost of Time and Labor	Expected Benefit	Output
No Protection	X	Y + A	If $Y + A > X$
Protection	X	Y + B	If $Y + B > X$

<sup>&</sup>lt;sup>13</sup> See SHAVELL, supra note 5, at 2-12.

<sup>&</sup>lt;sup>14</sup> See RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW, 36 (5th ed. 1998); see also Lee Hoskins & Ana I. Eiras, *Property Rights: The Key to Economic Growth, in* 2002 INDEX OF ECONOMIC FREEDOM 37-38 (Gerald P. O'Driscoll, Jr. et al. eds., 2002) ("More generally, the stronger the set of property rights, the stronger the incentive to work, save, and invest, and the more effective the operation of the economy. The more effectively an economy operates, the more growth it will produce for any set of resources.").

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The discussion above indicates that property rights are important for efficient resource allocation, and given the nature of intangible goods, property rights are even more important for spurring innovation. This would naturally lead to the debate regarding the optimal scope and duration of protection of IP. This paper, however, shall not delve into that issue.<sup>20</sup>

The aim of this paper is to argue against the uniform protection afforded to all kinds of innovations under the present patent system. This paper proposes that innovations can be divided into two groups. The first group consists of innovations which do not hinder the use of existing and future innovations and the second group consists of those innovations which may hinder the use of existing and future innovations. Thus, while protection of innovations in the first group may result in a *Pareto superior* move, the same cannot be said about innovations of the second group.

There may be various inventions that would fall in the second category; however, we shall focus on drugs, such as antibiotics, antivirals and other similar pharmaceuticals. We argue that the consumption of these drugs and the consequent development of resistance in pathogens due to cross-resistance impose a negative externality upon the society. Under the current IP regime, this externality is not internalized. Recognizing that cross-resistance is inevitable, we suggest that the detrimental effect of this externality can be offset by ensuring greater access to such drugs.

Part I of this paper, after analyzing relevant aspects of Locke's theory, goes on to argue that even though protection of most forms of IP is a *Pareto superior* move, protection of drugs, such as antibiotics, antivirals and other related pharmaceuticals, may not always be a *Pareto superior* move. Part II establishes that cross-resistance hinders the use of existing and future drugs. Further, this part discusses competitive market theory and argues that the cost of cross-resistance needs to be internalized. In Part III, we shall conclude by averring that a homogenous patent protection under the Agreement on Trade Related Aspects of Intellectual Property Rights is unreasonable (TRIPs). Finally, we shall suggest that appropriate changes should be made in the patent protection system in order to internalize the cost of cross-resistance.

I. INTERPRETING LOCKE'S THEORY AND UNDERSTANDING CROSS-RESISTANCE

According to Locke, people had natural rights that belonged to all humans from birth.<sup>21</sup> The right to property was one such right. Locke argued that if a person mixed his labor with a common resource then that person had a legitimate right to claim it as his

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It may be deduced from the above table that in the case of no protection, a rational individual, upon comparing the cost and benefit that accrue to him/her, would decide not to invest labor and intellect into the manifestation of an idea. As a consequence, a socially desirable creation or invention may not be created. However, in case of a regime protecting the creation, the probability of the invention being created increases, and hence, society may not be deprived of the invention.

<sup>&</sup>lt;sup>20</sup> See Ankur Sood & Vardaan Ahluwalia, *Property Rights and Investment Incentives in Intellectual Property: An Inter-disciplinary Approach*, 1 NAT'L U. OF JURID. SCIS. L. REV. 69, 74 (2008) (addressing the issue as to what is the right choice in the context of developing countries; a strong intellectual property regime as advocated by the adherents of TRIPS or a weak intellectual property regime such as a patent regime with a narrower scope and duration of protection.).

<sup>&</sup>lt;sup>21</sup> JOHN LOCKE, THE SECOND TREATISE OF GOVERNMENT, ¶ 27 ("For this labour being the unquestionable property of the labourer, no man but he can have a right to what that is once joined to, at least where there is enough and as good left in common for others.").

own. While Locke accepted this right, according to him, this right was subject to a precondition that there was "enough and as good left in common for others."<sup>22</sup> Scholars have interpreted Locke's second condition<sup>23</sup> to mean that acquisition of property is permissible where the same constitutes a *Pareto superior* move.<sup>24</sup> They argue that Locke justified his stand on the right to acquire property by emphasizing that a person's right over property, which previously belonged to nature, should be respected because it is his labor which gives him a claim far superior than the rest. They add that Locke argued that since the same source was available to every other person, such other has no right to object to its acquisition. Borrowing from the same, scholars have argued that the creator's title over IP is justified since every other person had access to the same knowledge base from which it was created.<sup>25</sup> They emphasize that ownership and consequent protection of IP by its creator is reasonable because "it makes the creator better off without depriving anyone else of anything to which he or she had prior access and use."26

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While accepting this idea, an exception is sought to be established in the case of antibiotics, antivirals, and other related pharmaceuticals.<sup>27</sup> The basic argument in this regard proceeds from Locke's twin criterion<sup>28</sup> for acquisition of property. The first

<sup>24</sup> A move from one distribution point to another is said to be *superior* when at least one party is better off and no one else is worse off. (This includes moves that benefit all parties; the essential concern is that no one is worse off after the move compared to welfare before the move.). See generally Microeconomic Lecture Notes, http://www.calbaptist.edu/dskubik/pareto.htm (last visited Feb. 21, 2008).

<sup>25</sup> See Adam Moore, Intellectual Property and Information Control: Philosophic FOUNDATIONS AND CONTEMPORARY ISSUES, 8 (Transaction Publishing/Rutgers University ed., 2001) (2004) ("First, intellectual works are non-rivalrous, meaning that they can be created, possessed, owned, and consumed by many individuals concurrently. Second, including allowances for independent creation, I argue that the frontier of intellectual property is practically infinite. Locke hints at this kind of practical infinity when he writes, 'Nobody could think himself injured by the drinking of another man, though he took a good draught, who had a whole river of the same water left him to quench his thirst .....' If I am correct, the case for Locke's water-drinker and the author or inventor are quite alike.").

<sup>26</sup> Kenneth Himma, The Justification of Intellectual Property: Contemporary Philosophical Disputes, BERKELEY CENTER FOR LAW & TECH., available at http://repositories.cdlib.org/bclt/lts/21. See also Adam Moore, Privacy, Intellectual Property, and Hacking, in INTERNET SECURITY: HACKING, COUNTERHACKING, AND SOCIETY 12 (Kenneth E. Himma ed., 2006) ("If no one is harmed by an acquisition and one person is bettered, then the acquisition ought to be permitted. In fact, it is precisely because no one is harmed that it seems unreasonable to object to what is known as a Pareto-superior move. Thus, the proviso can be understood as a version of a "no harm, no foul" principle").

<sup>27</sup> Apart from above, other instances can be pointed out where the society may be worse off due to granting of a patent. For instance, suppose that A is granted a patent on an extremely effective and useful drug. Also, let us suppose that A decides to withhold the drug from society. Now, due to an exclusive product patent, it can be said that potential consumers are worse-off because they have been denied the opportunity to gain access to the invention. Not because A withholds the patent but because the fact that the patent denies any other producer, who could have invented the same innovation, to make the product available to society. Some may argue that this illustration is also an example where intellectual property protection leaves society worse off. However, in this instance, we disagree because the invention does not affect the performance of any other invention in real terms. Further, such behavior has been addressed by the TRIPS regime through compulsory licensing and measures of a similar nature to reduce the incentive to act in such a manner. On the other hand, perhaps we should question whether granting a patent to some other person, who reinvents the drug, leaves society better off. Since the technology level in society would remain the same, a socially optimal solution would be to adequately reduce the incentive for A to act in a socially undesirable manner.

<sup>28</sup> LOCKE, *supra* note 21; MOORE, *supra* note 25, at 117.

<sup>&</sup>lt;sup>22</sup> See Id. <sup>23</sup> See Id.

condition pertaining to "labor" is easily satisfied by most forms of IP.<sup>29</sup> With regard to Locke's second condition, it has been argued that most forms of IP protection satisfy this condition because the use of newly created knowledge does not impede further use of already existing knowledge and future innovations and because the frontiers of creation of IP are infinite.<sup>30</sup>

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Taking cognizance of the ability of pathogens to develop resistance to drugs having similar attack mechanisms, we find that antibiotics, antivirals and other similar pharmaceuticals fail to satisfy Locke's second condition. For instance, if a pathogen is able to develop or acquire resistance to an antibiotic, then the pathogen becomes capable of resisting any drug that attacks the pathogen using a similar mechanism. This phenomenon is known as cross-resistance.<sup>31</sup> For this reason, we argue that, unlike other forms of IP,<sup>32</sup> protection of innovations in such pharmaceuticals cannot always be characterized as *Pareto superior* as it may impede further use of existing knowledge and future knowledge.<sup>33</sup> The process of development of resistance and cross-resistance is facilitated by the capability of pathogens to acquire resistance or cross-resistance through vertical<sup>34</sup> and/or horizontal evolution.<sup>35</sup> Medicinal history is replete with such examples. According to a recent finding:

<sup>30</sup> See MOORE, supra note 25, at 117. ("[I]ncluding allowances for independent creation, I argue that the frontier of intellectual property is practically infinite.").

<sup>31</sup> BUTTERWORTHS MEDICAL DICTIONARY 1462 (1999) ("Acquired resistance of a bacterial strain conferring simultaneous resistance to another anti-bacterial agent. It is an indication that two agents are related and have basically similar action.").

<sup>33</sup>Aidsmap – Cross-resistance, http://www.aidsmap.com/en/docs/D17AFE98-FAA4-4128-84C6-53D88A735A95.asp (last visited May 19, 2008).

<sup>34</sup> KENNETH TODAR, TODAR'S ONLINE BOOK OF BACTERIOLOGY (2006),

http://textbookofbacteriology.net/resantimicrobial.html (last visited May 19, 2008) ("Vertical evolution is strictly a matter of Darwinian evolution driven by principles of natural selection: a spontaneous mutation in the bacterial chromosome imparts resistance to a member of the bacterial population. In the selective environment of the antibiotic, the wild type (non mutant) is killed and the resistant mutant is allowed to grow and flourish. The mutation rate for most bacterial genes is approximately  $10^{-8}$ . This means that if a bacterial population doubles from  $10^{8}$  cells to  $2 \times 10^{8}$  cells, there is likely to be a mutant present for any given gene. Since bacteria generation during 15 minutes of growth.").

<sup>35</sup> *Id.* ("Horizontal evolution is the acquisition of genes for resistance from another organism. For example, a streptomycete has a gene for resistance to streptomycin (its own antibiotic), but somehow that gene escapes and gets into *E. coli* or *Shigella.* Or, more likely, some bacterium develops genetic resistance through the process of mutation and selection and then donates these genes to some other bacterium through one of several processes for genetic exchange that exist in bacteria."). *See, e.g.,* Ricki Lewis, *The* 

<sup>&</sup>lt;sup>29</sup> LOCKE, *supra* note 21, ¶ 27. Some may argue that intellectual property may not always be a result of "much" labor. For instance, a song or a poem may be created without much effort. *See, e.g.*, Himma, *supra* note 26, at 18. However, we argue that intellectual property is always the result of labor, either in the form of the innovator's earlier endeavors which provide him with the requisite inventive capability and/or as present efforts directed solely towards the manifestation of an idea, for instance, Graham Bell's invention of the telephone while he was working to invent a more complex form of telegraph. Furthermore, some may argue that the present patent regime fails to satisfy Locke's first condition as well since it fails to always reward labor. For instance, a person may independently labor and reinvent a product which has already been patented. Nonetheless, we would like to highlight that according to Locke, a person is entitled to a right in a common resource if he has improved it with his labor. In the context of intellectual property, improvement can be equated as an addition to the existing knowledge base. Now, it is a fact that reinventing a product is not an addition to a knowledge base unless the process of creation of product is new. However, the debate whether a process or product patent should be granted is outside the scope of this paper.

<sup>&</sup>lt;sup>32</sup> Id.

Single mutations or patterns of mutations in HIV can produce resistance to several different anti-HIV drugs. This means that once resistance to one drug has emerged, this HIV may also be resistant to drugs you haven't taken yet. . . . Cross-resistance may affect all currently available anti-HIV drugs to a greater or lesser extent. So resistance to one nucleoside analogue will affect your choice of other nucleoside analogues, resistance to a non-nucleoside analogue (NNRTI) drug will affect your choice of other NNRTIs, and resistance to a protease inhibitor will affect your choice of other protease inhibitors. Resistance to a fusion inhibitor seems likely to have implications for your chance of fusion inhibitors in the future. New classes of anti-HIV drugs are in development, but these too may well be affected by cross-resistance[.]<sup>36</sup>

It Broadly speaking, anti-HIV drugs can be divided into nucleotide analogues, non-nucleotide analogues, protease inhibitors and fusion inhibitors. Usage of any drug of a nucleotide variety can, and usually does, result in mutation of the HIV, resulting in the HIV becoming immune to the drug. The effect of the mutation of the HIV is often, unfortunately, not restricted to that particular drug, but results in the HIV becoming immune to a variety of other similar drugs as well. This result applies equally to mutations produced by drugs classified as non-nucleotide analogues, protease inhibitors and fusion inhibitors. Further, and perhaps even more importantly, a mutation produced as a consequence of existing drugs can result in the HIV developing a resistance to drugs that are not even in existence today. This is an instance of cross-resistance and clearly demonstrates how the phenomenon results in Locke's second condition not being satisfied in the case of intellectual property protection for certain drugs.

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Thus, due to cross-resistance, a cost in the form of a negative externality,<sup>37</sup> is being imposed upon the society because the performance of an innovation (antibiotic or antiviral, fungicide or other related pharmaceuticals) is affected in real terms.<sup>38</sup> For example, when I purchase a 28-inch television, my purchase would not force another to purchase a 28-inch television or to stop using his 14-inch television because my purchase would in no manner affect the performance of his television in real terms. However, my usage of a particular medicine might. Any cross-resistance developed by pathogens may regulate the decision of another when he chooses a medicine since the performance of his medicine may be affected in real terms.<sup>39</sup> Currently, if a patent were to be granted for the

<sup>39</sup> In the above example the behavior of the individual A is being regulated as if I was allotted a right

*Rise of Antibiotic-Resistant Infections*, United States Food & Drug Administration, http://www.fda.gov/Fdac/features/795\_antibio.html (last visited May 19, 2008) ("[w]hen penicillin became widely available during the second world war, it was a medical miracle, rapidly vanquishing the biggest wartime killer--infected wounds . . . . But just four years after drug companies began mass-producing penicillin in 1943, microbes began appearing that could resist it.").

<sup>&</sup>lt;sup>36</sup> Aidsmap–Cross-resistance, *supra* note 34 (emphasis added).

<sup>&</sup>lt;sup>37</sup> OXFORD DICTIONARY ON ECONOMICS 169 (1997) ("A cost or benefit arising from any activity which does not accrue to the person or organization carrying on the activity. External costs or diseconomies are damage to other people or the environment, for example by radiation, river or air pollution, or noise which does not have to be paid for by those carrying on the activity..."). See generally Shavell, supra note 5, ch. 10, at 1 ("One party's action will be said to have an *external effect*—or to create an *externality*—if it influences, or may influence with a probability, the well-being of another person, in comparison to some standard of reference.").

<sup>&</sup>lt;sup>38</sup> By real terms we imply material terms and not something intangible like, preference, etc. Also, this innovation may be existing drugs whose efficiency is hampered by the mutation or drugs developed in the future.

drug and the 28-inch television, the scope and duration of a patent for both would be the same. This demonstrates that the present IP regime does not internalize<sup>40</sup> the impact of innovations which in real terms adversely affect the performance of existing and future<sup>41</sup> innovations.<sup>42</sup> This, coupled with the reduction in efficacy and the consequent denial of a kind of drug or a whole group of drugs as an option for consumption or research and development, imposes an unreasonable restraint upon society.

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### II. THE NEED TO INTERNALIZE THE COST OF CROSS -RESISTANCE

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Some may choose to argue that cross-resistance is a natural process; hence, no entity as such can be said to be liable for the effects of cross-resistance. While this is true, it is equally true that there are certain factors, such as the production and consumption of drugs, which initialize and can accelerate this natural process. The cited examples only emphasize the effect of such factors.

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The assertion that the cost of cross-resistance should be internalized is best understood in the case of pollution control regimes. Regimes all over the world seek to ensure that polluters take into account the impact of their actions upon others.<sup>43</sup> It must be remembered that the characteristics which makes an element a polluting agent, for example mercury, are its own natural characteristics. The question whether an element is considered a polluting element is relatively determined and is often dependent upon the nature of the entity in respect to which the element is being discussed.<sup>44</sup> For instance, if a factory, in a locality where human beings reside, discharges an element, which let us say, after reacting with air or any other naturally occurring substance becomes poisonous, the factory shall be held liable for the same and it cannot escape liability.<sup>45</sup> The polluter is held liable because he willingly deals with gases which have such capabilities naturally.<sup>46</sup>

and hence, the individual had a duty to observe it.

<sup>&</sup>lt;sup>40</sup> OXFORD DICTIONARY ON ECONOMICS, *supra* note 38, at 246 ("internalizing externalities[:] Methods of getting those producing external costs or benefits to take account of them in their decision-taking. This is partly a question of information: once individuals or firms realize that their actions are causing external costs . . . there is a disincentive to causing external damage if one is made to pay for it, by taxes on activities causing external damage, or an obligation to compensate the victims . . . . ").

<sup>&</sup>lt;sup>41</sup> As is evident from the HIV drugs example above, there is a risk that due to cross-resistance the use of future innovations may also be adversely affected.

<sup>&</sup>lt;sup>42</sup> To elucidate further, in the above example, my decision, whether as a consumer who consumes a drug for curing disease or an innovator who earns a profit due to the consumption of his innovation, to derive benefit from a drug's consumption would not take into account the consequent impact of my actions on any other person, who can be either a consumer or an innovator researching on a drug having a similar attack mechanism.

<sup>&</sup>lt;sup>43</sup> In common law countries, pollution gives rise to cause of action in the tort of nuisance. *See* RANTANLAL AND DHIRAJLAL, THE LAW OF TORT 407 (Guru Prasana Singh ed., 2006); *see, e.g.,* India's Water (Prevention of Pollution and Control) Act 1974, Air (Prevention of Pollution and Control) Act 1981, Environment Protection Act, 1986, Public Liability Insurance Act, 1991; *see also* Wood v. Wand, 3 Exch. 748 (1849); Pakkle v. A.P. Aiyaswami, A.I.R. Mad. 351 (1969) (usually polluters are made to pay taxes or compensation to victims or are even jailed); *see generally* MACMILLAN DICTIONARY OF THE ENVIRONMENT 138 (Michael Allaby ed., 1994) ("It is the aim of the polluter pays principle to require polluters to meet the cost of avoiding polluting or remedying its effects, so internalizing the externalities.").

<sup>&</sup>lt;sup>44</sup> For instance, some substances which are poisonous for human beings or in any manner reduce the net wellbeing of the society.

<sup>&</sup>lt;sup>45</sup> For instance, according to the common law principle of Nuisance in Torts, every person is allowed to reasonably exercise certain rights in things. *See* RANTANLAL AND DHIRAJLAL, *supra* note 45, at 601. However, from an economic perspective, nuisance laws can be seen as rules which tend to internalize the

<sup>¶14</sup> The suggestion that that cost of cross-resistance should be internalized is further complemented by the Competitive Market theory<sup>47</sup> and economic theory which advocates that when parties act in a self interested way and do not take into account the impact of their actions upon others, legal rules and state intervention can be used to correct behavior.<sup>48</sup> Hence, we argue that even though cross-resistance is a naturally occurring phenomenon, entities which initiate the same should be made to internalize the cost imposed on society.

#### **III.** CONCLUSION

¶15 But, who is to be held liable? Is it the consumers, the producers,<sup>49</sup> or both? After all, in the case of pharmaceuticals, unlike the pollution example discussed above, the cross-resistance process is not kick-started unless the drug is consumed by the consumer. Simultaneously, it may be argued that, the producer should be held liable since here the consumer does not have a choice but to consume the medicine.<sup>50</sup> Nonetheless, since the information costs of determining the liability in such cases can be prohibitive,<sup>51</sup> perhaps intervention of state through legal rules is justified.<sup>52</sup>

<sup>46</sup> See M.C Mehta v. Union of India, 1 S.C.C. 395, 421 (1987).

<sup>47</sup> See MITCHELL A. POLINSKY, AN INTRODUCTION TO LAW AND ECONOMICS 88-90 (1989) (identifying the Competative Market Theory as saying that over pricing or under pricing of goods is economically inefficient and that if the costs of manufacturing a product are not fully internalized then the good is under priced leading to over consumption of the product).

<sup>48</sup> See Shavell, *supra* note 5, Ch. 9, at 16 (arguing that state intervention into the sale of property which causes harmful external effects directly or indirectly to other people is essential and justified since it is socially beneficial, and arguing that state intervention is reasonable in instances where other methods, such as liability may not perform satisfactorily).

<sup>49</sup> By "producers" we mean the whole pharmaceutical industry.

<sup>50</sup> Here the reader may differentiate between a drug consumer and a person buying a gun. The person who buys a gun shall have the choice to use it, either for purposes which cause a negative externality or for purposes which may not, whereas, in case of a drug, the consumer would have no control over the impact of his use of the drug. Nonetheless, it may be pointed out that the consumers can help decelerate the process of development of resistance by following guidelines and taking antibiotics, antiviral and other related pharmaceuticals when prescribed by the doctor. *See* Lewis, *supra* note 37.

<sup>51</sup> It may not be known which drug initiated the cross resistance phenomenon, facilitated within a single or various species of pathogens, to a particular attack mechanism. <sup>52</sup> See Shavell, supra note 5, at 17 (". . . general justification for state intervention in sales is to cure a

<sup>52</sup> See Shavell, supra note 5, at 17 ("... general justification for state intervention in sales is to cure a problem of lack of information on the part of a participant in the sale, in order to effect a type of transaction more closely in line with what would have been consummated had parties been informed.").

cost of unreasonable exercise of one's rights. It is no defense that all reasonable care was taken to prevent it. *See, e.g.,* Rapier v. London Ramways Co., 2 Ch. 588 (1893); Newsome v. Darton Urban District Council, 1 All E.R. 79 (1938). This principle evolved into the doctrine of strict liability. Rylands v. Fletcher, L.R. 1 Ex. 265, 279 (1866) ( "The rule of law is that the person who, for his own purpose, brings on his land and collects and keeps anything likely to do mischief if it escapes, must keep it in at his peril; and if he does not do so is *prima facie* answerable for all damage which is the natural consequence of its escape."). In India, this was developed into a regime in which the polluter was held to be absolutely liable, that is, the defenses to the doctrine of strict liability were not available. *See* M.C Mehta v. Union of India, 1 S.C.C. 395, 421 (1987) ( "Where an enterprise is engaged in a hazardous or inherently dangerous activity and harm results to anyone on account of an accident in the operation of such hazardous or inherently dangerous activity resulting, for example, in escape of toxic gas, the enterprise is strictly and absolutely liable to compensate all those who are affected by the accident and such liability is not subject to any of the exceptions which operate vis-à-vis the tortious principle of strict liability under the rule of *Rylands* v. *Fletcher* ....").

<sup>¶16</sup> An ideal regime in such a case would be one which is able to ensure that maximum number of people are able to afford drugs before they become useless, and that their consumption is regulated so as to increase their shelf life.<sup>53</sup> We are of the view that the scope and duration of protection of such innovations should be reduced. For instance, if product patents are disallowed or the protection term is reduced from the current norm of 20 years, then such a measure shall ensure the emergence of competitive markets over a shorter period of time and would make it difficult for firms to charge supracompetitive prices.<sup>54</sup> As a consequence, a greater number of people would be able to use the drug before the disease causing pathogens are able to develop resistance to the medicine.<sup>55</sup> This would offset the cost imposed upon the society by such innovations and reduce the deadweight loss in the society by increasing the access to an innovation.<sup>56</sup>

¶17

Such a measure would also ensure that the incentive for the enterprises/firms to research and develop such drugs reduces. This in turn would make investment in other forms of antimicrobials relatively more attractive,<sup>57</sup> and consequently, result in resources being channeled into exploring other alternatives, for instance, drugs which satisfy our interpretation of Locke's second condition.<sup>58</sup>Hence, instead of making the producer or

http://query.nytimes.com/gst/fullpage.html?res=9B0CE6D91038F932A15750C0A9649C8B63&sec=&spon=&pagewanted=all.

<sup>55</sup> See WORLD HEALTH ORGANIZATION, WHO MEDICINES STRATEGY: FRAMEWORK FOR ACTION IN ESSENTIAL DRUGS AND MEDICINES POLICY 2000-2003 7 (2000) (suggesting that nearly one third of the world's population lacks access to essential medicines.); see also Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research 280 SCIENCE, 698, 698 (May 1998); Implications of the TRIPS Agreement for Developing Countries,

http://www.southcentre.org/publications/trips/tripsmaintexttrans-04.htm (last visited May, 19, 2008); B. Chirac, et al., *Access to Essential Medicines in Poor Countries: a Lost Battle*?, 281 JAMA 362 (1999). Nonetheless, we concede that such a measure may be counter productive since reduction of scope and duration of intellectual property in antibiotics, antivirals and other related pharmaceuticals would reduce the incentive for pharmaceutical firms to invest in development of such drugs. Therefore, such a step should not be introduced if the expected benefit from increased protection of such innovations is greater than the excepted cost due to the consequent evolution of resistant pathogens and the deadweight caused as a consequence of the increased protection.

<sup>56</sup> The reduction in the scope and duration in the intellectual property regime can be seen as a compensatory measure. *See* sources cited, *supra* note 44.

<sup>57</sup> For instance, if the scope and duration of protection for a certain category of drugs is increased, it is rational to presume, all other things remaining equal that investment in research and development of that category of drugs would increase.

<sup>58</sup> University Of California, Los Angeles, 'Smart Antibiotics' May Result From UCLA Research, (September 23, 2004) SCIENCE DAILY, available at

http://www.sciencedaily.com/releases/2004/09/040923093007.htm. The article reports the discovery of certain antimicrobial agents which can be used as an inexhaustible resource to treat diseases caused by microbes. (Wherein, Jeffery F. Miller, professor and chair of microbiology, immunology and molecular genetics at UCLA states, "A problem with antibiotics is that bacteria can mutate and become resistant to a particular antibiotic, while the antibiotic is static and cannot change .... Bacteriophages ("phages") are

<sup>&</sup>lt;sup>53</sup> See Lewis, supra note 37; see also Union of Concerned Scientists, FDA's Approach to Antibiotic Regulation—"The Framework Document",

http://www.ucsusa.org/food\_and\_environment/antibiotics\_and\_food/fdas-approach-to-antibiotic-regulation.html (last visited May 19, 2008).

<sup>&</sup>lt;sup>54</sup> This is evident from, for instance, after an Indian pharmaceutical firm called Cipla, introduced a generic three-drug AIDS therapy at an annual cost of \$350 in Africa which was 1/30<sup>th</sup> of the US price of the drugs, global pharmaceutical firms such as Bristol-Myers and Merck had to accordingly reduce their prices. *See* Cipla Sees Exports of AIDS Drugs Increase Following Discount Offer,

http://www.kaisernetwork.org/Daily\_reports/rep\_index.cfm?DR\_ID=6792 (last visted May 19, 2008); see also Donald G. McNeil, Jr., New List of Safe AIDS Drugs, Despite Industry Lobby, N.Y TIMES, March 21, 2002, available at

consumer solely liable, perhaps applying a weaker IP regime as opposed to the current regime and laying down of global norms regarding drug consumption for consumers,<sup>59</sup> would be a step in the right direction.

nature's anti-microbials, and they are amazingly dynamic. If the bacterium mutates in an effort to evade, the bacteriophage can change its specificity using the mechanism we discovered, to kill the newly resistant bacterium." Also that, "Phage therapy has been practiced for nearly a hundred years in parts of the world, and even in the United States in the first half of the 20th century. But now, we think we can engineer bacteriophages to function as 'dynamic' anti-microbial agents. This could provide us with a renewable resource of smart antibiotics for treating bacterial diseases.")

<sup>&</sup>lt;sup>59</sup> See sources cited and discussion, *supra* note 55. Here we seek to draw a parallel with the argument that strict liability with contributory negligence can lead to socially optimal outcomes. *See* Shavell, *supra* note 5, Ch. 10, at 16.