# THE CONFLICT BETWEEN DRUG PATENTING AND ACCESS TO AFFORDABLE MEDICATION*

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***Abstract***

*This paper discusses the concept of pharmaceutical patents from a legal perspective, assessing the underlying conflict existing between an individual's rights of invention and the morale interest in providing medication for the need of the society. An analysis of law as a tool of public utility highlights how private rights with externalities, such as patents, may be limited by public interest when the general welfare of the people are threaded upon. The author concludes how pharmaceutical patents prescribed by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) are currently disproportionately favored against the general wellbeing*

***Abstrak***

*Paper ini membahas konsep paten obat-obatan dari perspektif hukum, dimana konflik mendasar antara hak penemuan tiap individu dan kepentingan moral untuk menyediakan pengobatan bagi kepentingan umum dianalisa. Analisis hukum sebagai alat utilitas umum menunjukkan bagaimana hak individual dengan eksternalitas, seperti pada paten, dapat dibatasi oleh kepentingan publik saat kesejahteraan umum dikorbankan. Penulis menyimpulkan bahwa penerapan paten obat-obatan seperti diinstruksikan oleh 'Agreement on Trade Related Aspects of Intellectual Property Rights' (TRIPS) saat ini masih secara tidak imbang diprioritaskan melawan kepentingan*

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*of those in need of the drugs. The justifications for patents are further eclipsed by the need of developing countries for ample and affordable medication, as a balance of rights can still be achieved through alternate means of reward and incentive for drug makers, without heaving penalties upon the society in need.*

*umum masyarakat yang memerlukan obat-obatan tersebut. Justifikasi untuk paten terlebih lagi tertutupi oleh kebutuhan negara-negara berkembang untuk pengobatan yang layak dan terjangkau, mengingat bahwa penyeimbangan kedua hak yang berbeda tersebut masih dapat dicapai melalui beberapa mekanisme insentif dan reward alternatif untuk para pembuat obat, tanpa menimbulkan penalti kepada masyarakat umum.*

***Keywords**: drug patent, monopoly, TRIPS.*

## A. Introduction

Among the various functions law deems to serve, protecting private property is one of the most intriguing notions. Originating from feudal eras when those who were endowed with the rights to property were highly revered, scholars today are divided whether the right of a person to own private property should be held highly or be regarded as an impediment to national progress. Nonetheless, law indeed has gone a long way from the days when a person's share of land is protected to an era where the very notion of *idea* itself is protected; changes inevitably induced by the rapid development of technology and innovation marking the turn of the century. It no longer suffice to confine the term 'property' to tangibles—items which may be grasped and seen—instead, the word has expanded to encompass ideas and other intangible assets (Mertokusumo, 1995). However, the underlying principle behind ownership is still steadfast; a person shall have sovereignty over matters which he has rightfully owned or conceived.

Among the most revered of mankind's technological developments are those of drugs and me-

dicinal treatments. Unfortunately, in the threshold of the second millennia, the world is still witness to modern day plagues. Too recently have we have seen the scale of destruction the avian flu pandemic had amounted to, the multitude of lives lost. We may have found *treatments* for lethal diseases such as AIDS and cancer, but a *cure* is yet to be found. Around the globe, the demand for fast and effective medication remains dire.

Despite eminent need, means to earn medication are constantly hampered on the basis of the protection of the intellectual rights of drug makers. Patents are more often than not enforced upon drugs, and have disabled many a nation in procuring sufficient drugs for its people; be it by reason of price or of insufficient quantity. By the time most patent expires and a country is allowed to issue generic drugs, countless lives may have been lost. There is a visible conflict of private and public interests pertaining to drug patents. Shall the rights of property of certain individuals be upheld at the expense of the majority?

### B. Rights to Property versus Public Utility

Scholars differ greatly in what may be interpreted as 'property'. Aristotle defines it as "an object of fair distribution", while Blackstone views property as means which provide its owner with complete control over resources, and freedom to control material things as the "guarding of every other right". But from a legal perspective, property is considered as a set of rights over resources that the owner is free to exercise, and is protected from interference by others; personal property rights are tools which enable a person to have liberty over his assets (Cooter & Ulen, 2000:74-75). Despite the universal recognition of personal property rights, there are, however, certain limitations to this notion. Law is a mechanism built for the mediation of conflicting rights, as one's exercise of right may oft impair another's. Such impairing factors are considered as *externalities*, and may be in private or public form (Cooter & Ulen, 2000:150-151). When externalities have become public, governmental officials may deem that it is no longer in the gene-

ral interest of the society to uphold the individual rights of a person. In the interest of justice and general order, the government may circumvent an individual's rights when that right infringes the rights or welfare of other entities. Thus we find that the freedom of our conduct is constantly limited by rules and legislation of the State.

### C. Functions of Law

One cannot detach the analysis of property rights, a breed of law, from the fundamental question of whether it fulfills the function of the installation of law. When it is deemed that an application of property rights is in violation of the purpose of law, the extent of such application should be limited, or even abolished.

One of the most basic functions of law is to maintain public order (Farrar & Dugdale, 1990:6). Although this is best achieved by ensuring to uphold as many legitimate interests as possible (thus contenting the majority), public order is impossible to achieve without trade-offs, as one cannot possibly attempt to simultaneously uphold two conflicting rights without constructing some form of limitations to each of the individual's rights. Law has historically evolved as an alternative to private feuds and vengeance, and as a mean to provide conclusive settlement to disputes. According to Alan Gewirth (1982:6), in clashes of rights utilitarian values such as national security, public safety, public order, public health, and public morality may outweigh human rights because they in turn also contain human rights elements.

Differing rights may be of differing value. To take an example, a person's right to life may compel him to smash the window of a store to escape in the event of a fire. The shop owner's rights to property (and of how it was violated by the damaging of his window) may be put aside in this matter as his entitlement to the store he owns is outweighed by the rights and the necessity of the first person to save his life (Mertokusumo, 1995:23). The first person's threat to life is more urgent than the damages the storeowner shall procure. It is the duty of a government to assess and weigh the worth of each right in a dispute in order to determine which rights shall prevail, and which shall be limited.

**D. Status Quo of Patents**

Rights of intangible matters such as trademarks, patents, design, and models are still in their infancy when compared to rights of tangible matters (Gautama, 1990:5). The development of intellectual property was due to the realization that not unlike material goods, intangible matters are also conceived by investments of time, talent, toil, and money on the creator's behalf. Furthermore, these matters, intangible as they are, also have economic value. When one purchases a book, one does not merely seek to possess a bundle, *any bundle*, of paper. Instead, it is the ideas, the creativity, and the wit of the author itself we are seeking for. The same goes for computer programs, musical compositions, artistic creations and even, certain wording and symbols. Intellectual property rights are in essence not rights to own a certain asset, but rather, a right to exclude others from using it. This impedes the general dissemination and application of the asset, awarding a substantial amount of economic gains to the holder of the right as a 'reward' of his or her innovation for a certain period of time.

Today, one of the most comprehensive international agreements on intellectual property right is the Agreement on Trade Related Aspects of Intellectual Property Rights, which is also known by its abbreviation; TRIPS. The brainchild of the World Trade Organization (WTO), member countries are bound to the provisions of the agreement, which sets forth minimum standards for intellectual property regulations in such countries. As of 23rd July 2008, the WTO has acquired 153 member states, including the United States, Zimbabwe, Indonesia, and the most recent, Ukraine. (WTO:2008)

TRIPS acknowledges several types of intellectual property which are protectable. These are; copyright and related rights, trademarks, geographical indications, industrial designs, patents, integrated circuit layout-designs and protection of undisclosed information (TRIPS, Art. 1, §2.). With the exception of the foremost, these aspects are considered as industrial property (The WIPO Convention, Art. 2, §ii.), meaning that enterprises of industry (including agricultural

and extractive) and commerce shall have the right to wield ownership claims and limitations of distribution of such properties.

### E. Analysis on Drug Patents

Patents are applied to technological innovations, and this includes drugs. In practice, there are countless of drugs subjected to patent, ranging from the cholesterol-lowering drug Lipitor, the blood thinner Plavix, to various AIDS drugs such as Efavirenz, and avian flu pills, for example Tamiflu. A patented drug will lose its license after 20 years (TRIPS, Art. 33), and until then patent holders virtually have every right to determine its price and reject and prosecute generic drugs deriving from it.

In understanding why such rights of intellectual property shall be upheld in the case of drugs, there are two reasons that one may take into account. First would be of how intellectual rights are conceived as the birthright of the creator; it is onlyjust that a person who has spent copious amounts of time developing and creating something (in this case, medication) to earn credit for his efforts and receive an economic compensation thereof.

Second of all, protection of such rights will fulfill a secondary, economic purpose of providing an incentive for people to continue on creating. If a person were to invest time and effort in inventing, but another person were to be able to copy and distribute the former's work in a heartbeat, then there would be very little drive for the creation of works of art, literature, medical advancements, everything which intellectual property stands for (European Federation of Pharmaceutical Industries and Association, 2008:12,15). Furthermore, taking away such economic incentive will result in a decline of investors willing to take part in the research process, which may take years and requires hefty funding (Lindsey, 2002:15). This will of course hinder the progress of humanity, especially when the products being worked upon are as crucial and as expensive to develop as drugs. This incentive will also act as a promoting agent of healthy competition (European Commission Development DG, 2008: 88), pushing companies to continuously develop more potent, practical, and cheaper means of medication, which in theory will

enable an easier access of medication for more people.

However, there are counter-arguments to the aforementioned reasons. One would be that it is not necessarily true that the inexistence of an incentive in the form of patent protection shall result in a lack of incentives for people to create. The fact that inventions and scientific discoveries are not 'claimable' does not result in a standstill of developments in the area. While one may argue how economic incentives may provide a push in the development of intellectual property, this is not always the case in reality. History shows how the pharmaceutical industry developed much rapidly in countries where patents were weaker (Boldrin & Levine, 2008:215). When the countries did introduce patent, no significant increase in innovation was to be seen (Scherer, 2003). Merges and Nelson (1990:916) explain 'When a broad patent is granted, its scope diminishes incentives for others to stay in the invention game, compared with a patent whose claims are trimmed more closely to the inventor's actual results'. If its scope is too excessive, a patent will act more as a roadblock than as a stepping stone to further innovations (Henry & Stiglitz, 2010: 241)

More importantly, it is mostly true that most groundbreaking and novel drugs, such as HIV/AIDS drugs, tend to be the sole contenders in the market and are the drugs which are the most expensive. This makes sense as patent rights are quintessentially rights of monopoly; creators of a drug shall be given, for a period of time, an exclusive right to monopolize their creation in enforcing the patent (Gautama, 1990:49-50).

Monopoly is extremely undesirable in the market as it gives a seller great control in determining the price of their goods as well as how much they shall produce. Especially in developing and lesser developed countries who have limited medicinal funding and who may not be able to afford these drugs, assigning a company with the rights to patent, to monopolize, may be a of question of life and death to its people.

### F. Conflict of Inventor Rights and Necessities of the Society

A major problem on the issue of drugs is its expense. Many coun-

tries have refused to acknowledge patent rights of certain medication, of these being HIV/AIDS drugs. As of December 2003, more than twenty million people worldwide had died from AIDS, and another forty million people were living with HIV/AIDS (Fisher III & Rigamonti, 2011:2). The rejections of these countries were made on the basis of how costly the patented medicine is, disabling governments to adequately cater to the needs of their citizens who are in dire need of such drugs. Even Brazil, then 12th largest economy in the world, opted for the bypassing of patent as the government deemed that the healthcare system would no longer be able to afford the medical bill of its 75,000 patients, amounting to $580 annually per patient for anti-retroviral medication (MSNBC, 2007).

But the real battle was fought in Africa, where the number of people living with HIV/AIDS accounts for two-thirds of the global sufferer, which was 11 percent of the world's population in the 1990s (UNAIDS, 2004). South Africa was the continent's most developed nation, but even there expenses to provide AIDS drugs tallied up to 20 percent of their gross domestic product. Less than 0,001 percent of people with the disease have access to anti-retroviral drugs in Africa, and by the end of 2003, fewer than seven percent of people in developing countries in urgent need of antiretroviral treatment had access to these medicines (p. 101-102)

The previous paragraph sums up the necessity and urgency of such drugs in the society, and of how, especially in developed and less than developed countries possible lifesaving treatments are continuously being denied to sufferers as a direct result of drug patenting. And cost is not the only issue. By continue on granting monopoly rights on medicine, we minimize the chance for other companies (or even governments) to supply these drugs as well, which means that we shall be utterly dependent on pharmaceutical companies to supply enough drugs as per demand.

TRIPS is in no way silent on these needs. The minimal access to drugs in least developed countries and those lacking production capacity are particularly addressed within the Doha Declaration, where

signatories have sought to accommodate growing health needs by imposing certain flexibilities on patent rights. However, these flexibilities are at best problematic, and do not thoroughly counter the unavailability or the high expense of drugs.

Compulsory licensing on vital drugs is one of these flexibilities. This mechanism allows the government to grant certain licenses and set up royalty on behalf of the patent owner, even at their disapproval. In theory, this would enable governments to supply a steady stream of affordable medicine to those in need, while not *per se* neglecting to reward a drug inventor if only at a reduced profit. Regrettably, this mechanism is not oft implemented for fear that pharmaceutical manufacturers would balk away from investing in countries who could curtain their profits by issuing such licenses.

Parallel importing is another viable, yet problematic option. By importing medicine cheaper than that of the local patented price, parallel importing ensures affordable access to crucial medication. However, this again maims the profit of pharmaceutical enterprises. As the incentive for research diminishes, so does the innovation of new drugs (Skoko & Krivokapic-Skoko, 2005:470). The issue of availability of drugs is also still not addressed by research exemptions. Albeit allowing the research for a drug based off another, prior to the expiration of the latter's patent, the mechanism still prescribes the halting of the manufacture and marketing of the newly developed drug until the patent for the base drug expires.

Generic drugs were regarded as a solution for such dilemmas. Generic drugs are essentially biochemical carbon copies of patented drugs, but they run much less expensive as they do not incur the cost of drug discovery. The average cost of discovering and testing a new drug is estimated to be as much as $800 million (DiMasi et al., 2003:151-185), while the true cost is estimated to be between $100–$200 million. The EU reports that in the period of 2000-2007 they have managed to save € 14 billion by the use of generic drugs, as two years after their entry, the price of generic medicine were on average

40 percent less than their patented counterparts (European Commission Development DG, 2008:85).

Prior to the establishment of TRIPS, patent protections for pharmaceutical drugs were virtually non-existent in poor, developing nations (Mayer, 1998:377,380). Generic drugs flourished, keeping the cost of medication low. Post TRIPS, however, most developing countries have been hesitant to breach intellectual property laws for fear of trade sanctions enforced by the WTO. As a result, generic medicine may only be derived after the patent of a brand-drug has expired; which means it will take at the very least 20 years to obtain cheaper, more accessible version of these vital drugs.

It is then apparent of how in the case of patented medication there is an eminent clash between the rights of property of pharmaceutical companies over their products and the immediate necessity of providing plenty and affordable medication to the world. In determining which governments should rightfully prioritize, one should look back on the theory of the functions of law. Governments, in wielding law as a beacon of public order, should strike balance to conflicting rights.

Despite pharmaceutical companies' rights to gain and benefit from their inventions, when enforcements of such rights have been proven to inflict more harm than good to the general society, governments should tip the balance of rights in favor of the majority. As elaborated in previous sections, private rights may be limited by public goods, or in other words, utilitarian values. Providing easy and affordable access to drugs to those who direly need them is indeed the holy grail of utilitarian motives.

One should bear in mind that the duty and aims of a government in upholding laws is not to protect a select few (drug companies) in the expense of others. In its function of a protector of human interests, law aims to either enforce what is ethically correct, or what brings the most benefit to the general society (Mertokusumo, 1990:64-68). Opting to limit property rights may inflict a degree of unfairness on the companies' behalf, but their loss is insignificant when compared to the loss of lives that may (and has oc-

curred) by the persistence to promote patented medicine to countries which cannot afford them.

### G. Solutions

It is not to be said, however, that governments should outright disregard the rights of pharmaceutical companies. There are several plausible measures which may be taken to reward innovation without limiting its dissemination and application. Instead of awarding credit to pharmaceutical companies in the form of a 20-year monopoly, the author proposes that the WTO and its member nations opt to assign economic compensation by means of an invention prize to the inventors of an innovative drug. In exchange for the paid sum, drug makers shall waive their rights of exclusivity of the drug while are still entitled to selling (and having a head start thereof) and producing their product.

Another option would be for the WTO to reassess its position trough a revision of the TRIPS. The WTO has attempted to reinstate how the agreement should be interpreted in light of the goal 'to promote access to medicines for all" as a response to various developed countries which are neglecting this zeal as a result of narrow reading of the terms of the TRIPS (Doha Declaration, 2011). Many developing countries have yet to implement TRIPS flexibilities (such as parallel importing, limits on data protection, and compulsory licensing), due to the lack of legal and technical expertise, which in turn has led these countries to directly copy the intellectual property legislation of developed countries (Finger, 2000:3).

The legality of generic medication, which is the championing vessel of inexpensive and widely available medication, is still unclear (and differing) in many of its member states. The author suggest that the issue of legalizing generic medication in certain developing nations which are financially unstable be looked upon and hopefully implemented, or at the very least, pharmaceutical companies shall charge a substantially lower rate for drugs in such areas.

A last option would be assigning governments with the obligation to (jointly or individually) commission the research and development of new drugs on their own expense, and then distribute them

with a minimal margin of profit (if any) to the society.

### H. Conclusion

In the balancing of intellectual property rights and the necessity of procuring essential medication for diseases, the author has concluded that the status-quo tilts too much in favor of personal rights of pharmaceutical companies. Although it is true that an entity is entitled to recognition and economic rewards for its ideas and innovation, this right is not without limitation. The patent rights of drugs in this case should be more restrained as it intervenes with general good and welfare.

The cause of providing medication to as many people as possible is an urgent and utilitarian one. By strictly upholding the rights of the companies in this manner, we are disabling many countries (especially developing and lesser developed countries) in adequately providing the necessary medication to its people. By continuing to revere patent rights above all other necessity, we are sacrificing the general good of the society.

Thus, in upholding the interest of justice and utilitarian as well as ethical purposes of law, pharmaceutical companies should seek to loosen patent policies especially for poorer countries, or the governments of the world and the WTO may invent new means of resolving this conflict of interest without hurting the utilitarian issue of the needs for medication. Property rights should not exceed humanitarian necessities, especially when it deals directly with the continuation of human lives.

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