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MAXIMISING UTILITY: APPLYING UTILITARIAN THEORY TO INTERNATIONAL PATENT LAW

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This article attempts to strike a balance between the need of pharmaceutical companies to stay profitable and the need of developing countries to access life-saving medicines. It is proposed that this balance can be achieved by applying a utilitarian approach to patent law, taking into consideration how best to maximise 'value' for both parties. There has been much debate on whether pharmaceuticals should be subject to patent law. The arguments for and against this protection will be examined, and it will be argued that it is not plausible to abandon intellectual property protection due to the large investments made by these companies into research and development. With this in mind, it will be suggested that in order to address the concerns of both parties, a distinction should be made for drugs for endemics and drugs for worldwide consumption. Compulsory licensing should be abandoned for the former to provide incentive for research and development that is much needed. Additionally, governments and charitable organisations should collaborate to contribute to the funding of these drugs. Differential pricing should be applied to drugs for worldwide consumption, as there is sufficient research and development incentive for these. Differential pricing will lead to and increase of sales and greater accessibility to medicine.

Access to affordable drugs is a perennial issue that plagues many developing and least developed countries (collectively referred to as DCs). Since the implementation of the Trade Related Aspects of Intellectual Property (TRIPS) Agreement in 1995, patent protection[1] has been maligned for making life-preserving drugs inaccessible for DCs.[2] This is because patent protection confers a limited statutory monopoly to the inventor[3] that prevents manufacturers from producing generic forms of the patented drugs. The implication of this is that it allows inventors/owners of patented drugs to control the price and supply of their products, often making them unaffordable and inaccessible to DCs. The grievances surrounding this issue culminated at the Doha Convention 2001 where amendments to compulsory licensing were made with the intention of making life saving drugs more accessible. However, these changes have failed to improve access to pharmaceuticals for DCs. Furthermore, little has been done to address the problem of availability of drugs for endemics. Pharmaceutical companies are reluctant to invest R&D into these types of drugs given that they are not considered profitable.

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[1] For basic information on patents generally see 'Patents' (*WIPO*) <http://www.wipo.int/patentscope/en/patents_faq.html#why_patents> accessed April 18th 2013

[2] Annex 1C of the Marrakesh Agreement Establishing the WTO, signed 15th April 1994, entered into force 1st January 1995

[3] Blakeney M, 'Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement' (Sweet and Maxwell, 1997) pp 2

With this background in mind, the ethical theory of utilitarianism will be applied to alleviate the problem of access to pharmaceuticals, as well as availability. It will be argued that utilitarianism, despite it's criticisms, is the most suitable ethical theory to apply, as this theory postulates that the action which produces the greatest good should be taken.[4] Moreover, the theory is in accordance with the public benefit justification for patents. Therefore, in the current instance, the greatest good must aim to strike a balance between the desire of pharmaceutical companies to remain profitable, and the need for drugs by DCs. This is an important and pressing issue because people die without these drugs. As such there is an ethical issue concerning how patent law should be structured to strike the most beneficial balance between the pharmaceutical industries and the DCs. Although classical utilitarianism focuses on maximizing utility without regard to distribution[5], this article will seek to distribute utility between both parties, with regard to the difficulties posed by the utilitarian calculation[6].

TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS AGREEMENT

Prior to the TRIPS Agreement, the Paris Convention for the Protection of Industrial Property 1883, administered by the World Intellectual Property Organisation (WIPO), was the most notable international agreement on patent protection[7] with 174 contracting parties. Despite its large membership, the Paris Convention was insufficient in the eyes of industrialised countries as the scope of protection offered was discretionary on a national basis, and as such, not extensive enough to satisfy industrialised countries.[8] The Convention was based on three main principles: non-discrimination, national treatment and the right of priority.[9] This allowed DCs the scope to omit certain inventions from patentability, and indeed, in 1988, pharmaceutical products were not patentable in 49 Paris Union States.[10]

DCs saw this Convention as a beneficial avenue to shape the international patent regime in a manner conducive to their development. The Convention was

[4] Bentham J, *An Introduction to the Principles of Morals and Legislation* (Oxford, Clarendon Press, 1789)
[5] Frey R, 'Utilitarianism and Persons' in Frey (ed), *Utility and Rights* (Basil Blackwell, 1985) pp 5
[6] Sidgwick H., 'The Methods of Ethics' (Hackett, 1981)
[7] Others major IP agreements include:
- Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations1961
- Berne Convention for the Protection of Literary and Artistic Works 1886

[8] Straus J, 'Implications of the TRIPS Agreement in the Field of Patent Law' in Beier FK and Schricker G (eds) *From GATT to TRIPS- The Agreement on Trade-Related Aspects of Intellectual Property Rights* (Max Planck Institute, 1996) pp 7
[9] Sell S., 'Intellectual Property as a Trade Issue: from the Paris Convention to GATT' (1989) 13 Legal Stud. F. 407
[10] WIPO, "Existence, Scope and form of generally accepted and applied standard norms for the protection of intellectual property" (WO/INF/29, September 1988)

administered under a '1 vote per country' system, allowing DCs to effectively veto unfavourable provisions.[11] More than this, the DCs attempted to use their voting power to mould the Convention to their satisfaction, leading to revisions in 1980, 1981, 1982 and 1984 focused on "more liberal provisions for compulsory licensing."[12] In contrast, the United States sought to increase protection. After the 1984 Conference ended in a deadlock, with no change effected to either strengthen or reduce protection, the United States brought the issue to the General Agreement on Tariffs and Trade (GATT).

At the Uruguay round of GATT, the United States pushed for stronger patent protection, with pressure being exerted by major U.S companies such as IBM, Microsoft and Pfizer[13], claiming that potential profits were lost due to the failures of pre-existing agreements.[14] Special emphasis was placed on patent protection for pharmaceuticals, due to the large amounts spent on research and development in this industry, and also, because of the direct role played by Pfizer in the strategic process. The economic argument regarding the losses suffered by this industry can be questioned, as it is arguable that persons in DCs probably could not afford the original version of the drugs, even if it was the only available option.[15] This argument will be further examined when considering the different research and development (R&D) incentives for drugs for worldwide consumption and endemics.

In 1972, newly appointed CEO of Pfizer, Ed Pratt, increased Pfizer's R&D budget from 5% to 15%-20% of sales, realising that Pfizer[16] could expand based on ability to innovate new drugs.[17] During this time he also spearheaded the effort to increase global IP protection. In 1981, Ed Pratt was appointed chairman of the U.S Advisory Committee for Trade Negotiations (ACTN), an organisation formed to collaborate U.S trade policy in accordance with the business sector[18], tasked with advising US federal trade representatives on matters pertaining to industry. Recommendations from the ACTN Task Force on Intellectual Property resulted in the strategic integration of intellectual property into GATT.

Why did the Developing Countries agree?

Considering that many of the signatories to the WTO agreement included many of those developing countries (DCs) that had failed to enforce patent protection

[11] Drahos P, 'The Universality of Intellectual Property Rights: Origins and Development' in *Intellectual Property and Human Rights,* (WIPO, Geneva, 1999) 8

[12] *ibid* 9

[13] Drahos P, 'Global property rights in information: the story of TRIPS at the GATT', 13 (1995) Prometheus , pp 7

[14] Straus J., 'Implications of the TRIPS Agreement in the Field of Patent Law' (n8) pp 7

ibid pp 8

[16] In the period 1980-1990, Pfizer underwent a period of growth due to the innovation of a series of drugs including: Feldene (Pfizer's first product to reach a total of U.S$1,000,000,000 in sales), Glucotrol, and Unasyn, and operated in more than 180 countries by 1989 - 'Pfizer Inc' (*Corporate Watch)* < http://www.corporatewatch.org/?lid=327> accessed February 1st 2013

[17] 'Pfizer Inc: Exploring Our History – 1951-19999' (*Pfizer*) < http://www.pfizer.com/about/history/1951_1999.jsp> accessed February 1st 2013

[18] Drahos P, "Global property rights in information: the story of TRIPS at the GATT", 13 (1995) Prometheus , pp 8

previously, and were aware of the purpose and potential effect of TRIPS, why did they agree? The answer to this question is linked to free trade. While the Paris Convention had focused on IP protection in isolation the WTO agreement linked IP protection directly to international free trade**.** Countries that were already members of GATT were eligible to become members of the World Trade Organisation[19] (WTO), which was born out of negotiations in the 1986-1994 Uruguay Round. Article XIV(1)[20] ensured that acceptance of the WTO Agreement also extended to multilateral agreements, including TRIPS.

Free trade is generally considered advantageous due to the reduction of customs duties and non-tariff trade barriers as well as allowing DCs to more easily access industrialised markets for the sale of agricultural products and textiles.[21] These benefits combined with the threats of "special 301" sanctions by the U.S,[22] induced DCs to join the WTO and by extension, TRIPS, as free trade was "so attractive to many DCs that they were willing to accept the burdens connected in their eyes with the protection of IP to the benefit of industrialised states."[23] TRIPS, which provided a unitary set of rules rather than the adaptable guidelines of the Paris Convention, achieved the U.S goal of strengthening international patent protection.[24] In addition, TRIPS also addressed other problems of the Paris Convention, by providing detailed rules on enforcement of provisions before national courts, and creating a binding and effective mechanism for resolving disputes between states.[25]

At this point it is important to note the vital role of economics in the development of TRIPS. The influence exerted by IP-based industries, particularly in the U.S, directly resulted in pressure being placed on DCs to

[19] 'Who we are' (*World Trade Organisation*) <http://www.wto.org/english/thewto_e/whatis_e/who_we_are_e.htm> accessed January 31st 2013

[20] URUGUAY ROUND AGREEMENT
Marrakesh Agreement Establishing the World Trade Organization
Article XIV Acceptance, Entry into Force and Deposit

1. This Agreement shall be open for acceptance, by signature or otherwise, by contracting parties to GATT 1947, and the European Communities, which are eligible to become original Members of the WTO in accordance with Article XI of this Agreement. Such acceptance shall apply to this Agreement and the Multilateral Trade Agreements annexed hereto. This Agreement and the Multilateral Trade Agreements annexed hereto shall enter into force on the date determined by Ministers in accordance with paragraph 3 of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations and shall remain open for acceptance for a period of two years following that date unless the Ministers decide otherwise. An acceptance following the entry into force of this Agreement shall enter into force on the 30th day following the date of such acceptance.

[21] Weitsman F, 'TRIPS, Access to Medicines and the "north-south" conflict after Doha: the end or the beginning?' (2006) 6 Asper Rev. Int'l Bus. & Trade 67, 72-81

[22] Blakeney M, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement* (Sweet and Maxwell, 1997) pp 5

[23] Straus J, 'Implications of the TRIPS Agreement in the Field of Patent Law' (n8) pp 14

[24] Crowne E, 'Fishing TRIPS: A look at the history of the agreement on Trade-Related Aspects of Intellectual Property' (202) 2 Creighton Int'l & Comp. L.J 77, 81-98

[25] Under the Paris Convention, there was little avenue for redress as the World Intellectual Property Organisation (WIPO) tended to focus more on pursuing consensus as to what the law should be, rather than the existing law

comply with this patent regime. As such, we see the value of financial gain being placed above the value of health. This article will attempt to reconcile these values in applying utilitarianism. Given the importance attached to financial value, it must be emphasised that any recommendation that proposes to diminish the economic position of pharmaceutical companies will be unrealistic as the current regime developed from the financial impetus. An attempt to do so will not be acceptable and consequentially, there will be no promotion of accessibility to drugs for DCs. In promoting accessibility, financial value must also be promoted or at least remain the same.

The effect of TRIPS

With the introduction of patent protection for pharmaceuticals, one of the most controversial Articles was Article 31, dealing with compulsory licenses. According to commentary on TRIPS produced by the Max Planck Institute, "a compulsory license, in the meaning of Article 31, is an authorisation for a third party, against or regardless of the patent owner's will, to perform acts that would legally require authorisation from the patentee."[26] Article 31 lists 12 provisions, including attempting to attain authorisation from the right holder on 'reasonable commercial terms'[27] and adequate remuneration for the right holder[28]. However, the most onerous condition is arguably Article 31(f), which states, "any such use shall be authorised predominantly for the supply of the domestic market of the Member authorising such use." It is this provision that was widely contested at the Doha round as member states that do not have manufacturing capacity cannot benefit from compulsory licenses. In 2005, Article 31bis was introduced to amend this provision. However, only 32 of 153 members have ratified it.[29] This amendment exempts members from the Article 31(f) restriction if both exporting and importing members fulfil a number of requirements such as notification of names and expected quantities of product, establishment of insufficient manufacturing capacity and special packaging for the product.[30] But remuneration was still payable to the patent holder under Article 31bis(2), either by the importing or exporting member.

Despite the changes introduced to compulsory licensing, the Doha round and subsequent rounds failed to adequately tackle the problem of access to essential medicines. Compulsory licensing has proved ineffective[31] as will be illustrated, and there have not been any measures to encourage production of drugs for endemics that is, the availability problem. Failure to differentiate between drugs for worldwide consumption and endemics has resulted in insufficient R&D being devoted to the latter. Many argue that abandoning patent protection for essential medicines is the ultimate solution (as will be explained in the next

[26] Stoll P, Busche J., Arend K., 'Trade-Realated Aspects of Intellectual Property Rights' (Max Planck Commentaries on World Trade Law, Vol 7, 2009) pp 556
[27] TRIPS Article 31(b)
[28] TRIPS Article 31(h)
[29] Brin A, 'Better Access o medicines: Why countries are getting tripped up and not ratifying article 31bis' (2010)1 Case W. Res. J.L. Tech.& Internet 165
[30] Stoll P., Busche J., Arend K., *Trade-Realated Aspects of Intellectual Property Rights* (Max Planck Commentaries on World Trade Law, Vol 7, 2009), 581
[31] Harris D, 'TRIPs after fifteen years: success or failure, as measured by compulsory licensing' (2011) 18 J. Intell. Prop. L. 367, 390-393

section), but this would be impractical in light of the philosophy of TRIPS and the unavoidable reality of the costs of R&D.

ETHICS, ECONOMICS AND THE LAW – THE CURRENT LEGAL ARGUMENTS FOR AND AGAINST PHARMACEUTICAL PATENT PROTECTION

The development of TRIPs demonstrates a clear commitment to an economic approach[32] to patent law, based on a circular strategy of incentivising the production of new drugs by providing patent protection as a reward. While this approach is pragmatic in that it fulfils the goals of pharmaceutical companies and in turn, countries that have pharmaceutical production as a major industry, it fails to take into consideration wider non-economic and deontological reasoning which oppose this system that restricts access to pharmaceuticals. As such this section looks at the arguments for and against the current patent regime.

Against patent protection

At the most basic level, patent protection makes medicines inaccessible to suffering masses in DCs. Sub-Saharan Africa is home to an estimated 2/3 of the world's infected HIV population, despite having only about 12% of the world's population.[33] Given the population density of those living with the disease in this region, it is essential that medicine be provided to treat those infected, as most of these individuals are of working age, and need to generate income to support their families and the economy as a whole.[34] The twenty years protection granted by patents can be seen as an excessive, especially when measured against terms of life expectancy, which, in Swaziland, the country with the highest HIV prevalence, is 49.42 years[35]. In fact, any period of time in which essential medicine is made inaccessible due to price would arguably be considered excessive to those suffering.

Patent protection for HIV/AIDs drugs creates a barrier, as only generic drugs are available for treatment. This means that new, improved drugs are inaccessible until patent protection has expired. Assuming the most effective treatment will result from the newest drugs, it would be desirable to make these drugs more easily accessible. This would require the removal of patent protection or more affordable pricing mechanisms. However, removing patent protection does not mean that the drugs in need will be manufactured or imported into DCs, nor does it guarantee that drugs will be distributed accordingly. But it would result in lower production costs, thus easing the strain of financial inaccessibility. While

[32] Spence M, *Intellectual Property*, (1st edn, Oxford University Press 2007) 43 -73

[33] 'Global HIV/AIDS Response: Epidemic update and health sector progress towards Universal Access 2011' (WHO/UNAIDS/UNICEF, 2011) <http://www.who.int/hiv/pub/progress_report2011/en/index.html> accessed February 9th 2013

[34] 'Country statistics' (*UNAIDS*) < http://www.unaids.org/en/regionscountries/countries/? Accessed April 24th 2013

[35] 'Swaziland – People and Society' (*CIA World Factbook)* <https://www.cia.gov/library/publications/the-world-factbook/geos/wz.html> accessed April 24th 2013

this point was acknowledged by the UK Commission on Intellectual Property, it was also highlighted that removing patent protection would eliminate any incentive into R&D for drugs for endemics.[36]

It can be argued that one to way mitigate the effects of patent protection would be to invoke Articles 31 and 31bis. However, these Articles only make provision in theory, whereas the reality is that only one country has made use of Article 31 bis; the Article which allows import of generic drugs.[37] In July 2007, Rwanda, the importing member, informed the WTO that it intended to import 3 anti-retroviral drugs from Canada.[38] The final shipment of these drugs was received by 2009, after which the manufacturer, Apotex, stated that it would not use the system again due to it being too complicated, with lengthy negotiations with patent holders and few incentives.[39] Article 31, which allows manufacture for the domestic market and thus applies to countries with manufacturing capability, has not had much more success, due to fear of retaliation.[40] This fear is well founded given that Thailand was censored by both the US and the EU after issuing a compulsory license under Article 31 in 2007.[41] However retaliation has not been limited to countries as pharmaceutical producer Abott responded to the compulsory license by withholding new products from the Thai market, including a heat resistant anti-retroviral drug.[42] Furthermore, the US has entered into more than 14 bilateral trade agreements that effectively prevent countries from using compulsory licensing.[43] With these numerous consequences, it is no surprise that compulsory licensing has been of little benefit.[44]

With the current unsatisfactory circumstances in mind, it is worth exploring the importance of health care globally to consider how this area has been addressed in other areas of law. Access to medications has been included in human rights instruments in international law, such as the United Charter, the preamble of the World Health Organisation Charter and the International Covenant on Economic, Social and Cultural Rights [45] (ICESCR). The shortcomings concerning these rights can be observed by reference to the ICESCR. ICESCR states have an obligation to take appropriate measures to observe the right to health. These obligations, according to Eide, are to "respect, protect and fulfil

[36] Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (London, November 2002) ch 2
[37] Harris D, 'TRIPS after fifteen years: success or failure, as measured by compulsory licensing' (n32), 383-393
[38] *ibid* 367, 383-393
[39] *ibid* 367, 389 - 390
[40] *ibid* 367, 383-393
[41] 'U.S. Trade Representative Places Thailand on Priori Watch List in Annual Report' (Medical News Today, May 3, 2007), < http://medicalnewstoday.com/articles/69507.php> accessed February 9th 2013
[42] Harris D., 'TRIPS after fifteen years: success or failure, as measured by compulsory licensing' (n32) 367
[43] *ibid* 367
[44] Gumbel M, 'Is article 31bis enough? The need to promote economies of scale in the international compulsory licensing system' (2008) 22 Temp. Int'l & Comp. L.J 161, 170-190
[45] Article 12 and General Comment 14 – only "essential drugs" (as defined by the WHO) are included within the scope of health as a human right

the right."[46] To summarize Hestermeyer's assessment of the execution of these rights, states should treat individuals as equals, undertake measures to ensure the rights are realised and to prevent third party interference with the exercise of rights.[47] These obligations are qualified by the availability of resources.

From this brief overview of the ICESCR, two problems arise in relation to patent protection. Firstly, the right to health is imposed on each state in relation to their population, rather than member states in relation to each other. Problems brought about by patents are usually due to the actions of pharmaceutical companies in states other than the ones in need,[48] but there is no interconnected duty for these industrialised states to curtail these issues. Even if there was, pharmaceutical industries are private entities, and the influence of the state would only be as strong as the provision of funding.[49] Secondly, the obligations are qualified by the financial capacity of the state to address them, which can result in DCs escaping these obligations by pleading lack of resources. This is all the more problematic considering that DCs cannot afford the price of patented medication in any case.[50] It can be argued that if patent protection is removed, the production of cheaper, generic drugs, would allow states to better observe their obligations, and thus improve the health of their citizens.

The problems identified are social, political and economic issues, but are all consequences of the antagonistic relationship between finance and health. Thusthe deontological perspective[51], the paradigm characteristic of anti-patent arguments for pharmaceuticals, suggests patent protection should be removed because the intrinsic value of human life should be put above all other considerations. As deontology is based on what is morally right or wrong, it is easy to see how an argument purporting to be beneficial to humanity can be emotionally appealing. However, these arguments do not fully consider the reality of the economic justification that governs patent law and the wider business relationships of the world.

For patent protection

The former CEO of Glaxo Wellcome, Richard Sykes, has said, "Our ability to invest such huge sums in R&D depends upon strong patent protection…no one would make such an investment without the prospect that their invention would enjoy a limited period of protection from copying."[52] The correlation between patent protection and R&D in the pharmaceutical industry is clearly evident from this statement. While there are other arguments in favour of patent

[46] Eide A, 'The Right to Adequate Food as a Human Right' (UN Doc E/CN.4/Sub.2/1987/23,1987)
[47] Hestermeyer H, 'Access to Medication as a Human Right' (Max Planck UNYB 8, 2004)
[48] Abbott F, 'The WTO Medicines Decision" World Pharmaceutical Trade and the protection of public health' (2005) 99 Am. J. Int'l L. 317, 317-326
[49] Story A, *The Oxfam "access to essential medicines" project: some patent and research and development issues* (Oxfam International, Oxford UK)
[50] Reinhold H, 'Patients v. Patents' (2001) 19 IPL Newsl. 1
[51] Sonenshein S, *A Note on Deontology* (Daren Business Publishing Virginia, 2000)
[52] Skyes, R, 'EC must tackle Spanish threat to drugs R&D', *The Guardian* (London, 18 November 1995)

protection, such as John Locke's labour theory[53], in relation to the pharmaceutical industry, pro-patent arguments generally have an economic basis, with the main theories relating to an incentive to create, reward and prospect.[54]

As Sykes stated, without patent protection, it is unlikely that invention would take place, thus, patent protection creates an incentive to invent. This consequentialist view is undermined by the fact thatinvention had taken place before the patent system was introduced, but the situation of the pharmaceutical industry is arguably unique because of the vast sums of money spent. The average cost of R&D differs depending on each drug and is a contentious figure; estimates range between $200-$500 million USD[55]. As already mentioned, without patent protection, generic manufacturers would be able to benefit from this investment, undercutting the profits of developers. The strength of the connection between patents and the profitability of a drug company can be questioned, however, since patent protection has been around since the 18th century, making a calculation is difficult. This is even in light of the absence of patent protection globally until TRIPS, as pharmaceutical companies would have derived benefit from national patent protection that could have impacted on profits.[56] Therefore, while it is impossible to calculate the profits that would be made in the absence of patent protection, if both new and generic drugs were to enter the market at the same price, the company that manufactured the product would have to invest heavily on marketing to be able to compete with the sales of the generic, as the money spent on R&D would need to be recouped. For example, assuming that patent protection is non-existent, Company A has spent $100 million USD on research and development of drug X. Company B has copied this drug and called it drug Y. Both drug X and Y retail for similar prices as A needs to remain competitive. Company A would need to sell $100 million USD worth of drug X before it could begin generating a profit, whereas company B would be generating profit almost immediately.

Directly related to the incentive to invent is the reward that is gained from the invention. It can take up to 15 years from invention to market before a drug starts making money, and that is dependant on getting approval from the Food and Drug Administration in the U.S or another relevant body[57]. Based on the lengthy time-span, patent protection is desirable as the work put in will not receive due reward if a generic company is allowed to copy the finished product

[53] Hughes J, 'The philosophy of intellectual property' (1989) 77 Geo. L. J. 287
[54] Kitch E, 'The Nature and Function of the Patent System' (1997) 20 J.L & Econ. 265, 268-271
[55] Story A, *The Oxfam "access to essential medicines" project: some patent and research and development issues* (Oxfam International, Oxford UK 2000)
[56] An exception would be the Swiss pharmaceutical industry which did not introduce patent protection until 1910. A study of this industry would be useful to indicate whether the absence of patents had any effect on earnings while taking into consideration the globalized nature of capitalism today - Dibble W., 'Justifying Intellectual Property' (1994) UCL Jurisprudence Rev. 74, 84
[57] Government Accountability Office, *Science, Business, Regulatory and Intellectual Property Issues Cited as Hampering Drugs Development Efforts* (Report to Congressional Requesters, November 2006) pp 12

and free-ride on the backs of drug developers.[58] While the reward theory can be opposed by pointing out that unsuccessful inventors who may have an equivalent timespan developing a drug are incapable of benefiting from similar rewards, it should be remembered that what receives the protection is the drug or process. As patent protection is granted before the relevant approval, unsuccessful inventors have not been treated unfairly as they too have received protection. Thus, the actual reward yields from the success of the product or process, which is protected by the patent. Furthermore, it can be noted that the patent owners are the companies rather than the scientists, who will be rewarded based on the salary they receive. This seems to undermine the reward theory, but it is the company that has facilitated the creation of these drugs through financial and infrastructural support.

The encouragement of competition is another point that can be advanced in favour of patent protection[59] according to the prospect theory. By granting a limited monopoly on a drug or process, competitors are encouraged to invent new drugs. This can be seen as beneficial to the market as well as people as it provides us with a wider selection of drugs than we would have had in the absence of competition, based on the assumption that pharmaceutical invention would be stifled in the absence of the patent system. This is qualified by the prospects of profitability and market need, as companies are more likely to pursue inventions that will yield the most financial benefit.[60] The idea that monopoly control can encourage competition appears oxymoronic, but considering that new drugs continue to be developed, the concept is less disparate than it seems.[61]

Balancing the arguments for and against patent protection discussed above leads to the conclusion that change is desirable because of the negative social effects of the current approach to patent law. An industry, which produces products essential to human health, should not only be spurred on by economic concerns. However, it is clear that this is the current state of affairs and is unlikely to change. As such, a new approach needs to weigh these concerns and determine how to balance them against the moral implications of this restrictive regime. Thus, it will be suggested in the next section that utilitarianism is a more suitable approach to achieve this balance.

A UTILITARIAN APPROACH TO PATENT PROTECTION

The ethical theory of classical utilitarianism as fathered by Jeremy Bentham is being advocated as the means of addressing the imbalance in the existing patent

[58] Bently L, Sherman B, *Intellectual Property Law* (first edition 2001, Oxford University Press 2009)
[59] *ibid*
[60] Story A, *The Oxfam "access to essential medicines" project: some patent and research and development issues* (Oxfam International, Oxford UK)
[61] Pollack A, 'F.D.A approves a new drug for advanced breast cancer', *The New York Times* (New York, 22 February 2013)

system concerning the relationship of financial incentives and human health. [62] As a branch of consequentialism, the objective of utilitarianism is to act in a way that creates the greatest amount of value overall. [63] Value was originally interpreted as a positive mental state but more recently has been recognised to be wider than this and can be described as 'interest-satisfaction'[64]. John Stuart Mill further developed this theory by expounding the utilitarian calculation as follows:

(i) Add up the pain and pleasure derived from an act
(ii) Determine where the largest number of people will benefit the most
(iii) Allow flexibility for efficiency

Many strands of utilitarianism have developed from Bentham's original proposition, including 'act-rule', 'economic' and 'ideal' to name a few. For the purposes of this article, classic utilitarianism is relied upon as this proposal has to consider large groups with divergent interests in the context of a change of system, rather than individual actions as in 'act-rule', or pure wealth maximisation for 'economic'.

Utilitarianism is a suitable solution to the problem at hand because it seeks to maximise value. In this case, there are two values that have to be reconciled, these are, health value for DCs and financial value for pharmaceutical companies. It may appear rudimentary to couch matters that are the source of international tension in such simple terms, but it is important to keep in mind that the aim is to effect change in a way that will benefit both parties and in order to do this, the main interests must be considered. In striking a balance between both values, the utilitarian framework will consider the current problems. The main problems faced by DCs are availability and access. Availability is an issue for drugs for endemics specific to DCs, as pharmaceutical companies do not devote R&D to these types of drugs as they do not see them as a way to generate profit. With regards to accessibility, drugs for worldwide consumption are being reduced as there are markets for them, but they are unaffordable in DCs. As such, a distinction is made between these two categories, drugs for endemics and drugs for worldwide consumption, in an attempt to promote both health and finance values.

Utilitarianism provides the scope to effectively balance these different values, unlike the current economic approach, which elevates finance to the detriment of health. By allowing for a more normative balance, the main problem caused by the economic approach, concerning access and availability to pharmaceuticals can be solved by utilising this utilitarian market structure to balance both values. As this framework will be applied in an international context, the main social and economic issues need to be addressed.

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[62] A full account of utilitarianism exceeds the scope of this article. For further information see *Stanford Encyclopedia of Philosophy*
<http://plato.stanford.edu/search/searcher.py?query=utilitarianism>

[63] Bentham J, 'An Introduction to the Principles of Morals and Legislation' (Clarendon Press,1789)

[64] Frey R, 'Utilitarianism and Persons' in Frey (ed), *Utility and Rights* (Basil Blackwell, 1985) pp 5

Socio-economic Background

In order for the framework to be realistic, the wider socio-economic context must be considered. The main issues are the market ideology by which pharmaceutical companies operate, that is, capitalism and problems and administrative problems in DCs that are potentially detrimental to healthcare.

Capitalism and shareholder primacy

Shareholder primacy, which is the accepted model of corporate governance, concerns the running of a company to increase share value.[65] This model is set against the background of capitalism.[66] It is under this system that pharmaceutical companies operate, which explains why the deontological arguments put forward by the anti-patent school are untenable. Recalling the reason that TRIPS came about in the first place, it is obvious that profitability is a major factor in this calculation. The implication of this is that any changes will have to seriously consider the effect on pharmaceutical profits. Thus, while the deontological approach would support giving free vaccines for the H1N1 epidemic, the reaction of Novartis to this suggestion in 2009 explains why this is not feasible.

Novartis refused to donate free vaccines when requested to do so by the World Health Organisation in 2009, to fight the outbreak of the H1N1. Stating that DCs should cover the costs, Novartis CEO said, "If you want to make production sustainable, you have to create financial incentives."[67] This statement aptly illustrates the current economic approach. Novartis went on to explain that it had made a loss for the last three consecutive years on flu vaccinations, so there was no 'extra wealth to redistribute', however, it was open to the idea of providing vaccines at a reduced cost.[68] On the other hand, GlaxoSmithKline (GSK) agreed to donate 50 million doses of the vaccines for free.[69] This generosity has to be viewed against GSK's predicted profit of £3 billion on H1N1 drugs.[70] While the different approaches could be indicative of the respective corporate social responsibility (CSR) policies of the companies, an examination of such would indicate otherwise.

Both Novartis[71] and GSK[72] have CSR policies that address the issue of global health care. In fact, with such idyllic policies, it can be questioned why adopting a utilitarian approach is necessary, as it appears that both companies are already addressing the issue of inaccessibility to drugs. However, the theories behind

[65] Berle A, 'Corporate Powers as Powers in Trust' (1931) 44 Harv. L. Rev 1049
[66] Taeusch C, 'What is "Captialism"?' (1935) 45 Intl' Journal of Ethics 221, 222
[67] Jack A, 'Novartis says 'no' to free flu vaccines' *Financial Times* (London, 15th June 2009)
[68] 'Novartis: Why we can't give free flu vaccine to poor countries' *Pharmexec.com* (21st July 2009)
[69] *ibid*
[70] Wachman R, 'Drugs giant GlaxoSmithKline predicts swine flu gold rush' *The Guardian* (London, 22nd July 2009)
[71] 'Access to Health care' (*Novartis) <http://www.novartis.com/corporate-responsibility/access-to-healthcare/index.shtml>* accessed April 1st 2013
[72] 'Responsibility' (*GlaxoSmithKline)* <http://www.gsk.com/responsibility.html> accessed April 1st 2013

CSR must be borne in mind when evaluating these policies. The most dominant theory is neo-liberal, which promotes CSR insofar as such policies will promote the success of the company, by increasing share prices.[73] As such, CSR is not used by companies because of philanthropic motivations, as Neo-Keynesian theory would advocate,[74] but rather because of economic motivations, in accordance with shareholder primacy and the broader ideology of capitalism.

This ideology explains why the R&D devoted to drugs for endemic use is virtually stagnant.[75] Advances in malaria drugs only became available when people from developed countries started travelling to countries where they could be susceptible to this disease and because of the threat it poses to foreign-based U.S. military,[76] clearly indicating the financial incentive of pharmaceutical companies. Furthermore, drugs are available for HIV/AIDs "because the disease exists in rich countries with enforceable patents, providing incentives for developing medicines."[77] The connection between profit and R&D, which has been expounded throughout this article, serves to prove why patent protection should be strengthened for drugs for endemic consumption. Although compulsory licenses are rarely used, drug companies still have to consider the risk that one may be invoked for a new drug, thereby disallowing them to recoup their R&D. Despite the fact that the provisions on compulsory licensing provide for remuneration for the patent holder, the opposition faced by the invocation of these Articles, as illustrated by the examples of Rwanda and Thailand, indicate that pharmaceutical industries find this to be insufficient.[78] As already acknowledged, it may seem counterintuitive that patent protection should be strengthened for these types of drugs when persons in DCs cannot afford patented drugs. This is an important consideration that will be addressed in the recommendations section by considering what strengthening patent protection would entail, and how to overcome the affordability problem.

Governance in Developing Countries

There are many factors that have contributed to the current disadvantageous economic and social circumstances in DCs. While historical events have contributed to their existence, factors that are still present today can affect any measures taken when applying the utilitarian calculation. One of the most pressing issues is corruption. Transparency International ranked countries based on level of corruption with 100 being the least corrupt and 0 being the most.

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[73] Broomhill R, "Corporate Social Responsibility: Key Issues and Debates," Dunstan Paper No.1/2007

[74] *ibid*

[75] Story A, *The Oxfam "access to essential medicines" project: some patent and research and development issues* (Oxfam International, Oxford UK)

[76] 'Part 3: Advancing Toward Better Malaria Control - Research and Development for New Antimalarial Drugs' *Saving Lives, Buying Time: Economics of Malaria Drugs in an Age of Resistance* (Washington, DC: The National Academies Press, 2004),
'Malaria Prevention Guidelines' (*Public Health England)* <http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1195733823080?p=1191942128258> accessed April 24th 2013

[77] Maskus K, 'Ensuring Access to essential medicines: some economic considerations' (2002) 20 Wis. Int'l L. J. 563 , 564

[78] Harris D, 'TRIPS after fifteen years: success or failure, as measured by compulsory licensing' (n32) 367, 383-393

Notably, many DCs that could benefit from increased accessibility to drugs were given low scores, for example, Swaziland received 37, India 36, Nigeria 27 and Somalia 8.[79] The implication of receiving such low scores is that financial measures are likely to be undermined by bribery and theft.[80] Considering that it is estimated that "80% of non-salary health funds never reach local facilities",[81] handling of finances needs to be carefully considered in the calculation.

Further exacerbating the problems of corruption are budgetary issues. Many DCs that are most in need of drugs have a low gross domestic product and large population.[82] Even if patent protection was granted to encourage R&D, it would have to be determined whether the government would be able to purchase the patented drugs. If this is an insurmountable challenge, there will be no change in the status quo for drugs for endemic consumption. Consequentially, the recommendation to lower prices for drugs for worldwide consumption for DCs will be met with greater hostility.

Even without these problems, there is the issue of distribution. If a deal is made and drugs for endemics are produced, there is no guarantee that these drugs will be properly distributed. Many DCs have inadequate health facilities, resulting in portions of the population being unable to access health care. Furthermore, different cultural and religious beliefs can be manifested in a rejection of modern medicine,[83] meaning that the value of health will not be fully maximised. Where patent protection is only one of many barriers to access to medicines,[84] the proposals in this article may not effect any change for some countries. However, it must be acknowledged that these vitiating factors are unavoidable, and as such no calculation will be perfect.[85]

Taking into consideration these contextual constraints, applying utilitarianism will, in so far as possible, mould patent law in a way that is conducive to maintaining and potentially increasing the profit of pharmaceutical companies. This will be achieved by expanding their markets through differential pricing for

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[79] 'Corruption Perception Index 2012) (*Transparency International)* <http://www.transparency.org/cpi2012/results> Accessed 1st April 2013

[80] 'Health' (*Transparency International)* < http://www.transparency.org/topic/detail/health? Accessed 1st April 2013

[81] *ibid*

[82] 'GDP per capita' (*The World Bank)*
< http://data.worldbank.org/indicator/NY.GDP.PCAP.CD> accessed May 1st 2013

[83] Maskus K, 'Ensuring Access to essential medicines: some economic considerations' (2002) 20 Wis. Int'l L. J. 563

[84] Attaran A., 'The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options under WTO Law' (2002) 12 Fordham Intell. Prop. Media & Ent. L.J. 859, 886

[85] This issue was highlighted by a submission from the EU at the Doha Round: "Any solution that may result from the current process in the TRIPS Council will not provide the universal panacea of solutions for the problem of access to medicines. Improving access to medicines requires a mix of complementary measures in different areas…" - Draft Communication from the European Communities and their Member States to the TRIPS Council. Concept Paper for Approaches Relating to Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health at para 4

drugs for worldwide consumption and creating new incentives for drugs for endemics, which in turn enhances the health value of DCs. Thus, the problems of access and availability are addressed by a financially viable proposal that will now be elaborated.

Drugs for Endemics

Applying utilitarianism to patent protection would first entail abandoning compulsory licensing under Article 31 and 31bis thereby strengthening patent protection. A cursory examination of this provision would lead one to believe that the health value is being promoted through encouraging access. However, the availability of compulsory licensing has acted as a deterrent to pharmaceutical companies that desire security over their investments. This fear may be unfounded due to limited instances of invocation, but in order to promote the health value, production of these types of drugs need greater incentive. Thus, abandoning compulsory licensing would promote financial value by ensuring pharmaceutical companies that whatever investment they make into these types of drugs will be protected. This would be one measure that could possibly increase R&D for drugs for endemics, but it will not work unless the cost issue is addressed, due to the current market regime that focuses on profitability as previously discussed.

While abandoning compulsory licensing would provide the desired level of security, this initiative will make no difference to the present situation if the pharmaceutical companies do not have a viable market. As such, governments will have to take an active role in covering the costs of these drugs and adjusting budgetary needs to suit. Without government support, it is unlikely that pharmaceutical companies will find a satisfactory market in DCs due to rampant poverty. This will be one of the major hurdles to overcome due to corruption in DCs that has been previously addressed. Government contributions are necessary in promoting the financial value, which in turn would promote the health value. Furthermore, since the cost of patented drugs is high, charitable organisations should contribute to the costs of buying these drugs. It would be better if any charitable donations were sent directly to the pharmaceutical company, as this would avoid susceptibility of money being misused due to governmental corruption. Transparency International would also be required to monitor governments. For this to be a realistic solution, there would have to be on-going dialogue between the pharmaceutical companies, governments and charitable foundations. While there are a number of diseases that can be researched, governments should prioritize their needs, also based on a utilitarian calculation, by determining which disease should be treated in order to most effectively increase the health value.

In order to make this situation attractive to pharmaceutical companies, a tendering process is suggested. Countries could collaborate with the WHO to invite pharmaceutical companies to make proposals based on estimated costs of developing a new drug for an identified disease. Before this is done, DCs should provide insight into realistic financial availability, so pharmaceutical companies could consider this during the tendering process. Ultimately, budgetary constrains would be the major barrier in applying the framework here, as

inability to fund would prevent the desired increase in financial value and consequently prevent an increase in the health value.

Drugs for Worldwide consumption

Drugs for worldwide consumption should be met with a different approach as these drugs, for disease such as HIV/AIDS, are sold all over the world.[86] The difference between these drugs and drugs for endemics is that the pharmaceutical companies have a stable market from which they will continue to generate profit. In order to promote the health and finance values, it is recommended that patent protection is maintained, but differential prices are applied to drugs in DCs and developed countries. In 1970, before TRIPS, India had stopped issuing patents for pharmaceuticals, allowing generic manufacturers to provide cheaper versions of drugs.[87] However, the observance of patent law via TRIPS has led to drugs becoming unaffordable. This issue is the crux of the argument for differential pricing. Since patented drugs are often unaffordable in DCs, how much money is really being lost? Generic manufacturers making money does not equate to pharmaceutical companies losing money if the patented version was unaffordable, as there would be low sales revenue from DCs anyway, resulting in detrimental effects to both finance and health values. A comprehensive study would need to be undertaken to consider what pharmaceuticals are earning now on patented drugs, to consider how a price reduction would affect profits. If it is found that profits would increase, differential pricing is a viable suggestion, as both the finance and health values are increased.

However, this would be subject to problems as according to Scherer and Watal, pharmaceutical companies may prefer to sell drugs to wealthy patients in small quantities rather than making drugs more affordable and thus sell larger quantities, as the former could be more profitable overall.[88] Again, a study would have to consider these issues in order to make the application of this framework realistic. Additionally, DCs that will benefit from this differential pricing should remove tariffs that can increase pharmaceutical prices by as much as 20% as is the case in Africe for example.[89] This can be done through a multilateral agreement under GATT Articles II and XXVIIIbis[90]. The anti-dumping provision[91] (related to differential pricing) of Article VI GATT should also be amended to include an exception for pharmaceutical companies. It is unlikely that this provision would cause a problem as governments of DCs will

[86] Maskus K, 'Ensuring Access to essential medicines: some economic considerations' (2002) 20 Wis. Int'l L. J. 563 , 564

[87] Cook D, 'India's cheap drugs under patent threat' *BBC* (London, 15 February 2007)

[88] Scherer F, Watal J, *Post-TRIPS Options for Access to Patented Medicines for Developing Countries* (WHO Commission on Macroeconomics and Health, 2001)

[89] Bale H, Consumption and Trade in Off-Patented Medicines, Commission on Macroeconomics and Health Working Paper No. WG 4: 3 (May 2001)

[90] Attaran A, 'The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options under WTO Law' (2002) 12 Fordham Intell. Prop. Media & Ent. L.J. 859, 883

[91] Article VI GATT – Dumping – "products of one country are introduced into the commerce of another country at less than the normal value of the products…when destined for consumption in the exporting country"

not object to more accessibly priced drugs, but it is better to make proposals consistent with existing law to avoid any hindrances.

A further limitation that needs to be addressed is the problem of arbitrage[92]. This would undermine the intended purpose of the measures suggested, and would furthermore affect profitability in developed countries which would be met with opposition by pharmaceutical companies.[93] To prevent this from occurring, packaging should indicate drugs that are intended for sale in a certain country, and arbitrage could be made sanctionable under TRIPS, with penalties both for the importing and exporting countries. But unavoidably there would be a question of fairness as it could be asked why somebody in India should pay less than somebody in America for drugs from the same company.[94] It should be emphasised that the utilitarian framework, unlike deontological ethics, does not consider actions based on notions of fairness. The goal here is to maximise the values of health and finance for the parties concerned. Even if the public of developed countries was considered, lowering drug prices in DCs neither adds nor diminishes value for them.

Criticism of utilitarianism

In addition to the socio-economic constraints that have been discussed above, it is necessary to acknowledge the criticisms of the utilitarian theory and furthermore, how these criticisms will affect this framework for international patent law.

In the first place, the complexity of maximizing value has led to criticisms of utilitarianism, as Mill fails to explain whether we maximise the total value of a group or the average good per person.[95] If total value is maximised, the value could be concentrated in a small number of individuals. On the other hand, if the average is sought, there would be more even distribution but each individual might end up with a mediocre level of value. The problem with this particular criticism is that it assumes value is limited, whereas in reality increasing value for some does not always result in a decrease in value for others. In the framework discussed, the increase of the health and finance values are intrinsically linked as it is suggested an increase to finance will in turn increase the health value. As such, the criticism of Mill is not applicable here because increasing value for pharmaceutical companies results in a co-related increase for DCs. A more suitable criticism is that based on the suggestions, value cannot be inversed. That is, the finance value unavoidably remains the focus of the framework as it is unlikely that seeking to promote health will in turn increase finance. This position can lead to questions of whether this framework suggests a genuine change or merely cloaks the current approach in broader terms. It is

[92] Attaran A, 'The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options under WTO Law' (2002) 12 Fordham Intell. Prop. Media & Ent. L.J. 859, 879

[93] *ibid*859, 879

[94] Fisher W, Syed T, 'Global Justice in Health Care: Developing Drugs for the Developing World' (2007) 40 Uc Davis L. Rev 581

[95] Sidgwick H, 'The Methods of Ethics' (Hackett, 1981)

argued that this is a genuine change because the current legislation with ineffective provisions for promoting access and availability, places emphasis on finance without making a bona fide effort to increase health, whereas the utilitarian framework suggested is inclusive of both values and strives to seek a realistic balance of the different interest groups.

Another criticism of utilitarianism is that the theory can be seen as supererogatory as it requires parties to take measures that may be considered onerous in order to promote value[96], a criticism that would be favoured by the pharmaceutical companies. Such obligation does not sit comfortably with shareholder primacy as there is no legal obligation to take stakeholders into account, and it is unlikely that companies will embrace a moral argument. This author accepts that this criticism as valid. Hence, the focus has been placed on promoting finance in a way that will enhance health, as discussed above. By using this approach, there is less likely to be objections from pharmaceutical companies that would be unlikely to embrace morally based obligations.

Justification of Utilitarianism

Acknowledging that there are criticisms to this theory, it also has to be considered why utilitarianism is the most appropriate ethical theory to apply to TRIPS. Utilitarianism is more appropriate than other ethical justifications because, firstly, as already discussed, deontological ethics would require pharmaceutical companies to be unrealistically altruistic. Likewise, other ethical theories such as feminist ethics and virtue ethics are inappropriate because they fail to accommodate the economic aspect of the current issue. Feminist ethics consider interactions based on personal relationships, and are thus totally unsuited to the situation at hand,[97] and virtue ethics are also too personal as it considers the role of character and virtue in considering whether an act is morally right.[98] Utilitarianism, on the other hand, considers the impact of an action on a group of people, without considering whether the act is intrinsically good, but rather considers the value produced by the act.[99] In doing so, utilitarianism assumes an impersonal position, more suited to the situation at hand.

In addition to its suitability when compared to other ethical principles, adopting a utilitarian ethical approach can be informed by one of the existing justifications for patents that is not currently advanced by pharmaceutical companies or DCs; the public benefit justification. Utilitarianism in isolation would be insufficient in justifying change as any change would have to consider existing theories for patents in order to comply with current intellectual property ideology. Failing to do so would make proposals susceptible to criticism for lack of a solid theoretical base. The public benefit justification purports that patents are justifiable on the basis that they result in technology being introduced to the

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[96] 'Deontological ethics' (*Stanford Encyclopedia of Philosophy)* <http://plato.stanford.edu/entries/ethics-deontological/> accessed April 27th 2013

[97] Driver J, 'Ethics- the fundamentals' (Blackwell publishing, 2010) ch 9

[98] *ibid* ch 8

[99] 'Consequentialism' (*Stanford Encyclopedia of Philosophy)* <http://plato.stanford.edu/entries/ethics-deontological/> accessed April 27th 2013

public, which consequently enhances welfare.[100] According to utilitarian theory, property rights are justified insofar as they benefit society.[101] In adopting a utilitarian approach, the public benefit will be promoted as accessibility to drugs will increase. Such an approach would address the concerns raised by those for and against pharmaceutical patents, as vital R&D interests remain protected, but at the same time, drugs are made more accessible, benefiting DCs.

Utilitarianism can also be considered against Article 7 of TRIPS which details the objectives and states that intellectual property rights should be protected and enforced "...to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[102]" This use of the term "mutual advantage" indicates that both parties should benefit from the TRIPS provisions, but as has been illustrated, this does not appear to be happening. On the one hand, there are the DCs who cannot afford patented drugs, and on the other, there are the pharmaceutical companies that need to recoup the costs of R&D. In order to facilitate mutual advantage, the distinction has to be made between drugs for worldwide consumption and endemics when applying the utilitarian calculation. Although Article 7 does not specify that the advantage should be maximised overall, it does recognise the values of health and finance (social and economic welfare) and the two parties concerned. The utilitarian calculation is thus appropriate because promoting value for different groups is an objective of TRIPS.

With the criticisms and justifications in mind, international patent law under a utilitarian framework would consider the values of health and finance. There have been no barriers in promoting the finance aspect under the current regime due to the way in which TRIPS developed and the measures that have been used by economically powerful countries to circumvent and discourage invocation of provisions that were supposed to help ensure access. As to availability, the current regime failed to address this problem, which is not surprising due to the tenuous connection with profit and drugs for endemics that has been elaborated on. Thus, under the utilitarian framework, it is suggested that differential pricing is applied to drugs for worldwide consumption as these drugs will continue to be produced due to the potential for profit. Pharmaceutical companies should increase their market potential by using differential pricing for DCs, but strict measurements would have to be taken to prevent parallel importation. Compulsory licensing should be abandoned for drugs for endemics and governments should collaborate to contribute to funding, to create incentive for pharmaceutical companies. Thus, international patent law for pharmaceuticals would be partitioned into two different categories; drugs for worldwide consumption and drugs for endemics. This portioning would better realise the unique problems of access and availability. Although the desired end result is the same, that is, an increase in health value overall, the barriers posed by each problem are different and thus should be treated as such.

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[100] Fisher W, 'Theories of Intellectual Property' in *New Essays in the Legal and Political Theory of Property* (Cambridge University Press, 2001) pp 15
[101] Dibble W, 'Justifying Intellectual Property' (1994) UCL Jurisprudence Rev. 74, 83
[102] TRIPS Article 7

CONCLUSION

In conclusion, a utilitarian interpretation of the TRIPS agreement in relation to patents for pharmaceuticals is desirable because both the manufacturers and consumers in DCs stand to benefit from it. This theory is well suited to the capitalist ideology that governs global markets as, unlike other ethical theories, it considers what action brings about the most value rather than the intrinsic morality of the action. The application of utilitarianism presents a realistic reconciliation of the two main conflicting interests, with mutually beneficial results that can be implemented for the advancement of both pharmaceutical companies and developing countries. This outcome reflects the public benefit justification for patents, giving credibility to this approach.