

*Investigating New Models of Pharmaceutical Innovation  
to Protect the Human Right to Health*

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## **Abstract**

*The TRIPS agreement has been widely criticised for its effect on limiting access of essential drugs to people in developing countries. This has led lawyers to examine the ways in which states can use the 'flexibilities' in TRIPS, such as compulsory licensing, to alleviate some of TRIPS' negative effects. This essay outlines the argument that the intellectual property model itself is flawed, and requires investigation of alternative models. This is because the patent system, as applied to pharmaceutical innovation, has failed. It is an economically inefficient way to correct the market failure of the undersupply of innovation. It also fails to create incentives for the creation of drugs that are needed the most. By allowing for monopoly pricing, it also drives up the prices of essential drugs and hinders access to these drugs to the developing world. This paper examines some of the key problems associated with the patent system. It then examines some of the alternatives models that have been put forward to create incentives for pharmaceutical innovation, such as Advanced Market Commitments and prizes. I conclude that a form of prize system, based on the therapeutic benefit of the drug, is likely to have a greater effect in making new medicines accessible to the developing world.*

Under the current TRIPS regime, the inventor of a new drug is able to apply for a patent for that drug, which will give the owner of the patent a monopoly right. The patent holder can then charge considerably higher than marginal cost for the drug. This is the main reason behind the intense criticism of the current patent system. Since it drives up the costs of certain drugs, it denies access to medicines to patients in the developing world who are unable to afford the high prices for patented drugs. The criticism of this system has been most intense in relation to the high prices charged for HIV/AIDS drugs in the developing world. Although there are many reasons being the lack of access to drugs in the third world, TRIPS has been targeted as one of the reasons behind prohibitive pricing of essential medicines.

The argument in defence of TRIPS, however, is that patents are the only way to create incentives for research and development (R&D). Without the patent, it is argued, pharmaceutical companies would have no incentive to invest the millions of dollars required to develop and test new drugs. This is because without the protection of a patent, a company could easily copy or reverse-engineer the drug and sell it without having to pay for the research, testing etc. The benefit of the patent is that it corrects the typical market failure associated with the undersupply of innovation. Although the consumer must pay higher prices for the drug, the patent system arguably leads to the

development of new and better drugs which benefit society as a whole. The pharmaceutical companies, driven by the financial incentive of developing a new patentable drug, invest billions of dollars into developing drugs that otherwise would never be developed. Furthermore, the risk associated with the drug development remains entirely within the private sector — the drug companies bear the cost of any failure. The patent system, it is argued, is the most efficient way to create incentives for pharmaceutical research.

Although patent law is a tool to encourage innovation, it is not the only, nor the most efficient way to do this. Proponents of the current patent system often frame the system as the only way to encourage research. Matsushita *et al* argue that rather than being an obstacle in developing countries, TRIPS is a key part of fulfilling the right to health:

The TRIPS agreement and the WTO are *essential* to ever begin to tackle health in the developing world. The TRIPS Agreement provides global patentability, which is part of the solution because it gives private pharmaceutical companies an incentive to develop medicines for diseases in tropical and other developing areas.<sup>1</sup>

However, the patent system is only one of many possible ways of encouraging and rewarding innovation. There are alternate models for encouraging research that are arguably more efficient, lead to better health outcomes and do not lead to some of the problems associated with the current patent system. Furthermore, Matsushita *et al* offer no evidence whatsoever to back their assertion that the patent system ‘encourages research for diseases in tropical and other developing areas’. According to *Médecins Sans Frontières*, pharmaceutical research has neglected tropical diseases, saying that ‘[o]f the 1,393 total new rugs approved between 1975 and 1999, only 1% (13 drugs) were specifically indicated for a tropical disease.’<sup>2</sup>

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<sup>1</sup> MATSUSHITA *et al*, “The World Trade Organisation: Law, Practice and Policy”, 718 (OUP, Oxford 2006).

<sup>2</sup> ‘Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases’, *Médecins Sans Frontières* Access to Essential Medicines Campaign and the Drugs for Neglected Diseases Working Group I, September 2001. <<http://www.msf.org/source/access/2001/fatal/fatal.pdf>>.

Firstly, is the current system an *efficient* way to create incentives for research? Consumers are paying billions of dollars in higher costs in pharmaceuticals to pay for research into new drugs. It is estimated that in 2005, prices were \$400- \$500 billion higher due to patent monopolies.<sup>3</sup> In the same period only \$51 billion was allocated to R & D. Love and Hubbard argue that '[c]onsumers pay eight or nine dollars in higher prices to stimulate one dollar in R&D spending.'<sup>4</sup> The patent system does not seem to be an efficient way of stimulating research. As Stiglitz argues

[w]e cannot expect innovation without paying for it. But are the incentives provided by the patent system appropriate, so that all this money is well spent and contributes to treatments for diseases of the greatest concern? Sadly, the answer is a resounding "no."<sup>5</sup>

The patent system also distorts the type of research that is undertaken. An optimal system of stimulating research would be one that creates incentives to invest in drugs that had the greatest therapeutic benefit for society. That is, research would be undertaken into the most deadly diseases and those that affect the most people. However, the current patent system seems to encourage research into drugs that have *less* therapeutic benefit. For instance, much of the research undertaken is on 'me-too' drugs, which are drugs that are similar to existing patented drugs, yet are different enough to allow a new patent. This kind of research does nothing to relieve the global disease burden, but increases the profits of pharmaceutical companies who attempt to evergreen their patents.

Possibly the strongest criticism of the current patent system is the fact that it creates no incentives to research drugs that will have the greatest therapeutic benefit for the developing world. The so called 'neglected diseases' such as malaria and tuberculosis receive relatively low levels of research investment from the private sector. There are a few reasons for this. If a company were to develop a new vaccine for malaria, for

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<sup>3</sup> LOVE & HUBBARD, "The Big Idea: Prizes to Stimulate R&D for New Medicines", The Ruby Hutchison Memorial Address, KEI Research Paper, no.1, (2007): 'The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) claims that global private sector investments in R&D were about \$51 billion in 2005, or less than percent of global sales. This is what we get for the \$400 to \$480 billion in higher prices.'

<sup>4</sup> LOVE & HUBBARD, *Supra*, note 3.

<sup>5</sup> STIGLITZ, "Prizes, Not Patents", Project Syndicate, 2007.

<[http://www.policyinnovations.org/ideas/commentary/data/prizes\\_not\\_patents](http://www.policyinnovations.org/ideas/commentary/data/prizes_not_patents)>.

instance, it would be unlikely that the company could re-coup its investment. Although there are millions of people who need malaria medication, they are not viable customers for the pharmaceutical companies, since people in the developing world would generally not be able to pay for it. If a company were to develop such a drug, there would also be pressure on the company to sell it cheaply or to give it away. There is therefore a kind of perverse incentive preventing research into the types of drugs that the world needs the most.

The patent system encourages development of the types of drugs with the least social utility. For instance, pharmaceutical companies invest in ‘lifestyle’ drugs for hair loss or impotence that have markets in the West and will be used by consumers many times over the course of their lives. In contrast, there is less incentive to create an effective vaccine that may be used once in a lifetime. An economic study of the IP system concluded that there is no link between the disease burden and the allocation of spending on R&D:

Indeed, there is evidence that demand in some countries actually has a negative effect in motivating drug development. The transmission mechanism of this perverse effect is cross-country importation policies and the pricing formulas of some countries that are based on the lowest price at which the drug is sold worldwide. These policies make it unprofitable to develop drugs to treat diseases where most sales will be in low-price countries.<sup>6</sup>

The current system, therefore, is not an efficient way to encourage research and innovation in the pharmaceutical industry. Moreover, there are problems with the patent system that affect the pharmaceutical industry as well. Hollis points out that:

The patent monopoly system does not serve the pharmaceuticals market very well – it leads to misdirected innovation, to substantial deadweight losses, to counterfeit drugs, to price controls, and arguably to excessive marketing and unnecessary risks to patients.<sup>7</sup>

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<sup>6</sup> CIVAN & MALONEY, “The Determinants of Pharmaceutical Research and Development Investments”, Contributions to Economic Analysis & Policy, vol. 5, no.1, (2006).

<sup>7</sup> HOLLIS, “An Efficient Reward System for Pharmaceutical Innovation”, Department of Economics, University of Calgary Institute of Health Economics, 17 January (2005) <<http://econ.ucalgary.ca/fac-files/ah/drugprizes.pdf>>.

Another problem is the level of litigation by pharmaceutical companies asserting their patent rights, which has increased significantly in the past decade. The patent system, although it does create incentives for R&D, is by no means the most efficient or effective way of doing this. It encourages research in the wrong fields, which means that there is less innovation on the types of diseases that have the greatest effect on humanity.

### **Responding to the failure of TRIPS**

Given these problems with TRIPS, what has been the response from human rights groups and the developing world? Rather than examining new models, much of the debate on TRIPS has focused on the way in which states can limit the negative effects of the TRIPS agreement. Given the fact that TRIPS can sometimes conflict with the enjoyment of the right to health, human rights lawyers have examined the ways in which States can give greatest effect to this right within the existing TRIPS framework.<sup>8</sup> This has led to a great deal of work on the ‘flexibilities’ that are allowed within the agreement, and the different ways that developing states can increase access to medicines.

The existing literature on TRIPS and the right to health propose two types of solutions. The first is to work within the existing TRIPS framework to find ways of balancing intellectual property rights with the right to health. The problem, according to this view, is not TRIPS *per se*, but the fact that developing countries do not have the resources and experience needed to implement the flexibilities contained in TRIPS.<sup>9</sup>

The claim that the TRIPS agreement and the WTO are blocking access to medicines in poor countries is demonstrably false. There are enormous political economic and structural problems that must be solved to make such access a reality. The TRIPS

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<sup>8</sup> KHOR, “Patents, Compulsory Licence and Access to Medicines: Some Recent Experiences”, Third World Network, February 2007.

<sup>9</sup> CULLET, “Patents and medicines: the relationship between TRIPS and the human right to health”, 79 (1) *International Affairs*, 139, 154 (2003) ‘Recent debates have focused mostly on the extent to which developing countries should be able to adapt the intellectual property rights system in situations where major problems have arisen. This does not address the question of whether the introduction of process and product patents in all WTO member states is generally reconcilable with the measures that states must take to foster the realisation of the right to health.’

agreement is not culprit, though it is an easy scapegoat because the real, underlying problems are hidden, complex and perhaps intractable.<sup>10</sup>

Matsushita *et al* argue that the flexibilities contained in TRIPS are enough to secure the right to health and that developing countries simply need assistance in implementing IP law. They argue that developing countries can and should use steps that are allowed under WTO law such as compulsory licensing, price controls or parallel imports to increase access to necessary drugs.<sup>11</sup>

However, there are a number of problems with seeing the TRIPS ‘flexibilities’ as a solution. The use of such flexibilities does nothing to solve the underlying problem that R&D is being focused on the wrong areas. Indeed, the flexibilities may even discourage investment in Third World diseases because pharmaceutical companies may view these as areas where their intellectual property rights will be least protected. This is because

compulsory licensing, especially if it becomes more common, brings back the first market failure of undersupply: Pharmaceutical companies will tend to spend less on the quest for essential medicines when the uncertainties of successful development, testing, and regulatory approval are compounded by the additional unpredictability of whether and to what extent companies will be allowed to recoup their investments through undisturbed use of their monopoly pricing powers.<sup>12</sup>

The flexibilities are also only used in response to ‘emergencies’ and do not combat the underlying problems associated with access to drugs in the developing world. Furthermore, the use of flexibilities as a solution to the problem seems to deny the importance of the human right to health. Cullet argues that ‘the fact that developing countries can use loopholes or unclear language in TRIPS to pursue the realisation of the right to health is unsatisfactory in so far as the central concern of health is consistently framed as an exception to a property right’.<sup>13</sup>

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<sup>10</sup> MATSUSHITA, *supra*, note 1, at 718

<sup>11</sup> MATSUSHITA, *supra*, note 1, at 710.

<sup>12</sup> POGGE, “Intellectual Property Rights and Access to Essential Medicines”, Policy Innovations, (2007) <[http://www.policyinnovations.org/ideas/policy\\_library/data/FP4](http://www.policyinnovations.org/ideas/policy_library/data/FP4)>.

<sup>13</sup> CULLET, *supra*, note 9, at 155.

The second view sees TRIPS as a fundamentally flawed agreement, and that ‘flexibilities’ such as compulsory licences only (slightly) mitigate the effects of an unjust global regime. It is this second view that is receiving growing attention within academic and policy circles. As the global health crisis continues, academics, politicians and NGOs are beginning to look at alternate systems that both encourage innovation but also lead to outcomes that are more conducive to realising the human right to health. Philosopher Thomas Pogge is one of the leading advocates of investigating global institutional reform, arguing that

It makes sense then to look for a more systemic solution that addresses the global health crisis at its root. Involving institutional reform, such a systemic solution is politically more difficult to achieve. But, once achieved, it is also politically much easier to maintain. And it pre-empts most of the huge and collectively inefficient mobilizations currently required to produce the many stop-gap measures, which can at best only mitigate the effects of structural problems they leave untouched<sup>14</sup>

A problem in this debate is the widely held view that patents are the only way of encouraging innovation. It presents a false dichotomy which supposes that there is a choice to be made between creating incentives for drugs and protecting human rights. In reality, there are possible policy alternatives for encouraging R&D that also allow greater access, affordability and quality of drugs. The challenge, then, is to develop a system that aligns these interests.

### **Alternative Models- Reforming or Replacing TRIPS**

The alternate models can be described broadly into two fields: so called ‘push’ and ‘pull’ models. ‘Push’ models intend to encourage R&D by using public or philanthropic funds to invest in research, either by private or public institutions. ‘Pull’ models intend to encourage innovation by offering a prize or some other financial incentive. The patent system itself is form of ‘pull’ model as it offers the prize of a patent right and the monopoly over the drug.

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<sup>14</sup> POGGE, “Boosting Innovation and Access”, Patent2, <[http://www.patent2.org/files/pop\\_dublin.pdf](http://www.patent2.org/files/pop_dublin.pdf)>.

The pull models attempt to 'offer the opportunity to harness the ... energy and creativity of the private sector. ... It is an open, transparent approach that is difficult for special interest to capture'.<sup>15</sup> The pull model, therefore, is still a market-oriented approach that sees that the market system as the best way to develop new drugs. However, in these models, the type of reward offered is not a patent right.

One reward system, advocated by Stiglitz and others, includes a system of prizes that are set up to reward pharmaceutical companies for developing new drugs. Stiglitz proposes

A medical prize fund that would reward those who discover cures and vaccines. Since governments already pay the cost of much drug research directly or indirectly, through prescription benefits, they could finance the prize fund, which would award the biggest prizes for developers of treatments or preventions for costly diseases affecting hundreds of millions of people.<sup>16</sup>

The prize can either be one developed before or after the creation of the new drug. For instance, one way would be to set up a prize to find a vaccine for a specific disease. This would mean that a company would have to meet a set of technical criteria before being awarded the prize. Another option is to calculate the prize based on the therapeutic benefit of the drug, calculated *after* the drug has been created. This leaves the type of innovation up to the private sphere, allowing companies to develop the types of drugs in which they have an advantage or specialisation. The benefit of prizes after the development of the drug is that they do not overly prescribe the types of drugs to be developed, allowing greater innovation.

Another alternative is to use the model of Advanced Market Commitments (AMCs) where a government or other organisation enters into a contract to guarantee a market for a drug once it has been developed. The most famous of these has been the guarantee by the Bill and Melinda Gates Foundation, which has an AMC worth US\$ 1.5 billion to develop vaccines for pneumococcal disease. A problem with AMCs is

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<sup>15</sup> HOLLIS, *supra* note 7.

<sup>16</sup> STIGLITZ., *supra* note 5.

that they are also often overly prescriptive in the type of new drug that is to be developed. This means that

is that it is necessary, in advance of a given vaccine being developed, to describe its technical profile. This automatically limits the flexibility of the AMC: if a vaccine is very close to good enough, it gets nothing, even if it is the only product available.

Pogge intends to avoid this problem by leaving the decisions entirely up to the market. His model is a version of the prize model. He describes it as a 'track 2' patent, as it would be designed to exist as a patent alongside and not instead of the existing system.

In contrast to prizes, which rely on planners and experts to set the direction of R&D, our plan is a market solution that leaves it to potential innovators — better informed and better motivated than planners — to decide how they can make the most cost-effective contributions.<sup>17</sup>

Under Pogge's plan, a company could give up its monopoly right to a drug but in return could get a new type of patent that would reward a company based on the therapeutic benefit of the drug worldwide. This would be paid for from funds established by a global treaty-backed payment system. The benefit of Pogge's plan is that it seems to align the commercial interests of pharmaceutical companies with the needs of the developing world by creating financial incentives to create accessible and effective drugs.

There are some notable problems with these types of models, however. The main criticism of 'pull' models is that they require a high level of bureaucracy and the use of public funds. This exposes the system to more political interference and the risk of corruption. Furthermore, since they still leave the decisions on R & D entirely up to the pharmaceutical companies, there remains a risk that they will not invest the money required to combat these neglected diseases.

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<sup>17</sup> POGGE, *supra* note 14.

Whereas the ‘pull’ model offers the promise of rewards in the future, ‘push’ models are put forward as a way of directly investing in the creation of new drugs. With a pull model, the risk is taken on the part of the pharmaceutical company. It will invest billions in research and there may be no way of recouping that expenditure. In a push model, the risk is shared between the private and public sphere. If the investment leads to nothing, both the company and the funding institution lose out. However, a push model creates a direct incentive to combat particular diseases rather than simply hoping that the market will develop the drug. Yet like the pull models, it would increase the bureaucratic and financial burden on the state.

Another innovation is using the idea of using ‘patent swaps’ to encourage research into neglected diseases. Companies currently spend research money on extending their patents through creating ‘me-too’ drugs that are similar to existing drugs, just to extend their patents. A system could be developed that allows patents on existing drugs to be extended if a company develops another drug that has a high therapeutical benefit. This could discourage the creation of ‘me too’ drugs, whilst rewarding the creation of new drugs with the ‘prize’ of extended patent rights on existing drugs.

A common element shared by the above models is that they include a great deal of intervention into the market. They can be criticised, therefore, for their high level of distortion into the private market system. However, it must be remembered that the current system is already an extremely distorted system. The patent system distorts the market by imposing monopoly rights which allow companies to charge at above market price. Furthermore, the current system already involves high level of public expenditure. Public funds are already used to fund research either directly or indirectly through insurance schemes, which are affected by the high cost of medicines. Much of the initial research that leads to new medicines are developed not in private labs, but in universities and institutes funded by governments. Furthermore, pharmaceutical innovation should be seen as different from other parts of economic activity, in that the creation of new medicines potentially benefits all humankind. There is a difference between using intellectual property law to protect the author of a book and the inventor of a new life-saving drug, as the drug has far more social utility. For this reason intellectual property law must take into account this social

value of pharmaceutical research, and this justifies the use of public funds to develop new drugs.

### *Conclusion*

Although TRIPS does create incentives for innovation, it is not an efficient system, and it creates incentives for research in the wrong fields. Moreover, the patent system should be seen as one of many possible designs of the global system. I examined some of the main reform proposals. A pull system of prizes, based on the therapeutic benefit of the drug would provide an economic incentive on the part of pharmaceutical companies to invest in the creation of drugs for neglected diseases and allow generic drug companies to sell the drug at much lower prices. Such a system would work best in conjunction with, and should not replace patents. Importantly, this system should be seen as only one part of a broader plan to combat the problem of access to drugs in the developing world. There are still issues in the developing world that impede access to drugs that are not associated with TRIPS— however, these proposals should be seen as part of a broader effort to make life saving drugs affordable to those who need them the most.