

# A PURPOSEFUL PATENT POLICY: REIGNITING THE SECTION 3(D) DEBATE IN THE LIGHT OF INDIA'S INTERNATIONAL OBLIGATIONS

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## ABSTRACT

The policy purposes of patent law in the healthcare sector have proven to be a difficult duo to balance, especially for developing countries. On one hand, strong incentives are required to ensure continual investment in useful and beneficial drug development. Post the TRIPS Agreement, these incentives have mostly been in the form of patent rights. On the other hand, there is a vast population of patients who urgently require life saving drugs that have already been developed. However, patent rights may act as an access barrier in obtaining drugs easily and inexpensively. Reconciling these two requires careful judgment and considerable flexibility in the policy space so as to allow countries to strike a suitable balance in their national laws. In this note, Section 3(d), a unique and controversial provision central to India's patent policy is examined against its alleged violation of India's international obligations under TRIPS. The note demonstrates it to be a legally tenable provision as well as a well crafted policy with creative legal flexibilities ensuring contextual realities of India as a developing country to be factored into its patent regime.

## INTRODUCTION

Patents are used as a mechanism for incentivizing socially beneficial innovations by providing exclusion rights to the innovator over the creation for a certain period of time. These exclusion rights are therefore permitted solely for facilitating the benefits that this process brings out. These exclusion rights, or the patent system is the current and dominating model for encouraging innovation today. From a policy perspective therefore, it is useful to ensure that patents successfully carry out this role, and that a balance is maintained between the social benefits and costs of such incentives. In the field of medicine, this translates to enabling the production of socially beneficial drugs, while ensuring that they are not unnecessarily rendered inaccessible to those who need them.

In 1970, India enacted the Patent Act, 1970<sup>1</sup> with the specific objective of helping the domestic pharmaceutical industry grow, as well as lowering rising product prices.<sup>2</sup> Keeping in view the needs and concerns of the pharmaceutical industry,

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1. Hereinafter the Act.

2. Santanu Mukherjee, *The Journey of Indian Patent Law Towards TRIPS Compliance*, 35 IIC 125, 127-128 (2004).

product patents were not permitted; patent protection periods were brought down to 7 years and a whole host of other measures were brought into being. Owing to these initial measures, the Indian pharmaceutical industry flourished<sup>3</sup>, generic versions of blockbuster drugs were made available at very low prices both domestically and internationally and the ire of major multinational pharmaceuticals was evoked. Taking the oft-quoted example of AIDS drugs, generics from India played a key role in reducing the price of ARV treatment by upto 98%.<sup>4</sup> However, with the signing of the TRIPS Agreement, there arose an obligation to make substantial changes in India's patent system, which till then granted only process patents on pharmaceuticals. This along with substantial internal political pressure, led to the slow but eventual compliance with the TRIPS Agreement in 2005, after 3 amendments to the Act. This was within the 10 year period given for transitioning into TRIPS compliancy. As per TRIPS requirements, and similar to the general standards all over the world, the Act requires novelty, non-obviousness and utility for the grant of a patent. However, there still seems to be considerable discussion over the nature and validity of a clarifying exemption provided in Section 3(d) of the Act. In this note, I aim to demonstrate that the Indian Patent law is both compatible with the TRIPS and is a good policy measure, especially in the context of India as an information importing country where the effective dissemination of information is considered to be significant.<sup>5</sup>

Part I briefly discusses the contours of Section 3(d) of the Act and its tenable interpretation. Part II presents an examination of Section 3(d)'s compatibility with India's international obligations under the TRIPS Agreement. The final part notes the risks which may undermine the success that Section 3(d) has marked for effective usage of policy space under TRIPS.

## **I. LEGAL PROVISION: 3(D)**

In a concerted effort to prevent 'ever-greening' of patents<sup>6</sup>, the Indian legislators inserted Section 3(d) into the scheme of Indian patent law. Looking at the legislative history of the provision, there was active intent to prevent 'ever-greening', however, the legislators did not precisely define the term. Looking at the context in which it was spoken about in the Lok Sabha debates, the term has been understood to mean: *a process of extending the term of patent protection on a drug while making*

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3. See generally J.M.Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 43 UNIV. OF PITTSBURGH SCHOOL OF LAW WORKING PAPER SERIES (2006).

4. *Africa Focus Bull India/Africa: Threat to Generic Drugs*, 7 March 2005, available at <http://www.africafocus.org/docs05/ind0503.php> (last visited on 22 Feb. 2011).

5. See K.E. Maskus, *Normative Concerns in the International Protection of Intellectual Property Rights*, WORLD ECONOMY 387-409 (Sept. 1990) [hereinafter Maskus, *Normative Concerns*].

6. See Lok Sabha Debates, 4th Sess., 14th Lok Sabha, Vol. VII No. 18, 22 March 2005, at 684-685.

*minor changes which do not increase the efficacy of the drug.* This is similar to a definition that the United States Federal Trade Commission has used as well: *a process whereby patent holders seek to unnecessarily extend the period of market exclusivity on a medicine by subsequently obtaining a patent protection on secondary features of existing medicines.*<sup>7</sup> For the purposes of the Section, this is the definition that will be considered. This kind of patent extension results in potentially severe welfare losses due to the minimal benefits received by society with the additional years of exclusion rights.

Section 3(d) of the Act reads as:

*The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least employs one new reactant.*

*Explanation- For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.*

Thus, it consists of three claims of exceptions to patentability, each of which shall be examined individually: *first*, the mere discovery of a known substance which does not result in the enhancement of the known efficacy of that substance; *secondly*, the mere discovery of any new property or new use for a known substance; *thirdly*, the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

#### **A. New Form of a Known Substance**

This element has proven to be the most controversial within the corpus of Section 3(d) and hence this note purposively analyses it in substantial detail. While the debate and discussion around this Section in the domestic as well as international circles has been limited to the pharmaceutical field alone, it is interesting to note that the Section itself does not mention pharmaceuticals or medicines anywhere. However, as regards the scope of this section, it is important to reiterate that the parliamentary debates have clearly indicated the objective as the prevention of ever-greening of patents in pharmacology and the welfare objective of ensuring access to

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7. Park et al., *Access to Medicines in India: A Review of Recent Concerns*, 20 July 20 2009, available at SSRN: <http://ssrn.com/abstract=1436732> (last visited on 22 Feb. 2011).

life-saving medicines to the common man.<sup>8</sup> As a rule of statutory interpretation, a provision must be read in the context of its objective, and it is then arguable that the scope of this provision is clearly limited to the field of medicinal drugs.

At the same time, it is relevant to consider the phrase ‘enhancement of known efficacy’. In light of the objective of improving access to medicines by providing such an exemption, ‘efficacy’ has been read to mean therapeutic efficacy<sup>9</sup> – increase in healing effect of a drug. It is possible to judge the enhancement of efficacy by using comparative details similar to the details used in finding the initial effect of a drug. Bio-equivalence is a commonly used test in the regulation of generic drugs, and can be used here too, to see if there has been enhanced efficacy.<sup>10</sup> Given the technical and scientific nature of medicinal drugs, it is pragmatic not to lay down a strict definition here, but to give leeway in determining on a case-by-case basis by those more qualified to determine it, i.e., the patent office.

The appended explanation to the Section creates a legal fiction by deeming all derivatives of a known substance to be the same unless they significantly differ in properties with regard to efficacy. The Section itself mentions as an exclusion, the mere discovery of a known substance (thus giving scope for the usage of the legal fiction created), which does not result in the enhancement of the known efficacy of that substance. Thus, read together with the explanation, it is clear that unless a substance differs significantly in properties with regard to efficacy, it cannot result in an enhancement of efficacy of that known substance. The Section therefore excludes substances that do not result in an enhancement of therapeutic efficacy, deeming them to be the same substance as the one they were initially derived from.

Read in the light of the object of the Section, i.e., to prevent ever-greening, it is evident that this Section must be operationalized so as to ensure that patents are not granted for merely substituting the formerly patented substance with a derivative, since the matter of switching between different forms of substances is for the most part, considered basic knowledge and is just a matter of testing. If a different form of a substance results in an enhancement of efficacy of the drug, this Section allows such a form to be patented. Conversely, an altered form which does not result in enhanced efficacy of the drug can not be patented. This ensures that a simple transformation of one form to another in the making of a drug does not entitle that drug to be patented, unless and until the new form used has made it more useful by

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8. See Maskus, *Normative Concerns*, *supra* note 5.

9. Novartis AG represented by its Power of Attorney Ranjna Mehta Dutt v. Union of India through the Secretary, Department of Industry, Ministry of Industry and Commerce and Others, 4 MLJ 1153 (2007).

10. See *generally* Guidelines for Bioavailability & Bioequivalence Studies, Central Drugs Standard Control Organization (March 2005).

enhancing the efficacy of the drug. This new more useful drug made with a changed form, is called an incremental innovation, as it builds on an existing innovation. By not allowing patents on ‘ever-greened’ derivatives, the Section encourages incremental innovation which addresses impending public health demands.<sup>11</sup>

Though the Indian Patent Act is the only one which explicitly carves out such exceptions in its patent law, it is certainly not the only one which practices it, other jurisdictions have done a similar job on grounds of novelty and/or obviousness.<sup>12</sup>

For example, in the U.K., though Courts have laid down that acceptance of ever-greening would give patents a bad name<sup>13</sup>, the Court of Appeal in *H. Lundbeck A/S v. Generics (UK) Ltd.*<sup>14</sup>, upheld the validity of a patent where the therapeutic effect of the claimed new form of the previously patented drug was entirely due to the new form. Similarly, in the U.S.A., the law in this regard holds that one must look into the nature and significance of the differences between the prior art and the claimed substance. In order to be patentable, it must be shown that the claimed substance must have superior properties.<sup>15</sup> On the same line, the U.S. Supreme Court in *KSR*<sup>16</sup> has also implied that an invention which was ‘obvious to try’ would not be patentable.

## B. New Use of a Known Substance

The second significant element of Section 3(d) bars the patenting of a mere discovery of any new property or new use of a known substance. It does not however, bar a claim on the process of using a known substance where the new use is based on unknown properties. Even though not universally accepted, a similar provision does exist in the U.S. The ‘doctrine of inherent anticipation’ would bar product patents based on the discovery of a new property or use, irrespective of whether the said property or use was previously known or not known. The E.U. and the U.K. however, allow these ‘Swiss claims’<sup>17</sup>, holding that a new result or use would be

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11. Shamnad Basheer, *The “Glivec” Patent Saga: A 3-d perspective on Indian patent policy and TRIPS Compliance*, available at <http://www.atrip.org/Content/Essays/Shamnad%20Basheer%20Glivec%20Patent%20Saga.doc> (last visited on 20 June 2011).

12. See generally Rajarshi Sen & Adarsh Ramanujan, *Pruning the Evergreen Tree or Tripping Up Over TRIPS? – Section 3(d) of the Indian Patents Act, 1970*, 41 IIC 170 (2010).

13. Les Laboratoires Servier v. Apotex Inc., [2008] EWCA Civ 445. However, the Court did this without addressing what ‘ever-greening’ is precisely, and when a substance is deemed to be ever-greened. It is important to define ‘ever-greening’ as a normative policy matter since all follow on patents are not necessarily inefficient.

14. [2008] EWCA Civ 311.

15. *In re Lohr*, 317 F.2d 388 (CCPA 1963); *In re Grier*, 342 F.2d 120 (CCPA 1965).

16. *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007).

17. Srividhya Raghavan, *A Patent Restriction on Research & Development: Infringers or Innovators?*, 1 U. ILL. J.L. TECH. & POL’Y 73, 84 (2004).

regarded as a functional “technical feature” which would give novelty to the claims.<sup>18</sup>

Section 3(d) in all its three elements, opens with the word ‘mere’ which implies that if there is some added criteria, then the provision may be inapplicable. Therefore, a claim can be made, not just on mere use, but perhaps a combination of uses which may constitute a novel claim.

### **C. Use of a Known Process, Machine or Apparatus**

The Section at first may seem strange, in that it declares known processes, machine or apparatus to be unpatentable, and then gives an exception only for known processes that employ a new reactant. However, its meaning is rather straightforward, as it provides an exception for that particular case. Section 3(d) has a rider clause, which says the use of a known process would be patentable if a new product is created as a result. Therefore, this section impliedly allows a known process to be claimed by describing the new product as part of that process claim.

## **II. ANALYSIS OF TRIPS FLEXIBILITIES AND COMPLIANCY**

Article 27.1 of the TRIPS Agreement<sup>19</sup> provides for 3 standards of patentability – novelty, non-obviousness and industrial application. However the Agreement does not define these terms anywhere, nor does it define what an invention is. Even in the setting of these minimum core standards, by electing to choose general rules rather than specific ones, there is necessarily a broader discretion left to member states to determine the level of stringency that they choose to implement regarding patentability. This is discussed in more detail below.

### **A. Object and Purpose of the Agreement**

Article 1.1 of the Agreement clarifies that while member states must give effect to the provisions of the Agreement, they shall be free to determine the appropriate method of implementing the provisions of this Agreement within *their own legal system and practice*.<sup>20</sup>

Article 3.2 of the World Trade Organization’s Dispute Settlement Understanding (“WTO DSU”) mandates that WTO Members recognize that the WTO dispute settlement system serves to clarify the existing provisions of the covered agreements in accordance with “customary rules of interpretation of public

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18. MOBIL OIL/Friction Reducing Additive III, G 2/88 (OJ 1990, 93).

19. Hereinafter the Agreement.

20. India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/AB/R S.VI (19 Dec. 1997) (the Court held that members were free to determine the appropriate method of implementing the provisions of this Agreement in the context of their own domestic legal system.).

international law.” The general framework for treaty interpretation is governed by Article 31 of the Vienna Convention on the Law of Treaties, 1969 (“VCLT”), which itself is considered customary international law.<sup>21</sup> The Appellate Body and the Panel too have recognized the principles of treaty interpretation enshrined in VCLT to be a part of customary international law and applied the same to interpret WTO obligations.<sup>22</sup>

Taking recourse to the mandate of Article 31 of the VCLT, it states that interpretation must be in accordance with the ordinary meaning to be given to the terms of the treaty, “in their context” and “in the light of its object and purpose”. It is significant to discern this object and purpose of the Agreement, perusing Articles 7 and 8 for the purpose.<sup>23</sup>

Article 7 on ‘Objectives’ emphasizes a balance being struck between technological advancement and social and economic welfare, to the mutual benefit of producers and consumers of technological knowledge. On the other hand, Article 8 on ‘Principles’ also sets forth some of the basic principles of the Agreement, providing that “members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health ... provided such measures are consistent with the provisions of this Agreement.”

Though more strongly present in the field of international human rights<sup>24</sup>, the rule of *in dubio mitius*<sup>25</sup> is useful to be stated here as well. It states that an ambiguous provision in a treaty must be interpreted in a way that least interferes with the territorial and personal sovereignty of a state, or involves less general restrictions upon the parties.<sup>26</sup> Therefore, different national authorities could conceivably reach different, yet lawful decisions regarding the application of the same international provision.<sup>27</sup>

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21. Maritime Delimitation and Territorial Questions (Qatar v. Bahrain), ICJ Reports 1995, at 6.
  22. United States - Standards for Reformulated and Conventional Gasoline, WT/DS2/AB/R, at 17; United States - Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58/AB/R, at ¶ 114.
  23. The Doha Declaration mandates that both art. 7 and art. 8 of the Agreement ought to be used to assess the “object and purpose” of the treaty. See Ernst-Ulrich Petersmann, *International Competition Rules for Governments and for Private Business: A “Trade Law Approach” for Linking Trade and Competition Rules in the WTO*, 72 CHI.-KENT L. REV. 545, 546 (1996). See also The Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2 (14 Nov. 2001), at ¶¶ 2-5 [hereinafter The Doha Declaration].
  24. Douglas Lee Donoho, *Autonomy, Self-Government, and the Margin of Appreciation: Developing a Jurisprudence of Diversity within Universal Human Rights*, 15 EMORY INT’L L REV 391, 457 (2001).
  25. James Cameron & Kevin R. Gray, *Principles of International Law in the WTO Dispute Settlement Body*, 50 INT’L & COMP. L.Q. 248, 254 (2001).
  26. See European Communities - Measures Concerning Meat and Meat Products, WT/DS26/AB/R and WT/DS48/AB/R, at ¶¶ 115-117, 154, 165-167 [hereinafter *EC – Beef Hormones* ABR].
  27. Yuval Shany, *Towards a General Margin of Appreciation Doctrine in International Law*, 16 EUR. J. INT’L L. 907, 910 (2006).

The Agreement was clearly envisioned as promoting technological innovation geared towards societal benefit, in terms of being conducive to social and economic welfare, with special regard to the protection of public health, protecting the intellectual property regime against the abuse of intellectual property rights and reducing trade distortions.<sup>28</sup> Lax patent standards can lead to grant of patents over trivial ‘innovations’. These patents can then block legitimate competition from the market, discouraging further innovation and creating market distortions, effectively harming public welfare.<sup>29</sup>

Section 3(d) of the Act therefore ensures that there are stringent standards of patentability so as to allow exclusion rights more properly proportionate to the benefits it brings to society. Thus by reiterating and clarifying the general standards of patentability specific to the Indian context, this Section protects the object and purpose of the Agreement as is discernable from Articles 7 and 8.

## **B. A Non-discriminatory Provision**

Another reigning concern with Section 3(d) is its alleged discriminatory character in as much as it applies only to new chemical entities. Article 27 of the Agreement mandates that “...patents shall be available for any inventions, whether products or processes, in all fields of technology...” and “...without discrimination as to ... the field of technology...” The question which arises is whether such a specific and differential approach, imposes, as it seems to do, special prohibitions on patentability of certain chemical processes and pharmaceuticals. If it does, then is it in violation of the Agreement? This question was dealt with in the *Canada – Patent Protection of Pharmaceutical Products*<sup>30</sup> where the Panel attempted to discuss the meaning of the term ‘discrimination’ distinguishing it from ‘differential’, holding that it extends beyond the concept of differential treatment, and refers to results of the *unjustified imposition of differentially disadvantageous* treatment.<sup>31</sup>

Section 3(d) simply clarifies the applicable standard of patentability to be applied to the unique characteristics of pharmaceutical patents. It is certainly ‘differential’ with regard to the field of technology, however it is not ‘differentially disadvantageous’ in its application and enforcement. It is also clear that the provision is for the purposes of preventing ever-greening and thus seeks to implement a

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28. This is supported by a combined reading of art. 7 and art. 8 of the Agreement read with the Doha Declaration.

29. Ernst-Ulrich Petersmann, *International Competition Rules for Governments and for Private Business: A “Trade Law Approach” for Linking Trade and Competition Rules in the WTO*, 72 CHI.-KENT L. REV. 545, 546 (1996).

30. *Canada – Patent Protection of Pharmaceutical Products*, WT/DS/114/R [hereinafter *Canada – Patent*].

31. *Id.* at ¶ 7.94.

particular policy measure aimed at addressing a specific issue which is particular to pharmaceutical patents. This gives it a bona-fide application, since it protects and preserves the objects and purposes of the Agreement in the Indian context.

### III. OTHER POLICY CONSIDERATIONS

Interestingly, no other country has a provision similar to Section 3(d) of the Act.<sup>32</sup> There may be a simple explanation as to why such a section is not available in any other jurisdiction's legislation. Though Article 65 of the Agreement allowed for a transition period for patent regimes of developing countries, only thirteen countries used this provision, and of these only six used the complete period. In the mean time, from 1995 till 2005 when the amendment was introduced, the global access to medicines movement became much larger, and there was much global mobilization for the concerns of developing countries' public health concerns. In the years between, this movement also resulted in the Doha Declaration of 2001 which reaffirmed a state's right to protect public health.

Furthermore, the access to medicines movement also facilitated the birth of a well-coordinated network of scholars, activists, and community-based organizations that were highly motivated and "remarkably aware of esoteric patent law developments."<sup>33</sup> Therefore, the knowledge bias that existed at the time of concluding the Agreement was effectively countered to make full use of the flexibilities provided within it. In addition to this, the circumstances at the time of legislating the Indian statute indicated a strong generic industry that could provide cheap access to medicines for the population which had allowed India to have some of the lowest healthcare prices. However, despite the strong generic industry, much of the population still could not afford healthcare, and thus, the policy decisions on pharmaceuticals were still based primarily on providing easy and cheap access to lifesaving drugs. Seen in the light of the Agreement's object and purpose, the reasoning behind exercising statutory flexibilities may well be justified.

However, looked at from a broader perspective, the pharmaceutical industry is far from what one could call stagnant.<sup>34</sup> At the same time, the productivity of the pharmaceutical's "research and development" sector has seen a decreasing number of therapeutically important new molecules brought to market per dollar spent on

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32. *Id* at 3.

33. *Id.* at 11. See also Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 *Yale Law Journal* 804 (2008).

34. See Davidson & Greblov, *The Pharmaceutical Industry in the Global Economy*, prepared for the Indiana Economic Development Corporation with the support of the Center for International Business Education and Research at the Indiana University Kelley School of Business.

R&D<sup>35</sup> - meaning that the amount of money being put into the developmental and production phase of the pharmaceutical industry is not correlating to the amount of new therapeutically important medicines being brought out. The liberal granting of patents, and ever-greening of existing patents, has led to pharmaceuticals becoming lax towards research and innovation. With the possibility of getting easy patents and hence monopoly periods, there is reduced incentive to spend more on researching for further innovation, especially in the areas of healthcare where there is little or no 'low hanging fruit'.<sup>36</sup> Prevention of ever-greening would lead generics to come in at the end of the duration of patent, and market forces would require them to do the incremental innovation without patents. Since major pharmaceutical firms will now not be taking up this market<sup>37</sup>, there are ample opportunities for the generics to provide cheaper access for the same products. It is hoped that having driven monopoly pricing out of this market, market forces would therefore then drive the same pharmaceutical companies to invest in research for more innovation, instead of stagnating over the same redundant work.

Further, it should not be forgotten that the Agreement, as well as the international push for stronger IP rights are being backed by developed economies which stand to profit the most from this 'harmonization'. Both, the majority of the world's population, as well as the majority of the world's diseased population are in developing and least developed economies. Drugs that are produced are not always accessible due to a variety of reasons, the primary being lack of affordable pricing strategies. There is a direct correlation between poverty and occurrence of diseases<sup>38</sup>, yet the 'strong patent' system, leads innovation in the exact opposite direction. It leads innovation towards those who can afford it. This is diametrically opposite to the goals of nations trying to improve the state of health in their countries.

Many developed countries, earlier, used a much weaker patent system while they were still developing.<sup>39</sup> However, now that they've reached greener pastures, they are trying to thrust their current stronger patent regimes on other developing economies. This would allow their developed industries to continue to profit since harmonization of IP laws opens out newer markets to them.

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35. Paul Grootendorst, *Patents, Public-Private Partnerships or Prizes: How should we support pharmaceutical innovation?*, available at <http://ideas.repec.org/p/mcm/sedapp/250.html#provider> (last visited on 22 Feb. 2011).
  36. By 'low hanging fruit', I am referring to the 'easy' innovations which usually require someone noticing that there is an simple solution to an existing problem, as opposed to putting in a lot of research and development into figuring out a solution, or in this case, a drug, which addresses the pressing concerns.
  37. Or would be competing at generic prices.
  38. See Fischella & Franks, *Poverty or Income Inequality as Predictor of Mortality: Longitudinal Cohort Study*, 314(7096) BRIT. MED. J. 1724 (1997).
  39. Developed countries have historically changed their IP regime so as to best suit their economic interest. See generally The Final Report prepared by the IPR Commission, available at [http://www.iprcommission.org/papers/text/final\\_report/chapter1htmfinal.htm](http://www.iprcommission.org/papers/text/final_report/chapter1htmfinal.htm) (last visited on 20 June 2011).

The TRIPS regime has already placed itself in a prominent position by tying itself up to the GATT and GATS.<sup>40</sup> Now is the time for the developing economies to be most cautious in ensuring that they use the flexibilities and contextual allowances in the Agreement to move towards their more exigent national interests. So as to not fall in the trap of having to bow down to international political pressure, it is better for countries to implement such flexibilities within their own domestic regime, rather than wait for an international political tussle over say, compulsory licensing<sup>41</sup>, for example.

## CONCLUSION

Clearly, India has acted in a resolute manner in implementing the Agreement by bringing the Act in consonance with its international obligations, without compromising on its own domestic policy agenda of ensuring access to cheap lifesaving drugs. Perhaps it will even act as a trendsetter for other developing countries. For the moment however, the multilateral 'battles' are passé. Developed economies are now engaging developing economies in bilateral and plurilateral forums.<sup>42</sup> While this type of pressure is certainly more focused and hence stronger, developing economies are now more equipped in terms of knowledge and resources than they've been in the past. By joining forces to declare their agenda, developing economies have also strengthened their position.<sup>43</sup> This current ferment is an optimal time for policy analysts to examine and advocate for more efficient and equitable drug innovation policies. India has led the way so far by making creative and effective use of the policy space allowed by the Agreement. By countering the negative externalities inherent in a classical patent system so as to allow easier and quicker access to its citizens, without compromising India's international obligations, India has reached an arguably fairer balance amongst the various tradeoffs that the patent system entails – certainly one that gives primacy to its large sections of poverty stricken population. It remains to be seen whether India will bow down to the oncoming pressure, or if it will continue to intelligently hold forte, and hopefully even influence other countries against the upward spiral towards needlessly stronger IP rights.

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40. When the WTO was opened for membership, nearly all countries rushed to become members so as to benefit from international trade. However, in order to join, all member states had to accept the Agreement, the GATT and the GATS in full.

41. *See* art. 31 of the Agreement (even though the Agreement allows the usage of compulsory licenses by governments, developing and least developed nations that have attempted to use these flexibilities have received much stricter scrutiny than their industrialized counterparts did.).

42. The EU-India FTA currently under negotiations is a prime example of this bilateral negotiation.

43. For e.g., the Development Agenda Group (DAG) within the WIPO consists of several developing countries seeking to implement a development oriented perspective on intellectual property issues.