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## PHARMACEUTICAL PATENTS AND HEALTHCARE

ABHAYRAJ NAIK\*

*An essay on how the post-T.R.I.P.S. regime relating to pharmaceutical patenting in India affects issues of public access to healthcare.*

### Introduction

The interface between patent law and health is particularly amplified when one considers the specific subject focus of this essay – the aspect of the patenting of pharmaceutical products of healthcare (drugs, medicines, and components thereof) and the implications of such patenting on actual public access to medicines and health. The complex subtleties involved in the issue are better appreciated if one examines the contextual setting within which patent law and issues of health get directly thrown into the same arena.

The existence of India's global commitments towards intellectual property may be significantly sourced to the contentious Agreement on Trade Related Aspects of Intellectual Property Rights,<sup>1</sup> [hereinafter T.R.I.P.S.] included in the Uruguay Round of multilateral trade negotiations concluded between 125 nations including India, in April 1994, at Marrakesh, Morocco.<sup>2</sup> Following the

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<sup>1</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization (W.T.O.), Annex-1C, LEGAL INSTRUMENT RESULTS OF THE URUGUAY ROUND, Vol. 1, 33 I.L.M. 181. Due to the successful conclusion of T.R.I.P.S. in 1994, it formed part of the legal obligations of the newly founded successor organization of the General Agreement on Tariffs and Trade [hereinafter G.A.T.T.], the World Trade Organization [hereinafter W.T.O.].

<sup>2</sup> In the interests of clarity, it remains apposite to reiterate three basic features of the T.R.I.P.S. agreement that help contextually locate its position in the hazy domain of international agreements and law: *First*, that along with approximately 25 other legal texts, the T.R.I.P.S. Agreement forms an integral part of the Agreement Establishing the World Trade Organization and therefore remains subject to the W.T.O. dispute settlement system; *secondly*, the T.R.I.P.S. Agreement covers all the main areas of intellectual property of which patents form a part and; *thirdly*, the T.R.I.P.S. Agreement lays down the minimum standards of protection for each area of intellectual property *and* provides for the remedies and procedures that can be availed of for rights holders to avail of their rights effectively. *See in this regard*,

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promulgation of The Patents (Amendment) Ordinance, 2004 [hereinafter Patents Ordinance, 2004],<sup>3</sup> on December 26, 2004, India has concluded the process of meeting its obligations under T.R.I.P.S. by the stipulated deadline of January 1, 2005,<sup>4</sup> with fresh attention turned towards the actual operation of pharmaceutical product patents on all products with a patent issued after January 1, 1995.<sup>5</sup> The Explanation to the newly introduced Section 92A of the Indian Patent Act, 1970 broadly defines “pharmaceutical products” as any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits for their use.<sup>6</sup>

One positive approach towards the T.R.I.P.S. Agreement has been to acknowledge that the Agreement can be interpreted in such a manner as to strike a balance between the short-term interest in maximising access to patented products and the long-term interest in promoting creativity, innovation, and in providing incentives for research through patent protection.<sup>7</sup> However, since it may be fairly accurately stated that the minimum obligatory standards of protection of intellectual property rights under T.R.I.P.S. with respect to the patenting of medicines bear greater proximity to those existing in developed countries like the United States of America [hereinafter U.S.] or the European Union [hereinafter E.U.] vis-à-vis the developing world,<sup>8</sup> the implementation of

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W.T.O., *Pharmaceutical patents and the T.R.I.P.S. Agreement*, available at [http://www.wto.org/english/tratop\\_e/tratop\\_e/T.R.I.P.S.\\_e/healthdeclxpln\\_e.htm](http://www.wto.org/english/tratop_e/tratop_e/T.R.I.P.S._e/healthdeclxpln_e.htm) (last visited on June 14, 2006). For a detailed interesting study of the developed-developing countries tussle in the follow-up to the T.R.I.P.S. Agreement, see, JAYASHREE WATAL, *INTELLECTUAL PROPERTY RIGHTS – IN THE W.T.O. AND DEVELOPING COUNTRIES* 11 – 47 (2001) [hereinafter WATAL].

<sup>3</sup> THE PATENTS (AMENDMENT) ORDINANCE, 2004, Ord. No. 7 of 2004, available at <http://lawmin.nic.in/Patents%20Amendment%20Ordinance%202004.pdf> (last visited on June 14, 2006).

<sup>4</sup> See Article 65 of the T.R.I.P.S. Agreement relating to transitional arrangements.

<sup>5</sup> In this regard, Article 27 of the T.R.I.P.S. Agreement provides that subject to certain exceptions, W.T.O. members have to provide patent protection for any invention, whether a product (including medicines) or a process (including methods of production of medicines). See also, Article 29 and Article 33 of the T.R.I.P.S. Agreement, which deal with conditions on patent applications and the term of protection respectively.

<sup>6</sup> See, § 54 of the Patents Ordinance, 2004.

<sup>7</sup> See, World Trade Organisation, *Pharmaceutical patents and the T.R.I.P.S. Agreement*, available at [http://www.wto.org/english/tratop\\_e/tratop\\_e/T.R.I.P.S.\\_e/healthdeclxpln\\_e.htm](http://www.wto.org/english/tratop_e/tratop_e/T.R.I.P.S._e/healthdeclxpln_e.htm) (last visited on June 14, 2006).

<sup>8</sup> See, WATAL, *supra* note 2, at 11 – 47.

T.R.I.P.S. brings with it fears of higher prices for patented medicines and consequent impediments to patented medicine access by the poor in developing countries.<sup>9</sup>

In response to fears that the T.R.I.P.S. agreement may make some drugs difficult to obtain for patients in poor countries, the developing countries succeeded in getting W.T.O. trade ministers at the Doha Ministerial Conference in November, 2001, to adopt the landmark Declaration on the T.R.I.P.S. Agreement and Public Health [hereinafter Doha Declaration],<sup>10</sup> which affirmed that public health took precedence over private patent rights, and reaffirmed the rights of governments to use inbuilt W.T.O. public health safeguards and other available measures to gain access to cheap medicines.<sup>11</sup>

It is the potential impact of these radical regime changes, which has led Farias and Zacharias to point out that the Indian pharmaceutical industry is a prime example of a growing, successful, and high-technology industry that is being forced to re-structure and re-conceptualise its long-term strategies and operating models in light of India's broad-ranging policy to open its markets to

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<sup>9</sup> In this regard, Gray has reiterated the well-accepted W.H.O. approach which emphasizes that affordable prices for rationally selected medicines constitutes a vital determinant of the access to medicines and health in both developed and developing countries. See, Andy Gray, *Access to Medicines and Drug Regulation in Developing Countries: a Resource Guide for DFID* (D.F.I.D. Health Systems Resource Centre, London, 2004), available at [http://www.dfidhealthrc.org/shared/publications/Issues\\_papers/ATM/Gray.pdf](http://www.dfidhealthrc.org/shared/publications/Issues_papers/ATM/Gray.pdf) (last visited on June 14, 2006) [hereinafter Gray]. Further, Scherer and Watal point out that since developing countries spend a much larger percentage of their private household health expenditures on drugs, the affordability of the patented drugs remains of vital importance. That apart, the implications of an H.I.V./A.I.D.S. pandemic have focused attention on issues of access and affordability of life-saving drugs. See, F.M. Scherer and Jayashree Watal, *Post-T.R.I.P.S. Options for Access to Patented Medicines in Developing Countries* (Paper No. WG4: 1, C.M.H. Working Paper Series, 2001), available at [http://www.cmhealth.org/docs/wg4\\_paper1.pdf](http://www.cmhealth.org/docs/wg4_paper1.pdf) (last visited on June 14, 2006) [hereinafter Scherer and Watal].

<sup>10</sup> Declaration On The T.R.I.P.S. Agreement And Public Health, WT/MIN(01)/DEC/2, adopted on 14 November 2001, available at [http://www.wto.org/english/thewto\\_e/minist\\_e/mino1\\_e/mindecl\\_T.R.I.P.S.e.htm](http://www.wto.org/english/thewto_e/minist_e/mino1_e/mindecl_T.R.I.P.S.e.htm) (last visited on June 14, 2006) [hereinafter Declaration].

<sup>11</sup> For a scathing analysis of the actual U.S. response to the mandate laid down at Doha, see, *US Bullying on Drug Patents: One Year after Doha* (Oxfam International Briefing Paper, 2002), available at [www.oxfam.org/eng/pdfs/pp021112\\_bullying\\_patents.pdf](http://www.oxfam.org/eng/pdfs/pp021112_bullying_patents.pdf) (last visited on June 14, 2006) [hereinafter Oxfam].

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global trade, and consequently, to meet a spectrum of global commitments including the adequate protection of intellectual property.<sup>12</sup>

In this context, this essay, while recognizing the existence of the problem of public access to health and its relevance to India and the Indian pharmaceutical industry, seeks to briefly suggest answers to two questions: *first*, what are the implications of the T.R.I.P.S. regime on pharmaceutical patenting in India and on public access to health within India and; *secondly*, what are the implications of the T.R.I.P.S. regime on public access to health (including creation of new medicines) with particular relevance to India's role as a leading producer and exporter of low-priced generic drugs.<sup>13</sup> The common focus, in answering both these questions, will remain on ascertaining and tentatively suggesting the optimum strategic, policy-level choices available to India, so as to meet with its global commitments under T.R.I.P.S. while adhering to the need to enable public access to health, as enshrined in the Doha Declaration.

It is hoped that a specific analysis and enumeration of this largely understudied though critically relevant area involving patent law and health, will help clarify the current situation regarding pharmaceutical patenting in India, post January 1, 2005 and the imminent potential impact on public access to health.

## **The Impact of T.R.I.P.S. and the Doha Declaration on Public Access to Healthcare**

### ***The Basic Balance under T.R.I.P.S.***

As stated earlier, Article 27 of the T.R.I.P.S. Agreement provides that patents shall be available for any invention, whether a product or process, in all fields of technology without discrimination, where those inventions meet the standard substantive criteria for patentability – namely, novelty, inventive step and industrial applicability. Further, under Article 33 of the T.R.I.P.S. Agreement,

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<sup>12</sup> See, Nilesh Zacharias and Sandeep Farias, *Patents and the Indian Pharmaceutical Industry*, available at <http://www.nishithdesai.com/Research.htm> (visited on June 14, 2006) [hereinafter Zacharias and Farias].

<sup>13</sup> As to the meaning of generics – ‘When copies of patent drugs are made by other manufactures, they are either sold under the name of the chemical ingredient (making them clearly generic), or under another brand name (which means they are still generics from the point of view of patents)’. See, W.T.O., *T.R.I.P.S. and Pharmaceutical Patents – Fact Sheet*, 2003, available at [http://www.wto.org/english/tratop\\_e/tratop\\_e/T.R.I.P.S.\\_e/factsheet\\_pharm00\\_e.htm](http://www.wto.org/english/tratop_e/tratop_e/T.R.I.P.S._e/factsheet_pharm00_e.htm) (last visited on June 14, 2006) [hereinafter Fact Sheet].

such patent protection has to last for at least twenty years from the date of filing the patent application. The basic patent right may be understood to mean that patents provide the patent owner with the legal means to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions.<sup>14</sup>

Under Article 27, Governments can refuse to grant patents for three reasons that could possibly relate to public health:

- inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health.
- diagnostic, therapeutic and surgical methods for treating humans or animals.
- certain plant and animal inventions.

Further flexibilities are inbuilt into the T.R.I.P.S. Agreement including - research exceptions and 'bolar' provisions under Article 30, anti-competitive practice and abuse of intellectual property rights under Article 8.2 read with Article 40, compulsory licensing under Article 31, and parallel imports and exhaustion of rights when read with Article 6 of the T.R.I.P.S. Agreement.<sup>15</sup> Such flexibilities and their significance find further mention later in this paper.

## The Role of the Doha Declaration

Since there existed a large degree of uncertainty regarding the interpretation of these T.R.I.P.S. flexibilities, and the extent to which their use would be respected, W.T.O. member governments stressed on the importance of implementing and interpreting the T.R.I.P.S. Agreement in a way that supported public health by promoting both access to existing medicines and the creation of new medicines, as part of the main Doha Ministerial Declaration of November 14, 2001. Consequently, the Doha Declaration on T.R.I.P.S. and Public Health responded to the concerns raised above in a number of ways:<sup>16</sup>

*First*, it emphasized that the T.R.I.P.S. Agreement does not and should not prevent W.T.O. member governments from taking measures to protect public

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<sup>14</sup> See, Fact Sheet, *Id.*

<sup>15</sup> See in this regard, Scherer and Watal, *supra* note 9.

<sup>16</sup> See generally, W.T.O., *The Separate Doha Declaration Explained*, available at [http://www.wto.org/english/tratop\\_e/T.R.I.P.S.\\_e/healthdeclxpln\\_e.htm](http://www.wto.org/english/tratop_e/tratop_e/T.R.I.P.S._e/healthdeclxpln_e.htm) (last visited on June 14, 2006).

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health, and reaffirmed the members' rights to use fully the provisions of the T.R.I.P.S. Agreement, which provide flexibility for this purpose.<sup>17</sup> The substantive import of such statements from all W.T.O. members supports the conclusion that the Doha Declaration is conclusive of the fact that W.T.O. member states will not try to prevent each other from using these provisions.<sup>18</sup>

*Secondly*, the declaration emphasizes that the T.R.I.P.S. Agreement should be interpreted and implemented in a manner that supports W.T.O. members' right to protect public health and, in particular, to promote access to medicines for all.<sup>19</sup> The Declaration also reiterates the importance of the objectives<sup>20</sup>

### **Objectives**

The protection and enforcement of intellectual property rights should contribute to the promotion of

- technological innovation and to the transfer and dissemination of technology, to the mutual advantage
- of producers and users of technological knowledge and in a manner conducive to social and economic welfare,
- and principles<sup>21</sup> of the T.R.I.P.S. Agreement for interpreting its provisions.<sup>22</sup>

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<sup>17</sup> ¶ 4 and 5, Doha Declaration, *supra* note 10.

<sup>18</sup> *See*, Fact Sheet, *supra* note 13.

<sup>19</sup> ¶ 4, Doha Declaration, *supra* note 10.

<sup>20</sup> Article 7 of the T.R.I.P.S. Agreement states: "*Objectives*

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, 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."

<sup>21</sup> Article 8 of the T.R.I.P.S. Agreement states: "*Principles*

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

<sup>22</sup> ¶ 5 (a), Doha Declaration, *supra* note 10.

*Thirdly*, the declaration contains a number of important clarifications regarding the flexibilities contained in the T.R.I.P.S. Agreement, which are made while reiterating members' commitments under the T.R.I.P.S. Agreement:<sup>23</sup>

On compulsory licensing, the declaration makes it clear that each member is free to determine the grounds upon which the licences are granted and further that each member has the right to determine what constitutes a national emergency or other circumstance of extreme urgency, with the reiteration that public health crises, including H.I.V./A.I.D.S., tuberculosis, malaria and other epidemics, can fit the bill.<sup>24</sup>

The declaration also refers to the exhaustion of intellectual property rights, and therefore addresses the question of a member's right to allow parallel imports. The declaration makes it clear that the T.R.I.P.S. Agreement's provisions on exhaustion in effect leave each member free to establish its own regime without challenge — subject to the general T.R.I.P.S. provisions prohibiting discrimination on the basis of a person's nationality.<sup>25</sup> Importantly, the declaration does not remove the need for each country to take the necessary steps domestically to use this flexibility where necessary if it wants to ensure that medicines are available at affordable prices.<sup>26</sup>

Finally, on the issue of importing under compulsory license, Paragraph 6 of the Doha Declaration assigned further work to the T.R.I.P.S. Council to sort out how to ensure extra flexibility so that countries unable to produce pharmaceuticals domestically, could obtain supplies of copies of patented drugs from other countries.<sup>27</sup> This aspect, which is often referred to as the Article 6 issue, was ultimately resolved on August 30, 2003, and has been studied in greater detail in the next section.

## **Article 6 of the Doha Declaration Clarified**

As mentioned earlier, as regards the issue of importing under compulsory license, the Doha Declaration had assigned further work to the T.R.I.P.S. Council to sort out how to ensure extra flexibility so that countries unable to produce

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<sup>23</sup> ¶ 5, Doha Declaration, *supra* note 10. *See also*, Scherer and Watal, *supra* note 9.

<sup>24</sup> ¶ 5 (b) and 5 (c), Doha Declaration, *supra* note 10.

<sup>25</sup> ¶ 5 (d), Doha Declaration, *supra* note 10.

<sup>26</sup> *See*, Fact Sheet, *supra* note 13.

<sup>27</sup> ¶ 6, Doha Declaration, *supra* note 10.



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pharmaceuticals domestically could obtain supplies of copies of patented drugs from other countries.<sup>28</sup> On August 30, 2003, W.T.O. member governments broke their final deadlock over intellectual property protection and public health and agreed on legal changes that will make it easier for poorer countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves.<sup>29</sup> Article 31(f) of the T.R.I.P.S. Agreement provides that products made under compulsory licensing must be “predominantly for the supply of the domestic market”. This applies directly to countries that can manufacture drugs including India — since it limits the amount they can export when the drug is made under compulsory licence, and it has an indirect impact on countries unable to make medicines and therefore wanting to import generics since they would find it difficult to find countries that can supply them with drugs made under compulsory licensing. The August 30, 2003 agreement allows any member country to export pharmaceutical products made under compulsory licences within the terms set out in the decision, and essentially takes the form of an interim waiver, which allows countries producing generic copies of patented products under compulsory licences, to export the products to eligible importing countries.<sup>30</sup> Significantly, the decision covers patented products or products made using patented processes in the pharmaceutical sector, including active ingredients and diagnostic kits, and the waiver would last until the W.T.O.’s intellectual property agreement is amended.<sup>31</sup> The stipulated conditions aim to ensure the beneficiary countries can import the generics without undermining patent systems, particularly in rich countries, and include measures to prevent the medicines from being diverted to the wrong markets and also require governments using the system to keep all other members informed, although W.T.O. approval is not required. At the same time phrases such as “reasonable measures within their means” and “proportionate to their administrative capacities” are included to prevent the conditions becoming burdensome and impractical for the importing countries.<sup>32</sup> Clearly, this decision carries a significant impact for India’s pharmaceutical industry, with its well-established capabilities for producing generic drugs.

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<sup>28</sup> *Id.*

<sup>29</sup> *See generally*, World Trade Organisation, *Decision removes final patent obstacle to cheap drug imports*, available at [http://www.wto.org/english/news\\_e/pres03\\_e/pr350\\_e.htm](http://www.wto.org/english/news_e/pres03_e/pr350_e.htm) (visited on June 14, 2006).

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *See* Fact Sheet, *supra* note 13.

## An Overview of Health and the Pharmaceutical Industry in India

India, with a large part of its population living below the poverty line, with high figures of out-of-pocket expenses towards health care, and with highly unsatisfactory health indices, clearly suffers from a significant health crisis with inadequate public access to health care as such, a situation which will undoubtedly experience further change once the T.R.I.P.S. regime as regards pharmaceutical patenting comes fully into effect in India.<sup>33</sup> Further, pharmaceutical patenting in India is of special relevance to issues of public health since Indian pharmaceutical firms are important suppliers of low-priced active pharmaceutical ingredients and finished products domestically and to several developing countries. Many fear that the introduction of product patents could possibly destroy these industries and thereby lead to increased drug prices,<sup>34</sup> thereby exacerbating the prevailing health crises in the areas of delivery of those drugs.

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<sup>33</sup> The National Health Policy 2002 details out the exact extent and nature of the current public health crisis in India. *See*, NATIONAL HEALTH POLICY 1 – 5 (2002), available at <http://mohfw.nic.in> (last visited on June 14, 2006). Significantly, paragraph 4.26 of this policy document reads:

“4.26 IMPACT OF GLOBALISATION ON THE HEALTH SECTOR

4.26.1 The Policy takes into account the serious apprehension, expressed by several health experts, of the possible threat to health security in the post-T.R.I.P.S. era, as a result of a sharp increase in the prices of drugs and vaccines. To protect the citizens of the country from such a threat, this policy envisages a national patent regime for the future, which, while being consistent with T.R.I.P.S., avails of all opportunities to secure for the country, under its patent laws, affordable access to the latest medical and other therapeutic discoveries. The policy also sets out that the Government will bring to bear its full influence in all international fora – U.N., W.H.O., W.T.O., etc. – to secure commitments on the part of the Nations of the Globe, to lighten the restrictive features of T.R.I.P.S. in its application to the health care sector.”

<sup>34</sup> Grace succinctly explains the line of reasoning connecting intellectual property, pharmaceutical firms in India, and issues of public health and access to medicines through the following words: “Enhanced IP protection can close off certain revenue options and cause a reorientation of firms’ strategies. This reorientation can affect industry structure and types of competition, and this can lead to changes in prices, quality levels and physical availability. Similarly, access to new medicines can also be affected by enhanced IP protection, but indirectly, through IP’s influence on a firm’s market orientation, and thus, the incentive structure to invest in R&D. The incentive to invest in R&D has implications for the number and type of new drugs that are developed through this investment.” *See*, Cheri Grace, *The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China - Considerations for Access to Medicines* (D.F.I.D. Health Systems Resource Centre, London, 2004), available at <http://www.dfid.gov.uk/pubs/files/indiachinadomproduce.pdf> (last visited on June 14, 2006) [hereinafter Grace].

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Data suggests that with an overall production of approximately \$7.3 billion (comprising domestic consumption of finished products and exports), Indian firms produce approximately 1.5% of the global pharmaceutical market of \$480 billion. Importantly however, this small share in value terms belies the importance of the Indian industry in volume terms, which has been estimated at more than 20% of global consumption.<sup>35</sup> Having undertaken a detailed study of the Indian pharmaceutical industry,<sup>36</sup> Grace concludes that the present production and functioning and the future prospects of the Indian pharmaceutical industry are of great significance from three perspectives: *first*, from the standpoint of domestic access to medicines within India; *second*, from the standpoint of international access to medicines produced wholly or in part by the Indian pharmaceutical industry and; *third*, and more specifically, from the standpoint of access to medicines within product segments that treat diseases specifically prevalent in poor countries.<sup>37</sup> Such a broad conclusion can be better appreciated once it is acknowledged that a key objective of policy-makers in the developing world has been to ensure the availability of new medical treatments, at affordable prices, to patients in the region, and this objective is vastly aided by adoption of a process-patent regime for pharmaceuticals which allows pharmaceutical firms in developing countries to specialize in the production of cheap, generic versions of on-patent drugs for domestic markets, as well as for export to other countries where similar patent regimes were in place.<sup>38</sup> Farias and Zacharias more or less sum up the situation by pointing out that the current industry players comprise several privately owned Indian companies that have captured a substantial share in the domestic pharmaceutical market owing to favourable government policies

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<sup>35</sup> Goldman Sachs, *Global Healthcare: Indian Pharmaceuticals*, PASSAGE FROM INDIA (March 16, 2004) at 1.

<sup>36</sup> See, Grace, *supra* note 34, at 13 – 27.

<sup>37</sup> With specific regard to this third perspective, it is apposite to draw the distinction between medical research and development related to “global” diseases such as cancer, which have a presence in both the developed and developing world, and research related to ‘poor’ country ailments such as malaria, tuberculosis, H.I.V./A.I.D.S., etc. found primarily in the developing world. The point essentially is that since poor country specific ailments such as malaria, T.B., etc. have no significant markets in the developed world, stronger intellectual property in the developing world itself might be the key to inducing new and better medical treatment for these ailments, subject to the commercial viability of such research and development projects. See generally, Rachel Glennerster and Michael Kremer, *A Better Way to Spur Medical Research and Development*, 23(2) REGULATION, available at <http://www.cato.org/pubs/regulation/regv23n2/kremer.pdf> (visited on June 14, 2006); Veena Mishra, *T.R.I.P.S., Product Patents and Pharmaceuticals*, 39(48) ECON. & POL. W’KLY. 4464 (2001).

<sup>38</sup> See, Veena Mishra, *Id.*

and limited competition from overseas, among other things.<sup>39</sup> Further, it is well documented that copied brands of drugs, patented in foreign countries, have typically been introduced in the Indian market soon after the introduction of these drugs in the original market by the patent-holder, thereby implying that pharmaceutical multinationals did not enjoy a substantial first-mover advantage in selling a newly developed drug on the Indian market.<sup>40</sup> This fact has significantly contributed to the trend wherein many multinational pharmaceuticals chose not to supply the Indian market at all because of lower likelihood of profits on account of cheaper domestic generic alternatives.<sup>41</sup>

### **Pre-T.R.I.P.S. and Post-T.R.I.P.S. Law Applicable to Pharmaceutical Patenting in India**

India initially had a product patent regime for all inventions under the Patents and Designs Act 1911, a situation that changed, in 1970, when the government introduced the new Patents Act, 1970 [hereinafter the pre-T.R.I.P.S. Act], which excluded pharmaceuticals and agrochemical products from eligibility for patents.<sup>42</sup> This exclusion was introduced to break away India's dependence on imports for bulk drugs and formulations and provide for development of a self-reliant indigenous pharmaceutical industry.<sup>43</sup> An amended form of the Act is on the statute books today, and this essay shall refer to the provisions of the Act applicable as law since 1970, until impacted upon by India signing T.R.I.P.S. in 1994, as pre-T.R.I.P.S. law. Post 1994, the Act has been amended in 1999,<sup>44</sup> 2002,<sup>45</sup> and 2004 (most recently through the Patents Ordinance, 2004).

Section 43 of the pre-T.R.I.P.S. Act broadly provided for the granting of patents on satisfaction of the necessary requirements, one exception to which was enshrined in Section 5, which unambiguously provided that with respect to inventions claiming substances intended to be used or capable of being used as food or as a medicine or drug, no patent would be granted to claims for the

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<sup>39</sup> See, Zacharias and Farias, *supra* note 12, at 1.

<sup>40</sup> See, J.O. Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: 'Heartless Exploitation of the Poor and Suffering?'*, N.B.E.R. Working Paper No. 6366, Cambridge, 1997.

<sup>41</sup> See, Zacharias and Farias, *supra* note 12, at 1.

<sup>42</sup> § 5, Indian Patent Act, 1970.

<sup>43</sup> See, Zacharias and Farias, *supra* note 12, at 1.

<sup>44</sup> See, The Patents (Amendment) Act, 1999 (17 of 1999).

<sup>45</sup> See, The Patents (Amendment) Act, 2002 (38 of 2002).

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substances themselves, but claims for the methods or processes of manufacture of the same substance were nonetheless patentable. The term of such process patents was for a period of seven years from the date of the patent or for five years from the date of sealing of the patent, whichever period was shorter.<sup>46</sup> In light of India's obligations under Article 27 of T.R.I.P.S. requiring availability of patents on all product inventions, Section 4 of the Patents Ordinance, 2004 provides that Section 5 of the Act is to be omitted, and consequently, the solely-process patent regime relating to substances intended to be used or capable of being used as food or as a medicine or drug as provided for in the exception-creating Section 5, which dates back to 1970, has now come to a definitive end. Section 53 of the Act, which provided specifically for the 5 or 7 year patent term for drugs or medicines, had been amended as recently as 2002, so as to provide for a uniform term of 20 years from the date of filing of the patent application for all patents, in consonance with Article 33 of T.R.I.P.S.

Carsten Fink has pointed out that under the pre-T.R.I.P.S. Act, there were four provisions which substantially limited the scope of available process protection,<sup>47</sup> and these may be conceptualized as provisions benefiting a scenario of greater access to medicines and drugs covered by patents: *first*, after three years from the date of sealing a pharmaceutical process patent, the patent was deemed to be endorsed with the words "licences of rights",<sup>48</sup> which implied that under Section 88(5) of the pre-T.R.I.P.S. Act, the patent owner was obliged to license the patented process to any interested party with a maximum possible royalty of 4 percent of the net ex-factory sale price in bulk of the patented article to be payable by the licensee; *second*, at any time after the expiration of three years from the date of sealing of a pharmaceutical patent, the government, if satisfied that the patented product was not available to the public at reasonable prices or that other public interests were not satisfied, could grant a compulsory license, the terms of which were to be set by the government, unless the patent owner and licensee could find agreement between themselves;<sup>49</sup> *third*, a patented

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<sup>46</sup> § 53(1)(a), the pre-T.R.I.P.S. Act.

<sup>47</sup> See, Carsten Fink, *How Stronger Patent Protection in India might Affect the Behaviour of Transnational Pharmaceutical Industries*, available at [http://wbln0018.worldbank.org/research/workpapers.nsf/0/5d9b67dfa077405852568e80065f3c4/\\$FILE/wps2352.pdf](http://wbln0018.worldbank.org/research/workpapers.nsf/0/5d9b67dfa077405852568e80065f3c4/$FILE/wps2352.pdf) (last visited on June 14, 2006) [hereinafter Fink].

<sup>48</sup> § 87, pre-T.R.I.P.S. Act.

<sup>49</sup> See, § 84 and § 85 of the pre-T.R.I.P.S. Act providing for applications for granting of compulsory licenses and matters to be taken into account when granting compulsory licenses respectively. Also see, § 90 of the pre-T.R.I.P.S. Act dealing with the interpretation of the words 'reasonable requirements of the public' in § 84.

pharmaceutical process must be worked in India within three years from the date of sealing the patent, and importation of a drug produced with the patented process is not considered as working the patent,<sup>50</sup> and; *fourth*, the burden of proof in case of patent infringement rests with the patent owner.<sup>51</sup> On such a basis, Fink concludes that in essence, the Act gave very limited protection to research-based pharmaceutical companies, and firms producing generic drugs only had to avoid patented processes, so as to legitimately copy a newly developed drug.<sup>52</sup> Further, Section 47(4) of the pre-T.R.I.P.S. Act expressly provided that the government may import any medicine or drug for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or those specified in such behalf by the Government. India's obligations under T.R.I.P.S. introduced radical changes to the understanding of such provisions under the Act:

Article 30 of T.R.I.P.S. provides that W.T.O. Members may provide limited exceptions to the exclusive rights<sup>53</sup> conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, provided that the legitimate interests of third parties have been taken into consideration. Further, Article 31 lays down a list of provisions applicable in all situations where the law of a W.T.O. Member country permits use of the subject matter of the patent without authorization of the patent holder.<sup>54</sup> Since Article 27.1 of T.R.I.P.S. states - "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced," – the agreement clearly does not permit any discrimination between an imported product and a domestic product leading to the conclusion that importation is equivalent to the working of

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<sup>50</sup> See, § 83 and § 84 (1), pre-T.R.I.P.S. Act.

<sup>51</sup> See, generally Chapter XVIII, pre-T.R.I.P.S. Act.

<sup>52</sup> See, Fink, *supra* note 47.

<sup>53</sup> Article 28 of T.R.I.P.S. enumerates the exclusive rights conferred by product and process patents.

<sup>54</sup> Article 31 includes, *inter alia*, that such authorization will be considered on its individual merits, that such use may be permitted only if, prior to such use, that the proposed user has made efforts to obtain authorization from the right holder at reasonable commercial terms and conditions that have been unsuccessful within a reasonable period of time, that such use shall be non-exclusive and non-assignable, that such authorization be liable to be terminated in certain conditions, that the right holder be paid adequate economic remuneration in each case taking into account the economic value of the authorization, that the decision as to authorization and as to remuneration provided be subject to judicial review, etc.

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a patent. Finally, Article 34 of T.R.I.P.S. provides that the burden of proof in cases of process patent infringement primarily lies upon the alleged infringer, subject to certain stipulated exceptions.

Accordingly the Patents Amendment Act, 2002, substituted Chapter XVI of the pre-T.R.I.P.S. Act for a new Chapter XVI which, *inter alia* – effectively omitted reference to the license of rights clause and its impact under Section 87 and Section 88 of the pre-T.R.I.P.S. law; considerably increased the stringency of requirements for the issue of a compulsory license under Section 84 of the Act; included importation with working under Section 83 and Section 84 of the Act; has placed the burden of proof in cases of infringement primarily upon the alleged infringer under the newly introduced Section 104A in accord with Article 34 of T.R.I.P.S. and; left untouched the provision under Section 47(4) of the Act. Further, through the introduction of five new clauses (clause (c) to clause (g)) under the general principles applicable to the working of patents under Section 83 of the Act, the importance of technology transfer, public health, and public access at reasonable costs, has been reiterated. The Patents Ordinance, 2004, does not change the position as regards any of these aspects. Further, in consonance with the August 30, 2003 clarification regarding Article 6 of the Doha Declaration, which has been discussed earlier, the Patents Ordinance, 2004 introduces Section 92A to the Act, which provides for compulsory licenses for manufacture and export of patented pharmaceutical products to countries having insufficient or no manufacturing capacity in the pharmaceutical sector.<sup>55</sup>

On consideration of the overall current scenario in light of the provisions of the pre-T.R.I.P.S. legislation, it is evident that on one hand, the Act has clearly moved towards a strengthening of intellectual property protection in the pharmaceutical sector, while on the other hand has repeatedly reiterated the importance of public health and reasonable public access to health despite increased patent protection. The coming days will indicate how such provisions operate in practice, and the extent to which they are accepted by the international community, particularly countries of the developed world.

### **Consequences of T.R.I.P.S.-Compliant Indian Legislation Relating to Pharmaceuticals**

The changes described above give rise to various concerns, especially in the context of pharmaceuticals, and it is apposite to briefly address the same

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<sup>55</sup> See, § 54 of the Patents Ordinance, 2004.



here. Broadly speaking, such concerns may be represented in the following manner:<sup>56</sup>

(I) *India's legislation formerly excluded patent coverage for pharmaceutical products, and once product patents in these areas are granted, indigenous research and development will be adversely affected.*

This argument tends to suggest that an enormous amount of money is spent by Indian pharmaceutical companies on research and development, while the actual figure has been estimated to be a mere 1-2% of drug sales, as compared to figures of 15% in Europe and North America and 10% in Japan.<sup>57</sup> Therefore, the argument that stronger patent protection encourages research and development and stimulates foreign direct investments into the sector, which in turn further stimulates indigenous research and development efforts, cannot be ignored. At one level, product patents could encourage multinational firms and larger Indian business groups to invest more in research and development in India, and India's advantage of low cost scientific manpower could then easily translate into the development of new drugs.<sup>58</sup> Secondly, stronger patent protection would also directly stimulate innovative indigenous pharmaceutical companies to directly invest in research and development, and such innovation would have the potential to take the Indian pharmaceutical forward, from just being a large industry of copied drugs.

(II) *Earlier, domestic pharmaceutical companies could develop new processes for new drugs, which were therefore introduced in India within three to five years following their arrival on the international market. With the introduction of product patents, these new drugs might not arrive in the Indian market for significantly long periods.*<sup>59</sup>

In response to such an argument, it is suggested that once product patents are introduced, the patent holders will be encouraged to market their products in

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<sup>56</sup> For a detailed treatment of this aspect, see, Amir Ullah Khan, *Ten Years of Intellectual Property Right Protection under the W.T.O.*, available at <http://www.idfresearch.org/pdf/IPRs2005.pdf> (last visited on June 14, 2006) [hereinafter Khan].

<sup>57</sup> See, Khan, *Id.*

<sup>58</sup> See, Grace, *supra* note 34.

<sup>59</sup> See for example, B.K. Keayla, *Patent Protection and the Pharmaceutical Industry*, in *INTELLECTUAL PROPERTY RIGHTS* (K.R.G. Nair and Ashok Kumar eds.,1994).



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India immediately (keeping in mind the large potential that the Indian market holds for such suppliers), without having to wait for the four to five years normally required for the development of alternative processes. The risk, of course, remains that certain necessary drugs will not be introduced in India on account of low potential for economic returns.

*(III) The requirements for compulsory licensing have been considerably strengthened thereby rendering such a provision virtually useless as regards ensuring of public access to healthcare.*

While it is undeniable that it will be more difficult to resort to compulsory licensing mechanisms, it is suggested that the language under T.R.I.P.S. and the amended Indian legislation will allow adequate use of the same in the interests of public health and public access to medicine.<sup>60</sup> Specifically, the amended Indian legislation still permits compulsory licensing, albeit under strict conditions – and it is hoped that such compulsory licensing will ensure that emergencies are successfully averted, while at the same time protecting the economic interests of the patent holders.

*(IV) The introduction of product patents could result in a monopoly for multinational pharmaceutical companies, which acquires added significance since the duration of the patent has been increased to twenty years. Consequently, drug prices in India could go up dramatically, and such a conclusion is inevitable when one considers cross-country prices for the same drug across post-T.R.I.P.S. and pre-T.R.I.P.S. countries.*

It is undeniable that as mentioned earlier, the system of process patents encouraged a large number of manufacturers to enter the pharmaceutical industry, and the resultant competition led to sharp drops in prices. Subsumed in these low costs are expenses saved in not having to spend money on research and development for a new drug, including recouping costs of failure and the saving of costs on clinical trials.<sup>61</sup> The transition periods allowed for under the T.R.I.P.S. regime give India an opportunity to ensure that the groundwork required for a complete transition to the product patent regime does take place. At the same time, Indian pharmaceutical companies should strengthen their research and development focus to prepare for the transition to a completely product-patent

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<sup>60</sup> See, Scherer and Watal, *supra* note 9.

<sup>61</sup> *Id.*

based regime. It is, of course, indisputable that with the introduction of product patents, drug prices are bound to go up, but there remain several undeniable reasons indicating that the fears of an overwhelming price rise are greatly exaggerated, and it is to this that we turn our attention next.

### Countering the Drug Price-Rise Hypothesis

Since the primary criticism against T.R.I.P.S. on the ground of access to health pertains to the inevitable rising price of drugs following the implementation of T.R.I.P.S., it becomes necessary to very briefly critically analyse the question of the relationship between the implementation of T.R.I.P.S. and increased drug prices.

*First*, the prediction that drug prices in India are going to rise exponentially following the full effect of T.R.I.P.S., is largely premised on cross-country comparisons of drug prices. In this regard however, it remains necessary to reiterate that cross-country comparisons of the prices of any item, drugs or otherwise, are fraught with problems. Significantly, such prices depend on several complex factors. Absence or presence of product patents would be but one of the factors playing in the situation, influencing price. For example, prices of drugs are often determined primarily by what the market can bear, which would explain why drugs are expensive in the U.S. where there exists a fairly comprehensive medical insurance system established.<sup>62</sup> Similarly, it is suggested that many drugs are cheap in India largely on account of the Drug Price Control Order [hereinafter D.P.C.O.],<sup>63</sup> which applies independent of the larger issue of product or process patents.<sup>64</sup> In this regard, it should be remembered that governments have a range of public policy measures before them outside the field of intellectual property to address issues of access to and prices of drugs, and Article 8 of the T.R.I.P.S.

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<sup>62</sup> *Id.*

<sup>63</sup> The Drugs Price Control Order (D.P.C.O.), 1995 is an order issued by the Government of India under § 3 of the Essential Commodities Act, 1955 to regulate the prices of drugs. The Order *inter alia* provides the list of price-controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by Government and penalties for contravention of provisions. Further, for the purpose of implementing provisions of DPCO, powers of the Government have been vested in the National Pharmaceutical Pricing Authority (N.P.P.A.). See, *Price Control Order (DPCO)*, available at <http://www.pharmaceutical-drug-manufacturers.com/pharmaceutical-policies/drugs-price-control-order.html> (last visited on June 14, 2006) [hereinafter D.P.C.O.].

<sup>64</sup> See, D.P.C.O., *Id.*

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Agreement makes it clear that W.T.O. Members may, in formulating or amending their rules and regulations, adopt measures necessary to protect public health and nutrition, provided that such measures are consistent with the provisions of the Agreement.

*Second*, the categorization of drugs as essential or non-essential under the DPCO assumes special significance. The rise in prices of non-essential drugs does not serve as a cause for grave concern, and essential drugs continue to be priced low under the D.P.C.O.<sup>65</sup>

*Third*, it is well documented that less than 10% of the essential drugs worldwide are covered by patents, with the rest having all become generic drugs implying no compulsion of granting a fresh round of patent protection to the same. Similarly, if one scans the Indian list of essential drugs, one discovers that less than 10% of them are covered by patents worldwide and therefore, at best, only a few drugs would be affected by the price rise. In the short run, the prices of most essential drugs will not be affected at all, while in the long run, as patent protection stimulates more research and development and more competition, the prices of all drugs should logically come down.<sup>66</sup>

*Fourth*, there is an impression that granting product patents necessarily implies monopolies for long periods of twenty years. Keeping in mind regulatory approvals, clinical trials, and the duration of time taken to bring a drug to the market, it is rare that a drug has a “monopoly” for more than a short period of five years or so.<sup>67</sup>

*Fifth*, it remains important to reiterate that a product patent does not necessarily confer a monopoly on the pharmaceutical company, especially in light of the fact that most new drugs are substitutes for existing drugs, with slightly different therapeutic or side effects, and therefore, even if a drug is on patent, there will generally be cheaper drugs that are off-patent and unaffected by monopoly considerations.<sup>68</sup>

*Finally*, even if some drugs are on patent now, one must remember that the exclusivity of patent protection does not extend indefinitely. For example, out of the drugs manufactured in India today, almost all are already generic, and with regard to the few new drugs under consideration, the patent protection will

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<sup>65</sup> *Id.*

<sup>66</sup> *See*, Grace, *supra* note 34.

<sup>67</sup> *Id.*

<sup>68</sup> *See*, Scherer and Watal, *supra* note 9.

definitely come to an end within a fixed period.<sup>69</sup> Clearly therefore, an exponential price rise following the effectuation of T.R.I.P.S.-compliant provisions is not the only possible future trajectory for India. The moot point however, is to ensure that adequate and necessary steps be taken to ensure that such a price rise does not occur.

### Concluding Remarks

Scherer states that it is reasonably well established in economic literature that, especially in a world of A.I.D.S. and resistant tuberculosis epidemics, low-income nations enjoy higher economic welfare when they can free-ride on pharmaceutical innovations made and patented in the first world than when they must pay monopolistic prices for the newest and most effective drugs,<sup>70</sup> and following a detailed economic analysis concludes that global welfare would also benefit greater by such free-riding as opposed to uniform patenting laws.<sup>71</sup> The measures that developing nations like India might adopt in the new T.R.I.P.S. environment to enhance low-cost access to the newest drugs, retaining benefits they enjoyed pre-T.R.I.P.S. where they pursued aggressive generic substitution policies previously, include several policy options - notably, compulsory licensing, utilizing parallel trade, enforcing price controls, encouraging the donation of vital medicines, and cooperating in international drug procurement efforts - all of which might be adopted without running afoul of the obligations imposed by T.R.I.P.S.<sup>72</sup> As discussed earlier, The Indian Patent Act, 1970 clearly includes several provisions greatly supportive and facilitative of public access to healthcare, and it remains vital that such provisions, along with alternate measures such as the Drug Price Control Order, are used in a manner most supportive of public access to healthcare.

As regards the supply of low-cost generic drugs to facilitate public access to healthcare, the Indian pharmaceutical industry has traditionally been an important supplier domestically, and to the less regulated markets of Africa, Asia and Latin America, and the clarity regarding Article 6 of the Doha Declaration can only add further value to such a trend. Due to the changed regime of international

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<sup>69</sup> See, Khan, *supra* note 56.

<sup>70</sup> F.M. Scherer, *A Note on Global Welfare in Pharmaceutical Patenting* (Working Paper NO. 03-11, Federal Reserve Bank of Philadelphia, 2002), available at [www.phil.frb.org/files/wps/2003/wp03-11.pdf](http://www.phil.frb.org/files/wps/2003/wp03-11.pdf) (last visited on June 14, 2006).

<sup>71</sup> *Id.*

<sup>72</sup> For an excellent detailed study of each of these aspects, see, Scherer and Watal, *supra* note 9.

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patent law during and after 2005, and the increasingly developed technological capacity of the industry, some commentators believe that Indian pharmaceutical firms could become major participants in the global marketplace, including the regulated markets (i.e. U.S. and E.U.) and with increasingly sophisticated products. In this regard, the characterisation of Indian pharmaceutical companies as copiers lacking innovativeness is understood to be increasingly inaccurate, and several Indian companies have been developing new drug delivery systems or alternative formulations of existing molecules so as to improve dosing regimens.<sup>73</sup> Therefore, in some ways, the future prospects for the pharmaceutical industry look bright provided that persistent strategic weaknesses are tackled appropriately and immediately.

At the end of the day, it falls upon India and other developing countries to make maximum legitimate use of the measures in-built into T.R.I.P.S. and consequently into domestic legislation, apart from alternate measures including drug price control, so as to ensure public access to health. While efficacious public policy measures can be put into force to enable public access to health, it is important to reiterate that India must ensure judicious use of such measures so as to ensure that it meets its global requirements under T.R.I.P.S. while at the same time it manages to ensure public access to health, without being dragged into the formidable W.T.O. dispute settlement process or into the sights of unilateral economic sanctions by developed countries.<sup>74</sup>

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<sup>73</sup> See, Grace, *supra* note 34.

<sup>74</sup> See in this regard, Oxfam, *supra* note 11.