

**CONTEXT AND AMBIGUITY: A COMMENT ON  
AMENDING INDIA'S PATENT ACT**

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## Abstract:

In implementing its patent-related obligations to the TRIPS Agreement, India decided to use the optional additional transitional provisions in Article 65(4). Thus, delaying the introduction of product patents in exempt technologies, notably pharmaceuticals, till 1 January 2005. Ostensibly, this gave it the opportunity to exploit changing circumstances to and emergent views on TRIPS-implementation; in particular exploring new interpretations to residual flexibility in TRIPS and any continuing legal ambiguity in TRIPS obligations. In terms of the latter, the Panel Report in *Canada – Patent Protection of Pharmaceutical Products* is pertinent in having exhibited rare reticence in stepping back from defining the principle of non-discrimination in Article 27(1), TRIPS Agreement. While maintaining legal ambiguity, this reticence also provides space for law-making and regulatory diversity. The article reviews the three amendments to India's *Patent Act, 1970* and finds mixed use of residual flexibility and some evidence of efforts to explore legal ambiguity. Thus, despite a favourable climate to TRIPS implementation and an active transnational access to medicine campaign, legislators in India have demonstrated a degree of caution. The article concludes that this caution is best explained in terms of deepening ambivalence concerning intellectual property within the government and the changing economic interests of sections of Indian pharma.

## Key words:

TRIPS Agreement, India, patent reform, Canada, pharmaceutical industry, generics.

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# CONTEXT AND AMBIGUITY: A COMMENT ON AMENDING INDIA'S PATENT ACT

## I. Introduction

In many senses, the signing of the Marrakesh Agreement establishing the World Trade Organisation in 1994, which also led to the Agreement on Trade Related Aspects of Intellectual Property,<sup>1</sup> heralds a unique phase of transglobal governance. Beyond its (high) universal minimum standards, the TRIPs Agreement incorporates strong surveillance provisions. Law-making in the South has possibly not previously witnessed such scrutiny and surveillance. Ironically, the focussed attention on implementing obligations to the TRIPs Agreement has also generated proliferation of forums and diversity of actors. In particular, forum-proliferation and intervention from non-state actors like global civil society has transformed the context of TRIPs-implementation. Beyond mitigating some of the technical and procedural asymmetries in negotiating TRIPs, these developments have called into question the principles that guide the transglobal governance of intellectual property rights (IPRs); thus, opening-up what was deemed to be settled principles within TRIPs. And, there have been concrete successes like the Doha Declaration on Public Health.<sup>2</sup> The scrutiny of implementation also comes with a vast growth in the legal, economic and policy literature. This literature seeks to identify residual flexibility in TRIPs that may promote (and protect) access to medicine, seeds, educational material and also the rights of users and traditional

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<sup>1</sup> Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, 33 I.L.M. (1994) 81; henceforth, TRIPS Agreement.

<sup>2</sup> WTO, Declaration on the TRIPS Agreement and Public Health, at Doha Ministerial Conference, 9-14 November 2001. WT/Min(01)/Dec/W/2; henceforth, WTO, Doha Declaration.

communities<sup>3</sup>. No doubt, there are multiple ways in which these obligations may be honoured; thus, suggesting that beyond residual flexibility there also is legal ambiguity.

The ambiguity is not merely a matter of different interpretations to TRIPs provisions but also a recognition that in certain instances the Agreement does not spell out its provisions. For example, in Article 27(3)(b), where Member countries are obliged to protect plant varieties ‘either by patents or by an effective *sui generis* system or by any combination thereof’. While the Agreement has ample provisions concerning patents it is silent on the parameters of an ‘effective *sui generis* system’. There is more to this notion of legal ambiguity. Here, the Panel Report in *Canada – Patent Protection of Pharmaceutical Products* is pertinent.<sup>4</sup> Among the issues addressed, the Panel also had to deliberate on the principle of non-discrimination in Article 27(1).<sup>5</sup> Despite an elaborate discussion, the Panel remained reticent and stepped back from defining the principle. Thus, generating legal ambiguity and potentially providing space for law-making by Member countries. In the face of legal ambiguity, Member countries have an opportunity for some autonomous action to build the architecture of domestic law in a way that promotes a desired policy objective that may otherwise be compromised by TRIPs.

How then has the changing context to TRIPs-implementation and prevailing legal ambiguity in TRIPs-provisions been either grasped and exploited in the South? For that matter, as we change our attention from concrete successes at *Geneva*, do we see those successes translated into statutory provisions in the South? In attempting to answer these questions the paper looks at India’s implementation of patent-related obligations to TRIPs. In

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<sup>3</sup> See for example, Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy, (London 2002).

<sup>4</sup> WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products (Canada – Generics)*, WT/DS114/R, adopted 7 April 2000; henceforth *Canada – Generics*.

<sup>5</sup> This article requires patents to be available and enjoyable without discrimination as to the field of technology, the place of invention and whether the products are imported or locally produced. Section III below discusses this Article and the *Canada – Generics* Panel Report.

this respect, the *Protection of Plant Varieties and Farmers' Right Act, 2001* is remarkable. Not only is it globally unique in accommodating rights for farmers and breeders within a single instrument but it is equally significant in differing from the template that has dominated the regulatory landscape of plant variety protection and Article 27(3)(b). Any study of Article 27(3)(b) and India's law would map this characteristic feature of exploring residual flexibility and ambiguity in the TRIPS Agreement and demonstrating how the statute incorporates principles from countervailing forums like the Convention on Biological Diversity and the Food and Agriculture Organisation.

With respect to its patent-related obligations, India decided to use the additional transitional provisions in Article 65(4); thus giving itself a final compliance date of 1 January 2005 for product patents in exempt technologies, notably pharmaceutical products. Thus, giving the opportunity to explore opportunities arising from the changing contexts to TRIPS-implementation and continuing legal ambiguity in TRIPs. This makes sense for a country that has consistently resisted moving intellectual property into General Agreement on Tariffs and Trade.<sup>6</sup> With these insights the article focuses on the series of amendments enacted to India's Patent Act, 1970 (IPA, henceforth) and pays particular attention to the third and final amendment in 2005 which introduced product patents in pharmaceuticals. In contrast to earlier amendments, the final amendment raised a relatively muted rhetoric<sup>7</sup> and exhibited a remarkably shared consensus (amongst critical commentators)<sup>8</sup>. The focus of the article is

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<sup>6</sup> Chakravarti Raghavan, *Recolonisation: GATT, the Uruguay Round and the Third World*, London, UK and Penang, Malaysia: Zed Books and Third World Network 1990), see Chapter 12, pp265-81.

<sup>7</sup> Here, compare Sukumar Muralidharan, Patent Capitulation, *Frontline*, vol. 15, (1998), pp. 100-101. and R Ramachandran, Disquiet over a New Regime, *Frontline*, vol. 15, (1999), pp. 90-91 (writing about the first amendment) with V. Sridhar and Siddharth Narrain, A Tempered Patents Regime, *Frontline*, vol. 22, (2005), pp. 28-32 and B. Punj, Patent Debate: An Unhealthy Plan for the Poor, *The Indian Express*, (New Delhi 2005) (writing on the third amendment)

<sup>8</sup> By way of example, recall the different opinions concerning the choice between using the additional transitional provisions or coming into full compliance at an early stage (see Sukumar Muralidharan, Patent Capitulation, *Frontline*, vol. 15, (1998), pp. 100-101 and Dwijen Rangnekar, This patent bill won't please WTO, *Economic Times*, 28 December 1998).

neither on the shared consensus amongst critical commentators<sup>9</sup> nor identifying the 'fountainhead of ideas' or the process of cognitive lock-in. Rather, it explores whether this *consensus* set too narrow an agenda for the third amendment; thus, failing to explore opportunities from delayed full compliance. In particular, were opportunities from changing context or continuing legal ambiguity not grasped? By focussing on domestic law-making, rather than in the Geneva process, the article seeks to draw attention to other factors that influence TRIPS implementation. In the case of India, the article concludes that the architecture of patent law is reflective of ambivalence within government and the changing self-interest of sections of Indian pharma.

The paper begins with a discussion of the globalisation of intellectual property rights where the changing circumstances to TRIPS Agreement implementation is analysed. This is followed by a discussion of the Panel Report in the Canada – Generics case. Here, particular attention is given to the Panel's discussion of the principle of non-discrimination in Article 27(1). Having mapped the context and identified the legal ambiguity (cf. Article 27(1)), the article discusses the three amendments to IPA. A conclusion closes the paper by drawing attention to ambivalence within the government and changing interests amongst sections of Indian pharma.

## **II. Limits to Globalising Intellectual Property Rights**

### ***A. The Globalisation of Intellectual Property Rights***

Three phases have been identified in the evolving architecture of global intellectual property governance: national, international and global.<sup>10</sup> A key feature differentiating the periods is the shrinking contours of the space for the sovereign determination of the protection to be granted within national territory. The global phase was initiated by the Uruguay Round

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<sup>9</sup> I explore this elsewhere; see Dwijen Rangnekar, 'No Pills for Poor People? Understanding the Disembowelment of India's Patent Regime', XLI Economic and Political Weekly 409 (2006).

<sup>10</sup> Peter Drahos, 'Thinking Strategically About Intellectual Property Rights', 21 Telecommunications Policy 201 (1997).

negotiations. To reiterate well rehearsed statements, the TRIPs Agreement not only consolidates pre-existing IP Conventions in a single agreement but is also comprehensive in its coverage of different instruments of IPRs. It goes well beyond previous multilateral treaties by establishing (high) universal minimum standards with time-tabled implementation and backed by regular surveillance for compliance. Finally, there is the WTO's dispute settlement system where these obligations are enforced and non-compliance dealt with by cross-sectoral sanctions.

These transformations are symptomatic of deeper reconfiguration of the space occupied by the state. While not altering territorial borders, contemporary globalisation seriously impacts the institutional encasement of national territory.<sup>11</sup> The reconstituted state, as it engages with supraterritorial organizations (and treaties), has to deal with multi-layered forms of governance which challenge its primacy as the site for scripting rules and providing governance. What Jan Aart Scholte terms transglobal governance exists in the TRIPs Agreement's surveillance provisions.<sup>12</sup> Member countries are obliged to report to and have their compliance reviewed by the TRIPs Council. This web of surveillance is completed by WTO's Dispute Settlement process.<sup>13</sup> None of this should suggest that states engage in and get impacted by these supraterritorial treaties in a similar manner. Global treaties are

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<sup>11</sup> S. Sassen, 'Territory and Territoriality in the Global Economy', 15 *International Sociology* 372 (2000).

<sup>12</sup> Jan Aart Scholte, *Globalization: A Critical Introduction*, (2nd ed. Basingstoke/New York: Palgrave Macmillan 2005).

<sup>13</sup> Peter Drahos, 'Bits and Bips. Bilateralism in Intellectual Property', 4 *The Journal of World Intellectual Property* 791 (2001).

inherently unbalanced and more powerful states succeed in extracting greater concessions.<sup>14</sup> Empirical studies assessing TRIPs Agreement outcomes corroborate this perception.<sup>15</sup>

Notwithstanding the transparent appeal of realist accounts, there are other factors at play. Law-based procedural consensus strategies intermingle with the exercise of power extrinsic to agreed rules at different stages of the negotiations.<sup>16</sup> Rounds tend to start with rule-based procedural consensus. However, negotiations are punctuated by the exercise of power expose the asymmetries between contracting parties as exemplified by Section 301 and Special 301 provisions of the US Trade Act of 1974.<sup>17</sup> These unilateral measures have been complemented by forum-shifting and threat of exiting negotiations.<sup>18</sup> Ironically, the call for multilateralism during the Uruguay Round has upon completion been followed by frantic unilateralism. In particular, a TRIPs-plus strategy to ratchet up IP-standards outside of The TRIPs Agreement is being pursued through bilateral treaties.<sup>19</sup>

### ***B. Challenges to the Globalisation of Intellectual Property Rights***

Are there any limits to what Steinberg (2002) identifies as the organized hypocrisy of the WTO? An answer is beyond the remit of the article, yet it is useful to acknowledge that

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<sup>14</sup> Peter M Gerhart, 'Why Lawmaking for Global Intellectual Property Is Unbalanced', 22 *European Intellectual Property Review* 309 (2000); Peter M Gerhart, 'The Triangulation of International Intellectual Property Law: Cooperation, Power, and Normative Welfare', 36 *Case Western Reserve Journal of International Law* 1 (2004).

<sup>15</sup> K. E. Maskus, 'Lessons from Studying the International Economics of Intellectual Property Rights', 53 *Vanderbilt Law Review* 2219 (2000); UNCTAD, *The Outcome of the Uruguay Round: An Initial Assessment*, (New York and Geneva: United Nations 1994).

<sup>16</sup> R. H. Steinberg, 'In the Shadow of Law or Power? Consensus-Based Bargaining and Outcomes in the GATT/WTO', 56 *International Organization* 339 (2002).

<sup>17</sup> While scholarly and activist attention tends to be fixated on the US, Peter Drahos, 'Developing Countries and International Intellectual Property Standard-Setting', 5 *The Journal of World Intellectual Property* 765 (2002), reminds us that in 1984 the European Community enacted a similar provision in Council Regulation 264/84, which was not used much because of insufficient consensus.

<sup>18</sup> R. H. Steinberg, above n 16.

<sup>19</sup> Drahos, above n 13, defines TRIPs-plus as provisions that require a Member to either implement more extensive standards, or eliminate an option, or introduce new rights. The proliferation of TRIPs-plus standards through bilaterals will eventually globalize a higher minimum norm outside the TRIPs Agreement.



'[P]eople will never trust in the balance of advantages and disadvantages in international trade which the GATT approach to intellectual property seeks to impose on them'.<sup>20</sup> Alongside this wariness, Southern negotiators have succeeded in mitigating some of the procedural and technical asymmetries in negotiations. Transnational campaigns have played a role in transforming the principles of the debate.<sup>21</sup> The TRIPs Action Network, a coalition of 189 NGOs, called for 'a fundamental re-thinking of TRIPS in the WTO ... urging WTO members to initiate a process of reviewing and reforming TRIPs'.<sup>22</sup> This sentiment recurs in the UK government's Commission on IPRs 'one size does not fit all' critique of The TRIPS Agreement.<sup>23</sup> The UNDP argued that the 'relevance of TRIPs is highly questionable for large parts of the developing world,' and called for an epistemic revolution with developing countries 'begin[ning] dialogues to replace TRIPs . . . with alternate intellectual property paradigms'.<sup>24</sup>

Testimony to these challenges is the post-TRIPs proliferation of inter-governmental agencies and forums dealing with IPRs. These forums include the World Health Organisation<sup>25</sup>, the Food and Agriculture Organisation<sup>26</sup>, the Conference of Parties of the

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<sup>20</sup> Hans Ulrich, 'GATT: Industrial Property Protection, Fair Trade and Development', in F. K. Beier and G. Schriker (eds.), *GATT or WIPO? New Ways in the International Protection of Intellectual Property*, (Munich, Germany: Max Planck Institute for Foreign and International Patents, Copyright and Competition Law 1989), 127-159 at 142.

<sup>21</sup> Susan K. Sell and Asim Prakash, 'Using Ideas Strategically: The Contest between Business and Ngo Networks in Intellectual Property Rights', 48 *International Studies Quarterly* 143 (2004).

<sup>22</sup> Anon., 'Joint Ngo Statement: Re-Thinking Trips in the WTO - NGOs Demand Review and Reform of Trips at Doha Ministerial Conference', <http://www.twinside.org.sg/title/joint5.htm> (visited 26 March 2005).

<sup>23</sup> Commission on Intellectual Property Rights, above n 3.

<sup>24</sup> UNDP, *Making Global Trade Work for People*, (London: Earthscan 2003), at 221-22.

<sup>25</sup> Most recently crystallized in the work of the Commission on Intellectual Property, Innovation and Public Health, set up in 2003 (see <http://www.who.int/intellectualproperty/en/>).

<sup>26</sup> The International Treaty on Plant Genetic Resources for Food and Agriculture has a number of articles with IP provisions, notably Article 12.3(d) requiring that recipients 'shall not claim any intellectual property or other rights that limit the facilitated access' to plant genetic resources, or their 'genetic parts or components', in the form received from the Multilateral System.

Convention on Biological Diversity<sup>27</sup>, and the UN Commission on Human Rights<sup>28</sup> among others. In studying forum proliferation scholars note the strategic use of ideas to frame debates and capitalize on policy crises. Of particular significance is the Doha Declaration on Public Health.<sup>29</sup> Beyond being an initiative of the coalition of the weakest, it is a concrete indicator of the success of the transnational NGO network. IP law making, it would seem, is not the exclusive privilege of the group of actors that succeeded in getting IPRs into GATT; thus, suggesting an emerging locus constituted by transnational NGOs and the Africa Group.

It's the sequence of events following Doha that point towards a likely reversal. The first of these is the withdrawal of the challenge<sup>30</sup> to South Africa's Medicines and Related Substances Control Amendment Act (1997) launched in 1998 by 38 pharmaceutical companies<sup>31</sup>. This amendment sought to help the government to respond to the looming HIV/AIDS crisis by, among other things, authorising parallel imports from third countries where the drug was being manufactured (cf. Section 15C). Following a transnational NGO campaign (Bond, 1999), the companies withdrew their challenge in April 2001. In this respect, the negotiations to procure supplies of ciprofloxin by the US and Canadian

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<sup>27</sup> The Convention's principles, among others, is the fair and equitable sharing of benefits arising from the use of genetic resources. Thus, it has a number of articles with IP-provisions that deal with technology transfer, access to and use of genetic resources and traditional knowledge, and informed consent.

<sup>28</sup> Resolution 2001/33 passed at the 57<sup>th</sup> session of the Commission recognizes access to medicine, particularly in pandemic situations, as a human right.

<sup>29</sup> WTO, Doha Declaration, above n 2; see Susan K. Sell and Asim Prakash, above n 21 for an account of the contest of principles and ideas. The politics of ideas aside, there are questions concerning the legal status of the Doha Declarations, see for example S. Charnovitz, 'The Legal Status of the Doha Declarations', 5 Journal of International Economic Law 207 (2002) and C. Otero García-Castrillón, 'The Legal Status of the Doha Declarations', 5 Journal of International Economic Law 211 (2002).

<sup>30</sup> An indication of imminent problems was the removal, in 1998, of South Africa from the Generalized System of Preferences, a preferential regime for accessing the US market. The following year, the country found itself on the S301 watch list.

<sup>31</sup> The Pharmaceutical Manufacturers' Association of South Africa et al vs The President of the Republic of South Africa et al, Notice of Motion, High Court of South Africa (Transvaal Provincial Division), 18 February, 1998.

governments for treatment of anthrax poisoning in October/November 2001 also played a role.<sup>32</sup>

Then the US aborted their challenge of compulsory licensing provisions in Brazil's *Industrial Property Law No. 9279* (of 1996) and in the *Presidential Decree on Compulsory Licensing* (Decree No 3201 of 6 October, 1999). Controversial, as claimed by the US, was the presumption that local working of a patent can only be satisfied by the local production and not importation.<sup>33</sup> While the US withdrew its challenge, it expressed strong views: 'The United States continues to view local manufacturing requirements as being inimical to the principles of free trade and inconsistent with various WTO rules, including the TRIPs Agreement. The US government will aggressively engage other countries that impose or maintain such requirements and, if appropriate, pursue WTO dispute settlement'.<sup>34</sup>

These events mark a dramatic reversal in the power structures that enframe the TRIPs Agreement.<sup>35</sup> Others remain cautious on the extent of the shift in power.<sup>36</sup> These differences aside, the events indicate a hesitation in following through the threats to law making in the South. This hesitation is also witnessed in rare instances of reticence by WTO Panels to articulate substantive meaning to key standard-setting terms as in the case of discrimination in Article 27 by the *Canada – Generics* Panel (discussed below). Thus, it is fair

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<sup>32</sup> This included news of seeking generic supply from India (see M Joseph, 'Indian Cipro Copies Don't Pay Off', [www.wired.com/news/medtech/0,1286,48153,00.html](http://www.wired.com/news/medtech/0,1286,48153,00.html) (visited 27 March 2005)) and federal appropriation of Bayer's patent in ciprofloxin and issuing compulsory licenses.

<sup>33</sup> WTO, Brazil – Measures Affecting Patent Protection: Request for Consultation by the United States, WT/DS199/1, 8 June 2000.

<sup>34</sup> US Trade Representative, 'Us, Brazil Withdraw HIV/Aids Dispute from WTO Litigation', <http://usinfo.state.gov/topical/econ/group8/summit01/www01062512.html>, 25 June 2001, last visited 30 June 2001.

<sup>35</sup> Susan K. Sell and Asim Prakash, above n 21.

<sup>36</sup> Peter Drahos, above n 17.

to speculate if this is a harbinger to 'revise, reinterpret, or supplement intellectual property protection standards adopted in the WTO and in WIPO?'<sup>37</sup>

### III. Residual Flexibility and Ambiguity – The Case of the Canada – Generics Panel Report

#### A. The Cause for Dispute

Article 27.1 strongly manifests the loss of sovereign autonomy noted above. This article requires patents to be available and enjoyable without discrimination as to the field of technology, the place of invention and whether the products are imported or locally produced. There are no comparable non-discrimination clauses elsewhere in The TRIPS Agreement.<sup>38</sup> Article 27.1, it is suggested, was aimed at prohibiting de jure discrimination, such as a blanket exclusion of particular subject matter,<sup>39</sup> notably pharmaceutical products.<sup>40</sup> The obligation has greater significance in introducing a principle of non-discrimination which requires explication, as do the three dimensions of field of technology, place of invention and source of product. The *Canada – Generics* Panel had to deal with these questions, among others.<sup>41</sup>

On 19 December 1997, the European Communities and their Member States requested consultation with Canada alleging, among others, that patent rights were not enjoyable without discrimination as to the field of technology. The two disputed provisions

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<sup>37</sup> Laurence R. Helfer, 'Regime Shifting: The Trips Agreement and New Dynamics of International Intellectual Property Lawmaking', 29 *Yale Journal of International Law* 1 (2004), at 4-5.

<sup>38</sup> UNCTAD & ICTSD, *Resource Book on Trips and Development*, (Cambridge: Cambridge University Press 2005) at 368-69.

<sup>39</sup> G. B. Dinwoodie and R. C. Dreyfuss, 'International Intellectual Property Law and the Public Domain of Science', 7 *Journal of International Economic Law* 431 (2004); see also Canada's submission to the WTO Panel, WTO Panel Report, *Canada – Generics*, above n 4, para 7.90.

<sup>40</sup> Kevin J. Nowak, 'Staying within the Negotiated Framework: Abiding by the Nondiscrimination Clause in Trips Article 27', 26 *Michigan Journal of International Law* 899 (2005).

<sup>41</sup> WTO Panel Report, *Canada – Generics*, above n 4.

were Sections 55.2(1) and 55.2(2).<sup>42</sup> The former, known as the regulatory review exception, states that '[I]t is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.' The latter, referred to as the stockpiling exception, states that '[I]t is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations,<sup>43</sup> for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires.' The European Communities claimed that these provisions were inconsistent with obligations under Articles 27.1 and 28.1 and that to the extent that Section 55.2(2) violates Article 28.1 it is inconsistent with Article 33. An estimated loss of C\$100mn per annum was also alleged.<sup>44</sup>

### **B. The Verdict in Canada – Generics**

The verdict in *Canada-Generics* has been widely commented upon and the intention is not to exhaustively review the literature. Instead, the focus is on the Panel's views on discrimination as this has greater significance to my discussion of the amendments to India's patent law. Some consider the overall decision laudable in applying Article 27.1's non-discrimination principle to Articles 30 and 31.<sup>45</sup> Others commend the Chair for his handling of the dispute, whilst differing on the interpretation of limited exceptions in Article 30 and the reasoning of

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<sup>42</sup> WTO, Canada - Patent Protection of Pharmaceutical Products: Request for Consultations by the European Communities, WT/DS/114/1, 12 January 1998.

<sup>43</sup> In the case of pharmaceutical products, the applicable period set out in the Manufacturing and Storage of Patented Medicines Regulations is six months, see WTO Panel Report, *Canada – Generics*, above n 4, para 2.1.

<sup>44</sup> *Ibid*, at para 4.7.

<sup>45</sup> Kevin J. Nowak, above n 40.

expanding non-discrimination under Article 27.1 to Articles 30 and 31.<sup>46</sup> Other critiques appeal for a stronger balance between rights and obligations through use of Articles 7 and 8.1.<sup>47</sup> The Panel's findings on non-discrimination have been considered most damaging and based on flawed principles of treaty interpretation.<sup>48</sup>

As regards the stockpiling exception, Canada, adopting a conventional dictionary meaning of limited as 'confined within definite limits' or 'restricted in scope, extent, amount'.<sup>49</sup> Thus, claiming consistency with Article 30 as stockpiling did not impinge on sales to the ultimate consumer during the term of protection. In contrast, the EC suggested that limited be interpreted as 'narrow, small, minor, insignificant or restricted'.<sup>50</sup> As stockpiling impinged on three of the five elements of the rights conferred under Article 28.1, viz. making, using and importing, the EC claimed inconsistency. Disagreeing with the genesis of the EC argument, the Panel reasoned that the stockpiling exception was not limited: 'With no limitations at all upon the *quantity* of production, the stockpiling exception removes that protection entirely during the last six months of the patent term, without regard to what other, subsequent, consequences it might have. By this effect alone, the stockpiling exception can be said to abrogate such rights entirely during the time it is in effect'.<sup>51</sup> The emphasis on quantity recurs in the Panel's reasoning when it agrees with the EC that 'six months was a commercially significant period of time, especially since there were no limits at all on the volume of production'.<sup>52</sup>

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<sup>46</sup> Frederick M. Abbott, 'Bob Hudec as Chair of the Canada-Generic Pharmaceuticals Panel - the WTO Gets Something Right', 6 *Journal of International Economic Law* 733 (2003).

<sup>47</sup> G. B. Dinwoodie and R. C. Dreyfuss, above n 39.

<sup>48</sup> Robert Howse, 'The Canadian Generic Medicines Panel. A Dangerous Precedent in Dangerous Times', 3 *The Journal of World Intellectual Property* 493 (2000).

<sup>49</sup> WTO Panel Report, *Canada – Generics*, above n 4, at para. 7.27.

<sup>50</sup> *Ibid*, at para 7.28.

<sup>51</sup> *Ibid*, at para 7.34, emphasis added.

<sup>52</sup> *Ibid*, at para. 7.37.

The Panel's deliberations on the regulatory review exception makes interesting reading for those who explore the contingency and temporality in law. The EC argued that the exception was not limited as it abrogated the entire right during the term of protection.<sup>53</sup> In its defence, Canada stated that no commercial sale occurs to the ultimate consumer; hence satisfying the requirement for limited exception.<sup>54</sup> In presenting its conclusion, the Panel observed that the exception had a 'narrow scope of its curtailment'<sup>55</sup> and that it didn't conflict with the normal exploitation of a patent.<sup>56</sup> Canada drew the Panel's attention to provisions in US patent law, popularly termed the Bolar provisions<sup>57</sup> and similar practice in other member countries following their implementation of obligations to The TRIPS Agreement.<sup>58</sup> It reminded the Panel that the United States agreed to the general language of Article 30 on the understanding its patent laws were consistent with the TRIPS Agreement.<sup>59</sup> The Panel acknowledged these points, but 'did not accord any weight' to existing US practice or understanding.<sup>60</sup> Remarkable as this might be, scholars conclude that the Panel's conclusion are 'hardly surprising' given practice in US, Germany and new accession states to the European Union.<sup>61</sup>

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<sup>53</sup> Ibid, at para 7.43.

<sup>54</sup> Ibid, at para 7.40.

<sup>55</sup> Ibid, at para 7.45.

<sup>56</sup> Ibid, at para 7.58.

<sup>57</sup> 35 United States Code, Section 271(e) which was passed to reverse a federal court decision ruling that the scientific use exemption could not be used as a defence against infringement where patented subject matter was used for the purpose of making submissions for regulatory approval (*Roche Products Inc. v Bolar Pharmaceutical Co., Inc*, 733 F.2d 858 (C.A.F.C. 1984)). It remains a puzzle as to why the EC never considered challenging the US for this provision in its law. For a brief discussion, see WTO Panel Report, *Canada – Generics*, above n 4, at para 7.41.

<sup>58</sup> Ibid, at para 7.42.

<sup>59</sup> Ibid, at para 7.41.

<sup>60</sup> Ibid, at para 7.47.

<sup>61</sup> D Vaver and S Basheer, 'Popping Patented Pills: Europe and a Decade's Dose of Trips', 28 *European Intellectual Property Review* 282 (2006), at 284.

### **C. Non-discrimination: Ambiguity in the Panel Report**

As regards non-discrimination, the question facing the Panel was whether non-discrimination in Article 27.1 applies across the board and is neutral to wider societal objectives as given in Articles 7, 8.1 and 30. The Panel observed that 'Article 27.1 prohibits discrimination as to the enjoyment of 'patent rights' without qualifying the term. Article 30 exceptions are explicitly described as 'exceptions to the exclusive rights conferred by a patent' and contain no indication that an exemption from non-discrimination rules is intended. A discriminatory exception that takes away enjoyment of a patent right is discrimination as much as discrimination in the basic right themselves. The acknowledged fact that the Article 31 exception for compulsory licences and government use is understood to be subject to the non-discrimination rule of Article 27.1 without the need for any textual provision so providing, further strengthens the case for treating the non-discrimination rules as applicable to Article 30'.<sup>62</sup> The decision, *Abbot* suggests, is best understood in a political context: 'In late 1999, the political pressures resulting from aggressive US and EC policies on TRIPS were building up, but public antipathy towards that conduct had not yet manifested itself at the level surrounding the Medicines Act trial in South Africa. The Doha Declaration on the TRIPS Agreement and Public Health was about two years off'.<sup>63</sup> This is a useful reminder notwithstanding the Panel's own claims of independence from de facto pressure.<sup>64</sup>

In its ruling on non-discrimination, the Panel agreed with the EC that 'the TRIPS Agreement would want to require governments to apply exceptions in a non-discriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers'.<sup>65</sup> Discrimination, the Panel suggests, is the 'results of the unjustified imposition of differentially disadvantageous

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<sup>62</sup> WTO Panel Report, *Canada – Generics*, above n 4, at para. 7.91.

<sup>63</sup> Frederick M. Abbott, above n 46, at 736.

<sup>64</sup> WTO Panel Report, *Canada – Generics*, above n 4, at para. 7.47.

<sup>65</sup> *Ibid*, at para. 7.92.



treatment' and 'may arise from explicitly different treatment, sometimes called "de jure discrimination", but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called "de facto discrimination".<sup>66</sup> In this particular instance, the Panel was not convinced by the evidence presented by the EC that de jure discrimination occurred and was satisfied by the assurances from Canada that Section 55.2(1) was not restricted to pharmaceutical products as it was scripted in a technologically neutral language.<sup>67</sup> Thus, in assessing de facto discrimination, the Panel focussed on the 'effect' and 'purpose' of Section 55.2(1). As regards 'effect', the Panel held that the EC had not demonstrated that the discriminatory effect would be limited to pharmaceutical products.<sup>68</sup> Its reasoning on 'purpose' is revelatory. There was little disagreement between parties on the purpose of the measure, which Canada itself made clear was focussed on pharmaceutical products. However, the Panel observed that 'preoccupation with the effects of a statute in one area does not necessarily mean that the provisions applicable to other areas are a sham, or of no actual or potential importance' and concluded that '[S]o long as the broader application is not a sham, the legislation cannot be considered discriminatory'.<sup>69</sup>

Despite this discussion on discrimination, the Panel stepped back from defining the term<sup>70</sup> and actually found no need to make a precise statement.<sup>71</sup> While this reticence is exquisite in its ambiguity, some fault lines are identifiable. To begin, Article 27.1 prohibition is not absolute but limited to the field of technology, the place of invention and whether the products are imported or locally produced. Discrimination based on other factors that are

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<sup>66</sup> Ibid, at para. 7.94.

<sup>67</sup> Ibid, at para. 7.99.

<sup>68</sup> Ibid, at para. 7.102.

<sup>69</sup> Ibid, at para. 7.104.

<sup>70</sup> Ibid, at para. 7.98.

<sup>71</sup> Ibid, at para. 7.105.

otherwise consistent with the TRIPs Agreement is not prohibited. There is wisdom here. For sometime, evolutionary economists have critiqued the received scholarship on intellectual property rights emphasising the sectorally differentiated relationship between IPRs, innovation patterns and appropriation strategies.<sup>72</sup> This relationship has been empirically documented<sup>73</sup> and analytically schematized in terms of the mode of technological advance.<sup>74</sup> In cumulative and networked technologies, broad patents and highly disaggregated rights can generate an anticommons leading to the underutilisation of the resource.<sup>75</sup> Remarkably, the US Federal Trade Commission has expressed concern about the detrimental consequences of patent thickets in sectors characterized by incremental innovation.<sup>76</sup>

The Panel notes that '[A]rticle 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas'.<sup>77</sup> Clearly prescient as it predates the Doha Declarations on Public Health<sup>78</sup> which is testimony to the special circumstances that exist in a particular field of technology. Not only have WTO members reaffirmed their

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<sup>72</sup> Giovanni Dosi, 'Technological Paradigms and Technological Trajectories: A Suggested Interpretation of the Determinants and Directions of Technical Change', 11 *Research Policy* 147 (1982); Giovanni Dosi, 'Sources, Procedures, and Microeconomic Effects of Innovation', 26 *Journal of Economic Literature* 1120 (1988); Richard R. Nelson and Sidney G. Winter, 'In Search of a Useful Theory of Innovation', 6 *Research Policy* 36 (1977).

<sup>73</sup> A. K. Klevorick, R. C. Levin, R. R. Nelson and S. G. Winter, 'On the Sources and Significance of Interindustry Differences in Technological Opportunities', 24 *Research Policy* 185 (1995); Edwin Mansfield, 'Patents and Innovation: An Empirical Study', 32 *Management Studies* 173 (1986).

<sup>74</sup> Robert P. Merges and Richard P. Nelson, 'On the Complex Economics of Patent Scope', 90 *Columbia Law Review* 839 (1990), who identify four broad categories: discrete technologies tend to be stand-alone developments (e.g. safety razor, ball-point pens and the toy industry); cumulative technologies are where technological advance builds on other technologies, research tools and resources (e.g., automobiles, aircrafts, electrical light systems and semiconductors); chemical processes is considered unique in that it mixes features of discrete and cumulative models; finally, science-based technologies are those where advance is mainly driven by current/recent developments in science (e.g. biotechnology, medical diagnostic equipment and nuclear).

<sup>75</sup> M. A. Heller and R. S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research', 280 *Science* 698 (1998).

<sup>76</sup> US Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, (Washington DC, USA 2003).

<sup>77</sup> WTO Panel Report, *Canada – Generics*, above n 4, at para. 7.92.

<sup>78</sup> WTO, Doha Declaration above n 2.

commitment to this special treatment<sup>79</sup> but measures for differential treatment of pharmaceutical products exist.<sup>80</sup> In this manner, WTO members give legitimacy to the differential treatment of pharmaceutical products.

The observation of the Panel on bona fide exceptions was prompted by submissions from third parties, which pointed to the puzzle that undifferentiated treatment could discriminate against particular fields of technology. Thus, ironically, differential treatment may be justified to restore 'parity of enjoyment', the US argued.<sup>81</sup> Here, obvious reference was to the practice in US and elsewhere of patent term extensions ostensibly to balance the provision for regulatory-review exceptions. The EC stopped short of emphasising this trade-off as that would suggest that Section 55.2(1) could be consistent with Article 30 if patent-term extension were introduced.<sup>82</sup>

India, as third party to the dispute, emphasized its 'systemic interest' in terms of the balance in TRIPs between private rights and societal interests.<sup>83</sup> Further, aligning itself with Canada, it found the provisions in dispute have an 'imperative if the interests of third parties were to be fully safeguarded'.<sup>84</sup> The next section of the paper explores how this systemic interest manifests itself in its domestic law and to what extent does the law deliver on the imperative.

#### **IV. Amending Patent Law in India**

Negotiating conflicting domestic and external exigencies, India decided to use the additional transition provisions in Article 65(4) and delay introducing product patents in exempt

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<sup>79</sup> Ibid, at para 4.

<sup>80</sup> Ibid, at para 6 and 7.

<sup>81</sup> WTO Panel Report, *Canada – Generics*, above n 4, at para. 5.36.

<sup>82</sup> Ibid, at para. 4.41.

<sup>83</sup> Ibid, at para. 5.20.

<sup>84</sup> Ibid, at para. 5.22.

technologies till at least 1 January 2005. Ostensibly, this provides an opportunity to benefit from changing circumstances to and the growing wisdom in interpreting the TRIPS Agreement. Charting the process of coming into full compliance with its patent-related obligations at TRIPs, the section evaluates how circumstances and wisdom have been exploited.

### **A. The First Amendment**

Under Article 65(4) India was obliged to put in place by 1 January, 1995 mechanisms for receiving product patent applications in these exempt technologies, the mail-box requirement of Article 70(8), and allow for the grant of exclusive marketing rights (Article 70(9)). An Ordinance in 1995 and a Bill in 1996 failed to be passed. Thus, setting the stage for the first TRIPS dispute in November 1996, with the United States alleging that India had failed to implement these obligations.<sup>85</sup> The Panel ruled that India's administrative system was inadequate<sup>86</sup> and the appellate body broadly upheld the Panel's decision.<sup>87</sup> Subsequently, India enacted the first amendment, *The Patents (Amendment) Act, 1999* (No. 17 of 1999), adding Chapter IVA titled exclusive marketing rights to the IPA.

### **B. The Second Amendment**

Through Article 70(9), India was obliged to fulfil its obligations under Article 65(2) by 1 January 2000 when the five-year transitional period ended. The *Patent (Second Amendment) Bill, 1999* was introduced in the Rajya Sabha on 20 December 1999 and immediately referred to a Joint Parliamentary Committee of both Houses of Parliament. The Committee held 39 meeting, received 42 memoranda, and heard oral testimonies from 51 witnesses and

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<sup>85</sup> WTO, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products: Request for Consultations by the United States*, WT/DS50/1, 9 July 1996.

<sup>86</sup> WTO Panel Report, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/R, adopted upon amendment by Appellate Body Report on 16 January 1998.

<sup>87</sup> WTO Appellate Body Report, *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, adopted 16 January 1998.

19 individuals and organisations. The Committee also visited a number of countries<sup>88</sup>. Based on its report, a revised the Bill was presented to Parliament and enacted as *Patents (Amendment) Act, 2002* (henceforth, the Second Amendment) on 25 June 2002.

The Second Amendment introduces over 70 changes to IPA which begin with a revision to sections dealing with non-patentable inventions. Such as, an exclusion similar to Article 27(2) of TRIPS and an elaborate list of non-patentable inventions (e.g. abstract theory, mathematical or business methods, computer programmes, and topography of integrated circuits, among others). Reflecting concerns regarding bio-piracy, there are changes to the patent application and examination process (cf. Section 10 & 25). The term of protection, in Section 53, was revised to come into compliance with Article 33 of TRIPS.

Of interest are the changes with respect to compulsory licenses. The Second Amendment removed earlier references to the automatic licenses of rights (e.g. sections 86, 87, 88). Further, Chapter XVI titled working of patents, compulsory licences and revocation was substantially revised. Section 84 provides for non-working as a basis for granting compulsory licences which includes the non-satisfaction of the 'reasonable requirements of the public', or that the patented product is not available at a 'reasonably affordable price' or it is 'not worked in the territory of India'. This includes adequate commercial production and importation that hinders commercial production within India. Section 89(a) mandates the Controller to review applications under Section 84 to promote working of patented inventions on a 'commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable'. In Section 92, dealing with compulsory licences on account of national emergency, extreme urgency or public non-commercial use, the earlier reference to working of a patent in India has been deleted.

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<sup>88</sup> This included Argentina, Brazil, Canada, China, Japan and South Korea. Srividhya Ragavan, 'Patent Amendments in India in the Wake of Trips', 8 CASRIP Newsletter 5 (2002), expresses disappointment at the exclusion of the US concluding that '[t]he elaborate tour of the world can now be interpreted as one more effort by India just to be stubborn and irrational when dealing with WTO issues'.

A number of commentators have expressed surprise at this script and suggest it conflicts with The TRIPS Agreement.<sup>89</sup> Daya Shanker<sup>90</sup> provides an elaborate explanation of the compatibility of non-working with TRIPs obligation. It is here that the aborted US challenge of compulsory license provisions in Brazil's laws is significant, which some have considered legally weak<sup>91</sup>. In maintaining non-working, India demonstrates its intent to explore space left open by legal ambiguity.

Coming into substantive compliance with The TRIPS Agreement required expanding the patent rights conferred in Section 48 to include importation. Following this, Section 107A was introduced to identify non-infringing acts. Paragraph (a) introduces the regulatory review exception which is akin to what was in dispute in the *Canada – Generics* case. Using the doctrine of international exhaustion, paragraph (b) makes importation of a patented product from a duly authorized person for sale or distribution a non-infringing act. Both these provisions indicate a desire to incorporate residual flexibility in The TRIPS Agreement and use recent Panel pronouncements.

### **C. The Third Amendment**

Finally, product patents in exempt technologies were to be enacted through the Patents (Amendment) Bill, 2003, but this lapsed with the dissolution of Parliament. The new government, the Congress-led and Left-backed, United Progressive Alliance introduced a marginally revised version as the Patents (Amendment) Ordinance, 2004 (Ord. No. 7 of 2004) (henceforth, the Ordinance) in light of the 1 January, 2005 deadline. Popular protest to the Ordinance organized through the Joint Action Committee against Amendment of the Indian Patent Act drew attention to residual flexibilities in the TRIPs Agreement that were not

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<sup>89</sup> Ibid, and Srividhya Ragavan, 'Can't We All Get Along? The Case for a Workable Patent Model', 23 Arizona State Law Journal 117 (2003), who expands the discussion.

<sup>90</sup> Daya Shanker, 'India, the Pharmaceutical Industry and the Validity of TRIPS', 5 The Journal of World Intellectual Property 315 (2002); Daya Shanker, 'Brazil, the Pharmaceutical Industry and the WTO', 5 The Journal of World Intellectual Property 53 (2002).

<sup>91</sup> Ibid.

being used.<sup>92</sup> Many of these recommendations, as will be discussed shortly, were incorporated into the Patents (Amendment) Bill, 2005 which later was passed by Parliament. At issue is whether there were opportunities that the debate failed to recognize and/or legislators failed to enact. Issues debated can be broadly classified into two groups:

- The criterion of patentability: conditions for grant of protection, pre- and post-grant opposition, and exclusions from patentability.
- Access to medicine: opening the mail-box, Doha provisions and compulsory licenses.

The first set of issues relate to practices of building patent thickets by securing multiple and overlapping patents around a single invention<sup>93</sup>. This raises transaction costs particularly in those sectors characterized by cumulative, networked and path-dependent technological trajectories. In pharmaceuticals, thickets arise when minor modifications like changes in size, colour, dosage, delivery mechanism, and composition, around a known and patented molecule are either simultaneously or sequentially patented. In addition, new formulations and combinations of existing active ingredients are also protected by patents. Between 1989 and 2000, of the 1035 new drug applications approved by the US Food and Drug Administration, 361 (or, 35%) were for new chemical entities and the balance, 65%, were incrementally modified drugs.<sup>94</sup> De facto, these practices render non-existent the finite time-limit of patent terms as new patents continue to keep the subject matter under protection; hence the term of evergreening patents.<sup>95</sup> This is not new; the 1959 US Senate

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<sup>92</sup> Joint action committee against amendment of the Indian Patent Act, 'Declaration', 3 January 2005, available at [http://pd.cpim.org/2005/0116/01162004\\_patemts%20stmn.htm](http://pd.cpim.org/2005/0116/01162004_patemts%20stmn.htm) (visited 26 March 2005).

<sup>93</sup> For a recent treatment see the US Federal Trade Commission, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, (Washington DC, USA 2003).

<sup>94</sup> National Institute for Health Care Management, Changing Patterns of Pharmaceutical Innovation, (Washington DC, USA 2002).

<sup>95</sup> Ibid; a recent example would be the anti-histamine, Fexofenadine, which Aventis initially patented in 1979 (US Patent No. 4,254,129). In 1996, prior to the expiry of this patent Aventis was granted a patent claiming a substantially pure compound, discussed in Padmashree Gehl-Sampath, Economic Aspects of Access to Medicine after 2005: Product Patent Protection and Emerging Firm Strategies in

Committee headed by Kefauver noted that many patents involved molecules that were manipulated and therapeutically similar to previous molecules.<sup>96</sup> During the debate in India, commentators drew attention to the 8,000 plus applications for product patents in the mailbox during a period (1995-2003) when the US Federal Drug Administration is said to have approved only 274 new chemical entities; thus, suggesting that a substantial number of applications were either me-too drugs or incremental modifications.

It is to practices like these that amendments to the Ordinance were proposed, recommending, inter alia, clearer language to raise the goal-posts for patentable subject matter and clarify exclusions from patentability. Amendments to the Ordinance included:

- In Section 2(ja), the definition of inventive step was amended with the addition of the following italicized text: *an invention that involves technical advance as compared to existing knowledge or having economic significance or both* and that makes the invention not obvious to a person skilled in the art.
- A definition for 'pharmaceutical substance' was introduced that had the phrase 'any new entity involving one or more inventive step'.
- Section 3(d), exceptions to patentability<sup>97</sup>, was re-drafted to read as follows: the mere discovery 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 of 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.

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the Indian Pharmaceutical Industry, *Studies prepared for the WHO's Commission on Intellectual Property Rights, Innovation and Public Health*, (Geneva 2005).

<sup>96</sup> William S Comanor, 'The Political Economy of the Pharmaceutical Industry', 24 *Journal of Economic Literature* 1178 (1986).

<sup>97</sup> In 2006, the Chennai Patent Office rejected Novartis's patent application for Glivec, an anti-cancer drug, citing several grounds including Section 3(d). Later in May, Novartis filed several writs claiming, among other, that Section 3(d) is arbitrary, illogical and conflicts with the TRIPs Agreement, see Sarah Hiddleston, Patent Trouble, *Frontline*, vol. 24, (2007).



- Provisions for pre-grant opposition were reinstated.

The second set of issues relate to access to medicine. As Abbott<sup>98</sup> notes, one of the issues concerned patent applications lying in the mail-box where the eventual grant of a patent could compromise the continuation of existing production into the future. The Ordinance failed to recognize the problem despite introducing provisions for opening-up the mail-box (cf. Section 11A(7)). Following criticism, the government introduced two measures. First, production can continue on cumulatively meeting the following conditions: substantial investment has been incurred, production and marketing has commenced prior to and continues subsequent to 1 January 2005, and a reasonable royalty rate is paid to the patentee. And, second, patentees cannot institute infringement proceedings against these producers.

The Ordinance was also criticized for not incorporating Doha measures. Even while India was active in the deliberations leading to the August 2003 Decision,<sup>99</sup> the Ordinance did not incorporate these provision. Responding to this lacuna, section 92A(1) was amended with the addition of the following text: 'or such country has by notification or otherwise allowed importation of the patented pharmaceutical products from India'. To complete this amendment, section 90(1)(vii) was redrafted to allow production under a compulsory license to also be exported upon meeting stipulated conditions.

Two recommendations from the Left parties, exclusion of micro-organisms from patentability and the introduction of a specific definition for new entities, were rejected and

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<sup>98</sup> Frederick M. Abbott, 'The Trips Agreement, Access to Medicines, and the WTO Doha Ministerial Conference', 5 *The Journal of World Intellectual Property* 15 (2002).

<sup>99</sup> WTO, *Decision of the General Council on Implementing Paragraph 6 of the Doha Declaration*, WT/L/540, adopted 30 August 2003. The key breakthrough meeting to secure an agreement was convened by Chair of the TRIPs Council, Vanu Gopala Menon of Singapore, and delegates from Brazil, India, Kenya, South Africa and US.

later referred to the Technical Expert Group on Patents chaired by Dr RS Mashelkar.<sup>100</sup> Among the tasks, the Expert Group had to consider whether 'it would be TRIPs compliant to limit the grant of patents for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps'.

The Expert Group received written and oral submissions from a variety of quarters and published their findings in December 2006.<sup>101</sup> Disturbingly, there is no legal analysis or references to the literature. Thus, summarily it concludes that the proposed exclusion is 'likely' to contravene TRIPs obligations<sup>102</sup> and tantalisingly notes the 'perception that even the current provisions in the Patents Act could be held to be TRIPS non-compliant'.<sup>103</sup> Unfortunately, we are neither told why this is likely nor whose perceptions were considered.

#### **D. Discussion**

This analysis of amendments to IPA show that there were mixed use of residual flexibility in The TRIPS Agreement and efforts to explore legal ambiguity. To begin, following the domestic exigencies that delayed implementing obligations under Article 65(4), India was self-assured enough to go through a WTO dispute and also appeal the decision. In the Second Amendment, in retaining local working it demonstrated its effort to exploit the legal ambiguity that arose from the withdrawal of US's challenge of Brazil patent laws. With respect to the *Canada – Generics* decision, it introduced provisions similar to the regulatory review exception. By not exploring the stockpiling exception it treaded a careful line. As noted earlier, the Panel's emphasis on the absence of quantitative limits to the stockpiling

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<sup>100</sup> Anon., Statement Issued at the Press Conference of the Four Left Parties, *People's Democracy*, 27 March 2005.

<sup>101</sup> Anon., Report of the Technical Expert Group on Patent Law Issues, (New Delhi 2006), available at <http://www.cptech.org/ip/health/c/india/> (visited 20 February 2007). Following allegations of plagiarism, which Mashelkar accepted, the report was withdrawn on 19 February 2007.

<sup>102</sup> Ibid, at para 5.6.

<sup>103</sup> Ibid, at para 5.11.

exception suggests a route around its conclusion that stockpiling violates The TRIPS Agreement.

It is with respect to the Panel's deliberations on the ambiguous space between differential treatment and (legitimate) discrimination that India's ambivalence is revealing. On the one hand, Section 3(d) introduced in the Third Amendment while reasonably neutral in its script is largely directed at the practice of evergreening patents.<sup>104</sup> This clause has an interesting genealogy. Though unique to Indian statutes it parallels guidelines that are otherwise given to Patent Offices elsewhere. Thus, for example, the European Patent Office has guidelines on how to apply patent standards for particular technologies.<sup>105</sup> Similarly, the US Patent and Trademark Office have specific guidelines for biotechnological inventions that spell out particular utility requirements.<sup>106</sup> As such, Member Countries are free to determine the standards of patentability and strong and higher standards have often been recommended for Southern members.<sup>107</sup>

On the other hand, the Left Parties proposed exclusions were rejected and submitted to an Expert Group. Without revealing their analysis, the Expert Group summarily found the proposed exclusion in conflict with The TRIPS Agreement and even suggested that existing provisions are felt to be in conflict with The TRIPS Agreement. It is a strange situation for the

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<sup>104</sup> Here, see the response of Kamal Nath, Minister for Commerce and Industry, to questions in the Lok Sabha (Lower House) where concern on evergreening patents was raised: 'There are so many provisions here. In regard to evergreening, I just want to read out section 3(d) ... There is no question of evergreening. There is no question that our compulsory licensing is loose ... I believe that I have tried to explain the apprehensions which the Members had. I believe that some of their fears have been allayed and I seek the support of the House to pass this Bill'. See Lok Sabha Debates (22 March 2005), <http://164.100.24.230/data/shom001/dailydeb/22032005.htm>, (visited 13 March 2007).

<sup>105</sup> Directive 2004/27/EC/ of the European Parliament and of the Council of 31 March 2004 Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use.

<sup>106</sup> US Patents and Trademark Office 'Guidelines for Examination of Applications for Compliance with Utility Requirements' 66 Fed Reg 1092 (5 January 2001).

<sup>107</sup> For example, the Commission on Intellectual Property Rights, above n 3 at 114-16, is of the view that '[T]here is therefore ample scope for developing countries to determine for themselves how strictly the common standards under TRIPS should be applied and how the evidential burden should be allocated' and then proceeds to conclude that '[T]he objective of any standard should be to ensure that routine increments to knowledge, involving minimal creative input, should not generally be patentable'.

government to have its Expert Group report back that there are likely conflicts with The TRIPS Agreement. The Panel's reticence to define discrimination left open an opportunity to explore novel law-making. Moreover, its deliberations indicated to a number of fault lines. The TRIPS Agreement only prohibits discrimination on the grounds of technology, location of invention and source of product. In addition, there is space to treat technologies differently and it is also possible to have bona fide exceptions directed at particular product areas. The distinction between de jure and de facto discrimination was also revealing. Having expressed its systemic interest and noted the imperative underlying provisions in Canada's laws, the government appears to have failed to meet its pledge domestically.

## V. Conclusion

This article sought to explore how changing circumstances in implementing and interpreting the TRIPS Agreement alongside continuing legal ambiguity might translate into law-making in India with respect to amendments to IPA. The evidence indicates a mixed use of residual flexibility and limited effort to explore legal ambiguity. Thus, for example, the Second Amendment maintained a revised local working requirement – a principle that US disputes but fails to challenge at the WTO – and simultaneously introduced a regulatory review exception. On the other hand, no substantive effort was made to explore the ambiguity concerning non-discrimination in Article 27(1) despite the reticence of a WTO Panel to step back and not define this key term. For that matter, apart from the proposal from the Left Parties, the debate failed to raise this point. The response of the government to this proposal is demonstrative of deepening ambivalence on IPRs. In this conclusion, I elaborate on this ambivalence.

A useful preface to the government's ambivalence is the legislation implementing obligations under Article 27(3)(b) of the TRIPS Agreement, *Protection of Plant Varieties and Farmers' Right Act, 2001*. This is legally imaginative in fulfilling TRIPS obligations whilst also introducing rights for farmers. The latter is achieved by incorporating rights (farmers' rights) and principles (e.g. access and benefit sharing) that reside in countervailing forums like the

Food and Agriculture Organisation and the Convention on Biological Diversity. Thus, the different outcomes in the area of patents could be reflective of the sectoral interests that permeate the industries and influence the government. For that matter, even in the area of plants there have been different influences. Notable in this respect were regulatory changes introduced through the 1980s that began with the release of publicly bred varieties to the private sector (1983) and were followed by relaxation of industrial licensing laws (1987). In fact, in 1990 – well before the completion of the TRIPs Agreement – the Government considered introducing plant breeder rights.<sup>108</sup> In 1986, the government considered joining the Paris Convention for the Protection of Industrial Property. The response from industry was mixed. The lobby group representing trade and industry interests, the Associated Chambers of Commerce and Industry (ASSOCHAM), came out in support of membership whereas the primary organ of Indian industry, the Federation of Indian Chambers of Commerce and Industry (FICCI) opposed the membership. Supporting FICCI was the lobby group representing the (small) domestic generic drug firms, the Indian Drug Manufacturers Association (IDMA).

The pharmaceutical industry was initially distributed between two lobby groups: the mainly domestic grouping of generic firms under IDMA and the MNC-affiliated grouping of the Organisation of Pharmaceutical Producers of India (OPPI).<sup>109</sup> However, in 1999 a new configuration of pharmaceutical firms was established, the Indian Pharmaceutical Alliance (henceforth, the Alliance), consisting of firms like Cipla, Dr Reddy's Laboratories, Lupin Labs and Ranbaxy that collectively account for 30% of domestic production and 33% of Indian

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<sup>108</sup> For a discussion see, Dwijen Rangnekar, 'Plant breeding in an era of privatisation: reflections on transformations in the Indian seed industry', in F-J Richter and Parthasarathi Banerjee (eds.) *The Knowledge Economy in India* (London: Palgrave Macmillan), 130-48.

<sup>109</sup> It is also the case that these two groups share common cause in terms of relaxing price regulations under the DPCO, Praful Bidwai, 'One Step Forward, Many Steps Back: Dismemberment of India's National Drug Policy', 1 Development Dialogue 193 (1995). Even generic drug companies have come under the scrutiny of the National Pharmaceutical Pricing Authority for alleged mark-up pricing, see S. Sardana, 'Govt. probes over-pricing of generic drugs' *The Indian Express*, 28 July 2005, available at [www.indianexpress.com](http://www.indianexpress.com) (visited 7 April 2005).

exports.<sup>110</sup> The Alliance is composed of pharmaceutical firms with mixed interests and areas of expertise: '[the Alliance]...is perhaps a little schizophrenic about where its members' interests lie. On the one hand many of them, such as Ranbaxy, wish to develop as research based companies and see the value of strong patent protection to achieve that. On the other hand, the overwhelming majority of their revenues remain derived from generic production, and accordingly they share many of the concerns of IDMA'.<sup>111</sup>

Lobby group re-shuffling is symptomatic of the structural and economic transformations in the industry. A recent study on Indian pharma finds a group of indigenous (and some MNC-affiliated) firms adopting a mix of cooperative and competitive strategies.<sup>112</sup> Beyond being keen on owning IPRs, these firms have adopted the following: exploring non-infringing processes, research on new chemical entities and generics, focussing on new drug delivery systems and biopharmaceutical research. On the one hand, some firms see their future in exploiting their comparative advantages in process innovations; thus, seizing the generic drug route. However, for these firms the domestic market presents a constraint on account of relatively low per capita income, limited access to medicine and negligible insurance coverage. Consequently, exports are their source of growth. Indian companies have sought approval for generic production of some 150 drugs in the US, of which approval for nearly 90 has been granted. The US market itself accounts for sizeable revenues of leading members of the Alliance: 32% in the case of Dr. Reddy's and 42% for Ranbaxy. Other Alliance members have achieved success in developing new molecules and are interested in seeking domestic and overseas protection. This competency has sparked of strategic alliances between domestic and foreign firms that go beyond one-off technology

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<sup>110</sup> Anon., 'Dr Anji Reddy Becomes New President of Indian Pharmaceutical Alliance', [www.pharmabiz.com](http://www.pharmabiz.com) (visited 7 April 2005).

<sup>111</sup> Commission on Intellectual Property Rights, 'Notes on the India Field-Trip', [www.iprcommission.org](http://www.iprcommission.org), 2001 (visited 14 April 2002).

<sup>112</sup> This paragraph is based on Padmashree Gehl-Sampath, above n 92, unless indicated otherwise.

transfers of a previous era and enter areas of shared research, overseas production and global marketing.<sup>113</sup>

The government itself is well aware of these structural transformations that follow from the IPA and have also enabled the industries integration into global supply chains of pharma production and innovation. This is well captured in the Minister of Commerce, Kamal Nath's, statement to Parliament introducing the Third Amendment: 'The pharma industry and the IT industry are the two sunrise sectors for India. The Ordinance amending the Patent Act provides for an enabling environment for both of these. Among the sectors that have experienced the greatest transformation in India, the pharmaceutical industry is perhaps the most significant. ...the transformed Indian pharma industry is itself looking for patent protection ...[...] Apart from the manufacture of drugs, the pharma industry offers huge scope for outsourcing of clinical research'.<sup>114</sup>

This explanation demonstrates that in moving analysis away from the Geneva process and towards national capitals there are a variety of other factors that come to influence law-making in intellectual property rights. It is well-established that technical assistance and programmes from the World Intellectual Property Organisation play a role in shaping legislation in the South.<sup>115</sup> Often an inclination to avoid a WTO dispute directs technical assistance towards close compliance and TRIPs-plus measures.<sup>116</sup> However, in the case of India this may not be a substantial factor in light of the ambivalence within government and the changing economic interests of parts of Indian pharma. As enforcement of TRIPs-obligations become more contested in the future activists and scholars will need to

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<sup>113</sup> GD Sandhya and S. Visalakshi, 'R&D Capability and Alliance Formation in the Pharmaceutical Industry in India', 27 Science and Public Policy 109 (2000).

<sup>114</sup> Kamal Nath 'Statement on the Ordinance relating to Patents (Third) Amendment', 28 December 2004, available at [www.cptech.org](http://www.cptech.org); last accessed 30 March 2005.

<sup>115</sup> Peter Drahos, above n 17.

<sup>116</sup> Ibid.

attend to the problematic of glocal factors. In this respect, the paper seeks to highlight how those factors come to play in implementing TRIPs obligations.

A final comment on the global civil society campaigns is also warranted in light of this call for sharing our attention on the Geneva-process with the dynamics of TRIPs-implementation and resistance in national capitals. Global civil society organisations have played a key role in mitigating much of the technical and procedural asymmetries in negotiating TRIPs. Their campaigns and forum shifting strategies have been effective. However, in as much as organisations differ, the forums selected for agenda-setting also differ. Some commentators note that the selection of the World Health Organisation as a forum by the 'Access to Medicine' Campaign may not be seen as an effort to roll-back IPRs; rather the agenda it sought was to use the residual flexibility in The TRIPS Agreement.<sup>117</sup> In this narrative, the World Health Organisation is portrayed as being equally reconciliatory and equally pragmatic. This begs the question whether such global campaigns and forum-selection have set too narrow an agenda for TRIPs-implementation? And, by extension, how these global campaigns and agendas relate to and influence domestic law-making in Member countries. As the paper on India reminds us, writing about TRIPs from the sites of implementing the obligations bring out new areas of resistance and new avenues for opposition. It is equally important and necessary to make this epistemic change.

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<sup>117</sup> Laurence R. Helfer, above n 37 at 40-49.



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