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**PROMOTION AND PROTECTION OF ALL HUMAN RIGHTS, CIVIL,  
POLITICAL, ECONOMIC, SOCIAL AND CULTURAL RIGHTS,  
INCLUDING THE RIGHT TO DEVELOPMENT**

**Report of the Special Rapporteur on the right of everyone to the  
enjoyment of the highest attainable standard of physical and  
mental health, Anand Grover\***

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\* Late submission.

## **Summary**

The present report, submitted in accordance with Human Rights Council resolution 6/29 briefly reflects on the activities of and issues of particular interest to the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (right to health). The Special Rapporteur took up his duties on 1 August 2008.

The first chapter of the report explains the relation between the right to the highest attainable standard of physical and mental health, specifically in regard to access to medicines, and intellectual property rights.

Chapter II is devoted to the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereafter TRIPS) and TRIPS flexibilities. The Special Rapporteur explores the way in which flexibilities have been used and incorporated into national patent laws of developing and least-developed countries.

Chapter III analyses free trade agreements and the effect of TRIPS - plus requirements on access to medicines.

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## Introduction

1. In its resolution 6/29 of 14 December 2007, the Human Rights Council extended the mandate of the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health (the right to health) for an additional three years. At its seventh session held in June 2008, the Human Rights Council nominated Mr. Anand Grover (India) as the Special Rapporteur. He assumed his duties on 1 August 2008, succeeding Mr. Paul Hunt whose six-year tenure expired on 31 July 2008.
2. In accordance with his mandate, the Special Rapporteur will continue to further develop cooperation with relevant national and international actors such as Governments, national human rights institutions, United Nations treaty bodies, international institutions, different agencies and programmes and independent experts, as well as health professionals, academics, civil society organizations, community-based organizations of affected peoples and other stakeholders.
3. The Special Rapporteur would also like to develop close cooperation with relevant government bodies to help them identify policies and programmes which promote the enjoyment of the right to health. In this context, he underlines the importance of including rights holders, particularly communities, in decision-making processes as they can offer a vast and diverse perspective to various issues central to the right to health. He will therefore consult with affected communities and concerned stakeholders around common goals to ensure the constant progress of the enjoyment of the right to health.
4. The Special Rapporteur intends to continue to promote, and encourage others to promote, the right to health. Recognizing the work done in unpacking the issues relating to the right to health and understanding the relation between health and human rights,<sup>1</sup> he envisages further developing the rights-based approach and the principles of equality, non-discrimination and participation in the context of the right to health. The Special Rapporteur also aims to identify best practices for the operationalization of the right to health.
5. In this report, the Special Rapporteur explores the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and “TRIPS plus” standards on access to medicines within the broader framework of the right to health. The Special Rapporteur commends the work done by the former Special Rapporteur on the right to health and the Office of the United Nations High Commissioner for Human Rights (OHCHR) on trade and intellectual property issues relevant to the right to health.<sup>2</sup> He found these reports highlighted the need for TRIPS flexibilities to be implemented and noted the adverse impacts of free trade agreements (FTAs) on access to medicines. The full use of TRIPS flexibilities can help countries meet their obligations to protect, promote and fulfil the right to health by improving access to affordable

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<sup>1</sup> E/CN.4/2003/58, E/CN.4/2005/51, A/61/338.

<sup>2</sup> E/CN.4/2004/49/Add.1, E/CN.4/Sub.2/2001/13.

medicines. The Special Rapporteur notes however, that use of TRIPS flexibilities has been variable and that there are growing instances of developing countries and least developed countries (LDCs) adopting TRIPS-plus standards that may have an adverse affect on the right to health. He therefore highlights the need to revisit trade-related agreements in light of their impact on the right to health and in particular on access to medicines.

6. After taking up his duties in August 2008, the Special Rapporteur had fruitful discussions with a number of State representatives, the World Health Organization (WHO), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Populations Fund (UNFPA) officials and several civil society organizations. The Special Rapporteur also had the opportunity to exchange views with members of the Committee on the Elimination of Discrimination against Women. He hopes to continue such exchanges with other United Nations treaty bodies in the future.

7. Since August 2008, the Special Rapporteur has participated in numerous consultations and conferences on the right to health. These include the International AIDS Conference in Mexico City, the symposium co-organized by the International Federation of Health and Human Rights and the Human Rights Centre of Essex University and hosted by the British Medical Association in London, the International Strategy Meeting on Economic, Social and Cultural Rights, organized by ESCR-NET, in Nairobi, consultations on the draft principles on extreme poverty and human rights in Geneva, a consultation on the right to health in Brazil organized by Conectas, and the fourteenth World Conference on Tobacco or Health in Mumbai.

## **I. THE RIGHT TO THE HIGHEST ATTAINABLE STANDARD OF HEALTH**

8. The right to health, enshrined in numerous international and regional human rights treaties and in many national constitutions,<sup>3</sup> is an inclusive right, extending not only to timely and appropriate health care, but also to the underlying determinants of health, such as access to clean water and sanitation, adequate housing and nutrition as well as social determinants such as gender, racial and ethnic discrimination and disparities.

9. The Special Rapporteur emphasizes that, if integrated into national and international health policymaking, the right to health can help establish laws, policies and practices that are sustainable, equitable, meaningful and responsive to the needs of those living in poverty.

10. In recent years, the Committee on Economic, Social and Cultural Rights, WHO and many others have developed an analysis of the right to health to make it easier to understand

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<sup>3</sup> The right to health was first addressed in the 1948 Universal Declaration of Human Rights. It is established under article 12 of the International Covenant on Economic, Social and Cultural Rights and is also well recognized in the Convention on the Elimination of All Forms of Discrimination against Women and the Convention on the Rights of the Child.

and apply to health-related laws, policies, programmes and practices.<sup>4</sup> Key elements of the analytical framework relevant to this report include the propositions that:

(a) All health services, goods and facilities shall be available, accessible, acceptable and of good quality. In the context of access to medicines this requires States to ensure that medicines are available, accessible, culturally acceptable, and of good quality;

(b) States have a duty to respect, protect and fulfil the right to health.

Furthermore, the Committee's general comment No. 14 (2000) on the right to the highest attainable standard of health reaffirms the framework as it adopts the aforesaid key elements of the right to health. In this regard, medical care in the event of sickness, as well as the prevention, treatment and control of diseases, are central features of the right to health. These features depend upon access to medicines. Therefore, access to medicines forms an indispensable part of the right to health.<sup>5</sup>

11. States have an obligation under the right to health to ensure that medicines are available, financially affordable, and physically accessible on a basis of non-discrimination to everyone within their jurisdiction. Developed States also have a responsibility to take steps towards the full realization of the right to health through international assistance and cooperation.<sup>6</sup> Moreover, all States parties to the International Covenant on Economic, Social and Cultural Rights have a legal obligation not to interfere with the rights conferred under the Universal Declaration of Human Rights and the Covenant, including the right to health.<sup>7</sup>

#### **A. State of health and access to medicines**

12. Health trends indicate that despite progress made in the last 30 years, massive inequalities remain in access to health services and medicines around the world.<sup>8</sup> "Diseases of poverty" (i.e. communicable, maternal, perinatal, and nutritional diseases) still account for 50 per cent of

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<sup>4</sup> See for instance, World Health Organization, *Human Rights, Health and Poverty Reduction Strategies*, (Geneva, 2005); Physicians for Human Rights, *Deadly Delays: Maternal Mortality in Peru*, (Boston, 2007).

<sup>5</sup> A/61/338, para. 40.

<sup>6</sup> E/CN.4/2004/49/Add.1, para. 28.

<sup>7</sup> Article 30 of the Universal Declaration of Human Rights, article 5 of the International Covenant on Economic, Social and Cultural Rights.

<sup>8</sup> WHO, World Health Report, *Primary Health Care Now More than Ever* (Geneva, 2008).

the burden of disease in developing countries, nearly ten times higher than in developed countries.<sup>9</sup> There has been a resurgence of tuberculosis and malaria in the last decade:<sup>10</sup> 58 per cent of malaria cases occur in the poorest 20 per cent of the world population and each year there are nearly 529,000 maternal deaths.<sup>11</sup>

13. The state of health correlates significantly with poverty. Public health spending in both high and low income countries benefits the rich more than the poor. People with the most means and often with less need consume the most care, while those with the least means and most need consume the least care.<sup>12</sup> Over 100 million people fall into poverty annually because they have to pay for health care.<sup>13</sup> In developing countries, patients themselves pay for 50-90 per cent of essential medicines.<sup>14</sup> A report from WHO and Health Action International on the results of surveys undertaken in 36 countries reported that in the public sector only one third of essential medicines needed were available and in the private sector only two thirds of such medicines were available.<sup>15</sup>

14. Nearly 2 billion people lack access to essential medicines.<sup>16</sup> Improving access to medicines could save 10 million lives a year, 4 million in Africa and South East Asia.<sup>17</sup> The inability of populations to access medicines is partly due to high costs.<sup>18</sup> In the context of HIV, as of 2007, only 31 per cent of people living with HIV who needed treatment received it.<sup>19</sup> Furthermore, it is

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<sup>9</sup> WHO, *Public Health Innovation and Intellectual Property Rights, A Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (Geneva, 2006) p. 3.

<sup>10</sup> *Ibid.*, pages 2 to 3.

<sup>11</sup> *Ibid.*, page 4.

<sup>12</sup> See footnote 8 above, p. xiv, box 1.

<sup>13</sup> *Ibid.*

<sup>14</sup> A/61/338, para. 75.

<sup>15</sup> A. Cameron et al., "Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis", *Lancet*, vol. 373, issue 9659, (January 2009), p. 240.

<sup>16</sup> WHO, "WHO Medicines Strategy: Countries at the Core, 2004-2007", (2004).

<sup>17</sup> A/61/338, para. 37.

<sup>18</sup> E. t'Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*, Diemen, AMB, 2009.

<sup>19</sup> WHO, *Towards Universal Access - Scaling up priority HIV/AIDS interventions in the health sector, Progress Report 2008*, p. 7.

estimated that people living with HIV will become resistant to their first-line medicine regimens and will need second-line treatment which can currently cost between 9 and 19 times as much as first-line medicines.

15. Accessibility of medicines has different dimensions.<sup>20</sup> This report specifically considers the dimension of financial affordability. In this regard intellectual property (IP) laws as they impact on the affordability of medicines can have a significant bearing on access to medicines.<sup>21</sup>

16. Current health inequalities regarding access to medicines demonstrate the need for States to respect their obligations under international law to protect the right to health. This includes ensuring that their laws and practices, including those related to IP, take into consideration the right to health and the need to ensure access to affordable medicines to all. This report highlights some measures that States can take to ensure that their national IP regimes protect the right to health.

### **B. Intellectual property laws and access to medicines**

17. IP law has an impact on the right to health, as it protects pharmaceutical products. It regulates the creation, use and exploitation of mental or creative labour and encompasses copyright, trademarks, geographical indications, industrial designs, layout designs of integrated circuits, patents and their designs, undisclosed information and trade secrets.

18. Patents confer legal rights on inventors, more importantly negative rights over process or product inventions. Patentees can, therefore, prevent persons not authorized by them from making, using, offering for sale, selling or importing the patented invention. Patents create monopolies, limit competition and allow patentees to establish high prices. While product patents confer absolute monopolies, process patents lead to relative monopolies.<sup>22</sup>

19. In regard to medicines, a product patent enables a patentee to set high prices. Higher standards of patent protection, which can reduce the number of easily granted patents, can

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<sup>20</sup> Accessibility has four dimensions; first, medicines must be accessible in all parts of the country; second, medicines must be affordable to all, including those living in poverty; third, medicines must be accessible without discrimination on any of the prohibited grounds; fourth, reliable information about medicines must be accessible to patients and health professionals for them to take well-informed decisions (A/61/338, para. 49).

<sup>21</sup> Intellectual property laws can also affect medical research and this can bear upon access to medicines. The Commission on Intellectual Property, Innovation and Public Health (CIPIH) has noted that, “There is no evidence that the implementation of the TRIPS agreement in developing countries will significantly boost R&D in pharmaceuticals on Type II, and particularly Type III diseases. Insufficient market incentives are the decisive factor.” See footnote 9 above, p. 85.

<sup>22</sup> Product patents can create absolute monopolies as they can restrict use of a product. Process patents only restrict the use of the patented process and therefore a generic version of the product could be made using an alternative process.

facilitate competition and lower the prices of medicines. Lower standards of patent protection, however, which can increase the number of easily granted patents can lead to higher prices. Generic competition in the field of pharmaceuticals has the potential to significantly lower prices and increase access.

20. The example of HIV medicines is particularly illustrative. In 2001, when the HIV crisis was at its peak and the need for antiretrovirals (ARVs) was the most acute, it was the availability of cheaper generic ARVs from developing countries that led to a reduction in prices from over US\$ 10,000 per patient per year to less than US\$ 350 per patient per year for a first-line combination therapy.<sup>23</sup> Today generic competition has helped reduce prices of first generation ARVs by more than 99 per cent.<sup>24</sup> The availability of generic medicines from developing countries like Brazil, India, South Africa and Thailand has exerted a downward pressure on prices and increased the range of affordable options for national treatment programmes.<sup>25</sup> Generic manufacturers have also been able to produce fixed-dose combinations of ARVs, which are easier to administer and use in developing countries and LDCs, including some combinations that are not available from patentees.<sup>26</sup> The importance of generic medicines continues to be underscored today by their prominence in international medicine supply programmes.

21. However, the continued supply of generic medicines is now in doubt. For developing countries including those that manufacture and supply generic medicines, the deadline for TRIPS compliance and the introduction of product patents came in 2005. With this deadline, there is concern that the ability of companies to patent new pharmaceutical products on a near-global scale could inhibit further competition and prevent the price reductions needed to make antiretroviral therapy more widely available.<sup>27</sup> For instance, several developing countries and LDCs expressed concerns to WHO that future, generic ARVs would not be available from India after 2005.<sup>28</sup> This issue is valid for medicines for other diseases as well. Even where some countries are able to continue to manufacture generic medicines, TRIPS implementation in other countries may make it difficult to import these medicines.

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<sup>23</sup> C. Perez-Cassas et al., “Accessing ARVs: untangling the web of price reductions for developing countries”, Médecins Sans Frontières, 2001, p. 3.

<sup>24</sup> Médecins sans frontières, “Untangling the Web of ARV Price Reductions”, 11th edition, 2008.

<sup>25</sup> UNAIDS/WHO, *AIDS Epidemic Update, 2008* (Geneva, 2008).

<sup>26</sup> WHO/UNAIDS, *Progress on Global Access to HIV Antiretroviral Therapy: a Report on “3 by 5” and Beyond* (March, 2006), p. 60.

<sup>27</sup> Ibid.

<sup>28</sup> Letter from WHO HIV/AIDS Director to Indian Health Minister, 17 December 2004. See also E. Kameni, “Implications of Indian intellectual property law on sub-Saharan African countries”, *The Botswana Review of Ethics, Law & HIV/AIDS*, vol. 2, No. 1 (2008), p. 57.

22. With growing concern over TRIPS implementation and its impact on access to medicines, several initiatives have been launched in recent years by countries, the private sector, charitable foundations and non-governmental organizations to increase access to existing medicines. However, these initiatives have not been sufficient to surmount the challenge of ensuring access to medicines.<sup>29</sup> Developing countries and LDCs should be enabled to take steps to modulate the implementation of TRIPS on access to medicines including by encouraging competition and being able to access affordable generic versions of patented medicines. The next section of the report discusses TRIPS and more particularly the flexibilities that can enable developing countries and LDCs in this regard.

## II. AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

### A. Background

23. TRIPS came into force along with the establishment of the World Trade Organization (WTO) in 1995. It was one of the most controversial agreements, as developed countries pushed for extensive IP protection and the harmonization of IP norms.<sup>30</sup> Developing countries argued that extensive IP standards would hinder their development prospects as they were not well-equipped to reap the benefits of such standards. Developing countries eventually gave way, under the pressure of developed countries as they were ultimately dependent on them for trade. It has to be noted, however, that TRIPS was a compromise. The ultimate goal of developed countries was and is the universal harmonization of IP laws according to their standards. Therefore, post-TRIPS, they have continued to push for standards of IP protection through various free trade and multilateral trade agreements, which conform to standards in their countries.

24. TRIPS establishes minimum global standards for all major IP rights and sets rules for their enforcement.<sup>31</sup> It marks a departure from the Paris Convention of 1883 as it ignores diversity of national needs and establishes patent protection for a minimum term of 20 years. The Paris Convention, and the subsequent agreements that built upon it, only required signatory States to adhere to the principles of non-discrimination, national treatment and priority. It gave countries sufficient flexibility to adapt their IP regime in light of their socio-economic needs and objectives and allowed States to exclude strategic sectors, such as the pharmaceutical and agrochemical industries, from patentability and to determine the length of protection. TRIPS is binding on all WTO member States and is legally enforceable through the Dispute Settlement Body, backed by sanctions. For most developing countries and LDCs, TRIPS implementation

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<sup>29</sup> World Health Assembly resolution WHA61.21, annex, para. 3 (Global strategy on public health, innovation and intellectual property).

<sup>30</sup> See generally, J. Watal, *Intellectual Property Rights in the WTO and Developing Countries*, (Oxford University Press, 2001).

<sup>31</sup> C. Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries*, (Oxford University Press, 2008).

requires them to update their IP standards, which in turn involves a complex set of reforms to redraft and update existing laws.<sup>32</sup> It also requires considerable increase in the financial and human resources allocated to IP issues.<sup>33</sup>

## **B. TRIPS flexibilities and their implementation**

25. TRIPS provides flexibilities that WTO member States can use. Article 1 establishes the core principle that member States can determine the appropriate method for implementing TRIPS within their own legal system and practice. Furthermore, the objectives and principles of TRIPS emphasize the balance of rights and obligations and provide the basis for countries to utilize the flexibilities and adopt IP protection at the national level to meet their social and developmental needs. Article 8 specifically provides that member States may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health. The Declaration on the TRIPS agreement and public health (Doha Declaration) adopted by the WTO Ministerial Conference in 2001 recognized concerns over the effect of IP on medicine prices and reaffirmed the right of member States to use TRIPS flexibilities to achieve public health needs and promote access to medicines for all.

26. Countries have varied in the extent to which they have implemented TRIPS flexibilities. While some countries lack sufficient awareness about the full use of flexibilities and have limited technical capacity to implement them, others have not sufficiently streamlined their patent laws to facilitate use. Furthermore, pressure from developed countries has played a prominent role in shaping the implementation of TRIPS flexibilities in developing countries and LDCs.

27. From a right to health perspective, developing countries and LDCs should be enabled to use TRIPS flexibilities. More particularly, their national laws should incorporate the flexibility to:

- (a) Make full use of the transition periods;
- (b) Define the criteria of patentability;
- (c) Issue compulsory licences and provide for government use;
- (d) Adopt the international exhaustion principle, to facilitate parallel importation;
- (e) Create limited exceptions to patent rights;
- (f) Allow for opposition and revocation procedures.

In addition, countries need to have strong pro-competitive measures to limit abuse of the patent system.

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<sup>32</sup> Ibid., p. 11.

<sup>33</sup> Ibid.

## 1. Transition periods

28. TRIPS grants member States different deadlines for implementation depending on their level of economic development. Developing countries had until 2000 to comply with TRIPS. Countries that did not grant product patent protection in certain areas of technology, such as India, Egypt and Brazil, had an additional five years to comply with TRIPS with respect to those areas of technology. LDCs had until January 2006 to implement TRIPS, which was extended to 1 July 2013. With respect to medicines, the Doha Declaration granted LDCs an extension to 2016.

29. The potential of the full use of the transition period to increase access to medicines is demonstrated in the case of India which has become a global supplier of affordable generic medicines.<sup>34</sup> This is primarily due to the fact that in the early 1970s, India eliminated product patent protection for medicines and only preserved process patent protection, thus encouraging the growth of the domestic pharmaceutical industry specializing in the production of generic versions of medicines that were patented in developed countries. This catapulted India from a country importing most of its medicines at extremely high prices to a country that has become one of the most important exporters of affordable life-saving medicines to the developing world.

30. While some developing countries such as India made full use of this transition period by providing product patent protection only in 2005 on the expiry of their TRIPS deadline, others such as Brazil introduced product patent protection for medicines before their respective deadlines. Several LDCs also complied with TRIPS before their deadlines. Twelve francophone LDCs, for example, brought their legislative standards substantially in line with TRIPS by 2002, 11 years ahead of their 2013 deadline.<sup>35</sup> Furthermore, at the time of the Doha Declaration, all but three (Angola, Ghana, and Malawi) of the 25 African member States already had laws which approved patents for medicines.<sup>36</sup> Cambodia and Nepal appear to be the only LDCs to have excluded pharmaceutical products from patentability until 2016.<sup>37</sup>

31. The importance of the transition period is underscored by the fact that the absence of product patents on medicines can, help establish local manufacturing capacity, promote generic manufacturing and facilitate the import of affordable medicines from other countries. Developing countries that have been successful in the use of the transition period in any of these

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<sup>34</sup> India is the main supplier of essential medicines for developing countries with about 67 per cent of medicines produced in India being exported to developing countries. See Médecins Sans Frontières campaign “Save the pharmacy of the developing world”.

<sup>35</sup> See footnote 31 above, p. 73.

<sup>36</sup> *Ibid.*

<sup>37</sup> S. Musungu and C. Oh, “The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?”, CIPIH, World Health Organization, 2006 pp. 13-15.

respects may present good examples for LDCs to consider in adapting to their own needs and circumstances. LDCs should also consider seeking further extensions of the transition period, as provided by article 66, paragraph 1, of TRIPS.

## 2. Patentable subject matter

32. Article 27, paragraph 1, of TRIPS requires patents to be available for inventions that are “new, involve an inventive step and are capable of industrial application”. It does not define these patentability criteria. Therefore, member States have the freedom to define each criteria according to their needs. Countries apply different standards to each of these criteria, either statutorily or through judicial development. While countries that apply a low level of patentability standards allow patents to be granted easily, those that provide higher patentability standards allow for patents only on genuine inventions.

33. Furthermore, article 27 allows member States to exclude certain categories of inventions from patentability. Thus, they can exclude from patentability those inventions whose commercial exploitation is detrimental to human life or health. They can also exclude diagnostic, therapeutic and surgical methods for treatment of humans from patentability. TRIPS does not provide an exhaustive list of permissible exclusions allowing countries to exclude certain categories of inventions in order to protect public health.

34. From a right to health perspective, the “evergreening” of patents by pharmaceutical companies is of particular concern. Evergreening refers to the practice of obtaining new patents on a patented medicine by making minor changes to it.<sup>38</sup> For example, patents are obtained on new uses, forms, combinations and formulations of known medicines in a bid to extend the period of the patentee’s monopoly. Such evergreening delays the entry of competitive generic medicines into the market.

35. The freedom to set high patentability criteria and exclude certain inventions is an important tool that countries can use to address evergreening and ensure that patents are granted only to genuine inventions in the pharmaceutical field. Thus, countries can deny patents on new uses, forms, formulations or combinations of known medicines. India and the Philippines for example, exclude from patentability new forms of known substances unless they are significantly more efficacious and new (or second) uses and combinations of known substances.<sup>39</sup> If implemented properly, this can help limit evergreening tactics. Reducing the number of patents granted on medicines can limit the impact of patents on access to medicines and facilitate the early entry of generic competition.

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<sup>38</sup> E/CN.4/Sub.2/2001/13.

<sup>39</sup> Indian Patents Act, 1970, section 3 (d), Intellectual Property Code, Philippines (amended by section 5 of the Universally Accessible Cheaper and Quality Medicines Act of 2008), section 22.1.

### 3. Compulsory licensing and government use

36. Compulsory licensing derives from article 31 of TRIPS. It enables member States to license the use of a patented invention for itself or a third party “without authorization” of the patentee. Although TRIPS places some restrictions on compulsory licences, member States are free to determine the grounds upon which to issue a compulsory licence, which can include: (a) refusal to license; (b) public interest; (c) public health and nutrition; (d) national emergency or situation of extreme urgency; (e) anti-competitive practices; (f) dependent patents; and (g) failure to exploit or insufficiency of working.<sup>40</sup> Member States also have the freedom to establish new grounds as they deem appropriate.

37. Paragraph 5 (b) of the Doha Declaration specifically reaffirmed the right of member States to determine the grounds for issuing compulsory licences. Countries are free to provide grounds to protect public health and promote access to medicines for all. TRIPS does not restrict the use of compulsory licences to situations of national emergency or other circumstances of extreme urgency, or to cases of HIV, tuberculosis and malaria. As such, the issuance of compulsory licences by Thailand on heart disease, cancer and HIV medicines is in compliance with TRIPS.<sup>41</sup>

38. Government use is a species of compulsory licence, which allows the use of a patented invention by or for a government for a public non-commercial use. Countries can issue such licences to third parties to make patented medicines for governments in order to make the medicines available to the public. The expression “public non-commercial purpose” is not defined and countries have the freedom to define and implement such use. The United States of America and the United Kingdom of Great Britain and Northern Ireland patent laws provide useful examples of how patents can be broadly used for almost any public non-commercial purpose.<sup>42</sup> The restriction under article 31 of prior negotiations with the patentee does not apply to government use. This allows for a speedy process that assists governments in meeting their obligations to provide access to medicines.

39. While many countries have adopted mechanisms to issue compulsory licences, the grounds for use have varied<sup>43</sup> and procedures in national laws are at times cumbersome and need to be streamlined and simplified to facilitate issuance of such licences.

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<sup>40</sup> See footnote 37, pages 28-30.

<sup>41</sup> F. M. Abbott and J. H. Reichman, “The Doha Round’s public health legacy: strategies for the production and diffusion of patented medicines under the amended TRIPS provisions”, *Journal of International Economic Law*, vol. 10, No. 4, (2007), p. 921.

<sup>42</sup> C. Oh, “Compulsory licences: recent experiences in developing countries” *International Journal of Intellectual Property Management*, vol. 1, No. 1/2 (2006), p. 22.

<sup>43</sup> See footnote 18 above, p. 61, Table 6.

40. Countries with little or no manufacturing capacity face difficulties in utilizing compulsory licences to import generic medicines as, article 31 (f) of TRIPS requires that goods produced under a compulsory licence should be for “predominantly” local use. This difficulty was recognized by the Doha Declaration, pursuant to which the WTO General Council provided a framework to address this issue through the decision of 30 August 2003. This decision is contained in a Protocol which if signed by two thirds of the WTO members by 31 December 2009 would become a formal amendment to TRIPS.

41. Countries have faced difficulties in implementing the 30 August decision as it entails complex administrative procedures. Even though a number of potentially exporting countries amended their national laws to incorporate the 30 August decision, their regulations have added further administrative requirements that make it difficult to implement.<sup>44</sup> The first and only case of export of a patented medicine under the 30 August decision occurred in 2008 to Rwanda, five years after the adoption of the decision. The case of Rwanda highlights the need to revisit the decision.

#### **4. Parallel importation and international exhaustion**

42. Parallel importation refers to the purchase of a patented medicine from a lawful source in an exporting country and its importation without seeking the consent of the “parallel” patent holder in the importing country.<sup>45</sup> It can be a useful tool for countries to save money as it allows them to import a patented product from countries where they may be sold at a lower price than on the domestic market.

43. Parallel importation depends on the principle of exhaustion. While a patentee has the exclusive right to prevent others from manufacturing or marketing the patented product, the principle of exhaustion bars the patentee from further exercising exclusive rights once the product is sold on the market. Article 6 of TRIPS specifically allows countries to determine the point at which IP rights have been exhausted, giving member States the discretion to choose the exhaustion principle applicable to their patent regimes.

44. The principle of exhaustion can be applied at, the national, regional and international levels. Under the national exhaustion principle, the patentee can oppose the importation of patented products marketed abroad. International exhaustion, on the other hand, prevents the patentee from exercising further control over the product once it has been sold in any part of the world and therefore facilitates parallel importation.

45. Countries have varied in the choice of exhaustion regime. While countries including South Africa, Kenya, Honduras and members of the Andean Community have adopted the

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<sup>44</sup> Richard Elliott, “Pledges and pitfalls: Canada’s legislation on compulsory licensing of pharmaceuticals for export”, *International Journal of Intellectual Property Management*, vol. 1, No. 1/2 (2006), p. 94.

<sup>45</sup> See footnote 9 above, p. 123.

international exhaustion regime to promote affordability and availability of essential medicines, a number of countries have adopted the national exhaustion regime.<sup>46</sup> Others have applied the regional exhaustion principle.<sup>47</sup> Countries, which have incorporated an international exhaustion regime, have greater ability to facilitate access to medicines.

### **5. Limited exceptions to the right of patent owners**

46. Article 30 of TRIPS allows member States to design limited exceptions to the exclusive rights conferred by a patent, as long as such exceptions do not unreasonably prejudice the rights of a patentee. This leaves considerable flexibility to create exceptions that facilitate access to medicines.

47. Exceptions for research and experimental use fall within the ambit of article 30. Such exceptions can be a useful way for researchers and manufacturers to encourage innovation of new medicines, particularly those for neglected diseases.

48. The “early working” or Bolar exception, allows competitors to import, manufacture and use a patented product for the purpose of seeking regulatory approval. Allowing for the completion of registration requirements before patent expiry, facilitates the prompt entry of generic medicines on the market once a patent expires. The WTO Dispute Settlement Panel, in 2000, upheld such an exception by Canada as permissible under article 30.

49. While the early working exception has been incorporated into the national patent laws of many countries, it is not as commonly found as the “research or experimental use” exception.<sup>48</sup>

### **6. Opposition and revocation procedures**

50. As TRIPS is silent on procedural aspects relating to patent examination, it allows for member States to establish mechanisms that subject patent applications to high levels of scrutiny. In this regard, countries can permit oppositions by any persons to patent applications before (pre-grant) and after (post-grant opposition and revocation proceedings) the grant of a patent. This allows concerned stakeholders including, civil society organizations and patient groups to oppose the grant of patents. Opposition proceedings can assist in subjecting patent applications and granted patents to higher scrutiny as patent offices are often understaffed and overburdened. India and Thailand allow for oppositions, which have been used successfully in relation to some

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<sup>46</sup> Brazil and Morocco for instance have adopted the principle of national exhaustion.

<sup>47</sup> Countries in west Africa signatory to the Bangui Agreement.

<sup>48</sup> See footnote 37 above, p. 56.

crucial HIV medicines.<sup>49</sup> Brazil adopts an additional mechanism to ensure higher scrutiny, where prior consent of the National Sanitary Supervision Agency (ANVISA) is required before a patent application relating to medicine is reviewed by the patent office.<sup>50</sup>

51. Traditionally, opposition proceedings were limited to competitors and governments. Lately, they have been broadened to include interested persons such as civil society organizations and patients' groups. This is particularly important when generic companies may not have an interest in opposing a patent on a medicine of public importance.

52. Ensuring higher scrutiny of patent applications before a patent is granted and of patents that have been granted can be a useful tool to limit the impact of patents on medicines.

## 7. Pro-competitive measures

53. Article 40 of TRIPS specifically recognizes the adverse effects of licensing conditions or practices relating to intellectual property rights (IPRs). It therefore allows member States to identify in their national laws licensing conditions or practices which may constitute an abuse of IPRs and have an adverse effect on competition. The South Africa Competition Commission for example, has held that the practice of a pharmaceutical company in not granting licences to generic companies amounts to an abuse of dominant position.<sup>51</sup> As such, note should be taken of reports of competition authorities of developed countries detailing anti-competitive practices in the pharmaceutical sector.<sup>52</sup>

54. The use of anti-competition law can be an important tool to promote access to medicines. TRIPS article 31 for example allows a relaxation of certain restrictions, such as prior negotiation with patentees and predominantly domestic use, relating to compulsory licences which may be useful to remedy anti-competitive practices.

55. While this report does not specifically further explore use of anti-competition laws, there is a need for countries to adopt and effectively apply pro-competitive measures allowed under TRIPS to prevent or remedy anti-competitive practices having a bearing on the use of patented medicines.

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<sup>49</sup> N. Ford and others, "The role of civil society in protecting public health over commercial interests: lessons from Thailand" *The Lancet*, vol. 363, No. 9408 (February 2004), p. 560.

<sup>50</sup> Brazil, Law No. 10.196 of February 2001.

<sup>51</sup> South Africa Competition Commission media release No. 30, 2003.

<sup>52</sup> See, for instance, European Union (EU) Directorate-General for Competition, *Pharmaceutical Sector Inquiry - Preliminary Report*, 28 November 2008.

### C. Concerns regarding the implementation of TRIPS flexibilities

56. Developing countries, while attempting to implement TRIPS flexibilities in order to address public health concerns, have experienced pressures from developed countries and multinational pharmaceutical corporations. In this respect, the cases of South Africa, Thailand and India are particularly illustrative.

57. In 1996, South Africa adopted a new National Drugs Policy with the goal of “ensuring an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa”.<sup>53</sup> Following the principles of the Policy, the South African Government amended its existing Medicines Act to improve access to medicines.<sup>54</sup> In response, South Africa was placed on the United States Special 301 Watch List<sup>55</sup> and 39 pharmaceutical companies filed a suit, challenging the amendments, contending that they would destroy patent protections by giving the Health Minister overly broad powers to produce or import cheaper versions of drugs still under patent.<sup>56</sup> Worldwide public outrage eventually led to a change in the US position<sup>57</sup> and to the withdrawal of the lawsuit by the pharmaceutical companies in 2001.

58. Thailand also faced pressure following its attempts to lower prices of medicines through compulsory licensing. Between 2006 and 2007, Thailand issued compulsory licences for HIV and heart disease medicines in order to meet its obligations to provide universal access to medicines.<sup>58</sup> In 2007, Thailand was placed on the Special 301 Priority Watch List.<sup>59</sup> The position of the European Commission was also unwelcoming of the measures taken by

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<sup>53</sup> National Drug Policy for South Africa, 1996, p. 3.

<sup>54</sup> Medicines and Related Substances Control Amendment Act No. 90 of 1997.

<sup>55</sup> See Special 301 Report 1999. This list is maintained under the United States Trade Act, 1974, in respect of each country. It is a precursor to trade sanctions that the United States may impose on any country unilaterally.

<sup>56</sup> Essential Drugs in Brief, issue No. 04, April 2001, Department of Essential Drugs and Medicines Policy, WHO.

<sup>57</sup> See Executive Order 13155, “Access to HIV/AIDS Pharmaceuticals and Medical Technologies” (10 May 2000).

<sup>58</sup> Compulsory licences were issued for clopidogrel for heart disease, and lopinavir/ritonavir and Efavirenz for HIV.

<sup>59</sup> Office of the United States Trade Representative (USTR), Special 301 Report, 2007.

Thailand.<sup>60</sup> One of the affected companies withdrew seven pending applications for registration of new medicines in Thailand, thus effectively withholding them from the Thai market.<sup>61</sup>

59. In 2008, noting the burden of cancer and the necessity for the Government health programme to provide access to cancer medicines, Thailand issued compulsory licences for three anti-cancer medicines.<sup>62</sup> A global campaign to support the Thai compulsory licences led to several statements of support for the use of this TRIPS flexibility,<sup>63</sup> however Thailand continues to face growing pressure in response to its use of compulsory licensing.<sup>64</sup>

60. Similarly, India faced pressure for its attempt to use safeguards. India, in 2005 included strict patentability criteria in its patent law to address the evergreening of patents.<sup>65</sup> This provision was challenged by a pharmaceutical company in the Madras High court alleging it was a violation of TRIPS and of the constitutional equality provision. The amendment was upheld, among other grounds as a fulfilment of the right to health obligations of the Government.<sup>66</sup> The Indian case also garnered significant global international support for the use of public health safeguards by developing countries in their patent laws.<sup>67</sup>

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<sup>60</sup> See footnote 41 above. In a letter dated 10 July 2007 to the Minister of Commerce of Thailand, the EU Trade Commissioner claimed that, “neither the TRIPS Agreement nor the Doha Declaration appear to justify a systematic policy of applying compulsory licenses wherever medicines exceed certain prices”.

<sup>61</sup> WHO Access to Medicines, Briefing Note - Country Experiences in Implementing TRIPS Safeguards, February 2008.

<sup>62</sup> A fourth drug, imatinib, for treating leukaemia and other cancers was also to have been subjected to a compulsory licence, but the licence was not implemented after it was given for free to a Thai public health programme.

<sup>63</sup> Asia Pacific Network of People Living with HIV/AIDS (APN+), *Our Health, Our Rights*, (2008), p. 73.

<sup>64</sup> 2008 PhRMA Submission to USTR for the Special 301 Report, excerpt on Thailand.

<sup>65</sup> The Patents (Amendment) Act 2005, section 3 (d).

<sup>66</sup> *Novartis AG v. Union of India*, (2007) 4 MLJ 1153.

<sup>67</sup> See footnote 63 above, p. 30.

61. The experiences of South Africa, Thailand, and India provide examples of difficulties countries have had to overcome to implement TRIPS flexibilities. Although they were successful in their attempts, there is fear that pressure from developed countries and pharmaceutical companies will thwart future actions.<sup>68</sup>

62. Furthermore, different aspects of the capacity of governments of developing countries and LDCs also contribute to variations in the use of TRIPS flexibilities. This includes the degree of technical expertise, of technological capacity and of engagement amongst national law and policymakers and the public in the implementation of TRIPS flexibilities.

63. Many developing countries and LDCs inherited IP laws from former colonizers. As a result, when TRIPS came into force, many countries did not necessarily have the technical expertise to effectively implement the agreement or take advantage of the flexibilities. In some cases, limited institutional capacity led to dependence on developed countries and independent bodies for technical assistance in drafting laws.<sup>69</sup> It should be noted that there have been concerns regarding the qualitative nature of assistance that is typically provided in relation to TRIPS<sup>70</sup> and in some cases LDCs seeking external assistance have adopted TRIPS-plus standards in their national laws.<sup>71</sup>

64. The capacity of countries is also influenced by the degree of participation by individuals, communities and their representatives. Experiences from Brazil, Mexico, South Africa, Argentina, India, and the Philippines indicate that public interest groups can help promote efforts to pass laws that facilitate access to medicines.<sup>72</sup> Furthermore, rights impact assessments can help highlight the impact of TRIPS and TRIPS-plus standards on the right to health.<sup>73</sup> Examples

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<sup>68</sup> Despite the 2001 Doha Declaration and other commitments, countries issuing compulsory licences as part of national drug programmes aimed at providing universal access to HIV/AIDS and other treatments continue to be placed on the United States Special 301 Watch List.

<sup>69</sup> *Integrating Intellectual Property Rights and Development Policy*, Commission on Intellectual Property Rights (CIPR), (London 2002), p. 138.

<sup>70</sup> *Ibid.*, see also United Nations Conference on Trade and Development (UNCTAD), *The Least Developed Countries Report*, 2007.

<sup>71</sup> For example, the Bangui Agreement contains TRIPS-plus standards. Furthermore, the 12 LDC members of the African Intellectual Property Organization (OAPI) brought most of their IP laws in line with TRIPS in 2002.

<sup>72</sup> See footnote 31 above, p. 208.

<sup>73</sup> E/CN.4/2004/49/Add.1.

and models to assess the impact of these provisions on access to medicines including in relation to affordability have also emerged.<sup>74</sup> Such initiatives should be encouraged to assist developing countries and LDCs in making decisions about the implementation of TRIPS flexibilities.

65. Few LDCs have local manufacturing capacities or any technological base to fully take advantage of TRIPS or TRIPS flexibilities.<sup>75</sup> In this regard, concrete steps towards the specific obligation under article 66, paragraph 2, of TRIPS of developed countries to provide incentives to promote and encourage technology transfer to LDCs in order to enable them to create a sound and viable technological base should be encouraged.

66. The lack of capacity and external pressures imposed by developed countries, significantly contribute to difficulties faced by developing countries, especially LDCs, in the use of TRIPS flexibilities. Therefore there is a real need for developing countries and LDCs to seek appropriate means to build up their capacity, and for developed countries to refrain from hampering the use of TRIPS flexibilities.

67. The next section of the report examines the effect of standards imposed beyond TRIPS (TRIPS-plus) by FTAs on access to medicines and the right to health. Due to space constraints, not all issues arising out of existing or proposed international trade agreements that affect access to medicines will be discussed.

### **III. FREE TRADE AGREEMENTS, THE RIGHT TO HEALTH AND ACCESS TO MEDICINES**

#### **A. Background**

68. Many countries have signed or are currently engaged in negotiations on extensive trade agreements, including bilateral investment treaties (BITs), FTAs, economic partnership agreements (EPAs) etc. Such agreements have extensive implications for pharmaceutical patent protection, which can directly impact access to medicines. Some developed countries, for example have negotiated FTAs which reflect their standard of IP protection.<sup>76</sup>

69. These agreements are usually negotiated with little transparency or participation from the public, and often establish TRIPS-plus provisions. These provisions undermine the safeguards and flexibilities that developing countries sought to preserve under TRIPS.<sup>77</sup> Studies indicate that

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<sup>74</sup> See for example, “Impact Assessment of TRIPS-plus provisions on health expenditure and access to medicines” report of a workshop organized by the Ministry of Public Health, Thailand and WHO, Bangkok 22-24 Nov. 2006; Miguel Ernesto Cortes Gamba, “Intellectual property in the FTA: impacts on pharmaceutical spending and access to medicines in Colombia”, Mision Salud and Fundacion IFARMA, Bogota, 2006.

<sup>75</sup> See footnote 69 above, p. 137 .

<sup>76</sup> US Trade Promotion Authority Act (2002), 116 STAT. 933, s. 2102 (b) 4 (A) (II).

<sup>77</sup> Several authors have written on this subject. See, e.g., C. Correa, “Implications of bilateral free trade agreements on access to medicines”, *Bulletin of the World Health Organization*,

TRIPS-plus standards increase medicine prices as they delay or restrict the introduction of generic competition.<sup>78</sup> It should also be noted that TRIPS-plus measures could also arise in other contexts such as terms for WTO accession.<sup>79</sup>

70. The need for public health to be taken into consideration in negotiating these agreements has been highlighted not only in developing countries and LDCs but also in developed countries. The European Parliament for example, in 2007, specifically asked the European Commission to take into consideration the need to protect public health in support of the Doha Declaration and refrain from negotiating TRIPS-plus provisions. Nevertheless, countries continue to negotiate and introduce agreements with TRIPS-plus standards.<sup>80</sup> TRIPS and the Doha Declaration specifically allow for countries to protect the right to health. As FTAs can directly affect access to medicines, there is a need for countries to assess multilateral and bilateral trade agreements for potential health violations and that all stages of negotiation remain open and transparent.

### **B. Restricting TRIPS flexibilities**

71. Several FTAs and BITs seek to restrict countries from implementing TRIPS flexibilities. An illustrative example is the attempt to broaden the scope of patentability.

72. As discussed, TRIPS flexibilities allow member States to define patentability criteria. However, a number of FTAs signed or currently being negotiated have restricted or even eliminated this flexibility by requiring that parties provide patent protections for second uses,<sup>81</sup> thereby allowing patentees to evergreen existing patents.

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vol. 84, No. 5 (May 2006), p. 399; F. Abbott, “The Doha Declaration on the TRIPS Agreement and public health and the contradictory trend in bilateral and regional free trade agreements”, occasional paper 14, Quaker United Nations Office (April 2004); Study of the Commission on Intellectual Property Rights, Innovation and Public Health (2005), executive summary.

<sup>78</sup> “All costs, no benefits: how TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines”, Oxfam Briefing Paper (March 2007). See also, UNDP-ICTSD conference: Monitoring the Impact of IP Protection on Public Health: Reviewing Progress, 2008.

<sup>79</sup> E/CN.4/2004/49/Add.1.

<sup>80</sup> European Parliament, Resolution on the TRIPS Agreement and access to medicines (12 July 2007). The Resolution specifically mentions prevention of use of data exclusivity and patent extension.

<sup>81</sup> See for example, article 17.9 (1), United States-Australia FTA, article 15.9 (2), United States-Morocco FTA and article 14.8 (2), United States-Bahrain FTA.

73. In addition, article 27 (3) (b) of TRIPS also allows members to exclude plants and animals from patentability as long as some sui generis system of protection for plant varieties is put in place. Some FTAs however, look to enhance patent protection for plants and animals, which can have an impact on access to medicine.<sup>82</sup>

74. Some FTAs also restrict procedural flexibilities, such as prohibiting pre-grant opposition procedures. Still others seek to limit the grounds on which compulsory licences can be issued.<sup>83</sup>

### **C. TRIPS-plus standards in the area of patent law in free trade agreements (FTAs)**

75. TRIPS-plus provisions in FTAs differ from agreement to agreement, but their purposes are by and large to:

- Extend the patent term
- Introduce data exclusivity
- Introduce patent linkage with drug registration and approval
- Create new enforcement mechanisms for IPRs

#### **1. Patent term extensions**

76. TRIPS provides for a 20-year patent protection term, starting from the date of filing the patent application. It should be noted that prior to TRIPS, developing countries only allowed 5-10 year patent protection while developed countries allowed 15-17 years.<sup>84</sup>

77. Several FTAs require an extension of the patent term for pharmaceutical products under certain circumstances.<sup>85</sup> The extension of patent life in developing countries and LDCs can significantly impact the ability of patients to access medicines, and may pose a burden for national health budgets. For instance, it has been estimated that the three-year patent extension

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<sup>82</sup> Article 15.9 (2) United States-Morocco FTA.

<sup>83</sup> United States-Singapore FTA, and draft United States-Thailand FTA.

<sup>84</sup> See footnote 30 above, p. 114.

<sup>85</sup> The United States-Jordan FTA, which requires a term extension for delays in marketing approval but not for patent grant procedures, is an exception. However, most United States negotiated FTAs require extension to “compensate the patent holder for unreasonable curtailment of the effective patent term” due to delays in the marketing approval of the medicines and the examination of the patent.

provision in the United States-South Korea FTA, would cost US\$ 504.5 billion and a four-year extension would cost US\$ 722.5 billion, consequently putting a strain on the national health insurance system in South Korea.<sup>86</sup>

## 2. Data exclusivity

78. Before a pharmaceutical company introduces a new medicine onto the market, it has to submit clinical test data to national drug regulatory authorities (DRA) to prove the medicine's safety and efficacy. In many countries, a subsequent generic manufacturer who seeks approval to market the generic equivalent is not required to submit fresh clinical test data but can show that its medicine is bioequivalent to the medicine of the originator company. Relying on the clinical test data of the originator, the DRA can grant marketing approval to the subsequent version. This allows generic medicines to enter the market quickly. Data exclusivity prevents such reliance on the original clinical test data by the DRA for a number of years and requires generic producers to submit their own clinical test data. Such a replication requires generic producers to allocate time and money to prove what is "already known" and also raises ethical concerns of replicating trials on human populations. Data exclusivity deters and considerably delays the entry of generic medicines and can lead to the maintenance of high prices of medicines.<sup>87</sup>

79. Although developed countries proposed the inclusion of data exclusivity in TRIPS, it was not adopted.<sup>88</sup> TRIPS does not require countries to provide data exclusivity. Where a national DRA requires the submission of undisclosed data for the registration of a medicine, TRIPS only requires countries to protect such data against "unfair commercial use" in case it relates to a "new chemical entity" and if the origination of such data involved a "considerable effort".<sup>89</sup> Countries can therefore determine how to protect such data. Reliance by the DRA on the clinical trial data of the originator company to approve a subsequent medicine does not amount to unfair commercial use.<sup>90</sup>

80. The requirement to impose data exclusivity features in several FTAs. For instance, the US-Morocco FTA provides for data exclusivity. In fact, it does not limit data exclusivity to a "new chemical entity", which is known internationally, but mandates the protection of test data of any "new product" defined as one previously unapproved in that territory.<sup>91</sup>

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<sup>86</sup> The Hankyoreh, "U.S. FTA may cost drug industry \$1.2 billion" (18 Oct 06).

<sup>87</sup> See footnote 9 above, p. 125.

<sup>88</sup> UNCTAD-ICTSD (2004), chapter 28 (Undisclosed Information), s.2.2 (Negotiating history), pp. 523-26.

<sup>89</sup> TRIPS Agreement, article 39, para. 3.

<sup>90</sup> Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (Geneva, South Centre, 2002).

<sup>91</sup> US-Morocco FTA, section 15.10.

81. In some cases, the period of data exclusivity may run during the life of the patent. However, there are a number of circumstances in which exclusive rights over test data can restrict the availability of medicines. Data exclusivity, being independent from patent protection, can allow pharmaceutical companies to secure monopoly rights for off-patent or non-patentable medicines. Evidence from Jordan indicates that pharmaceutical companies are choosing to rely on data exclusivity to enforce their monopoly instead of filing for patents.<sup>92</sup> In the context of developed countries, as evidence from Canada and Australia suggests, data exclusivity leads to higher costs of prescription medicines.

82. Data exclusivity may also block the production of generics after a compulsory licence is issued. Because marketing approval is independent from patent law, it is possible that a national DRA may refuse to approve a generic drug based on bioequivalence during the exclusivity period. This will pose a problem unless the law relating to data exclusivity provides an exception in the case of compulsory licences. However, even with this, there could be a delay in the entry of a generic version, as the marketing approval process may commence only after the compulsory licence is issued.

83. Data exclusivity is at odds with TRIPS flexibilities, such as those that allow governments to enforce their own criteria for granting patents, contest the validity of patents or issue compulsory licences. Therefore, in the context of developing countries and LDCs, data exclusivity may actually provide pharmaceutical companies with market monopoly without providing the public benefits and safeguards associated with the patent system.

### **3. Patent linkage**

84. Patent linkage is another TRIPS-plus obligation imposed through FTAs. It makes the marketing approval of a medicine dependent on its patent status. Thus if the medicine is patented, no marketing approval would be given to its generic version.

85. The laws of a number of countries permit national DRAs to grant marketing approval to a medicine, irrespective of its patent status.<sup>93</sup> Some countries, however establish a link between the patent system and drug marketing approval procedures.<sup>94</sup> For many developing countries and LDCs, patent linkages are introduced through FTAs that require the national DRA either to refuse to grant marketing approval for the generic version or to disclose to the patentee the identity of a third party seeking approval.

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<sup>92</sup> A country analysis of public health and patent law in Jordan has shown that of 103 medicines registered and launched since 2001 that currently have no patent protection in Jordan, at least 79 per cent have no competition from a generic equivalent as a consequence of data exclusivity. See footnote 78 above, p. 9.

<sup>93</sup> See footnote 90 above.

<sup>94</sup> Drug Price Competition and Patent Term Restoration Act (The Hatch-Waxman Act), United States 1984.

86. While some argue that patent linkage merely prevents governments from issuing patents while simultaneously permitting their infringement, it should be noted that patent linkage is at odds with the conception of patents as private rights.<sup>95</sup> It imposes an obligation on a country's DRA to prevent possible infringement of the private rights of patent holders either by denying registration or informing a patentee.

87. Further, it should be noted that the European Union (EU) does not have a system of patent linkages<sup>96</sup> and in the United States, the Food and Drug Administration has stated that it does not have the expertise or resources to review patents.<sup>97</sup>

88. This is of particular concern as patent linkage would affect the entry of generic medicines in the case of the patents being invalidated. By delaying the process of granting marketing approval, patent linkage provides patent holders with additional opportunities to prolong their monopoly rights and delays the entry of generic medicines into the market. In fact, a United States Federal Trade Commission study showed that the United States linkage system is subject to substantial abuse by patent holders.<sup>98</sup> The Canadian Federal Government and Supreme Court have also recognized that companies had been using the Canadian linkage system to evergreen their patents.<sup>99</sup>

89. Patent linkages, by not allowing the registration of generic versions of patented drugs can also adversely impact the early working exception, which ensures the immediate entry of generic competition after the expiry of the patent. Similarly, refusal to register also creates uncertainty in relation to compulsory licences.

#### **4. Intellectual property (IP) enforcement mechanisms**

90. The enforcement of IP claims should refrain from creating any undue barriers to access to medicines. In this respect, FTAs that impose TRIPS-plus IP enforcement measures are a

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<sup>95</sup> See TRIPS Agreement, preamble.

<sup>96</sup> "Patent linkage is considered unlawful under Regulation (EC) No 726/2004 and Directive (EC) No. 2001/83." See EU Directorate-General for Competition, *Pharmaceutical Sector Inquiry - Preliminary Report*, 28 November 2008.

<sup>97</sup> "FDA does not have the expertise to review patent information. The agency believes that its resources would be better utilized in reviewing applications rather than reviewing patent claims." 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994). See "Generic drug entry prior to patent expiration: an FTC study", Federal Trade Commission, July 2002, p. 44.

<sup>98</sup> *Ibid.*

<sup>99</sup> T.A. Faunce and J. Lexchin, "Linkage in pharmaceutical evergreening in Canada and Australia", *Australia and New Zealand Health Policy*, vol. 4, (2007), p. 8, referring to the two following sources: Government of Canada. Canada Gazette Part II Regulations amending the patented medicines (notice of compliance) regulations 2006, 140 (21): 1503-1525; *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2006 SCC 49.

cause for concern. For instance, proposals in the EU-CAN FTA under negotiation remarkably expand the scope of information that can be requested in IP infringement proceedings.<sup>100</sup>

91. The most important provisions of the EU-CAN (Andean Community of Nations) proposal remain those establishing criminal sanctions for IP infringement. Whereas TRIPS mandates “criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale”, the proposal encompasses intentional infringement on all IP rights, including patents with sanctions ranging from imprisonment, monetary fines, confiscation of equipment and products, destruction of goods to permanent closure of involved establishments. Criminalizing patent infringement is particularly worrisome given that patents challenged in court by alleged infringers are often found to be invalid.<sup>101</sup> Such overreaching provisions, with a low evidentiary standard, may have a chilling impact on producers of generic medicines who could be threatened with sanctions before the validity of the patent is even determined.

92. Furthermore, TRIPS-plus IP enforcement can adversely impact access to medicines. In this regard, the Special Rapporteur is concerned with reports of IP enforcement measures that have resulted in multiple seizures at some ports of shipments of generic medicines heading to developing countries and LDCs.<sup>102</sup> Customs regulations of some countries allow the seizures of goods suspected of IP infringement even if they are only in transit.<sup>103</sup> Such regulations impose a far higher standard of IPR enforcement than that required by TRIPS, which requires that IP enforcement measures should not create barriers to legitimate trade.<sup>104</sup> In effect, such actions can bring to naught TRIPS flexibilities exercised by developing countries and LDCs, and de facto impose IP protection on LDCs that are not yet required to comply with TRIPS as generic medicines they need do not reach them. In particular the use of compulsory licensing or the 30 August decision to export and import medicines is effectively negated.

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<sup>100</sup> In addition to the requirement mandated by the TRIPS Agreement that the infringing party provide the information, the EU proposal would also require any other person who was found in possession of, using, or providing the infringing goods or services on a commercial scale to provide the information.

<sup>101</sup> See “Generic drug entry prior to patent expiration: an FTC study”, Federal Trade Commission, July 2002, and K.A. Moore, “Judges, juries and patent cases - an empirical peek inside the black box”, *Michigan Law Review*, vol. 99, No. 2 (November 2000) p. 365.

<sup>102</sup> See Statement by Brazil at TRIPS Council: Public Health dimension of TRIPS Agreement, 3 March 2009 and UNITAID, statement on Dutch confiscation of medicines shipment, 4 March 2009.

<sup>103</sup> EU Council Regulation (EC) No. 1383/2003.

<sup>104</sup> Article 41, TRIPS Agreement.

93. The Special Rapporteur also notes possible concerns that recent developments in national legislation<sup>105</sup> and international negotiations on an anti-counterfeiting trade agreement (ACTA) may impose a TRIPS-plus enforcement regime.<sup>106</sup> The lack of transparency and secrecy surrounding the negotiations is of particular concern.

## V. CONCLUSIONS AND RECOMMENDATIONS

94. **The framework of the right to health makes it clear that medicines must be available, accessible, acceptable, and of good quality to reach ailing populations without discrimination throughout the world. As has been evident, TRIPS and FTAs have had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfil the right to health.**

95. **Similarly, lack of capacity coupled with external pressures from developed countries has made it difficult for developing countries and LDCs to use TRIPS flexibilities to promote access to medicines.**

96. **Flexibilities were included in TRIPS to allow States to take into consideration their economic and development needs. States need to take steps to facilitate the use of TRIPS flexibilities.**

97. **The Special Rapporteur therefore recommends that developing countries and LDCs should review their laws and policies and consider whether they have made full use of TRIPS flexibilities or included TRIPS-plus measures, and if necessary consider amending their laws and policies to make full use of the flexibilities.**

98. **LDCs should make full use of the transition period and in relation to medicines revoke or suspend their patent laws, if necessary, for the balance of the period. LDCs should also consider asking for a further extension of the transition period.**

99. **LDCs should use the transition period to seek the most effective technical and other assistance from countries and institutions to develop technical capacity and also explore options to establish local manufacturing capabilities.**

100. **Developing countries and LDCs should establish high patentability standards and provide for exclusions from patentability, such as new forms and new or second uses, and combinations, in order to address evergreening and facilitate generic entry of medicines.**

101. **Developing countries and LDCs should adopt the principle of international exhaustion and provide for parallel importation with simplified procedures in their national laws.**

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<sup>105</sup> Kenya Anti-Counterfeit Act and Uganda anti-counterfeit bill.

<sup>106</sup> EU Parliament resolution, INI/2008/2133 of September 2008.

**102. Developing countries and LDCs need to incorporate in their national patent laws all possible grounds upon which compulsory licences, including government use, may be issued. Such laws provide straightforward, transparent procedures for rapid issue of compulsory licences. There is also a need to revisit the 30 August decision and provide for a simpler mechanism.**

**103. Developing countries and LDCs should specifically adopt and apply pro-competition measures to prevent the abuse of the patent system, particularly in regard to access to medicines.**

**104. Developing countries and LDCs should incorporate both Bolar (early working) and research, experimental and educational exceptions in their patent laws and explore how additional limited exceptions could further promote access to medicines.**

**105. Developing countries and LDCs should establish liberal pre-grant, post-grant opposition and revocation procedures, which can be taken advantage of by all concerned stakeholders, including patients' groups.**

**106. Developing countries and LDCs should seek international assistance in building capacity to implement TRIPS flexibilities to promote the right to health. WHO and other United Nations bodies could provide such assistance.**

**107. LDCs and developing countries should actively promote the participation of individuals and communities in decision-making processes relating to TRIPS and TRIPS flexibilities and conduct impact assessments of the same.**

**108. Developing countries and LDCs should not introduce TRIPS-plus standards in their national laws. Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health.**

**109. All technical assistance and cooperation by developed countries, WHO and the World Intellectual Property Organization (WIPO), to developing countries and LDCs should be based on the obligation to respect, protect and fulfil the right to health.**

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