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ARTICLE 27.3(B) AND THE LEGALIZATION OF BIOPIRACY: TRENDS, IMPACTS AND WHY IT NEEDS TO BE AMENDED

I. INTRODUCTION

1. The purpose of this submission is to contribute to the work programme of the TRIPS Council under the review of Article 27.3(b) of the TRIPS Agreement, which is long overdue.

2. As noted in IP/C/W/545, the review of Article 27.3(b) is an issue within the mandate of the Doha Work Programme under paragraph 19 of the 2001 Doha Ministerial Declaration (WT/MIN(01)/DEC/1). It is also an issue within the mandate of the Doha Work Programme under Implementation-Related Issues and Concerns. In this regard paragraph 12 of the Doha Ministerial Declaration mentions the adoption of the Decision on Implementation-Related Issues and Concerns (WT/MIN(01)/17) to address a number of implementation problems faced by Members. It also clearly states that the "negotiations on outstanding implementation issues shall be an integral part of the Work Programme".

3. In the 15 years since the adoption of Article 27.3(b) we have witnessed a rush towards patenting of life forms and parts thereof, a trend which is most concerning due to the ethical and moral implications as well as the adverse impacts in areas of great importance for developing countries and indigenous peoples, such as food and agriculture, climate change and health, among others.

4. The aim of this submission is to highlight these trends and some of their impacts and resulting concerns, all of which support the call to amend Article 27.3(b) of the TRIPS Agreement to prohibit the patenting of life forms and parts thereof.

II. TRENDS IN PATENTING OF LIFE FORMS

5. Prior to the adoption of Article 27.3(b), life forms and components of life forms (such as cells, genes, biochemical substances and proteins) were generally not considered to be patentable.

6. The adoption of Article 27.3(b) established that Members shall provide patents to microorganisms, microbiological processes and non-biological processes. Article 27.3(b) also provided Members the possibility to provide patents on plants and animals as well as essentially biological process. Thus the adoption of the Article promoted a new phase of extension of capitalism into nature never seen before, that is allowing the privatization of life itself.

7. Article 27.3(b) triggered a process which led to the proliferation of policies and laws that permit life forms and parts thereof to be considered patentable subject matter. Article 27.3(b) also promoted the expansion of the scope of invention with the resulting effect of patents being granted to discoveries of the functions and characteristics of a living organism or parts thereof.

8. As a consequence, during those 15 years there has been a proliferation of patents and patent applications involving a wide range of life forms, including human life itself, and parts thereof such as proteins, genes, gene sequences, cells, cell lines or tissues. Several reports and studies have documented this phenomenon.

- In 1999, 918 patents on staples such as rice, maize, wheat, soybean and sorghum had been granted mostly to 6 agrochemical corporations[1].

- In 2000 an investigation uncovered that as of November 2000 patents were pending or have been granted on more than 500,000 genes and partial gene sequences in living organisms. Of these, there were over 9,000 patents pending or granted involving 161,195 whole or partial human genes, while the remainder related to plants, animals and other organisms.[2]

- A 2005 study revealed that nearly 20% of all human genes had been patented in the United States, in other words 4,000 of the nearly 24,000 human genes.[3]

- A study noted that patent publications relating to animal cells and tissues multiplied about 6 times between 2000 and 2003 (3 years) as compared to 1990-2000 (10 years).[4] Another study in 2010 found that 660 patents had been granted on animals.[5]

- In 2008, a report revealed that about 532 patent documents had been filed by agrochemical corporations on "climate ready" genes in plants that will be able to withstand environmental stresses such as drought, heat, cold, floods etc.[6] According to the report the patent claims also cover substantially similar genetic sequence in virtually all engineered food crops. Between 2008 and 2010, 1663 additional patents had been granted on genes and plant characteristics tolerant to climate changes and extreme climate conditions.[7]

III. ETHICAL AND MORAL CONCERNS

9. The patenting of life forms promoted by Article 27.3(b) raises serious ethical and moral concerns for many cultures and peoples around the world. These concerns have been raised in previous submissions on this matter by developing countries including by Bolivia in IP/C/W/545.[8]

10. The extension of patents to life forms and parts thereof as human inventions, promotes the concept of commodification of life and reduces the value of life and nature to the merely economic. Such a vision is alien (and in some cases considered intrinsically wrong) to the culture, beliefs and values of many societies, including indigenous peoples in developing countries, for which life is sacred and special, cannot be considered an invention of human beings and should not be treated as any other commodity.

11. A system that treats human beings and the features that make life essential as a commodity reduces the value of life to an economic value and consigns humanity to a lower level of moral development. Humanity and human progress should not be measured only or mainly in economic and commercial terms, but rather in terms of human values and dignity.

12. Moreover Article 27.3(b) fosters biopiracy as it facilitates appropriation of life forms and parts thereof that originate or that are sourced from developing countries and that have been sustained, conserved, discovered and even developed for centuries by indigenous peoples and local communities for various purposes. According to the 1999 UN Human Development Report the current patent system is leading to the "silent theft of centuries of knowledge" from developing to

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1 Action Aid, "Crops and Robbers", October 2001.

2 The GeneWatch and the Guardian, 2000, op.cit.

3 National Geographic, 2005

4 Carlos M. Correa, "Trends in Intellectual Property Rights Relating to Genetic Resources for Food and Agriculture", background paper study paper 49, Commission on Genetic Resources for Food and Agriculture, October 2009

5 Stop Animal Patents, 2010

6 ETC Group, "Patenting the "Climate Genes" And Capturing the Climate Agenda", May/June 2008 Communique

7 ETC, Gene Giants Stockpile Patents on "Climate-ready" Crops in bid to become "Biomassters", October 2010

8 For example see IP/C/W/206 Submission by African Group, September, 2000; JOB(01)/152/Rev.1 Compilation of outstanding issues raised by members. LDC proposals.;IP/C/W/404, Submission African Group, Jun 2003.

developed countries.[9] Thus in short allowing patenting of life forms is tantamount to condoning "theft" of knowledge developed collectively and used for millennia in developing countries.

13. In addition, the United Nations Declaration on the Rights of Indigenous Peoples, in many of its provisions, emphasizes the importance of the beliefs and the values of these peoples and the need to take them into account when agreements involve or affect those rights, values or beliefs.[10]

IV. NEGATIVE IMPACTS AND CONSEQUENCES

Concentration and monopoly

14. A general worrying trend is that a few transnational corporation now exercise monopolistic control over some of the most important sectors such as food, agriculture and health, a trend facilitated by the patent system. In 2008, a report revealed how the top-10 transnational corporations in each sector controlled major segments of their respective markets. For example 55% of the pharmaceutical market, 89% of the agrochemical market, 66% of the biotechnology market and 26% of the food and beverage market.[11]

15. A serious consequence of Article 27.3(b) has also been the concentration of the control of life forms, in the private sector, in particular in the hands of a few transnational corporations based in developed countries. For example 67% of the proprietary seed market being controlled by ten transnational corporations, with one particular corporation controlling nearly one quarter of this market. In the agrochemical sector two companies control nearly 40% of the market.[12]

16. The control a few developed countries' transnational corporations have on life forms, and parts thereof should be a cause of concern as important decisions affecting people all around the world in areas such as health, food, agriculture, climate change and environment, are being taken on the basis of profits and not the common good of humanity. In addition, the research realized and the technologies developed are likely to have the effect of reinforcing the monopolies and the profits of a few transnational corporations while creating more dependence for developing countries.

Access and use

17. Patents on life forms have negative effects in terms of access because they enable the private right holders to increase the costs of access and eventually to deny it, with serious consequences in terms of health, food security and food sovereignty.

18. A real concern to many developing countries is the very real possibility that patents on life forms could be used to restrict the use of organisms and parts thereof by developing countries and their indigenous peoples. Indeed if uses or applications of plants used by indigenous peoples in medicine or agriculture for example get patented, they could see themselves firstly, forbidden from using their own resources and continuing with their own practices so important for their livelihood and survival, and secondly, marginalised in various ways from accessing the resources as a result of commercial exploitation.

Trade and exports of developing countries

19. Patents on life forms and parts thereof can also adversely affect the exports and commercial

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[9] See p. 6 Human Development Report 1999, UNDP, available at http://hdr.undp.org/en/media/HDR_1999_EN.pdf

[10] United Nations Declaration on the Rights of Indigenous Peoples among others recognize the "...urgent need to respect and promote the inherent rights of indigenous peoples which derive from their political, economic and social structures and from their cultures, spiritual traditions, histories and philosophies, especially their rights to their lands, territories and resources,

[11] ETC Group, "Who owns nature Corporate power and the final frontier in the commodification of life", November 2008

[12] ETC Group, "Who owns nature Corporate power and the final frontier in the commodification of life", November 2008

activities of developing countries. Various cases of such impacts have been documented. For example the patent on the yellow bean Enola was used to prevent exports from developing countries farmers to the United States or the patent of Monsanto that was used to block exports of soya meal from Latin America to Europe. These cases indicate that a global solution is required to address concerns pertaining to the patenting of life forms and parts thereof. As patents on life forms and their parts proliferate and the pressure to enforce IPRs intensify cross border trade in food and agriculture as well as other products is likely to be very much affected with serious effects particularly for developing countries.

Innovation

20. The granting of patents on life forms and parts thereof is often justified on the basis that it is a necessary incentive to facilitate innovation and to stimulate research and development. However there is increasing evidence that this premise is fundamentally flawed and that this dominant model of innovation also frustrates innovation, stifles research and development and hinders science from fully benefiting the public.

21. Some of the problems posed by this dominant model of innovation include: (i) restrictions on access to information at different stages of innovation, thus obstructing the free flow of scientific information and impeding scientific progress; (ii) reduced or delayed information sharing among the scientific community as a result of patent requirements (e.g. that information must not be in the public domain at time of filing); (iii) licensing practices (e.g. narrow or exclusive license terms) that have restrictive effects on innovation; (iv) multiple licenses may be required to access single technology or research tool, thus making access complicated, time-consuming and costly; (v) uncertainty over the ability to obtain necessary licenses on fair terms and also conditions that discourage investment in research and development; (vi) tendency to reward creative efforts that may lead to commercial gains and as a result hindering innovation of products that have vast societal benefit but a limited market; (vii) patent specifications, which are meant to disclose the invention, are drafted by patent attorneys in a species of "legalese" reducing the quality of the patents –this is central to the monopoly protection based on disclosure central to the legitimacy of the patent system as well as mocking the commitment to innovation, values of open science and communication.

22. The above-mentioned problems are not a new discussion subject. They have been highlighted on numerous occasions by a number of prominent nobel laureates, academics, and experts in the field of life sciences. In our view the review of Article 27.3(b) is an opportune occasion to take bold steps to address these concerns.

IV. SPECIFIC CONSEQUENCES IN SOME SECTORS

Food and agriculture

23. The detrimental impact of allowing patenting of life forms and parts thereof is particularly felt in the area of food and agriculture. As noted above the current patent system has resulted in giving a handful of corporations unprecedented legal control over the food chain. The combination of market concentration with the ability to patent has paved the way for a comprehensive takeover of genetic resources, seeds, and even derived products by a few corporations leading to concentrated corporate power, high costs, an increase of food prices, and inhibition of agricultural innovation as well as undermining of farmers' rights.

24. For instance a 2005 report documents how a particular American company filed 90 lawsuits against American farmers over supposed infringement of seed patents and technology agreements, involving 147 farmers and 39 small businesses or farm companies.[13] The report notes that the result

[13] Center for Food Safety, "Monsanto vs. US Farmers", 2005

has been nothing less than an assault on the foundations of farming practices and traditions that have endured for centuries in this country and millennia around the world, including one of the oldest, the right to save and replant crop seed.

25. Innovation in agriculture is dependent on the use of existing genetic materials for further research and breeding, which is central to the preservation of agrobiodiversity and the development of farmers' seed systems. However the monopoly rights of the patent system prevents access to the protected germplasm and varieties. This problem is exacerbated by the multiplicity of patent claims over the materials and broad patent claims. For instance where functional claims are allowed, all the potential means to solve a problem may be covered.

26. In addition the scope of many of the patent applications cover conventional breeding, with extensively broad claims that encompass all the plant genetic resources, seeds, plants, the harvests and their use in food production, as well as the use of the patented plants in later generations and after further crossings.[14] Such applications and patents obstruct the use of genetic material and breeding methods and ultimately hampers innovation.

27. The adverse implications of patenting biological materials in the area of food and agriculture have been highlighted on numerous occasions. The UN Special Rapporteur on the Right to Food noted in his report to the UN General Assembly that "the expansion of intellectual property rights can constitute an obstacle to the adoption of policies that encourage the maintenance of agrobiodiversity and reliance on farmers' varieties. Intellectual property rights reward and encourage standardization and homogeneity, when what should be rewarded is agrobiodiversity, particularly in the face of the emerging threat of climate change and of the need, therefore, to build resilience by encouraging farmers to rely on a diversity of crops. In addition, intellectual property rights — particularly patents granted on plants or on genes or DNA sequences — can constitute a direct impediment to innovation by farmers".[15]

Climate change

28. Profiting from the threat that climate change represents for humankind, and in particular for developing countries, various transnational corporations from developed countries have engaged in a rush to patent plants and parts of plants that could in the future represent strategic resources for the very future of humanity.

29. A 2008 study revealed, during the climate change negotiations, that approximately 532 patent documents have been filed by agrochemical corporations on "climate ready" genes in plants that will be able to withstand environmental stresses such as drought, heat, cold, floods etc.[16] Between 2008 and 2010, 1663 patent documents were revealed with regard to genes and plant characteristics tolerant to climate changes and extreme climate conditions.[17]

30. Noting this trend, the problems generated for humankind by climate change would be compounded by the fact that transnational corporations hold 91% of the patent families pertaining to traits tolerant to climate change. Only six of those transnational corporations control 77% of these patent families, while three of the companies control 66%.[18]

31. Concentration of strategic resources in the hands of a few transnational corporations in developed countries can have serious implications for developing countries and indigenous peoples.

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[14] Christopher Then & Ruth Tippe (prepared for the international coalition of "no patents on seeds", www.nopatents-on-seeds.org), "The future of seeds and food under the growing threat of patents and market concentration", April 2009

[15] Olivier De Shutter, Report of the Special Rapporteur on the right to food, 2009 (A/64/170)

[16] ETC Group, "Patenting the "Climate Genes" And Capturing the Climate Agenda", May/June 2008 Communique

[17] ETC, Gene Giants Stockpile Patents on "Climate-ready" Crops in bid to become "Biomassters", October 2010

[18] ETC, Gene Giants Stockpile Patents on "Climate-ready" Crops in bid to become "Biomassters", October 2010

Although the historical responsibility of climate change lies with developed countries, it can be anticipated that developing countries will be asked to pay for access to resources that are critical to combat climate change and that in certain cases they themselves developed.

Health

32. The public health consequences of allowing patenting of life forms and parts thereof can be rather severe. Such patenting can have a negative impact on innovation in the health sector, create obstacles in accessing relevant technologies as well as may hamper access to medicines, vaccines and to essential treatment.

33. This has been amply demonstrated by patents on BRCA1 and BRCA 2 genes which are responsible for most cases of hereditary breast and ovarian cancers. The patents granted to Myriad gave the company the exclusive right to perform diagnostic tests on the genes and to prevent any researcher from even looking at the genes without first getting permission from Myriad. Myriad's monopoly made it impossible for women to access alternate tests or to get a comprehensive second opinion about their results and enabled Myriad to charge a high rate for their tests. Recently the New York Federal Court recognizing the far-reaching impact of the case on medical research and public health declared the patents invalid. This was so despite arguments by Myriad that such patents were actually inventions.

34. The issue of patenting of life forms and parts thereof is also being discussed in the context of the Pandemic Influenza Preparedness: Sharing of influenza viruses and access to vaccines and other benefits negotiations in the World Health Organization. In this regard significant concern has emerged that appropriation by developed countries' entities of influenza biological material shared on a voluntary basis will hamper relevant scientific research and access to technologies and vaccines. Concern has also been raised that allowing appropriation of biological material contributed for pandemic preparedness is unethical and thus cannot be condoned.

V. CONCLUSION

35. Allowing the patenting of life forms and parts thereof is simply unacceptable.

36. As noted above such patenting is considered unethical and immoral by many cultures and traditions. It also legitimises biopiracy.

37. Further allowing the patenting of life forms and parts thereof is likely to have serious dangerous consequences for humankind, in particular for developing countries. The control of life forms, and parts thereof, is now concentrated in the hands of a few transnational corporations quartered in developed countries, that are able to exercise monopoly control and exclusive rights of use. Such a situation has critical consequences for developing countries as key decisions with regard to food, health or climate change that affect all peoples will be made primarily with the aim of maximizing profits. These corporations are also in a position to dictate terms and conditions for accessing and using patented materials. Patenting of life forms and parts thereof also threatens the traditional practices of indigenous peoples and peasants as well as the agricultural exports of developing countries. It may frustrate innovation and stifle research and development. Its consequences are particularly worrying in the context of agriculture, food security, health and climate change.

38. Allowing patenting of life forms and parts thereof thus represents a danger for humankind and in particular for developing countries. The costs greatly exceed the benefits. It is a problem that the international community is facing as whole and thus it requires an international solution.

39. For all these reasons, Bolivia proposes to amend Article 27.3 (b) to prohibit all forms of patenting of life and parts thereof as an essential part of the mandate in the Doha Development

Round and as an important contribution of the WTO to the development objectives.

40. In this context we would like to recall IP/C/W/545 wherein it is proposed that Article 27.3(b) be amended to prohibit the patenting of all life forms, including plants and animals and parts thereof, gene sequences, micro-organisms as well as all processes including biological, microbiological and non-biological processes for the production of life forms and parts thereof.

41. Bolivia's proposal to prohibit the patenting of life forms and parts thereof might complement the "draft modalities for TRIPS related issues" in the sense that the obligation of disclosure would apply to patents claiming inventions developed using life forms and parts thereof, while the life forms and parts thereof themselves should not be considered patentable subject matter.