

Climate Change and Intellectual Property Rights for New Plant Varieties

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Abstract

Debates between developing and developed countries over access to technology to mitigate or adapt to climate change tend to overlook the importance of biotechnology. There has been little comparative analysis of competing IPR regimes for biotechnology. Moreover, the role that compulsory licensing might play in international biotechnology transfer has not been explored in depth.

This article focuses on the role of intellectual property rights (IPRs) in the international transfer of new plant varieties. Climate change will increase the importance of the development of new plant varieties (primarily genetically modified ones) that can adapt to changing (and more extreme) climactic conditions. We begin our analysis by examining the science and impact of climate change. We then provide an overview of the debates regarding IPRs and international technology transfer. We argue that the impact of IPRs on international technology transfer varies from one area of technology to the next. IPRs represent a more significant obstacle to international biotechnology transfer than they do in other technologies.

Subsistence farming increases developing countries' vulnerability to climate change and their need to access the biotechnology on favorable terms. In this regard, the issues that arise with respect to biotechnology are closer to those regarding pharmaceuticals than to those regarding clean energy technology. We therefore compare the economics of IPRs for biotechnology and pharmaceuticals. We then provide a comparative analysis of IPRs for biotechnology in the WTO TRIPS Agreement, the UPOV Convention and the Convention on Biological Diversity. This analysis sheds light on the policy options available to developing countries under the current international legal regime.¹

Introduction

Measures to mitigate climate change and measures to adapt to the impacts of climate change have implications for intellectual property rights (IPRs) and vice versa. IPRs affect access to technologies to mitigate and adapt to climate change, particularly in developing countries. As a result, there is an important debate regarding the need to modify laws relating to IPRs in order to remove obstacles to international technology transfer.²

Debates between developing and developed countries over access to technology to mitigate or adapt to climate change tend to overlook the importance of biotechnology. Instead, these debates focus on other technologies, particularly clean energy technologies. Moreover, there has been little comparative analysis of competing IPR regimes for

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² The availability of financing to develop and to acquire such technologies is an important, related issue. We address this issue in a separate article.

biotechnology. The role that compulsory licensing might play in international biotechnology transfer has not been explored in depth, in part because it is unclear how difficult it would be to reverse engineer genetically modified plants and in part due to uncertainty regarding the compensation that would be owed to the IPR owners.

In addition, debates over financing mechanisms for technology acquisition tend to be based on moral arguments and assumptions regarding the availability of financing in developed countries and the lack thereof in developing countries. However, recent economic crises in the Japan, the United States and Europe have diminished their financial capacities. At the same time, economic growth and technological developments in major emerging economies are expanding their financial and technological capabilities. Moreover, several major developing countries misallocate resources, to varying degrees, to subsidize the consumption of fossil fuels. The reallocation of those resources, while politically challenging, could prove to be an important source of financing.

This article focuses on the role of intellectual property law in the international transfer of new plant varieties. Climate change will increase the importance of the development of new plant varieties (primarily genetically modified ones) that can adapt to changing (and more extreme) climactic conditions. Indeed, a recent study shows that climate changes are already exerting a considerable drag on yield growth of for wheat and maize.³

We begin our analysis by examining the science and impact of climate change. We then provide an overview of the debates regarding IPRs and international technology transfer. We argue that the impact of IPRs on international technology transfer varies from one area of technology to the next, and depends on the availability of competing technologies, the technological development of each developing country and the vulnerability of developing countries to climate change impacts that each technology addresses. IPRs represent a far more significant obstacle to international biotechnology transfer than they do in other areas of technologies needed to mitigate and adapt to climate change. Subsistence farming is more widespread in developing countries, which increases their vulnerability and their need to access the biotechnology on favorable terms. In this regard, the issues that arise with respect to biotechnology are closer to those regarding pharmaceuticals than to those regarding clean energy technology. We therefore examine the economics of IPRs for biotechnology and pharmaceuticals and conclude that the need for strong IPRs is doubtful in both fields. However, we recognize the difficulty of achieving law reforms in the current international political environment. We therefore provide a comparative analysis of the relevant international legal obligations related to IPRs for biotechnology in the WTO TRIPS Agreement, the UPOV Convention and the Convention on Biological Diversity. This analysis sheds light on the policy options available under the current international legal regime.

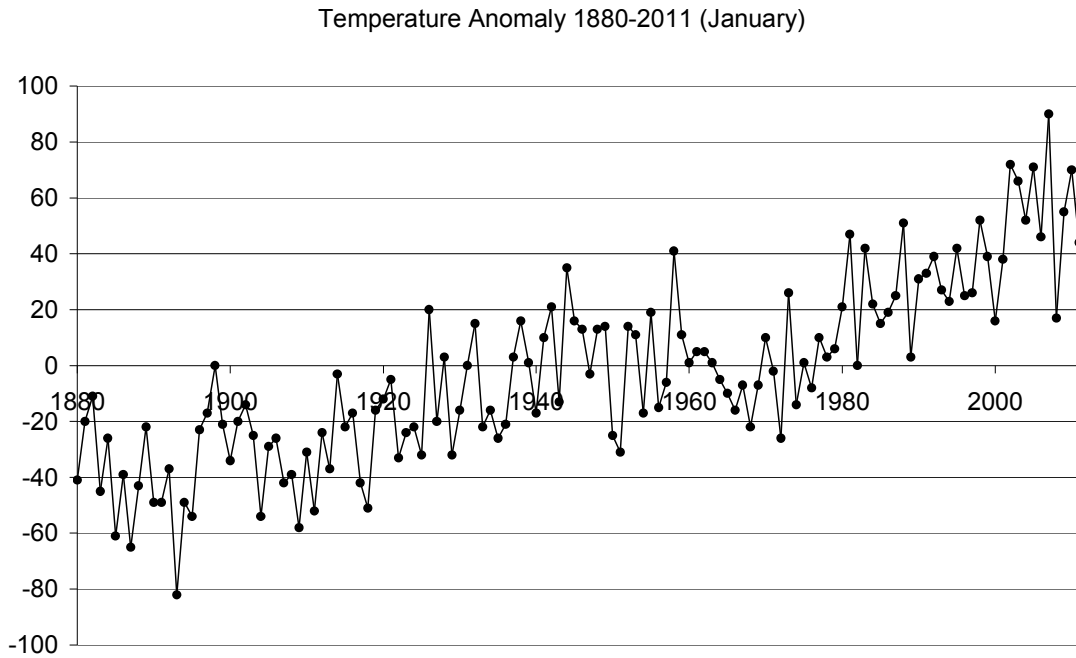
The Science of Climate Change and Its Impact

There has been a gradual change of the surface temperature over the past century. This change has been well documented. The mean temperature changed globally (Northern

³ David B. Lobell, Wolfram Schlenker and Justin Costa-Roberts, Climate Trends and Global Crop Production Since 1980, www.sciencexpress.org, 5 May 2011.

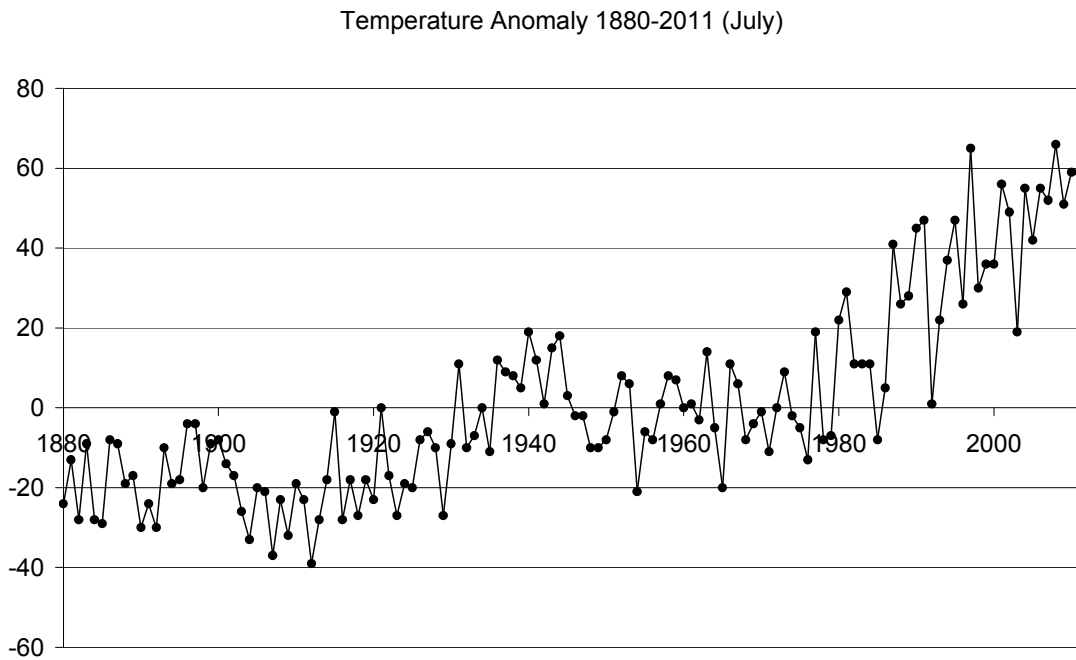
Hemisphere) in January and July between 1880 and 2011 (see Figures 1a and 1b). The scale is Celsius multiplied by 100. Thus, both in the coldest month and the hottest month of the year, there have been steady rises in temperature of about 1 degree C over the course of the past century. This change of just one degree may not sound like much, but there is clear scientific evidence that an additional change of temperature of 0.7 degrees Celsius will have dire consequences (see Figure 2 below).

Figure 1a



Source: <http://data.giss.nasa.gov/gistemp/tabledata/GLB.Ts+dSST.txt>

Figure 1b



Source: <http://data.giss.nasa.gov/gistemp/tabledata/GLB.Ts+dSST.txt>

There are clear links between human activities the rise in temperature principally through the emission of CO₂ and other greenhouse gases (such as N₂O, CFC, CH₄). The 2007 Fourth Assessment Report compiled by the IPCC (AR4) stated that “changes in atmospheric concentrations of greenhouse gases and aerosols, land cover and solar radiation alter the energy balance of the climate system.” It concluded that “increases in anthropogenic greenhouse gas concentrations *is very likely* to have caused most of the increases in global average temperatures since the mid-20th century.”⁴

What impact will it have on hunger, water shortage, flooding and diseases associated with rising temperature? The answer depends on the rise in temperature. Even if actions are taken now to reduce CO₂ emission, the emission will at least double by the end of 2100. This will produce a rise of mean temperature of 3 degrees C (with a 95 percent band of between 2 to 4.5 degrees C).⁵ In most cases, the number of people affected in each dimension mentioned above will depend on the temperature in a *nonlinear* way. All of that is demonstrated in Figure 2 below. We summarize here what Figure 2 exactly says. On the vertical left axis, we plot the impact on the number of people affected in terms of (1) hunger, (2) malaria and (3) flooding as a result of the temperature rise. (1) Rising temperature will cause more frequent droughts mostly in Africa and some other pockets such as Latin America and Asia. This impact will be felt starting at a temperature rise above 1.7 degree C. It will negatively affect agriculture in Australia. However, it will not increase hunger there, since Australia is already developed. In Africa, especially in Sub-Saharan Africa, the population increase is already outstripping the increase in food production. It will get much worse in the current century.⁶ (2) Malaria will reach new places. This process has already begun.⁷ (3) Climate change will result in rising sea levels. Investigations have predicted a rise in sea level in 2100 of between 0.5 meters and 1.4 meters.⁸ It will also lead to an increase in flooding of river basins.⁹ In addition, it will lead to more frequent flooding in other parts of the world.¹⁰ On the right hand side vertical axis, we plot the impact on water shortage. While hunger, malaria and flooding will affect tens of millions, the water shortage problem will affect hundreds of millions by 2080.

⁴ IPCC Report, 2007, p. 5. Available at http://www.ipcc.ch/pdf/assessment-report/ar4/syr/ar4_syr_spm.pdf

⁵ Reto Knutti & Gabriele C. Hegerl. 2008. The equilibrium sensitivity of the Earth's temperature to radiation changes. *Nature Geoscience* 1, 735 – 743.

⁶ Michael Herrmann. Food Security and Agricultural Development. UNCTAD Report No. 196 November 2009 (see Figure 5 on page 14).

UNCTAD/OSG/

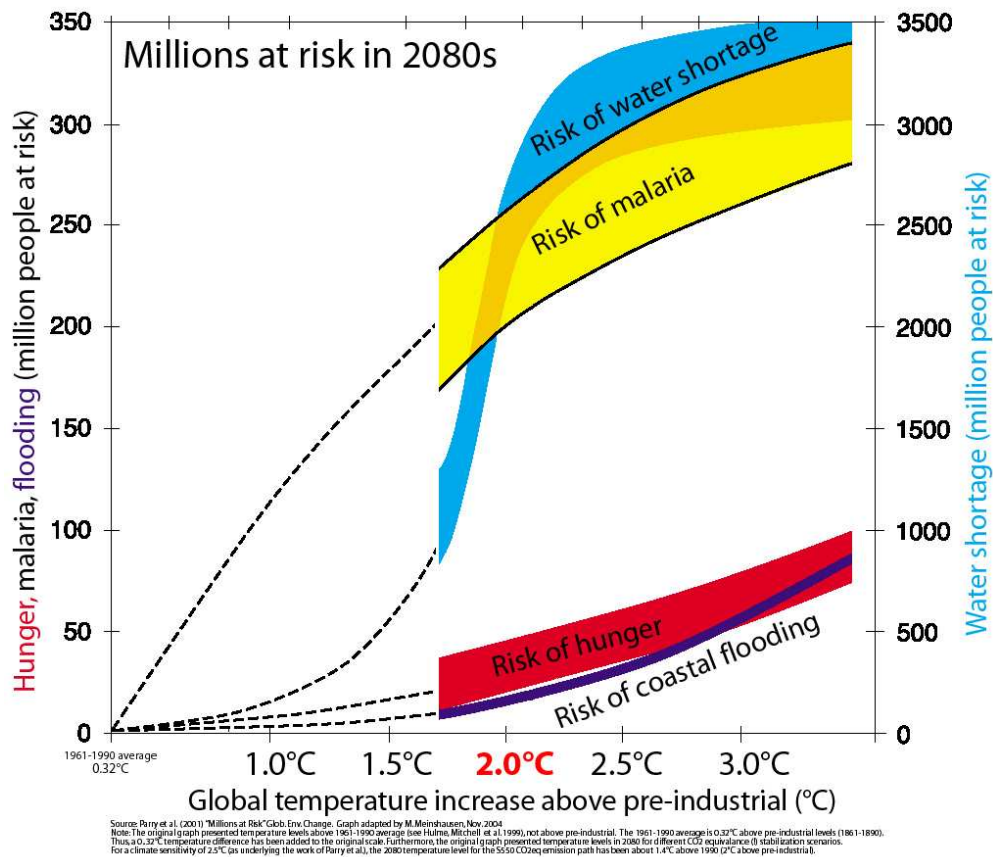
⁷ Simon I. Hay et al. Climate change and the resurgence of malaria in the East African highlands. 2002. *Nature*, Volume 415, p. 903-909.

⁸ Stefan Rahmstorf . 2007. A Semi-Empirical Approach to Projecting Future Sea-Level Rise. *Science*, Volume 315 no. 5810 pp. 368-370

⁹ M.J. Booij / *Journal of Hydrology* 303 (2005) 176–198

¹⁰ Jens H. Christensen, Ole B. Christensen. 2002. Severe summertime flooding in Europe. *Nature*, Volume 421, p. 805-6.

Figure 2



Intellectual property rights and international technology transfer

Discussions regarding intellectual property rights and international technology transfer are complicated by a lack of precision regarding the definition of the relevant technologies. In the WTO negotiations on environmental goods and services, Members have not been able to agree on which goods and services qualify as “environmental”. This experience demonstrates the potential difficulties involved in analyzing the issue of technology transfer without first defining the technologies under discussion.

In negotiations regarding IPRs, technology transfer and financing under the auspices of the UN Framework Convention on Climate Change (UNFCCC), some countries have argued that IPRs are best addressed in other forums, such as the WTO or WIPO.¹¹ The WTO TRIPS Agreement sets out international obligations regarding IPRs that are enforceable through the WTO dispute settlement system. For this reason, the TRIPS Agreement is often referred to as WIPO with teeth. The TRIPS Agreement includes provisions regarding IPRs for new plant varieties, as does the UPOV Convention and other international instruments, such as the International Treaty on Plant

¹¹ We analyze the UNFCCC elsewhere.

Genetic Resources for Food and Agriculture.¹² Thus, IPRs and technology transfer are debated in multiple international forums and regulated by multiple international agreements.

Clean energy technologies are often cited as an example of the kind of technology that needs to be developed and transferred internationally in order to combat climate change. In international debates regarding the effect of IPRs on the transfer of environmental technologies, developing countries often draw upon the experience regarding pharmaceutical patents. However, IPRs play a different role in the renewable energy industries than it does in the pharmaceutical sector, and seem less likely to create barriers to technology access.¹³ New plant varieties represent an equally important technology that developing countries, in particular, will need in order to adapt to the effects of climate change. The applicable intellectual property laws and the technology transfer issues are different again for biotechnologies such as plant varieties, where IPRs may create barriers to access that are similar to the pharmaceutical sector. Thus, it is not possible to analyze the subject of intellectual property rights and international technology transfer in a generalized manner. The analysis must be done according to specific categories of technology. The availability of competing technologies will diminish the impact of IPRs on their cost. Similarly, where a technology has no or few substitutes or IPRs are concentrated in the hands of relatively few firms, IPRs will increase costs due to monopoly pricing power.

Abbott compares the role of intellectual property rights in the pharmaceutical sector to its role in alternative energy resources and climate change mitigation technologies. He argues that technology transfer commitments resulting from climate change negotiations should be specific and concrete. He proposes a declaration, comparable to the Doha Declaration on the TRIPS Agreement and Public Health, with respect to intellectual property rights and climate change. He suggests that intellectual property rights may not present such an obstacle to technology transfer in alternative energy resources and climate change mitigation technologies as it has in the pharmaceutical sector. He also suggests that developing countries focus on establishing frameworks for mutually beneficial joint venture economic arrangements between developed and developing country enterprises that will stimulate innovation and concrete transfers of technology to address climate change. While he briefly mentions intellectual property rights for new plant varieties, he does not analyze this particular sector in any detail and does not explain how his arguments might change in relation to this sector.¹⁴

In spite of the different implications IPRs may have in different technologies, the debate over IPRs and technology transfer tends to divide along North-South lines, whether with respect to clean energy technologies, new plant varieties or other

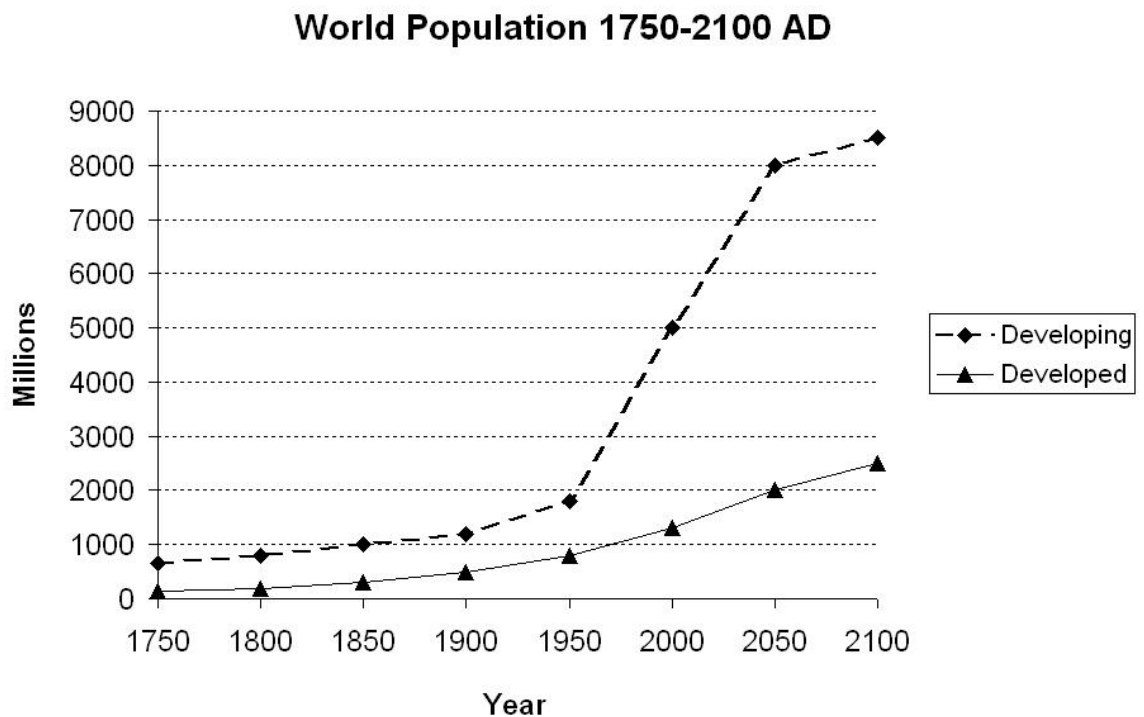
¹² For an analysis of the International Treaty on Plant Genetic Resources for Food and Agriculture, see GREGORY ROSE, *International Law of Sustainable Agriculture in the 21st Century: The International Treaty on Plant Genetic Resources for Food and Agriculture*, 15 *Geo. Int'l Envtl. L. Rev.* 583 (2003).

¹³ See, for example, John H. Barton, *Intellectual Property and Access to Clean Energy Technologies in Developing Countries: An Analysis of Solar Photovoltaic, Biofuel and Wind Technologies*, ICTSD Programme on Trade and Environment, Issue Paper No. 2, 2007.

¹⁴ Frederick M. Abbott, *Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health*, ICTSD Global Platform on Climate Change, Trade Policies and Sustainable Energy, Issue Paper No.24, 2009. Electronic copy available at: <http://ssrn.com/abstract=1433579>.

environmental technologies. In climate change negotiations, developing countries push for financing to acquire technology or relaxation of IPRs to lower the cost of acquiring technology, whereas developed countries tend to defend IPRs. This reflects the concentration of technologies and IPRs in developed countries and the prediction that there will be disproportionate impacts of climate change on developing countries. As the Figure 3 shows, the overwhelming majority of the world's population will still be in developing countries by the end of this century, when serious impacts from climate change are expected to be felt. What is notable about Figure 3 is that the countries which were in the developed country league in 1800, were the same in 2000 (with one clear exception: Japan). However, this will change substantially in the Twenty First Century. Among the countries with more than 100 million population, Brazil, China, India, Indonesia, Mexico, Russia will join the league of developed countries (along with a group of smaller ones). Some major developing countries have begun to produce both clean energy technologies (China for example) and new plant varieties (Brazil for example). This trend is likely to continue as other countries join the foray. Thus, the role that IPRs play in technology transfer in the more scientifically-advanced developing nations will be significantly different in poorer, less scientifically-advanced nations.¹⁵

Figure 3

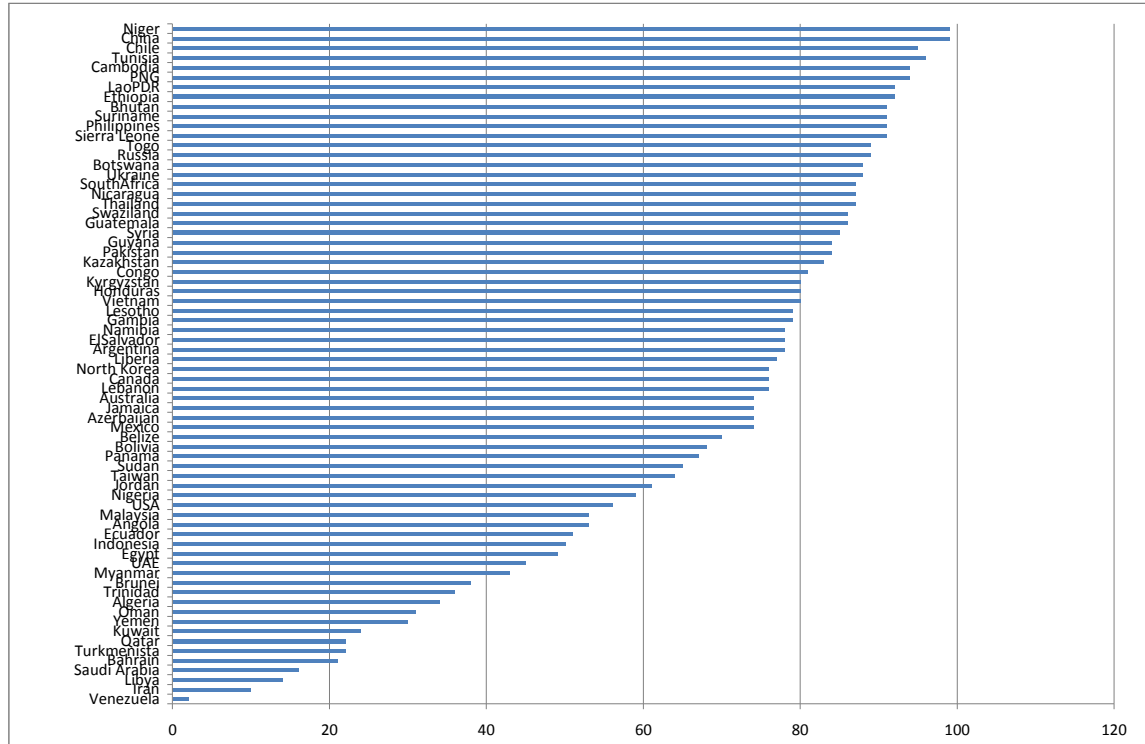


As Figure 4 shows, a large number of developing countries subsidize the consumption of fossil fuels. The world price of gasoline was slightly over 120 US cents in 2009. Venezuela sold it for 2 cents per gallon, and Iran for ten cents per gallon. In fact,

¹⁵ John H. Barton, *Intellectual Property and Access to Clean Energy Technologies in Developing Countries: An Analysis of Solar Photovoltaic, Biofuel and Wind Technologies*, ICTSD Programme on Trade and Environment, Issue Paper No. 2, 2007.

all the OPEC countries sold gasoline below production cost. Since they produce oil themselves, it has been justified as a subsidy that does not “cost” anything. Of course, in terms of opportunity cost, it does *cost*. A better way of spending the money would have been to give general grants to the poor, if this was meant to be a poverty alleviation program. In the current discussion, it simply raises the question of why these resources are not dedicated instead to the acquisition or development of clean energy technologies (keeping in mind the limitations on subsidies in the WTO Agreement on Subsidies and Countervailing Measures).

Figure 4



Source: GTZ Gasoline Price, 2009

As Table 1 shows, many non-OECD countries spend significant amounts of money on fuel subsidies. Some large countries with over 100 million people spend the bulk of the money (such as Brazil, China, India, Indonesia and Russia). Among them, India and China stand out for two reasons. First, both of them are large importers of oil and second, each of them has over a billion people. They are becoming significant air polluters on a global scale. During the course of this century, the other three, Brazil, Indonesia and Russia, net exporters of oil, will also contribute significant amounts of green house gases as they become developed countries.

Table 1

Energy Subsidy in non-OECD countries 2007

	Billions USD
Iran	58
Russia	52
China	39
Saudi Arabia	25
India	24
Venezuela	17
Indonesia	17
Egypt	15
Ukraine	14
Argentina	9
South Africa	8
Kazakhstan	8
Pakistan	7
Malaysia	7
Thailand	4
Nigeria	3
Taiwan	3
Vietnam	2
Brazil	2

Financial difficulties in developed countries, such as the United States and the European Union, reduce the likelihood that they will be in a position to finance the acquisition of technology in developing countries. Economic growth in major developing countries will increase the financial resources available to acquire technologies over time. Reallocating resources from fuel subsidies to the acquisition and development of clean energy technologies would increase the availability of financing for these ends. However, while generally available fuel subsidies are unlikely to violate the WTO Agreement on Subsidies and Countervailing Measures, subsidies that are targeted specifically to develop clean energy industries are likely to violate this agreement. While the agreement initially contained an exception for environmental subsidies, the exception expired. Thus, the current subsidies rules create perverse incentives to subsidize fossil fuels, but not clean energy technology. Moreover, the United States has complained to the WTO about

Chinese and Indian subsidies, including those for clean energy technologies, though without launching a formal dispute over this issue under the subsidies agreement.¹⁶

As technologies mature and IPRs expire, their cost will go down. However, newer technologies may be more effective and, hence, more desirable. Many of the relevant technologies are owned by private interests in developed countries, not governments, and would be acquired by private interests in developing countries. Private firms are not likely to transfer technology in a way that would hamper their competitiveness and would be concerned about creating competitors among the recipients of the technologies. Indeed, the US complaint regarding Chinese and Indian subsidies was motivated by concerns over their impact on the competitiveness of US firms in emerging clean energy technologies. As Sean Murphy has argued, the commercial and private nature of biotechnology and the rapid rate at which the technology changes makes segmented intergovernmental negotiations an inappropriate means for addressing concerns regarding biotechnology transfer.¹⁷

All of the foregoing factors indicate that the current shape of the debate over IPRs is likely to change over time. Nevertheless, the issues will continue vary from one technology to the next.

IPRs create more significant obstacles to biotechnology transfer than they do in the case of clean energy technology transfer, due to the concentration of IPRs among relatively few multinational firms. This is counterbalanced in part, since WTO Members have the right to issue compulsory licenses, subject to the obligation to pay compensation. However, developing countries that have issued compulsory licenses on pharmaceuticals have had to stand up to political pressure from the United States and the European Union to not exercise compulsory licenses. They have also come under pressure from the patent owners. In addition, reverse engineering GMO plants may prove more difficult than reverse engineering pharmaceuticals. This type of technological challenge may make compulsory licensing less feasible for GMO plants than for pharmaceuticals. Otherwise, there are strong parallels between biotechnology and pharmaceuticals with respect to the impact of IPRs on technology transfer.

The story of Abbott in Thailand provides a cautionary tale regarding the relationship between international technology transfer and the regulatory environment. Abbott threatened to withhold the latest version of an AIDS drug from the Thai market if the Thai government issued compulsory licenses on certain drugs for which Abbott owned the patents. In addition, the US government and the European Union exerted pressure on Thailand to not issue the compulsory licenses, in response to political pressure from the pharmaceutical lobby.¹⁸

In the case of GMO technology transfer, the risks are greater and the stakes are higher. The impact of climate change on agriculture will affect developing countries disproportionately, for several reasons. Climate change will have a greater impact on the viability of traditional plant varieties in developing countries in the tropics than in

¹⁶ <http://www.nytimes.com/2011/10/07/business/us-says-some-chinese-subsidies-violate-trade-rules.html?ref=business&pagewanted=all>, <http://www.ustr.gov/about-us/press-office/press-releases/2011/october/united-states-details-china-and-india-subsidy-prog>.

¹⁷ Sean D. Murphy, *Biotechnology and International Law*, 42 Harv. Int'l L.J. 47 (2001),

¹⁸ Bradley J. Condon and Tapen Sinha, *Global Lessons from the AIDS Pandemic. Economic, Financial, Legal and Political Implications* (Berlin: Springer Verlag, 2008), 161-162.

developed countries in temperate zones. This means that the need for GMO seeds will be greater in developing countries. However, a larger percentage of the population depends on agriculture in developing countries (50% in India, for example) and the poorest in developing countries depend on subsistence agriculture. Their poverty means that they rely on collecting seeds from traditional plant varieties to sow future crops. However, climate change will make these varieties increasingly untenable. As production in these varieties decline, developing countries will require greater access to GMO varieties that can raise yields and adapt to climate change. However, the vast majority of the rights to these GMO varieties belong to corporations in the United States, Europe and Japan. The percentage of GMO crops owned by Monsanto alone is staggering: 91% of soy, 97% of maize, 63% of cotton and 59% of canola. Thus, the food security of developing countries will depend on access to technology from developed countries, in particular private companies from developed countries. This will give a company like Monsanto tremendous bargaining power over developing country governments.¹⁹ The six large multinational companies (DuPont, BASF, Monsanto, Syngenta, Bayer and Dow) not only own the GMO crops, but they have patented 77 percent of all “climate ready crop genes” during June 2008 and June 2010.²⁰

Currently, IPRs represent a far more significant obstacle to international biotechnology transfer than they do in other areas of technologies needed to mitigate and adapt to climate change. This is due to the concentration of IPRs among a small number of multinational firms in developed countries and the vulnerability of developing countries to the impacts of climate change on agriculture and subsistence farmers.

Innovations in plant breeding play an important role in a number of public objectives, such as food security, environment, sustainability, and transitions in the rural economy. These innovations depend on specific knowledge, the development and application of new technologies and access to genetic resources and capital. Farmers and growers have an interest in competition in the seed market. However, stronger intellectual property rights have combined with technological developments to produce increasing consolidation among breeding companies, with only a few companies now controlling a large part of the world market for key crops. This makes a growing part of the global food supply dependent on a few companies that could hamper competition and access to biotechnology through strategic use of intellectual property rights and monopolistic behavior. The privatization and concentration of plant breeding also has implications for biodiversity, particularly in developing countries. Strengthening intellectual property rights may conflict with development objectives. Strengthening intellectual property rights, by contributing to a decreasing diversity in breeding companies, also threatens

¹⁹ The relevant literature on this topic includes: IP in Biodiversity and Agriculture: Regulating the Biosphere, (eds Drahos and Blakeney) (Sweet & Maxwell, London, 2001), Carliene Brenner, Integrating biotechnology in agriculture: Incentives, constraints, and, country experiences, (OECD, 1996). OECD-FAO Agricultural Outlook 2008-2017, (OECD-FAO, 2008). Michael Blakeney, Intellectual Property Rights and Food Security, (CABI, Wallingford-Massachusetts, 2009). The Bioeconomy to 2030: Designing a Policy Agenda, (OECD, 2009). Biotechnologies in Agriculture and Related Natural Resources to 2015, (OECD, 2009). Ad Hoc Open-ended Working Group on Access and Benefit-sharing WIPO work in progress on same topic.

²⁰ ETC Group, 2010. Gene Giants Stockpile Patents on “Climate-ready” Crops in Bid to become “Biomasssters”, available at <http://www.etcgroup.org/en/node/5220>.

innovation in plant breeding.²¹ These negative impacts of intellectual property rights will become more apparent as climate change begins to have a greater impact on crop yields. The combination of climate change, increasing intellectual property rights for new plant varieties and growing demand for food supplies raises serious concerns regarding affordable access to new biotechnologies and food staples in developing countries. Technological developments may also require a reassessment of policies regarding intellectual property rights for new plant varieties. Genetic use restriction technology or terminator genes render the harvested seed sterile. This technology prevents farmers from replanting saved seed and thereby consolidates the seed companies' monopoly. When applied to seeds that are protected by intellectual property rights, this technology not only prevents infringement of intellectual property rights and the application of the farmers' exemption, but also ensures the continuation of the monopoly beyond the life of any patent or breeder's rights.²² The advent of terminator genes raises the issue of whether, rather than strengthening intellectual property rights, governments should focus on strengthening competition laws to enhance access to new plant varieties that can adapt to climate change. Indeed, as Debra M. Strauss observes, the application of IPRs to biotechnology may undermine the public interest in the security of a global food supply.²³

Economics of IPRs for plants and pharmaceuticals

Some have proposed the negotiation of an agreement on intellectual property rights on technologies necessary for mitigation efforts in developing countries, based on the WTO decision on compulsory licensing of pharmaceuticals.²⁴ The benefit of this approach is that the negotiation could take place separately from the negotiation of the Doha Round. Others have argued that pharmaceuticals and environmental technologies are too different to adopt the same approach in the two areas, but have focused mainly on clean energy technologies.²⁵ It is true that, for environmental technologies such as those that address ozone depletion, the nature of international business strategies differ significantly from those in the pharmaceutical sector.²⁶ However, the extent to which solutions in one field of technology can be applied to another must take into account the specific legal and

²¹ Louwaars, Niels, Dons, Hans, Van Overwalle, Geertui, Raven, Hans, Arundel, Anthony, Eaton, Derek and Nelis, Annemiek, *Breeding Business. The Future of Plant Breeding in the Light of Developments in Patent Rights and Plant Breeder's Rights* (December 30, 2009). Netherlands Ministry of Agriculture, Nature and Food Quality (LNV), Wageningen, Centre for Genetic Resources (CGN) – Wageningen University and Research Centre, December 2009. Available at SSRN: <http://ssrn.com/abstract=1720088>.

²² Bonadio, Enrico, *Crop Breeding and Intellectual Property in the Global Village* (2007). *European Intellectual Property Review*, Vol. 29, No. 5. Available at SSRN: <http://ssrn.com/abstract=1677512>.

²³ Debra M. Strauss, *The Application of TRIPS to GMOs: International Intellectual Property Rights and Biotechnology*, 45 *Stan. J Int'l L.* 287 (2009), 291.

²⁴ H.A.C. Prasad and J.S. Kochher, *Climate Change and India - Some Major Issues and Policy Implications*, Working Paper No.2/2009-DEA, Department of Economic Affairs, Ministry of Finance, Government of India, March 2009. Available at <http://finmin.nic.in/WorkingPaper/Working%20paper%20Climate%20Change.pdf>, consulted 2 October 2011.

²⁵ Jérôme de Meeûs, *Patent Rules under Scrutiny in the United Nations Negotiations on Climate Change and Technology Transfer: Analysis and Observations*.

²⁶ Jayashree Watal, *CASE STUDY 3* INDIA: THE ISSUE OF TECHNOLOGY TRANSFER IN THE CONTEXT OF THE MONTREAL PROTOCOL*.

economic issues that arise in each area of technology. In this section, we analyze the economics of IPRs and consider the parallels between IPRs for pharmaceuticals and IPRs for new plant varieties.

Among the policy objectives of the TRIPS Agreement is to balance intellectual property rights against development needs. In WTO law more generally, there are numerous provisions that provide for differential treatment based on the level of development of WTO members. The theoretical foundation for TRIPS in general and patents in particular, lies in the economic argument that these monopoly rights are the sine qua non of innovation. In essence, this argument states that, without patents, inventions would cease, making the issue of affordable access to technology a moot point. The same theoretical argument underpins the intellectual property protection provided by breeders' rights or patents for new plant varieties. We have demonstrated elsewhere that this argument weakens considerably when it comes to incentives to invent treatments for poor country diseases.²⁷ Moreover, we have shown that the incentives for inventing treatments for HIV/AIDS come from the developed country markets, not developing or least-developed country markets because the low income individuals from developing countries simply do not have the buying power to afford such drugs. Biotechnology with respect to plant varieties is akin to pharmaceuticals for HIV/AIDS, since demand for the technology to grow weather and plague resistant plant varieties is global and there is sufficient purchasing power of the farmers in *developed* countries to create adequate incentives to invent the technologies. Biotechnology with respect to plant varieties is akin to pharmaceuticals for HIV/AIDS, since similar issues arise regarding the effect of monopoly rights on affordable access to the technology for the following reasons:

(1) In the case of HIV/AIDS, a large proportion of the population of the sub-Saharan countries is infected by the disease. For example, in Swaziland, 25.9 percent of the adult population in the age range 15 to 49 is HIV positive. In sub-Saharan Africa, the rate is 5 percent.²⁸ For developed countries, the proportion is far lower. For example, in the US, the prevalence rate is 0.6 percent. In Western Europe, the rate is between 0.1 and 0.2 percent. The drugs, developed for treating the patients in developed countries, can also be used to treat the patients in developed countries (although there are some differences in the subtypes of HIV that affect people in developing and developed countries). However, most patients in developed countries do not have the financial means to buy these drugs. In a parallel fashion, in developed countries, less than 10 percent of the population is engaged in agricultural activities today. In developing countries, the proportion is 70 to 80 percent. The situation of agriculture in developing countries today is similar to what it was in the developed countries a century ago. Moreover, most farmers in developing countries are subsistence farmers: They eat what they grow. They have very little surplus crop to sell. Traditionally, they have been able to use part of their crop for seeding. However, the currently available technologically enhanced varieties are sterile. That means the farmers have to buy the seeds to each crop. These seeds are monopoly products of international biotechnology companies. As a

²⁷ Bradley J. Condon and Tapen Sinha, "Global Diseases, Global Patents and Differential Treatment in WTO Law: Criteria for Suspending Patent Obligations in Developing Countries", 26:1 *Northwestern Journal of International Law and Business* 1-41 (2005).

²⁸ http://www.unaids.org/globalreport/documents/20101123_GlobalReport_full_en.pdf

result, a large number of farmers in developing countries will not be able to afford to buy seeds for their crops. In summary, a large number of HIV infections occur in the developing countries and a large number of farmers in need of hardy seeds would be in the developing countries. For HIV treatment, the patients in developing countries cannot afford to buy the antiviral drugs. For genetically modified seeds, the subsistence farmers will not be able to afford to buy such seeds.

(2) The impact of climate change on crops and the impact of HIV/AIDS on the population are slow moving. In the case of HIV/AIDS, a person infected with the virus takes a decade to manifest the signs of full blown AIDS. Thus, the impact of an infection is not immediately apparent. For the entire population, it thus takes several decades before the devastating toll of a slow burning virus will produce any discernable macroeconomic impact. We have shown elsewhere that such impact can be substantial.²⁹ Similarly, for climate change, year to year variations are small. Over the decades, the impact on agricultural products will become substantial – especially for subsistence farmers.³⁰ Most of the impact will not be felt during the first half of the twenty first century.

(3) In the case of HIV/AIDS, the impact has already manifested itself. The number of new infections is not going up by much. On the other hand, the main impact of climate change is yet to come. For this reason, the lessons we learned from HIV/AIDS can be useful for the future impact of climate change.

Beyond these critiques of the underlying economic premise for patents, there is an emerging view that questions the conventional view regarding the impact of patents on innovation. In some circumstances, patent rights may be used (or abused) so as to stifle innovation. The notion that competition spurs innovation and reduces prices to consumers is another theoretical underpinning of international trade. Patents, by granting monopolies, stifle competition. For this reason, their duration is limited, but at the end, arbitrarily set by governments. The tension between patents and competition points to the importance of achieving the correct balance in order to maximize social welfare and to minimize economic deadweight loss and regulatory capture.

In economics literature, the standard argument for pricing in a perfectly competitive market says that the socially desirable outcome (in economic jargon, Pareto efficient) is to have the price equal to the marginal cost of production of a good. This argument applies only when the cost of bringing a good to the market is relatively low. In many information intensive products, this is not so. For these products, the cost of producing the first unit is extremely high whereas the cost of producing subsequent units is very low. For example, it is expensive to produce working software. However, copying the same software is essentially free. The same applies for movies, data, pharmaceuticals and technologically advanced plant seeds.

For such goods, if feasible, the producer will charge different prices in different markets. Barton (2001, pp 476-478) provides a good example:

When the movie goes onto the market, the production costs are sunk costs, and the cost of showing the movie to each additional viewer is small. If the producer

²⁹ Condon, Bradley J and Sinha, Tapen (2008). *Global Lessons from the AIDS Pandemic: Economic, Financial, Legal and Political Implications*. Berlin: Springer.

³⁰ John F. Morton . The impact of climate change on smallholder and subsistence agriculture. *Proc Natl Acad Sci U S A*. 2007 December 11; 104(50): 19680–19685.

must choose a single price, he or she might choose the price at which marginal cost equals marginal revenue. But this leaves profits on the table for the benefit of the viewers. The producer would rather maximize his or her profits through price discrimination. To accomplish this, the producer first shows the movie at a high-price first-run theater, followed by discount theaters, and on down to post-midnight TV showings and remaindered videocassettes. By doing so, the producer can achieve a higher overall return....If, however, the movie is easily reproduced and distributed by third-parties in taped or internet form, a portion of the movie maker's market will be lost from the lost rents.³¹

A similar argument is normally used to make the case for other inventions, including plant varieties. However, for products that contain the elements of a public good, the dynamic efficiency argument of patent protection weakens considerably. Surprisingly, most economic analysis put forth by legal experts ignores this issue completely. Boldrin and Levine call this phenomenon "intellectual monopoly." They explain their idea as follows:

"Intellectual property" has come to mean not only the right to own and sell ideas, but also the right to regulate their use. This creates a socially inefficient monopoly, and what is commonly called intellectual property might be better called "intellectual monopoly." When you buy a potato you can eat it, throw it away, plant it or make it into a sculpture. Current law allows producers of a CDs and books to take this freedom away from you. When you buy a potato you can use the "idea" of a potato embodied in it to make better potatoes or to invent french fries. Current law allows producers of computer software or medical drugs to take this freedom away from you." (Boldrin and Levine 2002, p 210)

Boldrin and Levine argue that the cost of developing a new drug or new software or a new seed variety is a sunk cost and not simply a fixed cost. Fixed cost is the cost that does not vary with the level of output. Suppose a company has two employees: a janitor and a director. The cost of having the director is fixed. It does not vary with the level of output produced. But the cost of the janitor is variable. If the company does not produce anything, it would have no cleaning expenses. Hence, the janitor is not necessary. Sunk cost, on the other hand, is the portion of fixed costs that is not recoverable. For example, consider an investment in new technology to develop a new variety of seeds resistant to drought conditions. It is only necessary once. Thus, unlike the salary of the director, it does not have to be incurred every period. Note that in a one-period model, there is no difference between a fixed cost and a sunk cost. In a model with *multiple time periods* a fixed cost is incurred each period (but the cost does not vary with output) while a sunk cost is incurred only once (at the first period). A simple example of sunk cost is the opportunity cost of writing a paper. Once the time cost is incurred writing the paper, it cannot be avoided, eliminated or reduced no matter whether the paper is eventually published or not. In the above example of the janitor and the director, if the company ceases to exist, the director can be fired and the company does not incur the cost paying the director.

Boldrin and Levine further note that "As far as we know there is no organized movement to provide producers of potatoes, or any other commodity involving sunk

³¹ Barton, John. "The Economics of TRIPS: International Trade in Information-Intensive Products," 33 *George Washington International Law Review* 473 (2001).

costs, with a government monopoly” (Boldrin and Levine 2002, p 210). They go on to argue the following:

On the patent front, more time and energy seems to be spent on nuisance and defensive patenting of the obvious or well-known than is spent on actually innovating new ideas. Individuals exploit the relative ignorance of patent examiners by patenting ideas already in widespread use in hopes of collecting licensing fees, or at least greenmail, from a few large companies; large corporations patent and cross-license everything imaginable both to protect themselves against greenmail, and to suppress entry into their industry. That cross-licensing and “protection of intellectual property” can be instrumental in promoting collusion within an industry seems transparent. (Boldrin and Levine 2002, p 211)

This kind of defensive patenting seems to be what is going on with seed technologies. Half a dozen large multinational companies are patenting not only the plant varieties but also the DNA that produce that resistance of drought, frost and other adverse growing conditions. That means any other company needing to use the same DNA sequence for any other innovation will need to pay the current patent holders first. This kind of patent monopoly would stunt future innovations rather than spurring them on.

The importance of Boldrin-Levine model cannot be overstated. For example, Quah provides an extension of the Boldrin-Levine model with the following comment: “The Boldrin-Levine analysis is an important and profound development. It seeks to overturn nearly half a century of formal economic thinking on intellectual property, suggesting instead that perfectly competitive markets in intellectual assets function in the usual Arrow-Debreu way and therefore lead to socially efficient outcomes.” (Quah 2002)

Boldrin and Levine (2008, Chapter 9) provide the following evidence about the rate of innovation with and without patent protection for Italy, which provided a natural experiment for patent protection after their Supreme Court Decision of 1980: “During the period 1961-1980 a total of 1282 new active chemical compounds was discovered around the world. Of these, a total of 119 came from Italy (9.28%). During the period 1980-1983 a total of 108 compounds were discovered. Of these, 8 came from Italy (7.5%).” In other words, patent protection made no difference in the rate of innovation in Italy. Even the sunk cost (the one time only cost of producing new drugs) is also shared by the governments (and, by implication, the consumers as taxpayers). It is estimated that in 2000, some USD 70 billion was spent on research on pharmaceuticals. Of this amount, approximately USD 30 billion was spent by governments (Survey 2003).

The argument that strong patent rights are essential to provide incentives to invest in innovation has been used to support a balance between the rights of patent holders and users that favors the former. However, the Boldrin-Levine model demonstrates that such an “intellectual monopoly” approach to patent rights has the effect of stifling innovation because it provides an incentive to patent holders to invest in legal action to extend the life of their patents and to prevent others from developing new innovations. In economic terms, patents provide rights to the person first in the door of the patent office. This is an inefficient way of allocating economic resources.

In summary, we need to choose between two opposing stories of what patent rights really do. One view claims that patent rights spur innovation, and innovation leads to economic growth. The opposite view is that patent rights, as they stand today, lead to

patent monopoly. The monopoly itself is undesirable in economic terms as it is inefficient. This has led many economists to believe that there is no inherent reason for patent protection. For example, Scotchmer (2003a) notes that there is no economic rationale for protecting inventors per se.

Historical evidence seems to favor the latter view (that patent monopoly is economically harmful). For example, Boldrin and Levine (2008, Chapter 1) show how James Watt (of the steam engine fame) managed to set back the clock of the industrial revolution by lobbying for and getting his monopoly extended.

How do intellectual property rights in agriculture affect research in agriculture? The conclusions from Wright and Shih are not very encouraging:

In agriculture, (1) IPRs have not strongly encouraged the private production of basic, essential research that is risky and often only pays off in the long run, (2) IPRs on key research inputs can impede freedom to operate in public research, and (3) IPRs on research inputs have led to market concentration and price markups, which should discourage or delay adoption. However it appears that leading firms in the private sector have been particularly efficient in developing, promoting and disseminating commercial technology packages, relative to what one might reasonably expect of a typically competent public or non-profit entity, especially in the context of a disruptive and controversial technology.³²

The argument for patent rights in developing countries is based on several assumptions regarding the general economic impact of patents and the specific economic impact of patents in developing countries: (1) technological innovation promotes economic growth; (2) patent rights are necessary to provide research incentives to spur technological innovation; (3) patents in developing countries will provide research incentives to create technological innovations that serve the needs of developing countries; (4) patent rights in developing countries are necessary to promote the transfer of technological innovations from firms in developed countries and to promote technological innovation in developing countries; and (5) technology transfer to developing countries promotes economic growth in developing countries.

The theoretical foundation for patents lies in the economic argument that monopoly rights are necessary to spur innovation. In essence, this argument states that, without patents, the invention of new technologies would cease, making the issue of affordable access a moot point. However, are global intellectual property rights necessary to create research incentives to invent plant varieties for developing country markets? It is important to note that this issue is distinct from the issues of whether global intellectual property rights lead to differential pricing (Ramsey pricing) and how regulatory capture affects research incentives.

One of the reasons proffered for having global IPRs for new plant varieties is to provide research incentives for the development of extreme climate resistant seed varieties. Another argument is that the risk of compulsory licensing makes developing countries unattractive markets, even with global IPRs in place. However, WTO rules—and national legislation in markets such as the United States—permit compulsory licensing. The risk of compulsory licensing in the United States has not deterred

³² Wright, Brian D., and T. Shih. Forthcoming 2011. "Agricultural Innovation." In *Accelerating Innovation in Energy: Lessons from Multiple Sectors*, eds. R. Henderson and R. Newell, Chicago, IL: University of Chicago Press for National Bureau of Economic Research.

investment in the US market. Moreover, WTO rules require compensation for the patent holder when compulsory licenses are issued.

There are two main arguments against global IPRs. Even with IPR protection in developing countries, many of their markets lack the purchasing power needed to spur private investment in innovations tailored to their specific conditions. Another argument against the necessity of global IPRs is that they do not provide an incentive for innovation even where there is adequate purchasing power in the market as shown by Boldrin and Levine (2002). An “intellectual monopoly” approach to IPRs has the effect of stifling innovation because it provides an incentive to IPR holders to invest in legal action to extend the life of their IPRs and to prevent others from developing new innovations. In economic terms, IPRs provide rights to the person first in the door of the patent office. This is an inefficient way of allocating economic resources. This has led many economists to believe that there is no inherent reason for patent protection (Scotchmer 2003b). Historical evidence favors this view (Khan 2005).

Technology transfer and development in the WTO TRIPS Agreement

Specific technology transfer provisions in the WTO TRIPS Agreement reflect the need to analyze technology transfer issues according to the nature of the technology and the intellectual property rights related to each technology. Articles 7 and 8 set out the objectives and principles, respectively. Article 7 states, *inter alia*, that intellectual property rights “should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge”. Article 8.2 states:

Appropriate measures, *provided that they are consistent with the provisions of this Agreement*, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology. (emphasis added)

Neither Article 7 nor Article 8 establishes binding obligations regarding technology transfer. However, Article 7 establishes that technology transfer is a central objective of TRIPS. Moreover, Article 8 establishes that Members may need to take measures to achieve this objective. Nevertheless, Article 8 also establishes that those measures must be taken in accordance with other TRIPS provisions. Both articles need to be taken into account in the interpretation and application of these other TRIPS provisions, by virtue of Article 31 of the Vienna Convention on the Law of Treaties. However, Articles 7 and 8 both indicate that other TRIPS provisions set out the specific rules that establish the parameters within which governmental actions to promote technology transfer must take place.

TRIPS Article 66.2 provides that developed country Members “shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base”. While this provision appears to create a binding legal obligation, it is imprecise regarding specific outcomes and the types of incentives that would constitute compliance with the obligation. There is no specific obligation regarding the categories of technology or the quantities or qualities

of the technologies. The only obligation for developed country governments is to create incentives. Many developed countries could argue that their foreign aid programs already constitute compliance with this obligation, for example. There is no obligation for governments to *require* transfer technology to least-developed countries. Thus, it is unlikely that a least-developed country would succeed in persuading a WTO dispute settlement panel that a developed country has failed to comply with Article 66.2.³³ In addition, the obligation is limited to technology transfer to least-developed countries.³⁴ Thus, Article 66.2 cannot be used as a basis for requiring technology transfer to developing countries either.

However, Article 66.2 is not the only provision that is relevant to the issue of technology transfer. Other provisions are also relevant, but the technology and its related intellectual property rights will determine which other provisions are relevant in each case. For example, TRIPS has specific provisions regarding plant varieties that are relevant to determining how technology transfer might occur with respect to this area of technology. Similarly, TRIPS has specific provisions regarding patents for pharmaceuticals that are relevant to determining how technology transfer might occur with respect to this area of technology. While there may be some overlap between the relevant provisions for each of these two subjects, they must be analyzed separately. In addition, the relevant TRIPS provisions must be analyzed together with other relevant international norms in each area of technology. For example, in the case of new plant varieties, the relevant TRIPS provisions must be analyzed together with the UPOV Convention.

The objectives of TRIPS must be understood in light of the overall objectives of the WTO Agreement relating to developing countries. Two core objectives of TRIPS are to achieve a balance between the rights of producers and users of intellectual property and to promote development. TRIPS Article 7 and Article 8 support an approach to balancing TRIPS rights and obligations that differs with the level of development of the member in question. The TRIPS preamble seeks “effective and adequate protection of intellectual property rights,” while recognizing the developmental objectives of intellectual property protection and the special needs of least-developed countries for “maximum flexibility in the domestic implementation of laws.” These provisions reflect the concerns of developing countries in the Uruguay Round negotiations that earlier drafts of TRIPS did not adequately address the questions of the balance of the rights and obligations of rights holders, developmental concerns and public policy objectives. These concerns were reflected in the preamble so that they could be taken into account in the interpretation of the agreement.

Article XI of the WTO Agreement provides that: “The least-developed countries recognized as such by the United Nations will only be required to undertake commitments and concessions to the extent consistent with their individual development, financial and trade needs or their administrative and institutional capabilities.” Article 1

³³ See Report of the Panel, United States — Anti-Dumping and Countervailing Measures on Steel Plate from India, WT/DS206/R, adopted 29 July 2002, para. 7.110, in which the panel found that the imprecise language of Article 15 of the Antidumping Agreement did not impose any specific or general obligation to follow a particular procedure.

³⁴ The WTO recognizes as least-developed countries those countries that have been designated as such by the United Nations.

of The Decision on Measures in Favor of Least-Developed Countries leaves no doubt that this aspect of differential treatment applies to TRIPS and repeats the language from above: “if not already provided for in the instruments negotiated in the course of the Uruguay Round, notwithstanding their acceptance of these instruments, the least-developed countries... will only be required to undertake commitments and concessions to the extent consistent with their individual development, financial and trade needs or their administrative and institutional capabilities.” The WTO Agreement preamble also makes special reference to the needs of developing countries, “especially the least developed among them.” The reference to sustainable development in the WTO Preamble provides further support for the view that TRIPS should be interpreted in a manner that supports the development needs of the developing and least-developed countries. While the term sustainable development has received a great deal of attention with respect to its role in balancing trade and environmental protection, economic development is also an important aspect of sustainable development.

These provisions support the view that the balance to be struck between producers and users should shift in favor of developing and least-developed countries when they are the users under consideration. While the Uruguay Round negotiations on TRIPS rejected country-by-country transition periods, several members were of the view that the balance of rights between producers and users of intellectual property should take the needs of developing countries into account and that transition periods alone were not enough to meet their needs. Moreover, the promotion of innovation through the intellectual property regime was not an objective in and of itself but rather was a means of attaining other economic and social objectives. Existing international intellectual property conventions respected this and the fact that the relative costs and benefits of the protection on intellectual property rights varied from country to country depending on the level of economic development. In order for special and differential treatment to be effective in meeting the needs of developing countries, the correct balance must differ from one market to the next, rather than be universally applicable without regard to the conditions existing in each market. The absence of internationally agreed criteria that determine the needs of each country at different levels of economic and technological development makes this difficult to achieve. However, the context of specific provisions and agreements provide guidance regarding the criteria that would be appropriate.

When read together, the objectives of TRIPS and of the WTO Agreement integrate into TRIPS the twin themes of balancing intellectual property rights against development needs and providing differential treatment based on the level of development of WTO members.

TRIPS, UPOV and access to new plant varieties

New breeds of plants adapt to changing climate conditions. This is nothing new. However, what has changed is the manner in which new breeds of plants are created and the legal rights attached to those new breeds. Whereas farmers used to be able to harvest seeds from cross-bred plants, today genetically modified seeds produce plants that have many beneficial features but that do not necessarily produce viable seeds that can be harvested and planted by farmers. This changes the economics of farming. The creation of new breeds of plants are at once an economic response to climate change and a legal

and policy issue with respect to the intellectual property rights conferred on their inventors.

Growing concern over the effects of intellectual property rights, particularly in developing countries, has led to an expansion of sometimes competing international instruments that address various aspects of this area of law.³⁵ This section will analyze the legal issues that arise regarding patents for plant varieties under the TRIPS Agreement, protection of breeders' rights under the International Convention for the Protection of New Varieties of Plants (UPOV Convention) and the protection of traditional knowledge and genetic resources of the Convention on Biological Diversity (CBD).³⁶ It will analyze the relationship between these international agreements and the different approaches that each one takes with respect to the protection of new plant varieties. It will also consider how the evolution of climate change might affect these international agreements.

WTO Members continue to debate several issues regarding the protection of plant varieties, the protection of traditional knowledge and genetic resources and the manner in which these issues relate to each other. Japan and the United States argue that plant varieties should be protected to allow development of new technological solutions in the field of agriculture.³⁷ Several developing countries argue that the protection of plant varieties can have an adverse impact on food security, health and rural development in developing countries, and fails to protect traditional knowledge systems.³⁸ While the WTO Members have divided along developed and developing country lines on many issues, this is not the case for all of the issues. However, it is fair to say that developed countries with a strong biotechnology industry generally have favored stronger intellectual property protection for plant varieties, while developing countries generally have favored weaker intellectual property protection for plant varieties, particularly in countries with the greatest biodiversity or large numbers of subsistence farmers. Surprisingly, the relevance of climate change to this debate has not arisen in WTO negotiations.

³⁵ Helfer, Laurence R., *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*. Yale Journal of International Law, Vol. 29, p. 1, 2004; Loyola-LA Legal Studies Paper No. 2003-28; Princeton Law and Public Affairs Working Paper No. 04-004. Available at SSRN: <http://ssrn.com/abstract=459740> or doi:10.2139/ssrn.459740

³⁶ The International Treaty on Plant Genetic Resources for Food and Agriculture, available at <http://www.fao.org/legal/treaties/033t-e.htm>, contains similar provisions to those of the CBD regarding the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use. However, due to the similarity of the provisions in the two agreements, we will limit our analysis in this article to the CBD. For a discussion of the relationship between these two treaties and the TRIPS Agreement, see Helfer, *ibid.*, 39-42. Also see Linarelli, John, *Treaty Governance, Intellectual Property and Biodiversity*. Environmental Law Review, Vol. 6, pp. 21-38, 2004. Available at SSRN: <http://ssrn.com/abstract=517063>.

³⁷ Note by the Secretariat, Review of Article 27.3(b). Paper IP/C/W/369/Rev.1, revised 9 March 2006, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm, para. 45.

³⁸ *Ibid.*, para. 46. The countries that expressed this view are: the African Group; Peru; Zimbabwe; and Kenya.

TRIPS and patents

Governments grant patents to inventors on the national level, which means that they only have legal effect in the jurisdictions where the application for a patent has been granted. One of the conditions for granting a patent is that the inventor disclose the data used in the producing the invention. TRIPS established minimum standards for the protection of intellectual property rights in the national laws of WTO Members. TRIPS requires that patents be granted for a minimum of twenty years and that they provide patent owners with the exclusive right to prevent third parties from making, using, selling or importing a patented product without the owner's consent. However, TRIPS allows exceptions to these patent rights, including the right of governments to issue compulsory licenses under certain conditions, set out in TRIPS Article 31. A compulsory license authorizes a third party to produce and sell the invention without the patent owner's consent. This exception plays a key role in balancing the rights of patent owners against the needs of consumers of patented products. TRIPS also sets out more limited exceptions to patent rights in Article 30.³⁹

The right to issue a compulsory license on a patented product also provides countries with bargaining power to extract price concessions for patented products or to issue compulsory licenses if price negotiations fail. However, this bargaining power applies only to countries that have the capacity to produce the products, since the generic versions must be used to predominately supply the national market of the country that issues the compulsory license. Countries that lack domestic manufacturing capacity would need to be able to import generics manufactured under compulsory licenses in other countries in order to enjoy a comparable level of bargaining power. The Paragraph 6 Decision established rules to allow this to happen for pharmaceutical products, but not for other patented products.

Article 27 of the TRIPS Agreement

Article 27 of the TRIPS Agreement refers to patentable subject matter. The first sentence of Article 27.1 requires that patents be available for "any inventions", whether products or processes and in all fields of technology, provided they meet three requirements: (1) they must be "new"; (2) they must "involve an inventive step"; and (3) they must be "capable of industrial application". Inventions must meet each of these three criteria, but there is no definition of the term "inventions" or the term "new". However, footnote 5 indicates a certain degree of flexibility in the manner in which Members may define these requirements. Footnote 5 permits Members to deem the terms "inventive step" and "capable of industrial application" to be synonymous with the terms "non-obvious" and "useful" respectively. The first sentence of Article 27.1 makes the obligation regarding patentable subject matter subject to the provisions of paragraphs 2 and 3.

The second sentence of Article 27.1 requires WTO Members to make patents "available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced". This

³⁹ For a more detailed analysis of TRIPS Articles 30 and 31, see Bradly J. Condon and Tapen Sinha, *Global Lessons from the AIDS Pandemic. Economic, Financial, Legal and Political Implications* (Berlin: Springer Verlag, 2008), 188-195.

non-discrimination obligation is subject to Article 27.3. According to the Panel in *Canada – Pharmaceutical Patents*, the term ‘discriminate’ in Article 27.1 extends beyond the concept of differential treatment and is potentially broader than national treatment or most-favoured nation treatment. Discrimination may arise from explicitly different treatment (de jure discrimination) or from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects (de facto discrimination).⁴⁰ TRIPS Article 1.3 requires that treatment be accorded to “nationals” and that both the national treatment and MFN obligations in TRIPS apply to “nationals”, not products. Thus, in some cases, Article 27.1 only requires non-discrimination with respect to inventors, which would require evidence that any inventor of a competing product has been granted a patent in order for a complainant to meet its burden of proof under Article 27.1.

Article 27.3(b) permits Members to exclude from patentability “plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes”. However, Article 27.3(b) requires Members to “provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof”.⁴¹ Thus, Article 27.3(b) initially carves out an exception from the obligations contained in Article 27.1, by creating a right to exclude animals and plants from patentability, but then creates an obligation to provide intellectual property rights for inventors of plant varieties. However, those intellectual property rights do not have to be in the form of patents. Rather, they can be patents, an effective *sui generis* system or any combination of patents and an effective *sui generis* system. The obligation regarding intellectual property rights for plant varieties is more flexible than patent obligations for other products and processes. In this regard, it constitutes an exception from the non-discrimination obligation in Article 27.1. However, Article 27.3(b) also limits the right to exclude plants from patentability when “plant varieties” are involved.

Article 27.1 appears to apply the general requirements for subject matter to be patentable to patents for plant varieties. Thus, for example, existing plant varieties cannot be patented because they are not new inventions. Thus, only new plant varieties would be patentable. However, since a *sui generis* system is an alternative to a system of patents, the general requirements for subject matter to be patentable appear to not be applicable if a Member opts for a *sui generis* system of intellectual property rights for plant varieties. The only requirement for a *sui generis* system is that it be “effective”. This interpretation is supported by the use of the term “plant varieties” rather than the term “new plant varieties”; the plant varieties need only be “new” to qualify for a patent. However, should a Member choose a combined system of patents and a *sui generis* system, the general requirements for subject matter to be patentable would apply to the patents, but not to the *sui generis* system.

⁴⁰ Canada – Pharmaceutical Patents (Panel), para. 7.94.

⁴¹ The text in Spanish requires protection of “todas las obtenciones vegetales” (all plant varieties), whereas the English and French versions do not specify the scope of this obligation in this manner. This point has been raised in the Doha Round negotiations regarding the scope of the subject matter that is covered by the obligation. Note by the Secretariat, Review of Article 27.3(b). Paper IP/C/W/369/Rev.1, revised 9 March 2006, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm, para. 52.

The negotiating history of Article 27 shows that the negotiators were well aware of the negotiation of the UPOV Convention revisions at the time that Article 27 was negotiated.⁴² The negotiation history also shows that some parties wanted to exclude plants from patentability, while others believed that patents would promote innovation by requiring disclosure of the inventive process.⁴³ One party argued that plant variety rights were a distinct *sui generis* category of rights regulated by a separate convention and should therefore not be patentable subject matter.⁴⁴ The negotiating history thus indicates that Article 27.3(b) represents a compromise, in that it permits flexibility with respect to the use of patents, a *sui generis* system such as the UPOV Convention, or some combination thereof regarding plant varieties. However, while the negotiating history indicates that the *sui generis* system some parties had in mind was the UPOV Convention, the final text of Article 27.3(b) does not limit WTO Members to that particular *sui generis* system. Indeed, in the Doha Round negotiations several (mostly developed country) WTO Members have argued that UPOV does provide for an effective *sui generis* system as required by Article 27.3(b) and that its use should be widespread.⁴⁵ Other (mostly developing country) WTO Members have argued that Article 27.3(b) does not require Members to use UPOV as a model, although UPOV may be an important point of reference.⁴⁶ Members are free to choose a system based on other models, such as FAO's International Undertaking on Plant Genetic Resources or the CBD.⁴⁷ More particularly, Members are free to choose a model other than UPOV, such as those based on FAO's International Undertaking on Plant Genetic Resources or the CBD

Article 27.3(b) was to be reviewed four years after the date of entry into force of the WTO Agreement. This review requirement provides a further indication that Article 27.3(b) represented a compromise. However, Paragraph 19 of the 2001 Doha Declaration expanded this review to require the TRIPS Council also to examine the relationship

⁴² Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MEETING OF NEGOTIATING GROUP OF 12-14 JULY 1989, Chairman: Ambassador Lars E. R. Anell (Sweden), Note by the Secretariat, MTN.GNG/NG11/14, 12 September 1989.

⁴³ Ibid. See also Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MEETING OF NEGOTIATING GROUP OF 30 OCTOBER-2 NOVEMBER 1989, Chairman: Ambassador Lars E. R. Anell (Sweden), Note by the Secretariat, MTN.GNG/NG11/16, 4 December 1989.

⁴⁴ Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, MEETING OF THE NEGOTIATING GROUP OF 1 NOVEMBER 1990, Chairman: Ambassador Lars E. R. Anell (Sweden), Note by the Secretariat, MTN.GNG/NG11/27, 14 November 1990.

⁴⁵ Note by the Secretariat, Review of Article 27.3(b). Paper IP/C/W/369/Rev.1, revised 9 March 2006, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm, para. 61. The Members are: European Communities; Japan; Switzerland; United States; and Uruguay. For an analysis of what amounts to an effective *sui generis* system as required under TRIPS Article 27.3(b), see Ragavan, Srividhya and Mayer, Jamie, Has India Addressed Its Farmers' Woes? A Story of Plant Protection Issues (January 18, 2011). Georgetown International Environmental Law Review, Vol. 20, No. 97, 2007. Available at SSRN: <http://ssrn.com/abstract=1742708>.

⁴⁶ Note by the Secretariat, Review of Article 27.3(b). Paper IP/C/W/369/Rev.1, revised 9 March 2006, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm, para. 62. The Members are: Brazil; India; Malaysia; Mexico; Singapore; Zambia; Zimbabwe; and African Group.

⁴⁷ Note by the Secretariat, Review of Article 27.3(b). Paper IP/C/W/369/Rev.1, revised 9 March 2006, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm, para. 62. The Members that expressed this view are: Brazil; India; Zambia; Zimbabwe; and African Group.

between the TRIPS Agreement and the UN Convention on Biological Diversity (CBD), the protection of traditional knowledge and folklore. The Doha Declaration also requires work on these topics to be guided by the TRIPS Agreement's objectives (Article 7) and principles (Article 8), and to take development issues fully into account.⁴⁸ In the Doha Round negotiations, several Members have underlined the flexibility of Article 27.3(b) with respect to the choice of *sui generis* protection and several have argued that the term "effective *sui generis* system" requires further clarification.⁴⁹ The United States has argued that there are specific criteria that can be used to judge the effectiveness of a *sui generis* system, whereas some other Members have argued that the issue of whether a *sui generis* system is effective should be left to Members to decide.⁵⁰ Given the lack of criteria in the TRIPS Agreement and the ongoing debate among Members, it could be considered inappropriate for a panel or the Appellate Body to resolve this issue by defining the criteria. However, a WTO panel faced with an Article 27.3(b) effectiveness issue might consider the remedies that a WTO Member's legal system provides to institute and enforce judgments in favor of owners.⁵¹ Such an approach could be justified by interpreting the term "effective" in light of the obligations regarding enforcement of IPRs set out in Part III of the TRIPS Agreement.

WTO ministers meeting in Hong Kong in 2005 added a separate process of consultations on the relationship between the CBD and TRIPS, chaired by Director-General Pascal Lamy. The adoption of the Nagoya Protocol⁵² has added a new wrinkle to WTO discussions regarding the relationship between the CBD and TRIPS and the review of Article 27.3(b).⁵³ However, WTO Members have not reached any agreement on these issues. Moreover, only 13 countries had signed the Nagoya Protocol as of May 2011.⁵⁴ The experience in the Uruguay Round and the Doha Round both demonstrate the difficulties of WTO Members in reaching any clear agreements regarding the relationship between TRIPS obligations related to plant varieties and the provisions in other international agreements (in particular the UPOV Convention and the CBD).⁵⁵

⁴⁸ Ministerial declaration, 20 November 2001, WT/MIN(01)/DEC/1, Adopted on 14 November 2001, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm. Also see http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

⁴⁹ Note by the Secretariat, Review of Article 27.3(b). Paper IP/C/W/369/Rev.1, revised 9 March 2006, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm, para. 47. The Members are: Brazil; India; Kenya on behalf of the African Group; Thailand; and European Communities.

⁵⁰ *Ibid.*, para. 50.

⁵¹ Adam Masarek, TREETOP VIEW OF THE CATHEDRAL: PLANT VARIETY PROTECTION IN SOUTH AND SOUTHEAST ASIAN LEAST-DEVELOPED COUNTRIES, 24 *Emory Int'l L. Rev.* 433 (2010), 460.

⁵² The Nagoya Protocol was adopted by the Conference of the Parties (COP) to the UN Convention on Biological Diversity (CBD) at its 10th meeting on 29 October 2010 in Nagoya. The text of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol) is available at <http://www.cbd.int/abs/text/>.

⁵³ WTO News, "Nagoya gives new context to old views in intellectual property council", 1 March 2011, http://www.wto.org/english/news_e/news11_e/trip_01mar11_e.htm.

⁵⁴ Signatories to the Nagoya Protocol, <http://www.cbd.int/abs/nagoya-protocol/signatories/> consulted 10 May 2011.

⁵⁵ The progress made with respect to the review of Article 27.3(b) in the TRIPS Council is summarized in Note by the Secretariat, Review of Article 27.3(b). Paper IP/C/W/369/Rev.1, revised 9 March 2006, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm. The progress made in the

Article 27.2 creates a general exception to the patentability obligation of Article 27.1, first sentence. This exception permits Members to “exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law”. However, this exception does not apply to the non-discrimination obligation contained in Article 27.1, second sentence. Moreover, it appears that this exception would only apply in the case of plant varieties if a Member chooses to use patents to provide intellectual property rights for plant varieties. If a Member chooses a *sui generis* system, rather than patents, the exception in Article 27.2 would not apply.

The effect of Article 27.3(b) is that WTO Members have the right to exclude plant varieties from patentability, provided that they provide a *sui generis* form of intellectual property protection, such as the UPOV Convention. However, should Members choose not to provide *sui generis* protection, Article 27.3(b) obliges them to provide patent protection for plant varieties. The issue that remains is whether a Member could then invoke Article 27.2 to justify the exclusion of some plant varieties from patentability. The wording of Article 27 suggests that this is possible. Article 27.3 provides additional grounds for non-patentability to those contained in Article 27.2. Article 27.3 begins with the phrase, “Members may also exclude from patentability”. The obligation in Article 27.3(b) to provide patents and/or *sui generis* protection appears as an exception to the exception in 27.3(b). There is no indication that Article 27.2 can not be invoked to justify excluding certain plant varieties from patentability once a Member has chosen a system of patents instead of a system of *sui generis* protection. However, such exclusions would have to meet the criteria of Article 27.2. Nevertheless, if a Member chooses a system of *sui generis* protection, Article 27.2 could not be invoked to exclude certain plant varieties from *sui generis* protection, since Article 27.2 only provides a right to exclude from patentability. As of 4 April 2011, there were 69 UPOV Members, 46 of whom were parties to the 1991 Act and 23 of whom were parties to the 1978 Act.⁵⁶ The majority of UPOV Members are WTO Members, but the majority of WTO Members are not UPOV Members.

Assuming that a WTO Member has chosen a system of patents instead of a system of *sui generis* protection, which exclusions would meet the criteria of Article 27.2? The party invoking the exception in Article 27.2 has the burden of proof to show that (1) the commercial exploitation of the invention is prevented within its territory and (2) that prevention is “necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment”.

Director General’s consultative process regarding TRIPS and the CBD is summarized in Director-General Pascal Lamy, Report on Issues Related to the Extension of the Protection of Geographical Indications Provided for in Article 23 of the TRIPS Agreement to Products other than Wines and Spirits and those Related to the Relationship between the TRIPS Agreement and the Convention on Biological Diversity, TN/C/W/61 (also circulated as WT/GC/W/633), 21 April 2011, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm. See also the International Treaty on Plant Genetic Resources for Food and Agriculture (2001) adopted on 3 November 2001 in Rome. See <http://www.fao.org/ag/cgrfa/itpgr.htm>.

⁵⁶ MEMBERS OF THE INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS, <http://www.upov.int/en/about/members/pdf/pub423.pdf>, consulted 12 May 2011.

The phrase “necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment” echoes the language of GATT Article XX(a) (“necessary to protect public morals”) and GATT Article XX(b) (“necessary to protect human, animal or plant life or health”), as well as GATS Article XIV(a) (“necessary to protect public morals or to maintain public order”) and GATS Article XIV(b) (“necessary to protect human, animal or plant life or health”).

Given the similarity of the language in all of these exceptions, and since the AB in *US – Gambling* interpreted the term “necessary” in GATS Article XIV(a) to mean the same as the term “necessary” in GATT Article XX, it is reasonable to do the same in TRIPS Article 27.2. As the AB noted in *US – Stainless Steel (Mexico)*, WTO Members cite WTO jurisprudence in legal arguments in dispute settlement proceedings and take the jurisprudence into account when enacting or amending national legislation.⁵⁷ WTO Members also take the jurisprudence into account in trade negotiations. Thus, while the context of TRIPS Article 27.2 differs from that of GATS Article XIV and GATT Article XX (for example, the term “ordre public” is broader in Article 27.2 because it encompasses measures to “protect human, animal or plant life or health or to avoid serious prejudice to the environment”), the analytical process should be similar, given the language that is used.

In English and French, TRIPS Article 27.2 uses the same form of the word necessary as in GATT Article XX and GATS Article XIV, but in Spanish there is a small variation. The term in Spanish is “necesarias” in GATT and GATS and “necesariamente” in TRIPS Article 27.2. The text in Spanish suggests that the difference between TRIPS and GATT/GATS is due to grammatical differences in the structure of the provision: the Spanish text uses an adverb applied to a verb, whereas the French and English texts use an adjective applied to a noun. The text in French and English indicates that negotiators intended to convey the same idea in all three agreements.

GATT and GATS jurisprudence suggests the following analysis would be appropriate in TRIPS Article 27.2. First, the party invoking the exception must make a *prima facie* case that the policy goal at issue in its measure falls within the range of policies designed “to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment”. Once it is established that the policy goal fits the exception, the party would then have to prove that the measure is “necessary” to achieve the policy goal. To demonstrate that the measure is necessary involves weighing and balancing a series of factors. First, the greater the importance of the interests or values that the challenged measure is intended to protect, the more likely it is that the measure is necessary. Second, the greater the extent to which the measure contributes to the end pursued, the more likely that the measure is necessary. In *Brazil – Retreaded Tyres*, the AB observed that a measure adopted in order to attenuate global warming and climate change, the contribution of which is not immediately observable, could meet this requirement under Article XX(b); the same should be true under TRIPS Article 27.2.⁵⁸ Third, the less WTO-inconsistent the challenged measure is, the more likely it would be considered necessary. Fourth, whether a WTO-consistent alternative measure which the Member concerned could reasonably be

⁵⁷ *US – Stainless Steel (Mexico)* (AB), para. 160.

⁵⁸ *Brazil – Retreaded Tyres* (AB), para. 151.

expected to employ is available, or whether a less WTO-inconsistent measure is reasonably available. Regarding the fourth issue, the party invoking the exception may point out why alternative measures would not achieve the same objectives as the challenged measure, but it is under no obligation to do so in order to establish, in the first instance, that its measure is “necessary”. If the other party raises a WTO-consistent alternative measure that, in its view, should have been taken, the party invoking the exception would be required to demonstrate why its challenged measure nevertheless remains “necessary” in the light of that alternative or, in other words, why the proposed alternative is not, in fact, “reasonably available”. If the party invoking the exception demonstrates that the alternative is not “reasonably available”, in the light of the interests or values being pursued and the party’s desired level of protection, it follows that the challenged measure must be “necessary”.⁵⁹ One alternative that should be considered in the context of TRIPS is to issue a compulsory license under TRIPS Article 31, rather than denying patent protection altogether.

The party invoking the exception must also show that the “exclusion is not made merely because the exploitation is prohibited by their law”. Article 27.2 uses this phrase, which suggests that the inquiry must take place in a broader context than the national law of the Member in question; i.e. the justification for exclusion must be based on one of the permissible grounds for exclusion set out in Article 27. The negotiating history of the TRIPS Agreement appears to confirm this, since an earlier draft listed “law” as one of the permissible grounds for exclusion and was not included in the final text.⁶⁰ The patentability of the subject matter in other jurisdictions might support the view that the exclusion of patentability in the respondent’s measure is made merely because the exploitation is prohibited by the respondent’s law.

While the language of the chapeau in GATS Article XIV regarding arbitrary or unjustifiable discrimination reflects that of the chapeau in GATT Article XX, TRIPS Article 27.2 contains no comparable language. However, the Article 27.2 exception does not apply to the non-discrimination obligation of Article 27.1. Thus, Article 27.2 should be interpreted to require compliance with the broad non-discrimination obligation of Article 27.1⁶¹, which would have a similar effect to the non-discrimination requirements of the chapeau in GATS Article XIV and GATT Article XX. However, in the case of plants, Article 27.3 operates as an exception to the non-discrimination obligation in Article 27.1, except in the case of plant varieties. Moreover, the complainant would have the burden of proving a violation of the non-discrimination obligation of Article 27.1, whereas the respondent would have the burden of proof under the chapeau in GATS Article XIV and GATT Article XX.

⁵⁹ *US – Gambling (AB)*, paras. 310-311.

⁶⁰ MTN.GNG/NG11/W/76.

⁶¹ Regarding non-discrimination in Article 27, in *Canada – Pharmaceutical Patents*, the Panel stated: “Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than a frustration of purpose. It is quite plausible...that the TRIPS Agreement would want to require governments to apply exceptions in a non-discriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers.”

In the Doha Round negotiations, WTO Members have debated the kinds of exceptions that would be appropriate in a *sui generis* system of protection. This debate also provides a preview of the types of measures that might be justified under Article 27.2 or under other exceptions set out in TRIPS Articles 30 and 31. Suggested limitations and exceptions can be categorized in two groups. Exceptions regarding experimental use and the right to use a protected variety for further breeding aim to benefit other breeders and to promote further innovation (breeders' exemption). Exceptions that aim to ensure food security and preserve the integrity of rural communities include exceptions to the benefit of farmers, non-commercial use of plant varieties, and the system of seed saving and exchange as well as the selling among farmers (farmers' privilege). Compulsory licences might serve both objectives. While some Members agree that the breeders' exemption allows breeders to freely use plant varieties protected by plant breeders' rights in their breeding activities, others note that the scope of the exemption is unclear, particularly regarding compensation due to right holders. Some Members have argued that farmers' privilege allows farmers to replant on their own holdings propagating material of protected plant varieties that they have harvested on their own holdings, with the issue of remuneration left to the national legislator. Other Members have argued that farmers' privilege should not be limited to saving and re-planting the material only on a farmer's own holdings. Rather, the privilege should provide greater latitude in the case of subsistence and small farmers, as long as the commercial interests of plant breeders are protected. However there was disagreement regarding whether certain categories of commercial farmers in developing countries should benefit from farmers' exceptions.⁶²

While there have been no disputes in the WTO regarding TRIPS Article 27, some of these issues have been analyzed in the Supreme Court of Canada.⁶³ In *Monsanto Canada Inc. v. Schmeiser*, Monsanto owned a patent that disclosed the invention of chimeric genes that confer tolerance to glyphosate herbicides such as Roundup and cells containing those genes. Canola containing the patented genes and cells was marketed under the trade name "Roundup Ready Canola". Schmeiser grew canola commercially in Saskatchewan and never purchased Roundup Ready canola nor obtained a licence to plant it. Tests of Schmeiser's 1998 canola crop revealed that 95-98 percent was Roundup Ready Canola. Monsanto sued Schmeiser for patent infringement.

A majority of five ruled that the patent was valid, even though the Supreme Court of Canada had previously ruled that plants and seeds, as higher life forms, are unpatentable. The majority reasoned that Monsanto did not claim protection for the genetically modified plant itself, but rather for the genes and the modified cells that make up the plant. They also found the patent valid on the grounds that a process could be validly patented even where the subject matter it manufactures is not patentable, because it constitutes unpatentable subject matter.

A minority of four dissented on the issue of whether the patent was violated. They decided that Schmeiser was entitled to rely on the reasonable expectation that plants, as unpatentable subject-matter, fall outside the scope of patent protection. Thus, the cultivation of plants containing the patented gene and cell did not constitute an infringement. To conclude otherwise would confer patent protection on the plant.

⁶² Note by the Secretariat, Review of Article 27.3(b). Paper IP/C/W/369/Rev.1, revised 9 March 2006, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm, paras. 55-56 and 61.

⁶³ *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902.

Moreover, to find that possession of plants, as the embodiment of a gene or cell claim, constitute a “use” of that claim would have the same effect as patenting the plant. However, this would not prevent Monsanto from licensing the sale of seeds that they produce from their patented invention and imposing contractual obligations, such as prohibition on saving seeds, on the licensee. Allowing gene and cell claims to extend patent protection to plants would render meaningless the right to exclude plants from patentability under TRIPS Article 27(3)(b).

UPOV Convention

IPRs for plant varieties have been characterized as having some elements that resemble patent rights and other that resemble copyright, and have evolved along with the technology, which now focuses more on genotype than phenotype.⁶⁴ The UPOV Convention established the International Union for the Protection of New Varieties of Plants (UPOV).⁶⁵ The 1961 UPOV Convention has been revised in 1972, 1978 and 1991. In the review of TRIPS Article 27.3(b), WTO Members have debated the merits of the various UPOV conventions and their relationship to the TRIPS Agreement. Some advocate 1991 Act of the UPOV Convention (UPOV 1991) as the most appropriate system and level of protection. Others argue that, since the UPOV 1991 does not permit limits on the eligibility for protection of varieties by species of plant, newly developed varieties of species of plant that would not have been eligible for protection under the 1978 Act are now eligible for protection under the 1991 Act.⁶⁶

The UPOV Council has adopted a series of Explanatory Notes on the UPOV Convention.⁶⁷ The Preambles in these Explanatory Notes contain this proviso: “The only binding obligations on members of the Union are those contained in the text of the UPOV Convention itself, and these Explanatory Notes must not be interpreted in a way that is inconsistent with the relevant Act for the member of the Union concerned”. However, this proviso is silent regarding the effect of these Explanatory Notes on the interpretation of the provisions of the UPOV Convention. The interpretation of the Convention is not the same thing as the interpretation of the Explanatory Notes. Thus, while the Explanatory Notes do not create binding obligations, they are relevant to the interpretation of the binding obligations, as well as the rights, set out in the Convention itself, by virtue of Articles 31 and 32 of the Vienna Convention on the Law of Treaties.

UPOV 1991 obliges Contracting Parties to “grant and protect breeders' rights” (Article 2) and to apply UPOV 1991 “to all plant genera and species” (Article 3). The minimum period of protection is 20 years from the date of the grant of the breeder's right and, for trees and vines, 25 years (Article 19). Thus, the minimum period of protection

⁶⁴ Mark D. Janis and Stephen Smith, THE PROTECTION OF RIGHTS IN PLANT VARIETIES: TECHNOLOGICAL CHANGE AND THE DESIGN OF PLANT VARIETY PROTECTION REGIMES, 82 Chi.-Kent L. Rev. 1557 (2007). Phenotype conceptualizes plants primarily in terms of observable characteristics. Genotype characterizes plants by molecular information.

⁶⁵ INTERNATIONAL CONVENTION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS of December 2, 1961, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991, available at <http://www.upov.int/en/publications/conventions/1991/act1991.htm>.

⁶⁶ Note by the Secretariat, Review of Article 27.3(b). Paper IP/C/W/369/Rev.1, revised 9 March 2006, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm, para. 64.

⁶⁷ Available at http://www.upov.int/en/publications/explanatory_notes_index.htm.

for trees and vines is 5 years longer than for patents under the TRIPS Agreement. Contracting Parties must provide national treatment to nationals of other Contracting Parties insofar as the grant and protection of breeders' rights (Article 4).

The length of protection varies among *sui generis* systems. Thailand grants rights for a maximum of twelve, seventeen, or twenty-seven years, depending on the type of plant involved. India grants protection for fifteen or eighteen years, also depending on the type of plant variety involved. Some argue that the length of protection that IPRs confer should vary with the particular technology.⁶⁸ For example, twenty years of patent protection for pharmaceuticals confers a shorter term in practice, due to the length of time required to obtain marketing approval for the product.

Article 1(vi) of UPOV 1991 defines the term "variety" in the following terms:

a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics and
- considered as a unit with regard to its suitability for being propagated unchanged;

The TRIPS Agreement does not define the term "plant varieties" that is used in Article 27.3(b). Indeed, WTO Members have debated whether to define several terms that are used in Article 27.3(b), whether WIPO or the WTO should define the terms, and how to define the terms.⁶⁹ It has been suggested that the 1991 UPOV definition inform the definition of the term "plant varieties" that is used in Article 27.3(b).⁷⁰ Some critics argue that biotechnology advances, particularly molecular marker technologies, are making the very concept of plant variety obsolete.⁷¹

UPOV 1991 Article 5 provides that the breeder's right shall be granted where the variety is new, distinct, uniform and stable. This provision is more detailed than the requirements of TRIPS Article 27.1 (new, inventive step and useful) and adapted to the specific situation of plant varieties. However, advances in biotechnology also make these UPOV criteria more difficult to apply in practice, since the analysis must take place at the molecular level and molecular information can be used more easily to avoid detection of

⁶⁸ Masarek, 463-464.

⁶⁹ Note by the Secretariat, Review of Article 27.3(b). Paper IP/C/W/369/Rev.1, revised 9 March 2006, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm. The terms debated are plants and animals, micro-organisms, and non-biological and micro-biological processes.

⁷⁰ Note by the Secretariat, Review of Article 27.3(b). Paper IP/C/W/369/Rev.1, revised 9 March 2006, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm, para. 68.

⁷¹ Mark D. Janis and Stephen Smith, THE PROTECTION OF RIGHTS IN PLANT VARIETIES: TECHNOLOGICAL CHANGE AND THE DESIGN OF PLANT VARIETY PROTECTION REGIMES, 82 Chi.-Kent L. Rev. 1557 (2007), 1577-1578.

IPR infringements.⁷² UPOV 1991 defines novelty (Article 6), distinctiveness (Article 7), uniformity (Article 8) and stability (Article 9) of plant varieties, whereas the comparable criteria of TRIPS Article 27.1 are not defined. The decision to grant a breeder's right must require an examination for compliance with the conditions in Articles 5-9 (Article 12). Any breeder who has filed an application for the protection of a variety in one of the Contracting Parties has a right of priority in filing an application for the same variety with any other Contracting Party for twelve months (Article 11). This provision is comparable to the right of priority for patents in the Paris Convention. TRIPS Article 27.3(b) does not specify whether there is an obligation to incorporate a novelty requirement in *sui generis* systems. However, not having a novelty requirement enables the government to protect plant varieties that nationals have long used for traditional purposes, which prevents outside investors from patenting those plant varieties in their own countries by providing evidence of lack of novelty in the particular use of the plant.⁷³

Article 14, subject to Articles 15 and 16, requires that the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder: (i) production or reproduction (multiplication), (ii) conditioning for the purpose of propagation, (iii) offering for sale, (iv) selling or other marketing, (v) exporting, (vi) importing, and (vii) stocking for any of the foregoing purposes. The same acts with respect to harvested material obtained through the unauthorized use of propagating material of the protected variety also require the authorization of the breeder. Contracting Parties may add other acts to this mandatory list. These provisions also apply to varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety (Article 14(5)(a)(i)), varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety (Article 14(5)(a)(ii)) and varieties whose production requires the repeated use of the protected variety (Article 14(5)(a)(iii)). Again, advances in biotechnology make these criteria more difficult to apply in practice.⁷⁴

Article 15(1) provides compulsory exceptions to the breeder's right. The breeder's right shall not extend to (i) acts done privately and for non-commercial purposes, (ii) acts done for experimental purposes, and (iii) acts done for the purpose of breeding other varieties (the breeder's exemption), and, except where the provisions of Article 14(5) apply (varieties which are essentially derived from the protected variety), acts referred to in Article 14(1) to Article 14(4) in respect of such other varieties.

The breeder's exemption is also affected by technological advances. New "reverse breeding" techniques shorten the time needed to create new varieties, thereby shortening the *de facto* period of exclusivity enjoyed by the original breeder. This has led to proposals to phase in the breeder's exemption according to the time it takes to reverse

⁷² Mark D. Janis and Stephen Smith, THE PROTECTION OF RIGHTS IN PLANT VARIETIES: TECHNOLOGICAL CHANGE AND THE DESIGN OF PLANT VARIETY PROTECTION REGIMES, 82 Chi.-Kent L. Rev. 1557 (2007), 1583-1592.

⁷³ Adam Masarek, TREETOP VIEW OF THE CATHEDRAL: PLANT VARIETY PROTECTION IN SOUTH AND SOUTHEAST ASIAN LEAST-DEVELOPED COUNTRIES, 24 Emory Int'l L. Rev. 433 (2010), 462.

⁷⁴ Mark D. Janis and Stephen Smith, THE PROTECTION OF RIGHTS IN PLANT VARIETIES: TECHNOLOGICAL CHANGE AND THE DESIGN OF PLANT VARIETY PROTECTION REGIMES, 82 Chi.-Kent L. Rev. 1557 (2007), 1596-1597.

breed new varieties.⁷⁵ Such proposals are comparable to proposals to increase the patent term for pharmaceuticals to account for the time required to obtain marketing approvals and appear designed to extend monopolies that would limit access.

The Explanatory Notes on Article 15(1)(i) set out examples of acts “possibly” not falling within the scope of the exception for acts done privately and for non-commercial purposes:

5. The wording of Article 15(1)(i) indicates that acts which are both of a private nature and for non-commercial purposes are covered by the exception. Thus, non-private acts, even where for non-commercial purposes, may be outside the scope of the exception.

6. Furthermore, the wording indicates that private acts which are undertaken for commercial purposes do not fall within the exception. Thus, a farmer saving his own seed of a variety on his own holding might be considered to be engaged in a private act, but could be considered not to be covered by the exception if the said saving of seed is for commercial purposes. A separate optional exception (see Article 15(2)) has been created within the Convention to address farm-saved seed (see Section II).⁷⁶

The Explanatory Notes on Article 15(1)(i) also set out examples of acts “possibly” falling within the scope of the exception for acts done privately and for non-commercial purposes:

7. The wording of Article 15(1)(i) suggests that it could allow, for example, the propagation of a variety by an amateur gardener for exclusive use in his own garden (i.e. no material of the variety being provided to others), since this may constitute an act which was both private and for non-commercial purposes. Equally, for example, the propagation of a variety by a farmer exclusively for the production of a food crop to be consumed entirely by that farmer and the dependents of the farmer living on that holding, may be considered to fall within the meaning of acts done privately and for non-commercial purposes. Therefore, activities, including for example “subsistence farming”, where these constitute acts done privately and for non-commercial purposes, may be considered to be excluded from the scope of the breeder’s right, and farmers who conduct these kinds of activities freely benefit from the availability of protected new varieties.⁷⁷

According to this explanation of Article 15(1)(i), if I am an amateur gardener, I propagate a protected variety of roses in my garden, my neighbor invites me over for dinner and I

⁷⁵ Mark D. Janis and Stephen Smith, THE PROTECTION OF RIGHTS IN PLANT VARIETIES: TECHNOLOGICAL CHANGE AND THE DESIGN OF PLANT VARIETY PROTECTION REGIMES, 82 Chi.-Kent L. Rev. 1557 (2007), 1604-1605.

⁷⁶ EXPLANATORY NOTES ON EXCEPTIONS TO THE BREEDER’S RIGHT UNDER THE 1991 ACT OF THE UPOV CONVENTION, UPOV /EXN/EXC /1, adopted by the Council at its forty-third ordinary session on October 22, 2009, paras. 5 and 6, http://www.upov.int/export/sites/upov/en/publications/pdf/upov_exn_exc_1.pdf.

⁷⁷ Ibid, para. 7.

bring my neighbor a bouquet of those same roses, I am in violation of Article 15(1)(i). However, it seems a bit of a stretch to consider such an act a “commercial purpose”.

Regarding Article 15(1)(ii), the Explanatory Notes simply state, “The breeder’s right does not extend to the use of the protected variety for experimental purposes”.⁷⁸ No definition of the term “experimental purposes” is provided in the Explanatory Notes or the Convention itself. However, this term should not cover “acts done for the purpose of breeding other varieties”, since those acts are subject to the breeder’s exemption in Article 15(1)(iii). To interpret Article 15(1)(ii) otherwise would make Article 15(1)(iii) redundant, contrary to the principle of effective treaty interpretation.

Regarding the breeder’s exemption in Article 15(1)(iii), the Explanatory Notes state, “there are no restrictions on the use of protected varieties for the purpose of breeding new plant varieties”.⁷⁹ However, the explanation in paragraph 11 of the second part of Article 15(1)(iii) illustrates that the previous statement must be read carefully:

11. The following scheme illustrates a hypothetical situation where a breeder uses a protected variety A and a non-protected variety B for the breeding of a new variety C. The scheme demonstrates that no authorization is required to breed variety C. Furthermore, the commercialization of variety C would not require the authorization of the breeder of variety A except where variety C was an essentially derived variety, or was a variety that required the repeated use of the protected variety A or was a variety which was not clearly distinguishable from the protected variety A (see Article 14 (5) of the 1991 Act of the UPOV Convention).⁸⁰

Article 15(2) provides an optional exception to the breeder's right.

Each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14(5)(a)(i) or Article 14(5)(a)(ii).

Regarding the farmer’s exemption in Article 15(2), the Explanatory Notes state:

13. When considering the way in which the optional exception might be implemented, the Diplomatic Conference of 1991 (see page 63 of UPOV Publication No. 346(E) “Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants”) developed the following recommendation:

“The Diplomatic Conference recommends that the provisions laid down in Article 15(2) of the International Convention for the Protection of New Varieties of Plants of December 2, 1961, as Revised at Geneva on November 10, 1972, on

⁷⁸ Ibid, para. 8.

⁷⁹ Ibid, para. 9.

⁸⁰ Ibid, para. 11.

October 23, 1978, and on March 19, 1991, should not be read so as to be intended to open the possibility of extending the practice commonly called ‘farmer’s privilege,’ to sectors of agricultural or horticultural production in which such a privilege is not a common practice on the territory of the Contracting Party concerned.”

14. The Diplomatic Conference recommendation indicates that the optional exception was aimed at those crops where, for the member of the Union concerned, there was a common practice of farmers saving harvested material for further propagation.⁸¹

However, there are two aspects to note about this explanation. First, the Diplomatic Conference note uses the phrase “should not be read”, which indicates that this interpretation of Article 15(2) is not mandatory. Second, the Diplomatic Conference note would constitute negotiating history or preparatory history (*travaux préparatoires*) under Article 32 of the Vienna Convention on the Law of Treaties and only be relevant as a supplementary means of interpretation of Article 15(2) if the interpretation under Article 31 of the Vienna Convention on the Law of Treaties proves inadequate.⁸²

The Explanatory Notes go on to state:

15. Article 15(2) states that “each Contracting Party may, [...] restrict the breeder’s right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14(5)(a)(i) or (ii).” [emphasis in original]

16. That wording indicates that the optional exception may be considered to relate to selected crops where the product of the harvest is used for propagating purposes, for example small-grained cereals where the harvested grain can equally be used as seed i.e. propagating material. Taken together with the recommendation relating to Article 15 (2) of the Diplomatic Conference of 1991 (see above), the wording also indicates that it may be considered inappropriate to introduce the optional exception for agricultural or horticultural sectors, such as fruit, ornamentals and vegetables, where it has not been a common practice for the harvested material to be used as propagating material.⁸³

Regarding the phrase “reasonable limits and safeguarding of the legitimate interests of the breeder”, the Explanatory Notes provide a more detailed commentary that expands the breeder’s right and limits the farmer’s exemption far beyond what the text of

⁸¹ Ibid, paras. 14-15.

⁸² However, there is some disagreement among experts regarding the role of Article 32. See John H. Jackson, *The Jurisprudence of GATT and the WTO: Insights on Treaty Law and Economic Relations*, 145, note 37, arguing that preparatory history is to be used only when the means specified in Article 31 do not resolve an interpretative problem. Also see Stephen M. Schwebel, *May Preparatory Work be Used to Correct Rather than Confirm the “Clear” Meaning of a Treaty Provision?*, in Jerzy Makarczyk, ed., *Theory of International Law at the Threshold of the 21st Century*, 541 (1996), arguing that preparatory work must be given a greater role in treaty interpretation than the words of Article 32 might suggest.

⁸³ EXPLANATORY NOTES ON EXCEPTIONS TO THE BREEDER’S RIGHT UNDER THE 1991 ACT OF THE UPOV CONVENTION, UPOV /EXN/EXC /1, adopted by the Council at its forty-third ordinary session on October 22, 2009, para. 15, http://www.upov.int/export/sites/upov/en/publications/pdf/upov_exn_exc_1.pdf.

Article 15(2) suggests. They suggest a series of factors to consider in order to determine whether the implementation of the farmer's exemption in national legislation introduces limits to the breeder's right that are reasonable and whether the national legislation safeguards the legitimate interests of the breeder:

- (1) Type of variety: whether there has been a common practice of farmers saving harvested material for further propagation and whether it would be appropriate to introduce the optional exception for such types of varieties.⁸⁴
- (2) Size of farmer's holding / crop area / crop value: small farmers with small holdings (or small areas of crop) might be permitted to use farm-saved seed to a different extent and with a different level of remuneration to breeders than "large farmers", taking into account the circumstances of each country.⁸⁵
- (3) Proportion or amount of harvested crop: the maximum percentage of the harvested crop or maximum acreage which the farmer may use for further propagation in relation to the size of farm (or crop area) and/or the level of remuneration, taking into account the quantity of the protected variety originally obtained by the farmer, the amount appropriate to plant on the farmer's holding, or the amount to be reasonably consumed by the farmer and his dependents.⁸⁶
- (4) Changing situations: changes in the level of harvested material used for further propagation, evolution of farming practices and breeding and propagation methodologies, and economic developments could lead to changes in the level of harvested material used for further propagation and justify limiting the level of farm-saved seed to those levels which had been common practice before the introduction of plant variety protection.⁸⁷
- (5) Remuneration: A requirement to provide remuneration to breeders might be considered as a means of safeguarding the legitimate interests of the breeders.⁸⁸

The Explanatory Notes go on to emphasize that the farmer's exemption does not extend to propagating material which was produced on the holding of another farmer.⁸⁹ They then assert that the use of the words "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder" means that the farmer's exemption should be implemented "in a way which does not undermine the incentives provided by the UPOV Convention for breeders to develop new varieties".⁹⁰

The Explanatory Notes then suggests that Contracting Parties consider several factors in deciding if and how it wishes to implement Article 15(2): the impact on breeding, the costs and mechanisms required for implementation and the overall economic impact on agriculture. They also suggest consultation with the interested parties⁹¹ and introducing the farmer's exemption in a manner that facilitates modifying

⁸⁴ Ibid, para. 19.

⁸⁵ Ibid, para. 20.

⁸⁶ Ibid, para. 21.

⁸⁷ Ibid, para. 22.

⁸⁸ Ibid, para. 23.

⁸⁹ Ibid, para. 24.

⁹⁰ Ibid, para. 25.

⁹¹ Ibid, para. 26.

the legislation over time to adapt to the evolution of farming practices and breeding and propagation methodologies, as well as economic developments.⁹²

WTO Members have debated UPOV provisions regarding the farmers' exemption. Some argue that UPOV 1978 allows farmers to save, exchange and, to a limited degree, sell seeds of protected varieties, whereas UPOV 1991 gives the government discretion as to whether to permit farmers to save seeds for use on their own holdings and makes this exception subject to "reasonable restrictions" and the protection of the "legitimate interests" of the breeder. Moreover, the exception only applies to material that has been harvested on the same holdings and not to propagated material (just "the product of the harvest"). Thus, this exception does not benefit farmers in the case of GMO varieties that do not produce viable seeds (terminator technology).⁹³ Many Members, particularly developing countries, therefore argue that UPOV 1991 would have a negative impact on food security in developing countries and create dependence on foreign commercial breeders for seeds.⁹⁴

Article 16(1) governs exhaustion of the breeder's right in the following terms:

The breeder's right shall not extend to acts concerning any material of the protected variety, or of a variety covered by the provisions of Article 14(5), which has been sold or otherwise marketed by the breeder or with his consent in the territory of the Contracting Party concerned, or any material derived from the said material, unless such acts

(i) involve further propagation of the variety in question or

(ii) involve an export of material of the variety, which enables the propagation of the variety, into a country which does not protect varieties of the plant genus or species to which the variety belongs, except where the exported material is for final consumption purposes.

Article 16(1) gives Contracting Parties less discretion than TRIPS Article 6 gives to WTO Members. TRIPS Article 6 leaves WTO Members free to determine their own regime with respect to exhaustion of patent rights, subject to national treatment and most-favoured-nation treatment.⁹⁵ Some WTO Members argue that UPOV 1991 limits exhaustion of the right to sell or otherwise market plant varieties made within the national territory of the contracting party concerned, in contrast to Article 6 of the TRIPS Agreement, which leaves the issue of exhaustion of intellectual property rights to the discretion of each Member. For the foregoing reasons, several WTO Members argue that legislation based upon UPOV 1978 provides effective *sui generis* protection for plant variety rights for the purposes of Article 27.3(b). However, other Members argue that the farmers' exemption can be justified under Article 27.3 (b) as an exception to plant variety protection or under Article 30 of the TRIPS Agreement as an exception to patent protection, for farming activities are limited to small, subsistence farms who customarily

⁹² Ibid, para. 27.

⁹³ For a discussion of terminator genes, see JASON A. BARRON, Genetic Use Restriction Technologies: Do the Potential Environmental Harms Outweigh the Economic Benefits? 20 Geo. Int'l Env'tl. L. Rev. 271 (2008).

⁹⁴ Note by the Secretariat, Review of Article 27.3(b). Paper IP/C/W/369/Rev.1, revised 9 March 2006, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm, para. 65.

⁹⁵ See Declaration on the TRIPS Agreement and Public Health, para. 5(d).

reuse seed because they lack access to financial resources for new seeds every growing season or where commercial activities of farmers are limited geographically.⁹⁶

Article 17 of UPOV 1991 limits restrictions on the exercise of the breeder's right as follows:

- (1) Except where expressly provided in this Convention, no Contracting Party may restrict the free exercise of a breeder's right for reasons other than of public interest.
- (2) When any such restriction has the effect of authorizing a third party to perform any act for which the breeder's authorization is required, the Contracting Party concerned shall take all measures necessary to ensure that the breeder receives equitable remuneration.

Article 9 of the 1978 UPOV Convention has a similar provision:

- (1) The free exercise of the exclusive right accorded to the breeder may not be restricted otherwise than for reasons of public interest.
- (2) When any such restriction is made in order to ensure the widespread distribution of the variety, the member State of the Union concerned shall take all measures necessary to ensure that the breeder receives equitable remuneration.

What would qualify as “public interest” justifications for restricting a breeder’s right? At the very least, if a WTO Member issues a compulsory license in accordance with TRIPS Article 31, such compulsory licenses should qualify. Since TRIPS Article 27.3(b) permits WTO Members to choose between patents and *sui generis* protection for plant varieties, there should be no inherent conflict between UPOV and TRIPS. The negotiating history of TRIPS indicates that the negotiators were aware of UPOV 1991, as well as the fact that many countries might prefer UPOV 1978 to UPOV 1991, when they drafted Article 27.3(b). This interpretation would be consistent with the presumption against conflicts between treaties.

Neither UPOV 1978 nor UPOV 1991 defines “equitable remuneration”, as in the case of TRIPS Article 31(h), which requires “adequate remuneration” according to the circumstances of each case taking into account the economic value of a compulsory license. The TRIPS agreement sheds some light on this issue, since Article 1.1 permits WTO Members to determine freely the adequate method of applying TRIPS provisions according to their own legal system and practice. Another issue in Article 17 is what measures are considered “necessary to ensure that the breeder receives equitable remuneration”.

The ruling of the majority of the Supreme Court of Canada in *Monsanto Canada Inc. v. Schmeiser* provides an example of how remuneration might be calculated. By cultivating a plant containing the patented gene and composed of the patented cells without license, Schmeiser deprived Monsanto of the full enjoyment of the monopoly granted by the patent. Monsanto elected to seek an account of profits, rather than

⁹⁶ Note by the Secretariat, Review of Article 27.3(b). Paper IP/C/W/369/Rev.1, revised 9 March 2006, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm, para. 66.

damages, under the Patent Act. To calculate this award, the majority compared Schmeiser's profit attributable to the invention and Schmeiser's profit had they used the best non-infringing option. Since the Court found that Schmeiser's profits were precisely what they would have been had they planted and harvested ordinary canola, they earned no profit from the invention and Monsanto was entitled to nothing on their claim of account.

Two different and overlapping categories of intellectual property rights now exist for plants: patents and plant variety rights. Lenßen considers this to be a problem and proposes an integrated or harmonized system of patents and plant variety rights.⁹⁷ However, given the different views among WTO Members on this issue and the importance of flexibility in the face of climate change, it seems more appropriate to leave WTO Members with the flexibility that TRIPS Article 27.3(b) currently allows.

The balance of rights between producers and users of biotechnology seems more balance in the TRIPS Agreement than in UPOV 1991. UPOV 1991, particularly when read together with the Explanatory Notes, favors the interests of plant breeders far more than the interests of farmers. This is particularly true with respect to the restrictive interpretation of the farmer's exemption in the Explanatory Notes, which, if accepted, would far more restrictive than the exception for compulsory licensing of patents in TRIPS Article 31.

TRIPS Article 27.3(b) and the Convention on Biological Diversity

There are 193 Parties to the CBD. The CBD contains provisions regarding use of traditional knowledge and access to genetic resources, in particular with respect to prior informed consent and the equitable sharing of benefits derived from traditional knowledge and access to genetic resources. WTO Members have raised two general issues regarding the relationship between the TRIPS Agreement and the CBD: (1) whether there is conflict between the TRIPS Agreement and the CBD and (2) whether something needs to be done to ensure that the two instruments are applied in a non-conflicting and mutually supportive way, and if so, what.⁹⁸ Some Members argue that there is a conflict between the TRIPS Agreement and the CBD, for two reasons. First, the TRIPS Agreement provides for the appropriation of such genetic resources by private parties in a way that is inconsistent with the sovereign rights of countries over their genetic resources as provided for in the CBD, by requiring that certain genetic material be patentable or protected by *sui generis* plant variety rights and by not preventing the patenting of other genetic material. Second, the TRIPS Agreement provides for the patenting or other intellectual property protection of genetic material without ensuring that the provisions of the CBD, including those relating to prior informed consent and benefit sharing, are respected. Similar points have been made about the relationship between the TRIPS Agreement and the provisions of the CBD relating to the traditional

⁹⁷ Lenßen, Markus, The Overlap between Patent and Plant Variety Protection for Transgenic Plants: Problems and a Solution (May 2006). Available at SSRN: <http://ssrn.com/abstract=924343>.

⁹⁸ THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY: SUMMARY OF ISSUES RAISED AND POINTS MADE, Note by the Secretariat, IP/C/W/368/Rev.1, 8 February 2006, para. 6.

knowledge of indigenous peoples and local communities.⁹⁹ Some Members argue that the TRIPS Agreement needs to be amended to avoid patents being granted on existing traditional knowledge or genetic resources subject-matter, without the prior informed consent of the source countries, while others argue that no amendment is required to achieve these objectives.¹⁰⁰

Sabrina Safrin rejects both the patenting of genetic material in countries such as the United States, and the push for strong patent rights for genetic material in agreements such as TRIPS and the UPOV Convention, and the sovereign-based response to such patenting by genetically diverse developing countries, exemplified by the CBD. She argues that collectively the developed countries' patent-based systems and the developing countries' sovereign-based systems have overreached in permitting or asserting ownership rights over genetic material. Together, these approaches have ended the global commons or open system for genetic resources. Many developing countries now restrict access to raw genetic material within their borders and link the granting of intellectual property rights to compliance with the source countries' access laws. She argues that placing such conditions on patentability may be inconsistent with TRIPS Article 27.1 (although she does not analyze whether such restrictions might be justifiable under Article 27.2). She argues further that these access-limiting regimes are deterring companies and researchers from bioprospecting in genetically rich countries. At the same time, the patent system for genetics in some developing countries has overreached and is inhibiting innovation by creating “patent thickets” in which a series of overlapping patents become too difficult to negotiate in order to acquire the permissions necessary to develop new innovations. Thus, the combined effect of the two competing systems is to limit genetically based innovations and to create obstacles to international conservation and collaboration. Collaboration between scientists of different countries now requires clearing their actions with either national government authorities, patent owners or both.¹⁰¹

CBD Article 8(j), subject to national legislation, requires Contracting Parties to encourage the equitable sharing of the benefits arising from knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity. Since the obligation merely is to “encourage” and is “subject to national legislation”, it is not clear that this provision contains any meaningful obligation regarding equitable sharing of the benefits

⁹⁹ THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY: SUMMARY OF ISSUES RAISED AND POINTS MADE, Note by the Secretariat, IP/C/W/368/Rev.1, 8 February 2006, para. 15.

¹⁰⁰ THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY: SUMMARY OF ISSUES RAISED AND POINTS MADE, Note by the Secretariat, IP/C/W/368/Rev.1, 8 February 2006, paras. 8-15. Director-General Pascal Lamy, Report on Issues Related to the Extension of the Protection of Geographical Indications Provided for in Article 23 of the TRIPS Agreement to Products other than Wines and Spirits and those Related to the Relationship between the TRIPS Agreement and the Convention on Biological Diversity, TN/C/W/61 (also circulated as WT/GC/W/633), 21 April 2011, para. 27, available at http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

¹⁰¹ Sabrina Safrin, HYPEROWNERSHIP IN A TIME OF BIOTECHNOLOGICAL PROMISE: THE INTERNATIONAL CONFLICT TO CONTROL THE BUILDING BLOCKS OF LIFE, 98 A.J.I.L. 641 (2004).

from traditional knowledge. Traditional knowledge is not protected effectively, especially compared to provisions regarding genetic resources.¹⁰²

CBD Article 15(1) recognizes that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. However, this provision does not oblige national governments to take any particular course of action in their legislation. CBD Article 15(3) provides that, for the purpose of the CBD, the genetic resources being provided by a Contracting Party, as referred to in Articles 15, 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with the CBD. CBD Article 15(4) provides that access, where granted, shall be on mutually agreed terms and subject to the provisions of Article 15. CBD Article 15(5) provides that access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party. These provisions are an important source of bargaining power for developing countries, in particular when it comes to the provisions in Articles 16 and 19 (see below).

CBD Article 15(7) requires each Contracting Party to take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources, upon mutually agreed terms. The wording of this provision does not set out any meaningful obligation regarding equitable sharing of the benefits from genetic resources, unless the source Party uses its authority to determine access to the genetic resource to negotiate access to the benefits that may arise. It is not clear what “as appropriate” means. It is not clear what “aim” means. The obligation to share benefits is subject to reaching an agreement on “mutually agreed terms”. This amounts to a mere obligation to negotiate, rather than an obligation to reach a particular set of terms. Thus, these CBD provisions regarding the equitable sharing of the benefits do not really have any teeth unless the source Party uses its authority to determine access to the genetic resource to enhance its bargaining position. However, developing countries that are not a source of the genetic material would lack such bargaining power.

It is not clear how the CBD provisions regarding informed consent can be made effective. Some WTO Members have expressed concern that the TRIPS Agreement allows the granting of patents for inventions that use genetic material without requiring that the provisions of the CBD in relation to prior informed consent and benefit sharing are respected. Some have proposed national solutions to this issue, including legislation on access and benefit sharing and contracts, outside the intellectual property system, to directly regulate the conduct in question.¹⁰³ Others have suggested disclosure requirements for patent applicants as a supplementary measure to national legislation and

¹⁰² For a summary of the WTO debate on this issue, see THE PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE: SUMMARY OF ISSUES RAISED AND POINTS MADE, Note by the Secretariat, IP/C/W/370/Rev.1, 9 March 2006.

¹⁰³ THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY: SUMMARY OF ISSUES RAISED AND POINTS MADE, Note by the Secretariat, IP/C/W/368/Rev.1, 8 February 2006, paras. 28-29.

contracts, including in international forums other than the WTO. A proposal has been made to amend the TRIPS Agreement to oblige WTO Members to require that an applicant for a patent relating to biological materials or to traditional knowledge provide the following information, as a condition of acquiring patent rights: (i) the source and country of origin of the biological resource and of the traditional knowledge used in the invention; (ii) evidence of prior informed consent from the authorities under the relevant national regime; and (iii) evidence of fair and equitable benefit sharing under the relevant national regime.¹⁰⁴

Paragraphs 1-5 of CBD Article 16 must be read together, since these paragraphs contain cross references that explicitly require that they be interpreted and applied consistently with each other. Article 16(1) recognizes that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of the Convention. It provides that each Contracting Party undertakes (subject to the provisions of this Article) to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that make use of genetic resources.

Article 16(2) provides that access to and transfer of technology to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. Article 16(2) also provides that access to and transfer to developing countries of technology subject to patents and other intellectual property rights shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. Thus, while paragraph 1 contains a mere undertaking regarding access to technology, paragraph 2 contains an obligation to provide such access in a manner that protects intellectual property rights. The access of developing countries to biotechnology takes a back seat to intellectual property rights and depends on access to financing. Concessional and preferential terms of financing are subject to reaching a mutual agreement. In effect, developing countries are required to pay for biotechnology that is subject to intellectual property rights and negotiate further for favorable financing of those purchases. Even this uncertain access to favorable financing is subject to a necessity test, which could depend on the financial and economic situation of the developing country that seeks the financing. Finally, the application of paragraph 2 must be consistent with paragraphs 3, 4 and 5 of Article 16. When read in light of Article 15, these provisions of Article 16 mean that the source Party must use its authority to determine access to the genetic resource to negotiate favorable terms before intellectual property rights are granted. However, developing countries that are not a source of the genetic material would lack such bargaining power.

Article 16(3) requires each Contracting Party to take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources, are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights,

¹⁰⁴ THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY: SUMMARY OF ISSUES RAISED AND POINTS MADE, Note by the Secretariat, IP/C/W/368/Rev.1, 8 February 2006, para. 71.

where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5. Thus, even where developing countries are the source of the genetic resources that are used to create biotechnologies, their access depends on negotiating financing and is subject to a needs test. The requirement that access be in accordance with international law is vague. However, it likely includes intellectual property rights treaties to which the developing country in question is a party, such as the TRIPS Agreement and the UPOV Convention. Once again, the source Party must use its authority to determine access to the genetic resource to negotiate favorable terms before intellectual property rights are granted. However, developing countries that are not a source of the genetic material would lack such leverage.

Article 16(4) requires each Contracting Party to take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 for the benefit of both governmental institutions and the private sector of developing countries. Since this paragraph requires each Contracting Party in this regard to abide by the obligations included in paragraphs 1, 2 and 3, it implies an obligation to protect intellectual property rights. It might also be read to encourage the use of the compulsory licensing provisions of TRIPS Article 31, for example in the case of biotechnology that is subject to patents. However, Article 31 requires that compulsory licensing of patents predominantly serve the domestic market of the WTO Member that issues the license. This means that the measures taken under CBD Article 16(4) would not include obliging the private sector to transfer biotechnology to developing countries. However, it might include other measures, such as tax incentives. The effectiveness of such incentives would be doubtful if the private sector would stand to lose more by facilitating access to, joint development and transfer of technology to developing countries than it would gain through the tax incentives. Thus, it is doubtful that Article 16(4) will result in the adoption of any meaningful measures, absent political will.

Under Article 16(5), the Contracting Parties recognize that patents and other intellectual property rights may have an influence on the implementation of the CBD and requires them to cooperate in this regard, subject to national legislation and international law, in order to ensure that such rights are supportive of and do not run counter to its objectives. An obligation to cooperate is not an obligation to reach a particular outcome. WTO Members have been trying to cooperate in this regard in the context of the WTO negotiations on TRIPS Article 27.3(b) and the Director General's consultations on the relationship between the TRIPS Agreement and the CBD, but have failed to reach any agreement.

CBD Article 19 governs handling of biotechnology and distribution of its benefits. Article 19(1) requires each Contracting Party to take legislative, administrative or policy measures, *as appropriate*, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and *where feasible* in such Contracting Parties. Article 19(2) requires each Contracting Party to take all *practicable* measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting

Parties. Such access shall be on mutually agreed terms. Again, to make these provisions effective, the source country would have to use its bargaining power when it decides whether or not to grant access to genetic resources.

It is difficult to see how legal conflicts could arise between the CBD, on the one hand, and the TRIPS Agreement or UPOV Convention, on the other hand, with respect to biotechnology. The CBD contains no meaningfully binding legal obligations regarding protection of traditional knowledge or sharing of the benefits of biotechnology that is subject to intellectual property rights, with the notable exception of cases in which the biotechnology in question was developed using the genetic resources of a particular source country. Even those obligations are subject to compliance with the TRIPS Agreement or UPOV Convention, as the case may be, and subject to the source country using its bargaining power regarding access to the genetic resources. Unless the source country uses this bargaining power to negotiate later access to any technology that may be developed as a result of access to the genetic resource, its access will be subject to the intellectual property rights. There is no obligation in the CBD to make the granting of intellectual property rights subject to proving prior informed consent of countries that are the source of genetic material. Even if there were such an obligation, it would only benefit the source countries. Thus, while the CBD preamble speaks of awareness “that conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technologies are essential”, it does not provide legally binding obligations to achieve these goals.

The provisions of the CBD could be relevant to determining compliance with TRIPS Article 27.2. TRIPS Article 27.2 provides a right to exclude from patentability, not an obligation to do so. Lack of informed consent or other inconsistencies with the CBD, particularly with respect to use of traditional knowledge, might justify exclusion from patentability on public policy grounds, particularly in developing countries. However, such an approach could be undermined by the use of terminator technologies or the refusal by multinational holders of intellectual property rights to introduce technologies into countries that exclude biotechnology from patentability.

The effect of climate change on TRIPS, UPOV and CBD

The right of WTO Members to choose between patents, the UPOV Convention or some other form of *sui generis* intellectual property protection for new plant varieties provides the flexibility that is necessary to adapt policies as climate change alters the environment. For this reason, it is preferable to a more harmonized approach that would seek to confer stronger IPRs for plant varieties.¹⁰⁵ Indeed, the more flexible or vague a provision is, the more its interpretation can take into account changing circumstances. Climate change is a moving target. Provisions such as TRIPS Article 27.3(b) have an important role to play in ensuring that WTO Members can confront the challenges posed by climate change. It is therefore important to interpret such provisions flexibly. While this approach leads to more ambiguity and less predictability than many would like, the shifting circumstances of both global food security and global environmental concerns require a flexible

¹⁰⁵ For a contrary view, see Clemens Kerle, International IP Protection for GMO -- a Biotech Odyssey, 8 Colum. Sci. & Tech. L. Rev. 147 (2007).

approach to policy making. Moreover, the inherent flexibility in Article 27.3(b) facilitates avoiding conflicts between TRIPS obligations and the obligations contained in other treaties, such as the UPOV Convention and the CBD. The flexibility of Article 27.3(b) facilitates an evolutionary approach to its interpretation that can take into account changing environmental conditions and changing technologies. Existing WTO jurisprudence supports such an evolutionary approach to interpretation.¹⁰⁶

Conclusion

Climate change, technological change, and economic change are converging to make current intellectual property laws, and current debates regarding IPRs and access to technology, obsolete. In this environment, making the right policy choices is increasingly difficult.

The role of current international agreements on IPRs in spurring technological innovation is now in question, for two principal reasons. First, the necessity of IPRs to stimulate investment in innovation has come into question in the economic literature. In this regard, it is doubtful that IPRs are as important for innovation as many suggest. Indeed, faulty IPR regimes may stifle innovation by limiting competition. Even if one accepts that IPRs are necessary to create economic incentives for innovation, those incentives depend on purchasing power that does not exist in many developing country markets.

Second, technological advances are altering the effect of IPRs in practice, particularly in the field of biotechnology. Technological advances in biotechnology are eroding the ability of IPRs to create barriers to entry and barriers to access in two ways. First, technological advances in developing countries heighten the potential effectiveness of compulsory licensing as a policy option under TRIPS and the UPOV Convention, by increasing their scientific capacity to reverse engineer new plant varieties. The Convention on Biological Diversity are difficult to enforce in practice to restrict access to genetic resources in developing countries, but could prove useful as an additional basis for denying patentability of certain biotechnologies or justifying recourse to compulsory licensing. Second, technological advances, notably the speed with which genetically modified plant varieties can be reverse engineered, shorten the de facto term of protection of right holders with respect to the breeder's exemption in the UPOV Convention. As a result, public investments in scientific and technological capacity in developing countries provide an important means to increase access to biotechnology. Therefore, developing countries should resist proposals to extend the monopoly of breeders by introducing a phased in delay of the breeder's exemption.

Several developing countries currently invest significant sums in subsidies for fossil fuels. They would be wise to redirecting these funds to develop scientific and technological capacity in innovations in biotechnology and other climate change mitigation and adaptation technologies. However, such strategies run the risk of violating

¹⁰⁶ See Reports of the Appellate Body in *US – Shrimp* (taking into account international environmental agreements and emerging views of environmental protection) and *China – Audiovisual products* (applying provisions to technologies that developed after the provisions were drafted). Regarding evolutionary interpretation more generally, see Bradley J. Condon, *Environmental Sovereignty and the WTO: Trade Sanctions and International Law* (2006).

WTO obligations in the Agreement on Subsidies and Countervailing Measures. Therefore, developing countries should seek to design such programs to comply with this agreement and also push for the reintroduction of environmental exceptions in the same agreement.

There are some important implications for global economic governance and for policy choices in multilateral forums such as the WTO. The impasse in the negotiation of the WTO Doha Round may prove to be a mixed blessing. While it would be helpful to advance the negotiations with respect to environmental goods, services and subsidies, a one-size-fits-all approach to IPRs for biotechnology is inappropriate. As it now stands, TRIPS Article 27.3(b) allows WTO Members considerable flexibility with respect to the IPR regime they chose for new plant varieties. A harmonized approach to IPRs for new plant varieties would restrict the policy options available to countries and hamper the ability of governments to design regimes that meet their individual requirements. Thus, the impasse in the negotiations under Article 27.3(b) may prove to be a good thing. Indeed, the impasse itself may be a sign that reducing existing flexibilities through the adoption of a new multilateral regime is not the best course of action.