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INTERNATIONAL IP PROTECTION FOR GMO – A BIOTECH ODYSSEY

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This paper deals with IP protection for genetically modified organisms (GMOs) under the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs). It outlines the potential of GMOs and shows why effective patent protection is a necessary prerequisite for research in this area. It argues that the TRIPs minimum requirements do not mandate sufficient standards for GMO patents – they do not require patent protection for most biotechnological inventions.

Subsequently, it explores the consequences of this lack of harmonization. Employing salient arguments for and against IP-harmonization, it demonstrates that harmonized effective patent protection for GMOs confers significant advantages on the participating countries, but hardly any disadvantages. Moreover, it indicates that effective IPRs mitigate the more widespread use of Genetic Use Restriction Technology(ies) (GURTs). It concludes with showing why *multilateral* harmonization is necessary and why developing countries are deterred from unilaterally raising the standard of IP protection for GMOs.

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LIST OF ABBREVIATIONS

DNA	Deoxyribonucleic Acid
EPO	European Patent Office
FDI	Foreign Direct Investment
GATT	General Agreement on Tariffs and Trade
GM	Genetically Modified
GMO(s)	Genetically Modified Organism(s)
GURT(s)	Genetic Use Restriction Technology(ies)
IP	Intellectual Property
IPR	Intellectual Property Right(s)
PBR(s)	Plant Breeders' Right(s)
R & D	Research and Development
TRIPs	Agreement on Trade-related Aspects of Intellectual Property Rights
UPOV	International Convention for the Protection of New Varieties of Plants
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

BIOTECH ODYSSEY: A LONG WANDERING AND EVENTFUL JOURNEY[1]

The promises and risks of biotechnology, the harmonization of IPRs (Intellectual Property Rights), the ever-explosive relationship between rich and poor, and the developed "North" and the developing "South"[2] are among the issues touched upon by controversial IP protection for GMOs (Genetically Modified Organisms).

The Agreement on Trade-related Aspects of Intellectual Property Rights[3] appears to have become the epicentre of this GMOs' IP protection controversy, which is rich and heterogeneous in quality and content, with such a confusing mixture of myth, fiction, and reality that its developments can be best described as an "odyssey". Following the enactment of TRIPs, after years of negotiations, the "long wandering" appeared to have come to an end. However,

> "while . . . Article [27 of TRIPs] settled the longstanding conflicts over pharmaceutical product patents, [it] has created new complications regarding protection for biological matter and agricultural biotechnology in particular."[4]

Thus, the journey might not be over yet. Numerous scholars have addressed the complications that TRIPs, and specifically Article 27, has created, underlining the importance of the questions that this agreement raises and, arguably, leaves unanswered.[5]

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[1] *See* Answers.com, http://www.answers.com/topic/odyssey-1 (last visited Apr. 20, 2007).

[2] This distinction is simplified, but is nonetheless relevant in this paper as "a stylization of asymmetric innovative capacities." *See* S. Scotchmer, *The Political Economy of Intellectual Property Treaties* at 4 (Nat'l Bureau of Econ. Res., Working Paper No. W9114, 2002). *See also* Ana M. Pacón, *Implications of the TRIPs Agreement in the Field of Patent Law*, in *From GATT to TRIPS* 329, 333 (Friedrich-Karl Beier & Gerhard Schricker eds., 1996) for a critical view of the North/South concept.

[3] Agreement on Trade-related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakech Agreement Establishing the World Trade Organization, Annex 1 C, Legal Instruments-Results of the Uruguay Round, 1869 U.N.T.S. 299 [hereinafter TRIPS].

[4] *See* E. Binenbaum et al., *South-North Trade, Intellectual Property Jurisdictions and Freedom to Operate in Agricultural Research on Staple Crops*, at 21 (Env't & Prod. Research Div., Int'l Food Policy Research Inst. Discussion Paper No. 70, 2003), http://www.ifpri.org/divs/eptd/dp/papers/eptdp70.pdf.

[5] Concerns that TRIPS and harmonized IP standards might be detrimental for some (developing) countries are frequently expressed. Beyond the significance of this debate for these countries, the controversies around IPRs for biotechnology have been identified as crucial for the future of TRIPS itself. *See* Frederick M. Abbott, *The Enduring Enigma of TRIPs - A Challenge for the World Economic System*, 1998 J. Intl. Econ. L. 497, 514-15 (1998).

This paper focuses on an essential part of the odyssey – IP protection for GMOs mandated by TRIPS – and aims to provide an alternate view of welfare and development implications resulting from IPR harmonization in this field. I will argue that TRIPs, and Article 27 in particular, leave too much flexibility for the WTO member states in that respect; I will show that this flexibility results in suboptimal IP standards for GMOs, particularly in developing countries.

The following threefold structure will be used to prove this argument: First, I will define the term GMO, indicate the economic and scientific potential of genetic engineering, and outline relevant factors that influence biotechnological research. Assuming that continuing such private research and development (R&D) is desirable, I will demonstrate why patent protection appears to be essential from a utilitarian viewpoint. Second, I will show that the built-in flexibility in TRIPs permits the reduction of GMOs eligible for IP protection to an extent where most would fall outside the mandated minimum requirements for inventions. I will conclude that in fact no harmonization has been achieved in this field. Third, I will analyze the consequences of such a lack of harmonization. While the overall effects of IP harmonization on the global economy may be ambiguous, I will distinguish the creation of new GMOs from other innovative areas of economic activity and argue that harmonized effective patent protection is to be regarded as crucial for sufficient private investment in R&D in this area. I will show that multilateral harmonization is necessary because developing countries are deterred from unilaterally raising the standard of IP protection for GMOs. In conclusion, I will describe how this odyssey can have a happy ending.

1. THE PROMISES OF EMBARKING ON THE ODYSSEY – THE RATIONALE OF GMO PROTECTION

1.1. *GMOs and their potential*

GMOs are biological entities created or altered to serve a certain purpose. According to one definition, a GMO is "an organism whose genome has been altered by techniques of genetic engineering so that its DNA contains one or more genes not normally found there."[6] Genetic engineering enables scientists to transfer certain biological characteristics across species; its potential is not confined to the exchange of genes between organisms that would be capable of sexual reproduction with each other. The possibility of moving genes (and consequently, their phenotypic expression) from one species to the other might permit scientists to create "tailor-made" organisms, perfectly apt for whatever purposes they are designed. Among other things, GMOs could potentially greatly contribute to developing countries' economies even though their benefits have so far been mainly confined to the developed world.[7]

First, the creation of crops designed for specific environments such as arid lands[8] and having enhanced nutritional value (e.g., vitamin A-rich golden rice)[9] that will produce higher yields or reduce the amount of pesticides, fungicides and herbicides required to control insects and plant pests seems achievable. In this way, biotechnology can contribute to increased food security and help fight hunger and poverty.[10] Second,

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[6] Edward Wheeler, *Genetically Modified Organisms: Salvation of Humanity or Monsters in the Closet?*, Ecoworld, Dec. 15, 2004, http://www.ecoworld.com/home/articles2.cfm?tid=362.

[7] *See* Fink & Braga, *Technology Transfer in Agricultural Biotechnology: The Developing Countries Perspective*, in *Intellectual Property: Trade, Competition, and Sustainable Development*, at 406 (Cottier & Mavroidis, eds., 2002). Although China, South Africa and Argentina can be regarded as exceptions, it seems that the GMOs grown there were originally developed for the U.S. market. *See also* E. J. DaSilva, E. Baydoun & A. Badran, *Biotechnology and the Developing World*, 5 Electronic J. of Biotechnology 66 (2002), http://www.ejbiotechnology.info/ content/vol5/issue1/full/1/1.pdf.

[8] *See* Da Silva et al., *supra* note 7.

[9] *See* Binenbaum et al., *supra* note 4, at 26; *see also* G. Tansey, *Food Security, Biotechnology and Intellectual Property*, at 5 (2002).

[10] *See* R. Taylor & J. Cayford, *American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change*, 17 Harv. J.L. & Tech. 321, 329; *see also* Cottier, *The Protection of Genetic Resources and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law*, in *The International Intellectual Property System: Commentary and Material*, at 1823 (Abbott, Cottier & Gurry eds., 1999). *See* Tansey, *supra* note 9, at 3 (outlining a critical view of the role of biotechnology).

scientists envisage projects such as "vaccination through nutrition,"[11] which points out a diabetes vaccine contained in tobacco plants. Third, the development and production of drugs for (orphan) diseases might be facilitated through the use of biotechnological means, particularly trough transgenic organisms producing pharmaceuticals – a process often referred to as "bio-pharming."[12] The potential of transgenic animals is similarly breathtaking, even though the "blue revolution" has just begun.[13] In short, GMOs are capable of positively influencing many areas, even those not intuitively related to biology, and might help to overcome some of the problems the developing world is facing.

However, although the "first wave"[14] of GMOs may already consist of "tailor-made" organisms to some extent, they are almost exclusively created to grow in temperate climate zones. As Gaisford notes, "the potential benefits of biotechnology have not [yet] reached countries with subtropical and tropical climate."[15] Evidently, there seems to be very little private R&D spending for these regions.[16] It seems clear that the scarcity of privately funded research is caused by many factors: smaller local R&D capacities and markets, regulatory obstacles, consumer fears,[17] and political considerations.[18] The list is obviously not exhaustive, and many other factors might have an influence on this regrettable situation. One might suspect, however, that the

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[11] *See* Da Silva et al., *supra* note 7, at 66.

[12] *See Bio-Pharming*, Transgenic Crops, http://cls.casa.colostate.edu/TransgenicCrops/hotbiopharm.html (last visited Apr. 20, 2007).

[13] *See* Carol Lewis, *A New Kind of Fish Story: The Coming of Biotech Animals*, *2001 FDA Consumer Magazine*, Jan.-Feb. (2001), http://www.fda.gov/fdac/features/2001/101_fish.html.

[14] *See* J.D. Gaisford, *Agricultural Biotechnology and the FTAA: Issues and Opportunities*, 3 Estey Centre Journal of International Law and Trade Policy 328, 331 (2002); Comm'n on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, at 64 (2002), http://www.iprcommission.org/papers/text/final_report/reporthtmfinal.htm [hereinafter CIPR Report].

[15] Gaisford, *supra* note 14, at 331.

[16] *See* Abbott, *supra* note 5, at 501 (highlighting the need for more private investment). Needless to say, public spending on R&D is equally important. *See* Tansey, *supra* note 9, at 14.

[17] *See* Fink & Braga, *supra* note 7, at 406.

[18] On October 12, 2002, for example, the Zambian president rejected donated GM corn, offered by the World Food Program, for his starving people, on the grounds that it would be "poisoned food." Whether such action can be justified in the event of a famine, is questionable; certainly, however, such events have a strong impact on the future development of GM food. *See* J. Ziegler, *Das Imperium der Schande – Der Kampf gegen Armut und Unterdrückung*, at 240 (2005).

comparatively weak IP system in the "South" also plays a significant role.[19] Referring to a common critique of "northern" IP systems, the (UK) Commission on IPR "considers that, if anything, the costs of getting the IP system 'wrong' in a developing country are likely to be far higher than in developed countries."[20] This statement seems intuitively right – perhaps developing economies are more vulnerable to wrong policy choices. But in light of the sluggish (biotechnological) progress in these regions and, or perhaps *in spite of*, weak IPRs, it is also tempting to ask how much worse it could get *with* stronger IPRs.

1.2. *Destination: effective protection*

IP protects the results of intellectual efforts in a variety of forms – books, widgets, databases, CDs and even biological material, through the possibility of excluding others from their use. Over time, societies have developed many different kinds and shapes of these rights – copyrights, patents, plant breeders' rights (PBRs), industrial designs, various *sui generis* rights, as well as trademarks and trade secrets. As far as the former types of IPR are concerned, the most commonly accepted rationale for their existence is that they induce innovation and provide incentives for disclosure and dissemination of new knowledge through granting limited monopolies.[21]

While this underlying basic mechanism is commonly accepted, the ideal scope and duration of these rights is practically impossible to determine, and therefore remains controversial. Kitch, however, has legitimately pointed out that "whether or not [patent law] works in practice is a matter of experience, not theory."[22] Reality seems to prove that the current system does work.

Organisms, as well as their parts, have only become eligible, as a practical matter, for IP protection in recent decades.[23] The first regimes aimed to protect the results of

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[19] *See* T. Cottier, *The Prospects of Intellectual Property in GATT*, in *The International Intellectual Property System: Commentary and Material*, at 690 (Abbott, Cottier & Gurry eds., 1999). *See also* Abbott, *supra* note 5, at 503. Obviously IP can only be regarded as one factor that hinders substantial innovation in developing countries.

[20] *See* CIPR Report, *supra* note 14, at 4. The UK Secretary of State for International Development established the Commission on Intellectual Property Rights in May 2001.

[21] *See, e.g.*, François Lévêque & Yann Ménière, *The Economics of Patents and Copyright*, at 4 (Berkeley Electronic Press 2004), http://www.bepress.com/leveque/.

[22] Edmund W. Kitch, *Comment on the Tragedy of the Anticommons in Biomedical Research*, in *Perspectives on Properties of the Human Genome Project*, at 271, 271-73 (F. Scott Kieff ed., 2003).

[23] These legal systems mainly exist in the developed world. *See* Geertrui Van Overwalle, *Patent Protection for Plants: A Comparison of American and European Approaches*, 39 IDEA 143 (1999). The first IPRs for living things were already granted in the nineteenth century, but

traditional plant breeding, but with the rise of modern biotechnology, these systems became insufficient and, in many legal systems, a variety of IPRs are now available for the result of modern biotechnological research.[24] This seems only logical – like other products of intellectual effort, biological inventions are also (largely) non-excludable. Therefore, in the absence of protection, free "copying" and using could not be prevented, and recouping R&D investments would be impossible. Thus, the economic justification for the existence of IPRs in general is equally valid for bio-IPRs, because due to their nature, organisms (and their parts) can be reproduced practically without cost and indefinitely by almost anybody.

As a response to recent technological progress, and the need for private R&D in this field, biological material has become generally *patentable* in many jurisdictions.[25] But that in itself may not suffice, because the protection that is actually available is quite diverse in different legal orders – for several reasons:

First and foremost, large differences exist as to what kind of biological material can qualify for protection. Theoretically, as far as GMOs are concerned, the following processes and products might be encompassed by principally patentable subject matter: the transgenic organism itself, a cell containing the altered DNA, the isolated and purified gene or gene sequence that is later inserted into the alien DNA, the respective processes, and the respective products by these processes.[26] Other relevant biotechnological patents could include vectors and plasmids; more generally, patents might be awarded for essential biotechnological techniques such as the famous "Cohen-Boyer" patent, which, based on the first successful expression of recombinant proteins, covers one of the most fundamental building blocks of genetic engineering.[27]

Secondly, and although there is a fairly broad consensus within the academic

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their number and significance remained small for a long time. From 1930 onward, plant innovations have been specifically addressed by laws such as the U.S. Plant Patent Act. *See* Li Westerlund, *Biotech Patents: Equivalency and Exclusions under European and U.S. Patent Law*, at 1 (2002). *See also* Brian D. Wright & Philip G. Pardey, *The Evolving Rights to Intellectual Property Protection in The Agricultural Biosciences*, 2 Int'l J. Tech. & Globalisation 12, 3-4 (2006).

[24] This is not to say that other IPRs are irrelevant for biotechnological research. See Donald D. Evenson, *Patent and other Private Legal Rights for Biotechnology Inventions (Intellectual Property Rights – IPR)*, in *Agriculture and Intellectual Property Rights*, at 11, 11 (Vittorio Santaniello et al. eds., 2000) for an overview. *See also* V.C. Bennett, *Plant Biotechnology*, in *The Law and Strategy of Biotechnology Patents*, at 171, 171 (Kenneth D. Sibley ed., 1994).

[25] *See* Cottier, *supra* note 10, at 1821 (describing how legal systems have responded in the past to the allocation of new resources).

[26] *See* Carlos M. Correa, *Intellectual Property Rights, The WTO and Developing Countries*, at 179 (2000).

[27] *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 Colum. L. Rev. 839, 906 (1990), for a discussion of the Cohen-Boyer work.

community that granting biotech patents is in principle an advantageous policy choice,[28] a different issue arises as to how far the patent protection extends and what constitutes infringement. The impact of patents on an economy depends to a large extent on their shape, defined mainly by their duration and scope. The former seems to be a "settled issue,"[29] while the latter, largely within the discretion of the granting authority, is delineated by the claims of a patent, where the applicant specifies the limitations of the legal monopoly for which he is applying.

It is important to note that drafting patent claims is a complex task. The broader the monopoly sought, the greater the risk of invalidity but the higher the potential reward.[30] As more competing activity can be legally prevented, more profits can be potentially made.[31] The significance of a patent scope for a biological invention can be illustrated with an example: If a gene that leads to increased herbicide resistance is protected by a patent, the crucial question to answer is whether or not unauthorized propagation of a plant containing this gene infringes the exclusive right of the owner. Should this be answered in the negative, the patent can effectively only prevent further research on this particular gene; otherwise, it might be used by a seed company to effectively control the marketing of its product or even catch cases of "pollen drift."[32]

It follows from the above that the concept of "biotech patents" can in principle embrace a large variety of different kinds of patents with very broad or rather narrow scopes, protecting inventions with largely differing characteristics at quite different stages of (bio)technological development. This is also to say that "biotech patents" can be obtained for results of upstream as well as downstream research,[33] which adds further

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[28] Even the most prominent critics focus on the shape rather than the basic economic justification and rationale of granting biotech patents. *See, e.g.*, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698 (1998); Merges & Nelson, *supra* note 27; Adam B. Jaffe & Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System Is Endangering Innovation and Progress, and What To Do About It*, at 48 (2004). See OECD, *Overview of Recent Changes and Comparison of Patent Regimes in the United States, Japan and Europe*, at 10-13 (2004), http://www.ige.ch/E/jurinfo/documents/j110404e.pdf, for an overview of problematic developments. *See also* The Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science*, at 17 (2003), http://www.royalsoc.ac.uk/displaypagedoc.asp?id=11403.

[29] David Vaver, *Intellectual Property Law: Copyrights, Patents, Trademarks*, at 1 (1997).

[30] *Id*. at 139.

[31] *See* Merges & Nelson, *supra* note 27, at 906.

[32] Neil D. Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*, 6 Drake J. Agric. L. 81, 103 (2001).

[33] The upstream/downstream dichotomy roughly distinguishes between research results depending on marketability. Downstream research aims at results that can be directly used in a marketable product (e.g., GM corn), whereas upstream or pre-market research generally strives to

complexity to the highly intricate task of assessing the economic impacts of biotech patents. Therefore, if the concept of biopatents in general is analysed, it is almost impossible to arrive at an unambiguous conclusion. However, if we focus on GMOs only, such a result can be obtained.

When it comes to biopatents in general, scholars seem particularly concerned about overly broad patents,[34] patent "thickets" impeding further innovation through largely increased transaction costs – the now famous "anti-commons" theory,[35] "bracketing,"[36] detrimentally low non-obviousness and utility standards[37] and blocking/increasing costs of ongoing innovation through the patenting of upstream "research tools."[38]

There are many responses to each issue. First and foremost, as mentioned above, empirical evidence weakens the persuasiveness of these arguments. The influence of all these allegedly problematic developments on biotechnological research cannot be that detrimental – after all, in no other country does related R&D flourish at a comparable level as the U.S.,[39] on which most scholarly critiques focused.[40] Second, the patent system probably needs some time to adapt itself to this new technology. For example, it seems that the U.S. Patent and Trademark Office (PTO) has partially reversed some of its allegedly most problematic practices, such as granting patents for expressed sequence tags without the disclosure of a specific use.[41] Third, it appears that most critics are concerned mainly about detrimental upstream patents. While those might, in addition to the ordinary incentive theory, serve a valuable "prospect function,"[42] upstream patents

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provide scientific foundations for further upstream or downstream research (e.g., the polymerase chain reaction technology). The accessibility of upstream research results is often a prerequisite for ongoing innovation. *Cf.* Heller & Eisenberg, *supra* note 28, at 698.

[34] Merges & Nelson, *supra* note 27.

[35] Heller & Eisenberg, *supra* note 28, at 698.

[36] Tansey, *supra* note 9, at 21.

[37] J. Barton, *Non-obviousness*, 43 IDEA 475 (2003).

[38] Jaffe & Lerner, *supra* note 28, at 48.

[39] *Cf.* Kitch, *supra* note 22.

[40] *See* Tansey, *supra* note 9, at 18, for a particularly critical view.

[41] *See, e.g.*, CIPR Report, *supra* note 14, at 116.

[42] E. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & Econ. 265, 276-77 (1977) (positing that this prospect function enables firms to invest in a research project without worrying that somebody might appropriate their research); *see also* N. Gallini & S. Scotchmer, *Intellectual Property: When Is It the Best Incentive System?*, 2 Innovation Policy and the Economy 65 (2001) (arguing that even in the context of upstream patents, benefits outweigh the

are only of limited direct relevance for GMOs. Obviously it is impossible to draw a clear line between upstream and downstream research; clearly downstream products will never enter the market without the respective upstream research.

Despite these considerations, it must be emphasized that in most cases GMOs are marketed products themselves; therefore, it appears safe to say that a vast majority of useful GMOs will fall into the downstream product category. Thus, many of the concerns scholars have expressed with regard to biotech patenting do not seem to be applicable to GMOs, or perhaps only to a lesser extent.

For these reasons, an interim result can be noted: patenting GMOs is probably in principle not detrimental to continuing innovation. To the contrary, if private investment is regarded as desirable, awarding patents for such inventions must be considered as necessary.[43] This essay does not intend to provide detailed guidance on the exact shape of GMO patents. For the purposes of this paper, it suffices to hold that GMO patent protection must be effective, and must ensure that the recouping of sunken investments is possible. The minimum requirements for effective protection, and whether this interim conclusion is true for every economy in an international context, will be addressed in greater detail below.

The analysis so far has shown that patents are essential for private innovations in this field. However, two other ways of protecting GMOs exist, which are seemingly of enormous potential, particularly for the agricultural sector: through contract agreements or self policing techniques.

Parties can use contracts to establish IP-like protection, or to extend granted statutory rights.[44] However, like every other IP protection technique that has been described so far, "bag label," "seed wrap" licences and the like come with a significant disadvantage for the inventor: enforcement of his rights is difficult and controversial.[45] Seed developers would have to send out employees to test crops of non-customers for protected characteristics[46] in order to detect infringers and collect evidence. This might be a very labor-intensive task due to the high degree of similarity between protected and unprotected types of plants.[47] Besides, contracts could obviously not bind those who had not, or who could not be deemed to have accepted their terms.

From the inventor's perspective, the solution might lie in "self-policing" technologies – means to prevent the reproduction of plants. Farmers growing certain

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costs).

[43] *But see* Wright & Pardey, *supra* note 23.

[44] Binenbaum et al., *supra* note 4, at 11.

[45] Hamilton, *supra* note 32, at 90.

[46] Dan L. Burk, *Lex Genetica: The Law and Ethics of Programming Biological Code*, 4 Ethics & Info. Tech. 109, 110 (2002).

[47] *Cf. Monsanto Can. Inc. v. Schmeiser*, [2004] S.C.R. 902, ¶ 63 (indicating how much effort such tests could require).

crops such as corn are already supplied with seeds that do not produce progeny with the same quality,[48] and are forced to purchase new seeds every year. Modern biotechnology has begun to offer even more effective means of controlling the use of GMOs: Genetic Use Restriction Technologies (GURTs).[49] These include the famous "terminator gene" – which makes plants containing the gene kill its seed by producing a toxin, thus effectively sterilizing the organism. This appears to be only the first step.[50] More sophisticated methods already appear on the horizon:

> In one embodiment of the technology, it is possible to introduce into the seed a genetic 'switch' that will express, or turn off, the toxin production when the seed is exposed to a particular chemical. This in effect supplies a chemical 'password' to seed activate germination, and which can be used to control the terms of seed usage from year to year. Yearly application of the control chemical, obtained from the seed owner for payment, would allow the owner to activate or deactivate seeds in return for prescribed payment. One can easily envision other types of switches, sensitive to temperature, precipitation, soil alkalinity, or other environmental factors, that could be used to limit use of the seed to certain geographical regions or seasonal applications.[51]

Such prophecies for the agriculture of tomorrow have led to public outcry in some regions[52] and will confront legal systems with various complex issues. These technological control mechanisms potentially provide the inventor with more control than any legal means could ever do.

While any IP law grants a more or less limited monopoly for a definite period, which is often combined with exceptions (e.g., fair use, research exception, farmer's privilege) and is inherently incomplete, technological protection could, in principle, be infinite and absolute. It remains to be seen how legislators and courts respond to more widespread use of such technologies.[53]

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[48] Hamilton, *supra* note 32, at 107.

[49] Geoff Tansey, *Trade, Intellectual Property, Food and Biodiversity*, at 4 (1999); Binenbaum et al., *supra* note 4, at 12.

[50] Colo. State Univ. Dep't of Soil & Crop Sci., *Transgenic Crops: An Introduction and Research Guide: Terminator Technology*, http://cls.casa.colostate.edu/TransgenicCrops/terminator.html (last visited Apr. 20, 2007); *see also*, Martha L. Crouch, *How the Terminator Terminates* (1998), http://www.biotech-info.net/howto.html.

[51] Burk, *supra* note 46, at 110.

[52] Hamilton, *supra* note 32, at 108.

[53] *Id*.; *see also* Burk, *supra* note 46, at 112; Derek Eaton et al., *Economic and Policy Aspects of "Terminator" Technology*, 49 Biotechnology & Dev. Monitor 19 (2002), http://www.biotech-

GURTs can certainly overcome the imitation problem that the inventor faces. But contrary to patents, they are not limited rights granted by the public in exchange for something novel, non-obvious and useful. Therefore, whether a GMO enjoys technological protection or not, and more importantly, for how long, is largely within the discretion of the seed companies that can use such technologies.[54] That means that firms could potentially acquire market power for products that would otherwise not be protected. Even if this was improbable due to the availability of close substitutes, which would be likely in such a case, GURTs could artificially extend the IP protection beyond its statutory length.

The existence of GURTs could induce more research into new GMOs, which could be subsequently protected by these means. In this way, a prediction as to their effects might resemble the patent incentive theory. However, one of patent law's crucial features, which is of great benefit for the public, is the disclosure requirement. If GURTs became sufficiently effective and subsequently replaced patents, the public would be deprived of this benefit.

Obviously, widespread use of GURTs might also have implications for agronomic development[55] – research and further improvement of the plant containing a terminator gene, not being able to be propagated any longer, would most probably be impossible or more difficult. Basically, innovation that builds on previous results would be largely impeded.

Furthermore, a study[56] on the welfare implications of different levels of appropriability[57] in the seed industry leads to the conclusion "that the optimum level of IPR appropriability is greater than that which existed in the North American seed corn market in 1996 and 1997, but that it is lower than would exist if GURTs were to become

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monitor.nl/4907.htm (outright "terminator bans" might be legally complicated).

[54] Of course, as with digital rights management, absent laws preventing them, the length of such a monopoly could also be shortened by those seeking to disable or circumvent the protection. However, it seems currently impossible to determine the likelihood of these scenarios. *Cf.* S. Dussolier, *Electrifying the Fence: The Legal Protection of Technological Measures for Protecting Copyrights*, 6 Eur. Intell. Prop. Rev. 285, 285 (1999); J. H. Reichman & Jonathan A. Franklin, *Privately Legislated Intellectual Property Rights: Reconciling Freedom of Contract with Public Good Uses of Information*, 147 U. Pa. L. Rev. 875, 943 (1999); Digital Millennium Copyright Act, Pub. L. No. 105-304 (1998).

[55] Hamilton, *supra* note 32, at 107.

[56] Sergio H. Lence et al., *Welfare Impacts of Property Rights in the Seed Industry* (2002), http://www.econ.iastate.edu/workshops/ispw/Sergio-Dermot-seed-paper.pdf.

[57] *Id*. at 3 (stating that the appropriability parameter is determined by the strength of the relevant IPRs and the possibilities of enforcement and is defined as "the degree to which the developer of an improved farm input can appropriate the benefits associated with the innovation").

widely used."[58]

For these reasons, this chapter can be concluded as follows: While protection against GMO piracy through patents appears to be an advantageous policy choice, the level of beneficial protection can be exceeded. The above results indicate that self-policing means such as GURTs might have the potential to lead to such results. The implications of this finding for IP policy will be further addressed below.

2. THE END OF THE ODYSSEY? INTERNATIONAL IP PROTECTION FOR GMOS UNDER TRIPS

2.1. *History and background*

When a country protects the works of inventors with IPRs, but its trading partners do not, the inevitable result is trade distortion between the countries.[59] As the country with weaker standards begins to imitate foreign inventions, these replace the otherwise incoming imports of the IPR protected goods. Furthermore, the research and creativity inducing effect of a territorial IP regime might vanish when the respective market is confronted with large amounts of imported imitations.

To prevent such effects, erecting insurmountable trade barriers through IPR enforcement would be necessary. This is prima facie disadvantageous for all concerned countries due to a less efficient allocation of resources, stemming from fewer opportunities for cross-border trade in IPR-protected goods.[60] A more or less harmonized network of territorial IP regimes has been conceived as a solution to this problem for a long time. International agreements on this matter are almost as old as the national IPRs.[61] Responding to the "expanded forces of globalisation" and proliferation of "means for low-cost copying,"[62] TRIPs came into existence, which unquestionably took

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[58] *Id*. at 29.

[59] *See* N. Pires de Carvalho, *The TRIPS Regime of Patent Rights*, at 31 (2002); K. E. Maskus, *Intellectual Property Rights in the Global Economy*, at 110 (2000); *see also* J. Straus, *Implications of the TRIPs Agreement in the Field of Patent Law*, in *From GATT to TRIPS, The Agreement on Trade-Related Aspects of Intellectual Property Rights*, at 160, 162 (Friedrich-Karl Beier & Gerhard Schricker eds., 1996); J. H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. Int'l L. & Pol. 11, 14 (1996) (criticizing the possibility of free riding under non-harmonized IP regimes).

[60] Michael J. Trebilcock & Robert Howse, *The Regulation of International Trade*, at 2 (3rd ed. 2005) (demonstrating that trade liberalization is always a beneficial policy).

[61] *See, e.g.*, U. Anderfelt, *International Patent Legislation and Developing Countries* n.65 (1971); *see also* Daniel J. Gervais, *The Internationalization of Intellectual Property Law: New Challenges from the Very Old and the Very New*, 12 Fordham Intell. Prop. Media & Ent. L.J. 929 (2002).

[62] Keith E. Maskus, *The International Regulation of Intellectual Property*, at 12 (1997),

international harmonization one step further. As a part of the GATT/WTO framework, these obligations became subject to its dispute settlement and enforceability rules. It seems crucial to note that in the course of the negotiations that led to the creation of the WTO, consensus on the topic of international IP protection was eventually reached by concessions of the developed world in other fields: TRIPs was part of a "package," and contains "the price" that poor countries paid in exchange for more market access for the goods that they produced.[63] To some extent, this *quid pro quo* nature of the WTO "deal"[64] might explain the widespread belief that all aspects of TRIPs must be detrimental for developing countries.[65]

2.2. *IP Protection of GMOs under TRIPs*

Generally, there might be some truth in Correa's claim that "TRIPs basically universalizes standards of protection."[66] It is admitted, however, that "[t]he agreement leaves a certain room for manoeuvre at the national level,"[67] a view shared by many scholars.[68] In this section the issue of whether TRIPs obliges member states to adopt such universal standards for biotechnological inventions, and more specifically, GMOs, shall be explored.

Musu expresses a common opinion that "countries cannot deny patents for microbiological processes, and this amounts in practice to excluding a selective patentability for biotechnological innovations."[69] This opinion seems questionable, in particular for the biotechnological subcategory of GMOs. As we will see, the relevant

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http://siteresources.worldbank.org/INTRANETTRADE/Resources/maskus3.pdf.

[63] Carvalho, *supra* note 59, at 50; *see also* A. O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries and the Doha Solution*, 3 Chi. J. Int'l L. 47, at n.59 (2002); *see also* Straus, *supra* note 59, at 169, 180.

[64] Mark A. Groombridge, *The TRIPS Trade-Off – Reconciling Interests in the Millennium Round*, 6 J. World Intell. Prop. 991, 992 (1999).

[65] Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 Yale J. Int'l L. 1, at n.3 (2004); *see also* Groombridge, *supra* note 64, at 1009 (presenting other reasons why IP is conceived as inherently disadvantageous including the focus on pharmaceuticals).

[66] Correa, *supra* note 26, at 5.

[67] *Id*.

[68] *See, e.g.*, Reichman, *supra* note 59, at 14.

[69] Ignazio Musu, *Intellectual Property Rights and Biotechnology: How to Improve the Present Patent System*, at 7 (Fondazione Eni Enrico Mattei Research Paper No. 83.05, 2005), http://ssrn.com/abstract=744444.

provisions of TRIPs are arguably flexible to an extent that does not oblige member states to grant any effective GMO protection. The main provision for an assessment of the questionable patentability requirements for GMOs is Article 27. This provision comprises many undefined terms that leave wide margins for interpretation.[70] Some terms, such as "invention," the patentability requirements (new, non-obvious, useful)[71] as well as "micro-organism," "micro-biological process," "(essentially) non-biological process" and "plant varieties," outline the mandatory scope of patentable subject matter. Others, such as the public morality exception of Article 27.2, "plants," "animals" and "essentially biological processes," constitute optional exceptions to the subject matter covered by the first group of terms. If the mandatory inclusions are understood narrowly and the optional exemptions are interpreted broadly, the scope of patentable subject matter is rather confined.[72] This TRIPs compatible "minimum-protection for GMOs"-approach will be delineated below.

It must also be noted again that TRIPs in general is widely regarded as a fairly flexible instrument,[73] and the preamble itself establishes the need for "maximum flexibility" with regard to the implementation of the agreement in least developed countries.[74] However, so far the jurisprudence of the WTO bodies on TRIPs is rather strict,[75] indicating that members enjoy less "wiggle room" than expected. However, the discussion about the obligations with respect to biotechnology innovation, particularly under Article 27, appears to be somewhat different.

First, the flexible nature of this provision is the outcome of strong resistance of the developing world.[76] Article 27.3 contains a review requirement.[77] In the course of

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[70] *See* Tansey, *supra* note 49, at 7.

[71] TRIPS, *supra* note 3, at art. 27(1) (using the "European" criteria of "inventive step" and "capable of industrial application," which are deemed equivalent with "non-obvious" and "useful"). This paper uses the latter expressions.

[72] S. Bhatti, *Globalizing Economies of Knowledge: The Scope of Patentable Subject Matter under Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights Regarding Genetic Resources and Biotechnological Inventions* n.277 (2004) (unpublished manuscript, archived at Duke University).

[73] *See* J. H. Barton, *Issues Posed by a World Patent System*, 7 J. Int'l. Econ. L. 341, 343 (2004); *see also* Reichman, *supra* note 59, at 14.

[74] TRIPS, *supra* note 3; *see also* Taylor & Cayford, *supra* note 10, at 367.

[75] *See, e.g.*, Appellate Body Report, *Canada – Term of Patent Protection*, WT/DS170/AB/R (Sept. 18, 2000); *see also* Appellate Body Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997); Trebilcock & Howse, *supra* note 60, at 418-23 (criticizing the WTO jurisprudence in that respect).

[76] *See* Tansey, *supra* note 49, at 8.

[77] TRIPS, *supra* note 3, art. 27(3).

the ongoing review, members have expressed largely differing views[78] on the article's meaning, which shows the existence of considerable uncertainty. Second, other relevant international treaties containing rather cautious approaches to IPRs for biotechnological inventions have come into force.[79] Even though they probably do not directly affect the obligations under TRIPs, their influence on TRIPs interpretation is hardly deniable.[80] Third, the political circumstances[81] make it implausible that stringent standards will be forced upon members. In light of the ongoing controversies, remaining ethical and increasing consumer concerns around the globe,[82] a WTO panel would perhaps be receptive to pleas for flexibility. Therefore, it seems likely that the TRIPs compatible minimum standard will be close to the margins of interpretation.[83]

2.2.1. *The patentability requirements for entire (transgenic) organisms*

The analysis of the TRIPs' mandatory patent protection for GMOs begins with entire organisms for a simple reason: If protection for GMOs appears desirable, it would arguably be the most straightforward approach to allow the patenting of transgenic plants, animals and micro organisms. This would not only ensure the protection of most

[78] *See* Tansey, *supra* note 49, at 13; Council for Trade-Related Aspects of Intellectual Property Rights, *Note by the Secretariat: Review of the Provisions of Article 27(3)(B)*, IP/C/W/369/Rev.1 (Mar. 9, 2006); D. Matthews, *Globalising Intellectual Property Rights: The TRIPs Agreement*, at 109 (2002) (some countries even urge for the complete deletion of this article).

[79] *See* Tansey, *supra* note 49, at 14 (describing the Convention on Biological Diversity (CBD)); Tansey, *supra* note 9, at 12 (describing the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR)); *see also* Helfer, *supra* note 65 (arguing that these developments are the outcome of a "regime shifting" strategy of the third world).

[80] *See* Trebilcock & Howse, *supra* note 60, at 545-56; D. Brack & K. Gray, *Multilateral Environmental Agreements and the WTO*, at 22-23 (2003), http://www.chathamhouse.org.uk/pdf/research/sdp/MEAs%20and%20WTO.pdf.

[81] *See, e.g.*, Ch. R. McManis, *Patenting Genetic Products and Processes: A TRIPs Perspective*, in *Perspectives on Properties of the Human Genome Project*, at 93 (F. S. Kieff ed., 2003). The author, perhaps exaggerating, states that "the international political climate began to change in the wake of the clouds of tear gas that engulfed the aborted 1999 WTO Ministerial Conference in Seattle." *See also* J. H. Reichman & D. Lange, *Bargaining around the TRIPs Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions*, 9 Duke J. Comp. & Int'l L. 11, 12 (1998).

[82] S*ee* Hamilton, *supra* note 32, at 89-90. Such concerns seem to be particularly significant in countries such as India.

[83] *See* Reichman & Lange, *supra* note 81, at 23-24 (predicting that the "wiggle room" will be exploited).

downstream products,[84] but would also make possibly problematic interpretations concerning the scope of patents for (sub)cellular subject matter unnecessary. But TRIPs does not contain such obligations; it stipulates in Article 27.3(b):

> "Members may also exclude from patentability: . . .
> (b) plants and animals other than micro-organisms . . . . However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."[85]

This issue is prima facie fairly obvious: Plants and animals do not need to be protected, whereas micro-organisms must be eligible for patents, and patents, *sui generis* rights or a combination of these rights must be provided for plant varieties. Many of the controversies about Article 27.3(b) concern the mandatory protection for plant varieties,[86] which is largely irrelevant for GMOs.[87]

Because (transgenic) plants and animals do not have to be patentable themselves, the span of the word "micro-organism" becomes crucial. Some of the most heated debates relating to TRIPS have focused on this issue. In the absence of a clear definition, numerous opinions have been expressed as to the correct interpretation of this word, which vary substantially.[88] Simply put, it is unclear where plants and animals end and micro-organisms begin. Ultimately, the essential question is whether "micro-organisms" also embraces parts of organisms, specifically (sub)cellular elements (e.g., cells and

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[84] *See* McManis, *supra* note 83 (criticizing TRIPs for requiring the patentability of upstream research (microbiological) based on the assumption that most macrobiological inventions would be downstream products).

[85] TRIPS, *supra* note 3, art. 27(3)(b).

[86] *See, e.g.*, Biswajit Dhar, *Sui Generis Systems for Plant Variety Protection – Options Under TRIPs* (2002), http://www.quno.org/geneva/pdf/economic/Discussion/Sui-Generis-Systems-for-Plant-Variety-Protection-English.pdf; *see also* Silvia Salazar, *The World of Biotechnology Patents*, in *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*, at 117 (Christophe Bellmann, Graham Dutfield & Ricardo Melédendez-Ortiz eds., Earthscan Publications, 2003); Marion Motari, *Agricultural Biotechnology and the Millennium Development Goals: Revisiting the Role of Intellectual Property Rights*, http://www.atdforum.org/IMG/pdf/IPRMDGPDF.pdf (last visited Apr. 20, 2007); Carlos Correa, *The TRIPs Agreement: A Guide for the South* (1997).

[87] This is due to the fact that transgenic plants are not per se "varieties;" in fact, very few GM inventions will qualify for PBRs. *See* Reichman, *supra* note 59, at 37; *see also* Westerlund, *supra* note 23, at 259; *but see* Nathan A. Busch, *Jack and the Beanstalk: Property Rights in Genetically Modified Plants*, 3 Minn. Intell. Prop. Rev. 1, 81 (2002).

[88] *See* Mike Adcock & Margaret Llewelyn, *Micro-organisms, Definitions and Options Under TRIPs* (Quaker UN Off. – Geneva and the Int'l Centre for Trade and Sustainable Dev., Occasional Paper No. 2, 2000), http://www.quno.org/geneva/pdf/economic/Occassional/Adcock-Llewelyn.pdf; *see also* Correa, *supra* note 26, at 68.

genes). This shall be addressed in detail below.

At the largely uncontroversial core of the textual scope of this term are entire, (living) organisms, which are not normally perceptible by the eye, including the following classes: bacteria, fungi, algae, protozoa (and viruses);[89] for these organisms, patentability is clearly obligatory, if they meet the "classic" criteria discussed below. In principle, transgenic micro-organisms should therefore be able to qualify for patent protection. While the significance of this obligation for certain industries such as the pharmaceutical sector must not be underestimated,[90] it has to be emphasized that a large number of GMOs – almost all transgenic plants and all animals – do not enjoy (direct) protection under TRIPs.

2.2.2. *The patentability requirements for (sub)cellular subject matter*

"Higher life forms aside, not many biotechnological inventions have been left out of mandatory patentability."[91] As far as biotechnological *products* are concerned, this claim assumes that "micro-organisms" covers (sub)cellular subject matter in principle and that such inventions regularly meet the patentability criteria of Article 27.1 of TRIPs. It appears that both assumptions can be challenged.

As to the meaning of micro-organisms in Article 27.3(b), it is argued in essence that the inclusion of entire micro-organisms must necessarily encompass "smaller" things, such as cells (and even)[92] genes. The European Patent Office guidelines, for example, specify that cells must enjoy the same legal treatment as entire micro-organisms, because they could also be propagated in a laboratory.[93]

Both arguments do not offer an explanation as to why the size or the propagation characteristics should be of legal relevance. It is difficult to comprehend why the patentability of bacteria should necessarily result in patentability for plant cells due to their comparatively smaller physical size. These arguments also omit (and possibly fail to consider) the economic and scientific importance of such a broad interpretation. When TRIPs was negotiated, the biotechnological revolution had already begun. It seems improbable that such a crucial matter would have been overlooked by the negotiators, and

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[89] *See* UNCTAD-ICTSD, *Resource Book on TRIPs and Development*, at 392 (2005), http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm [hereinafter Resource Book]; Correa, *supra* note 26, at 68.

[90] *See* Adcock & Llewelyn, *supra* note 88.

[91] *See* Carvalho, s*upra* note 59, at 177.

[92] *See* Joseph Straus, *Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions*, 9 Duke J. Comp. & Int'l L. 91, 101-02 (1998).

[93] Eur. Patent Off. Guidelines, part C chapter IV, 3.5, http://www.european-patent-office.org/legal/gui_lines/e/index.htm.

that (sub)cellular subject matter would not have been explicitly included. In fact, a former draft required the patentability of "parts of micro-organisms;"[94] that this wording was omitted in the final version of the TRIPs agreement speaks in favor of a narrow understanding of this term.

Furthermore, advocates of a narrower interpretation point out that it would be illogical to exclude plants and animals from mandatory patentability, and require patent protection of its parts (or genes) at the same time, as this would allow patent applicants to circumvent the exclusion of plants from patentability by claiming all cells (or genes) of a plant instead.[95] This issue will be discussed further below. However, this does not seem to be a necessary consequence.

Moreover, according to McManis, a narrow understanding of "micro-organism" would in practice amount to "a flat ban . . . of precisely the sort explicitly prohibited by Article 27.1."[96] Indeed, if neither (sub)cellular elements nor transgenic higher life forms can be patented, very little biotechnological innovation is left that is eligible for patent protection. However, much depends on the definition of "the field of technology." If understood sufficiently broadly, biotechnology consists of much more than the isolation and altering of genes. In any event, patents for transgenic "micro-organisms" would still have to be granted. Thus, whether the exclusion of (sub)cellular matter really is a prohibited discrimination of an entire field of technology remains questionable.

Another argument in favour of a broad interpretation of "micro-organism" claims that a narrow understanding would infringe Article 70.8 of TRIPs – the "mailbox provision."[97] This article obliges member states to grant "exclusive market rights" (Article 70.9) resembling patent protection for agricultural and pharmaceutical chemical products. It is submitted that some sub(cellular) substances fall under this category, and not protecting them would violate the respective article.

However, whether such a wide interpretation of the term "chemical" is really permissible, appears highly questionable; the analysis so far has shown that TRIPs was probably not intended to create mandatory protection for cells, genes, DNA and the like. It would be a rather odd result of legal interpretation if the "mailbox provision" that was meant to grant some interim protection for existing products could be used to widen the scope of Article 27.3(b), or to serve as an interpretation guideline for this provision.

For all these reasons, one must come to the conclusion that "micro-organisms" have a fairly, perhaps intended, ambiguous meaning under Article 27.3(b) TRIPs. On top of that, additional "wiggle room" stems from Article 27.1:

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[94] Daniel Gervais, *The TRIPs Agreement: Drafting History and Analysis*, at 145-46 (1998).

[95] Dan Leskien & Michael Flitner, *Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System*, in 6 *Issues in Genetic Resources* 19 (Jan Engels ed., 1997), *available at* http://www.ipgri.cgiar.org/publications/pdf/497.pdf.

[96] McManis, *supra* note 81, at 92.

[97] *See* Leskien & Flitner, *supra* note 95, at 19.

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any *inventions*, whether products or processes, in *all fields of technology*, provided that they are *new, involve an inventive step and are capable of industrial application*. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.[98]

It follows from this provision that in principle, all products and processes are patentable if they fulfill certain criteria: the exclusion of inventions, including biotechnological inventions, from being eligible for patent protection solely due to its field of technology is prima facie prohibited under TRIPs.[99] However, the above discussion has shown that (sub)cellular matter might not be patentable under a TRIPs minimum approach. But even if it is in principle eligible for protection, much might be excluded on other grounds.

First, the agreement neither specifies what exactly an invention is,[100] nor does it address the controversial invention/discovery dichotomy.[101] Regardless of whether something new meets the patentability criteria, many jurisdictions do not award patents for discoveries,[102] which are regarded as "mere recognition of what already exists,"[103] as opposed to inventions, which are "artificial creations that stem from the need to solve technical problems."[104] One view grounds the distinction on the significance of the invention/discovery in the production process: discoveries are deemed too far in the upstream research stage to be applicable in practice.[105] However, if that was the only basis for the distinction, most discoveries would fail to qualify for patent protection when their utility is tested.

Another factor also appears to shape this dichotomy – namely that patents are granted for intellectual efforts that lead to an "invention;" they award targeted thoughts. The patent system is in principle not designed to reward a party for finding something by

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[98] TRIPS, *supra* note 3, at art. 27(1) (emphasis added).

[99] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries*, at 50 (2000).

[100] *Id*. at 51.

[101] See Li Westerlund, *Biotech Patents: Equivalency and Exclusions under European and US Patent Law*, 20-21 (2002) for a brief explanation of why the invention/discovery distinction deserves attention in the context of biotechnology patentability.

[102] B.C. Reid, *A Practical Guide to Patent Law*, at 13-14 (2d ed. 1993).

[103] *Correa*, *supra* note 99, at 52.

[104] N. Pires de Carvalho, *The TRIPS Regime of Patent Rights*, 146 (2002).

[105] *Id*. at 146-47.

chance, which could be considered as "mere discovery."[106]

Whatever the roots for this distinction, it leaves members manoeuvre space to determine the span of the term "invention." With regard to biotechnological inventions, it is thus arguably TRIPs-compatible to exclude from patentability pre-existing substances.[107] Although many countries regard natural products such as unaltered genetic sequences as eligible for patent protection,[108] particularly if they are "isolated or purified,"[109] TRIPs probably does not prevent the exclusion of such subject matter based on a discovery/invention distinction.[110] As far as potential GMO-patents are concerned, such an approach might lead to barring from patentability isolated genes that would later be inserted into a foreign organism. A large number of famous biotech patents or patent claims would not exist if that view had prevailed.

Second, narrowing the circle of potential candidates for patent protection even further, similar conclusions can be drawn from an analysis of the "classic" patentability criteria – novelty, inventive step and industrial applicability.[111]

Novelty appears to be the least controversial and almost irrelevant for this paper. A patent application is rejected on grounds of not being "novel" if the claimed invention is known prior to the application (i.e., published or used).[112] Its purpose is to deter people from investing intellectual efforts in activities that would lead to already existing

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[106] *But see* Correa, *supra* note 99, at 52 (noting that both inventions as well as discoveries have often been the outcome of chance); *see also* Silvia Salazar, *The World of Biotechnology Patents*, in *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*, at 117, 123 (Christophe Bellmann, Graham Dutfield & Ricardo Melédendez-Ortiz eds., 2003) (arguing that isolated genes are inventions because they do not exist in that form naturally, and their eligibility for patent protection is based on an analogy with isolated chemical compounds).

[107] *See* P. Kanavos & C. Golna, *WTO and Patents – The Impact on the Pharmaceutical Industry*, at 56 (2000).

[108] This approach has been adopted, for example, in the United States, Japan and the countries of the EPC. *See generally* Geertrui Van Overwalle, *Patent Protection for Plants: A Comparison of American and European Approaches*, 39 IDEA 143 (1999).

[109] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries*, at 52-53 (2000).

[110] *Id*. at 54. *But see* Ch. R. McManis, *Patenting Genetic Products and Processes: A TRIPS Perspective*, in *Perspectives on Properties of the Human Genome Project*, at 79, 89 (F. S. Kieff ed., 2003).

[111] *See* J. H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. Int'l. L. & Pol. 11, 30 (1996) (providing arguments in favour of high patentability standards in the third world).

[112] *See* Chisum, *Chisum on Patents* § 3.1 (2006).

solutions.[113] GMOs that did not exist prior to the application should regularly overcome this threshold. However, insofar as (sub)cellular elements are concerned, this outcome is less likely with the other two elements of non-obviousness and utility (industrial applicability).[114]

Allegedly low non-obvious standards have been the target of much scholarly critique, particularly in the United States. Indeed, in the light of the immense progress that the biotechnological sector has experienced, some research results for which patents were initially granted, such as automatic sequencing work that is now performed by machines, should arguably no longer be rewarded with such protection.[115] However, this is not to say that all such applications should be rejected for these reasons. Rather, patent offices should ensure that the non-obviousness condition is really met. Some arguably overly generous granting practices have already been partially reversed in the United States. For example, it seems that the function of a gene now must be disclosed in order for an application to be successful.

Whether or not a TRIPs compatible non-obvious standard could be set high enough to rule out any patents for (sub)cellular subject matter, and consequently, all patents relevant for GMOs, appears highly unlikely. Successfully engineered DNA that is capable of reproduction seems doubtlessly inventive enough, at least at this stage of (bio)technological development. But for certain DNA fragments, specifically those not assigned a certain function and only described as "to some extent identical" with other genes, a higher threshold may be difficult to satisfy in some cases.[116]

A stringent interpretation of the criterion of "utility"[117] might further narrow the scope of principally patentable subject matter. The effect of a utility test on the patentability of GMOs (or related research) will ultimately depend on how "close" the invention for which the patent is sought has to be to an actual "industrial application" in order to be patentable. Even though utility and industrial applicability are deemed equivalent in a footnote to Article 27.1 of TRIPs, their meanings in the jurisdictions where these terms originate vary. "Utility" appears to be the broader concept, also protecting purely experimental inventions.[118]

But an approach that requires an invention to be virtually immediately applicable

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[113] *Id*.

[114] *See* Resource Book, *supra* note 89, 359-61.

[115] *See generally* CIPR Report, *supra* note 14, at 116; Resource Book, *supra* note 89, at 409; Reichman, *supra* note 59, at 36-40.

[116] *See* Report of the Trilateral Cooperation, *Trilateral Project 24.1 – Biotechnology: Comparative Study on Biotechnology Patent Practices*, http://www.trilateral.net/projects/biotechnology/patent_practices/biotechnology_patent_practices.pdf.

[117] *See* Resource book, *supra* note 89, at 361; *see also* Correa, *supra* note 26, at 60.

[118] *See* Correa, *supra* note 26, at 60.

in a production cycle also seems consistent with TRIPs. In any event, these considerations mainly concern upstream patents: most (sub)cellular inventions relevant for GMOs would most likely be considered as useful if, for example, the ultimate purpose of an isolated gene is already determined.

2.2.3. *The patentability requirements for processes*

The already discussed Article 27.3(b) of TRIPs also stipulates that "essentially biological processes for the production of plants or animals other than non-biological and microbiological processes" may be excluded from patentability. Compared to the ambiguities explored above, this issue appears rather straightforward. The distinction between essentially biological and non-microbiological processes primarily serves the purpose of permitting members to exclude conventional breeding methods from the scope of patent law. On the other hand, *processes* based on modern biotechnology (e.g., tissue culture, insertion of genes in a plant) must be patentable.[119]

This is not to say that the borderline between essentially biological and non-microbiological processes is not somewhat blurry as well. The latter category appears to encompass most essentially biotechnological procedures.[120] However, the matter becomes problematic when a process can be divided into several steps, of which some employ purely biological reproduction and others include "direct human interference" (on a microbiological level).[121]

Many claim that if one essential step is microbiological, then the entire processes is "essentially microbiological," and therefore patentable.[122] But Article 27.3(b) does not speak of "essentially *microbiological*" but rather of "essentially *biological*" processes. Thus, it is arguable that we could exclude all processes from patentability that essentially involve even just one biological step.[123]

The consequences of such an approach would mainly depend on what is considered to be a "step." If every division of cells or even each "natural" reproduction of DNA is regarded as a step, hardly any relevant microbiological processes apart from the initial genetic altering of the DNA would be patentable. The patented process would

[119] *See* Resource Book, *supra* note 89, at 393.

[120] *But see id*. at 394 (claiming that microbiological processes are such which involve the use or modify "micro-organisms"). However, it seems very improbable that the scope of "micro-organism" and "microbiological process" match; the former arguably only contains entire micro-organisms, in a narrow sense, the latter every application of "microbiology."

[121] *See* Carvalho, *supra* note 59, at 178.

[122] *See* Resource Book, *supra* note 89, at 394; *see also* Carvalho, *supra* note 59, at 178; EPO Guidelines, *supra* note 93, pt. C, ch. IV.3, ¶ 3.5.

[123] *See* Leskien and Flitner, *supra* note 95, at 22-23; *but see* Carvalho, *supra* note 59, at 178 (suggesting that "essentially biological processes" should be read in a "restrictive manner").

then not encompass the creation of an entire (transgenic) organism, but only its first step. On top of that, the consideration on the general patentability criteria can be applied analogously. The results of the analysis for processes resemble the one for products. If TRIPs is read narrowly, only a few relevant patents have to be issued for GMOs (and related technologies).

2.2.4. *Effective protection of GMOs under a TRIPS minimum approach?*

As mentioned above, a GMO patent could in practice contain product claims encompassing either 1) the transgenic organism itself or a cell containing the altered DNA, or 2) the isolated/purified gene or gene sequence that is later inserted into the alien DNA. Moreover, process claims could include the processes ranging from the actual genetic engineering stage to cell reproduction and propagation of the entire organism.

As far as entire organisms are concerned, only transgenic micro-organisms enjoy mandatory protection, whereas subcellular elements – isolated DNA parts and altered cells – do not, or do so only to a small extent. Similar conclusions can be drawn from exploring the span of obligatory protection for biotechnological processes.

The "morality exception" of Article 27.2 might further diminish the field of patentable biological material.[124] An extreme view (probably incompatible with TRIPs) might exclude all such patents on these grounds.[125] TRIPs also permits other fairly broad exceptions.[126]

In any event, the scope of the respective minimum requirements as to what subject matter must be patentable is clearly ambiguous. A persuasive case could possibly be made for more far reaching obligations that would, for example, extend the meaning of micro-organism to include subcellular elements, or to encompass a broader range of processes.

Ultimately, however, the exact delineations of what is in principle patentable only matter so much. As indicated above, the essential factor in determining the economic impact of a bio-patent is its scope. But TRIPs does not regulate how far the protection of a particular patent extends. Rather, it "leaves full freedom to Member countries to determine the limits of allowable claims."[127]

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[124] CIPR Report, *supra* note 14, at 115; Gervais, *supra* note 94, at 148; *but cf.* Carvalho, *supra* note 104, at 168 (arguing that exclusion from patentability will not stop technological development).

[125] *See* Straus, *supra* note 59, at 180 (arguing that TRIPs allows Members to block technological development altogether in certain fields by denying patents, but not to market unpatentable products).

[126] *See* Kanavos & Golna, *supra* note 107, at 58 (outlining the possible wiggle room for research exceptions and compulsory licensing regimes).

[127] Correa, *supra* note 26, at 70; *see also* Reichman, *supra* note 61, at 33 (stating that "no agreed international minimum standards currently regulate claims interpretation").

The fact that biological entities are capable of reproducing themselves distinguishes them from other patentable inventions. Every part of an organism contains "instructions" for infinite propagation. The absence of any provision regulating the scope of protection is therefore particularly crucial in the area of biotech patents, where the spectrum of possible patent breadths is enormous. For example, if a patent for a genetically modified cell does not extend to the entire organism containing that cell, or to the offspring of this organism, it might be easy to circumvent as a practical matter.

The same is true if product-by-process patents are not allowed (or if the product's copies fall beyond the protected area). In other words, where patent law only protects the original microbiological invention, the possibility of lawfully reproducing the organism that contains this invention makes the patent effectively worthless. This is even more of a problem in the case of marketed and widely disseminated downstream products such as GMOs. Costless reproduction of the transgenic creations can prevent recouping of investments.

It was probably this insight that led to the mandatory inclusion of progeny in patents for "biological material" in the European Community.[128] Similarly, the Supreme Court of Canada held that growing a plant containing a patented cell constitutes "use."[129] Thus, the unauthorized reproducer was held liable for patent infringement, despite the fact that higher life forms are considered unpatentable in Canada.[130]

However, if a country wishes to adopt a minimalist approach to patents for biotechnological inventions, it certainly can do so, as none of this can be considered mandatory. The scope of GMO patents could be much more limited. Therefore, protecting only entire genetically altered micro-organisms and not extending protection to their progeny would be compatible with TRIPS.[131]

The disincentives to research from this finding are further exacerbated by the "Achilles' heel" of TRIPs: its enforcement provisions, which, according to Reichman and Lange, constitute *true* minimum standards.[132]

This suffices to conclude that a TRIPs minimum approach will not award inventors with sufficient means to recoup investments, as it does not provide *effective* protection.[133] It is, as shown above, a complex and almost impossible task to determine

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[128] Council Directive 98/44/EC, art. 8, 1998 O.J. (L213) 13 (EC).

[129] *Schmeiser v. Monsanto Canada Inc.*, 1 S.C.R. 902 (Can. 2004).

[130] Harold C. Wegner, Schmeiser knocks out Harvard Mouse, 23 Biotech. L. Rep. 414 (2004).

[131] Correa, *supra* note 26, at 68 n.14 (illustrating this with the example of Brazil, where biotech patents can only be awarded for "organisms . . . that . . . express a characteristic that cannot normally be achieved by the species under natural conditions").

[132] Reichman & Lange, *supra* note 81, at 34.

[133] Other aspects that limit the potential economic value of a patent include the possibility of introducing extensive compulsory licensing regimes and broad (research) exceptions. *See* TRIPs, *supra* note 3, art. 30, 31; *see also* Correa, *supra* note 26, at 75 (explaining the general rules

the ideal level of biotech and GMO patent strength. But it is fairly safe to say that the TRIPs minimum requirements set too low a standard with regard to GMOs. In that respect it can be argued that hardly any harmonization has been achieved.[134] The odyssey is not over yet.

3. SCYLLA & CHARYBDIS: THE DANGERS OF INAPT LEVELS OF INTERNATIONAL GMO PROTECTION

The analysis in the first section of this paper indicated that effective patent protection for GMOs is necessary. The second section concluded that such protection is not obligatory under TRIPs. The following section then deals with the issue of international protection achievable only through IPR harmonization.[135] It should be noted that the following discussion does not address the implications of patent duration.[136]

3.1. *Scylla: The flip side of non-harmonization*

Every IP regime, whether national or international, strives to establish a balance between providing sufficiently large incentives while not granting overly broad exclusive rights, which would result in supra-marginal deadweight costs without compensation through offsetting innovation.[137]

> Employing "Odyssey"-terminology, IP protection that is too weak can be referred to as "Scylla," while "Charybdis" can stand for overly strong protection; the alternatives are named after the two mythical sea monsters that live on two sides of a narrow sea channel and are so close to each other that

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concerning exceptions under TRIPs art. 30); Correa, *supra* note 26, at 89 (explaining the compulsory licensing provisions under TRIPs art. 31).

[134] *See* Straus, *supra* note 59, at 180 (providing relevant discussions); *see also* Reichman, *supra* note 59, at 36-37 (concluding that the WTO framework cannot be used to oblige members to grant patents for biotechnological inventions).

[135] *See* Scotchmer, *supra* note 2, at 2, where harmonization, in the context of international IPR protection, "refers to provisions by which signatory states agree to a common set of protections. The first step toward harmonization is usually to state minimum standards, both in the subject matter protected and the length of protection." This paper investigates the effects of (real) harmonization in the sense of 1) more standardized subject matter protection, and 2) a mandatory minimum patent scope, that would ensure effective protection for GMOs and their progeny.

[136] This paper does not address the implications of patent duration. It can be assumed that it will remain 20 years long, as mandated by TRIPs, for a considerable amount of time. *See* TRIPs, *supra* note 3, art. 33.

[137] Lévêque & Ménière, *supra* note 21, at 4.

> sailors attempting to avoid Charybdis will pass too close to Scylla and vice versa.[138]

This is precisely the kind of predicament policy makers and patent offices face in regard to IP regimes. Accurate manoeuvring, both statutory and administrative, is necessary to sail safely through the narrow passage, with the dangers of too weak or too strong protection threatening from each side. [139]

In an international context, the "Scylla" threat manifests itself through the existence of very little obligatory IP protection for GMOs. In practice, the vast majority of countries with little or no IPRs for such inventions are developing nations.[140] Thus, the analysis will focus on them and will employ the admittedly oversimplifying North/South distinction.[141]

Many would welcome the above results as good news for the developing world, as IP harmonization in general, and specifically with regard to IPRs for biotech, is often perceived as (almost inherently) detrimental for "the South".[142] Furthermore, it is generally questioned whether "all countries should maintain the same level of IP

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[138] *See* Wikipedia, *Scylla*, http://en.wikipedia.org/wiki/Scylla (last visited Apr. 22, 2007).

[139] In practice, much will depend on a balanced application of the patentability criteria by the national authorities responsible for granting patents. Due to a lack of institutional capacity, this balance is harder to achieve for poor countries. CIPR Report, *supra* note 14, at 137. However, as will be shown below, the legislative situation is also more complex for developing countries on their own "biotech odyssey."

[140] *See* Bonwoo Koo et al., *Plants and Intellectual Property: An International Appraisal*, 306 Science 1295, 1296 (2004); *see also* CIPR Report, *supra* note 14, at 115.

[141] Although reality is of course much more complex, it suffices for the purposes of this paper to divide the world into a rich North, located in temperate climate, with highly developed innovative capacities, and a poor, tropical South with very limited possibilities in the R&D field. *Cf.* Cottier, *supra* note 19, at 688.

[142] *See, e.g.*, CIPR Report, *supra* note 14, at 74 (arguing that developing countries should generally not provide patent protection for plants and animals); *see also* Carlos M. Correa, *Harmonization of Intellectual Property Rights in Latin America: Is There Still Room for Differentiation?*, 29 N.Y.U. J. Int'l L. & Pol. 109, 123-24, 126 (1996) (suggesting that harmonization would not increase global welfare); Sanjaya Lall, *Indicators of the Relative Importance of IPRs in Developing Countries*, 13 UNCTAD-ICTSD Project on IPRs and Sustainable Dev., Issue Paper No. 3, 2003), http://www.ictsd.org/pubs/ictsd_series/iprs/CS_lall.pdf. (arguing for a cautious approach to IPRs for developing countries); Helfer, *supra* note 67, at 3-4 (questioning the benefits of TRIPs for the developing world); Gerard Downes, *Implications of TRIPs for Food Security in the Majority World*, at 46 (2003), http://www.comhlamh.org/assets/files/pdfs/implication-of-TRIPs-for-food.pdf (concluding that the TRIPs agreement would be detrimental to the developing world).

protection."[143] Numerous arguments highlighting possible advantages and disadvantages have been put forward, of which the most salient will be addressed here. The economic impact of IP is clearly case-sensitive,[144] meaning that it varies within different types of industries. Among the aspects that distinguish GMO development from other fields of innovative activity are the following: the (global) structure of the relevant industry,[145] the geographical confinement of most biotechnological products, and the self-reproducibility of biological entities. These specific characteristics will be highlighted in a GMO-specific analysis of harmonization arguments.[146]

The crucial question on the general harmonization issue is whether potential harmonization benefits outweigh the static losses[147] that result from the rather obvious rent transfers from consumers to producers. Admittedly, due to the complexities of theory and empirical evidence, it seems almost impossible to reach an unambiguous conclusion on the implications of harmonized IP standards in general. But the analysis below will indicate that harmonized IP standards for the protection of GMOs would indeed be beneficial for virtually all concerned countries, as anti-harmonization arguments are comparatively weak, and pro-harmonization arguments largely convincing in this context.

First, an important caveat must be noted: this paper works from the (fairly safe) assumption that international minimum standards for IPRs will not decrease in the near future; it will therefore only strive to answer whether "TRIPs plus" provisions are desirable for GMOs in a post-TRIPs world.

3.1.1. *The shortcomings of anti-harmonization arguments in the GMO context*

As complex and controversial as the relationship between development and

[143] *See* Trebilcock & Howse, *supra* note 60, at 397.

[144] *See* Merges & Nelson, *supra* note 27, at 839; *see also* Abbott, *supra* note 5, at 504 (emphasizing the importance of adequate IPP for pharmaceutical research due to its easy reproducibility). An analogy can be drawn for GMOs where "copying" is even more simple. *See* Maskus, *supra* note 62, at 20 (identifying biotechnology as a field where patents matter).

[145] *See* John H. Barton, *Intellectual Property, Biotechnology, and International Trade: Two Examples in Intellectual Property: Trade, Competition, and Sustainable Development*, at 295 (Thomas Cottier & Petros C. Mavroidis eds., 2002).

[146] However, this paper will not investigate whether or not (deeper) IPR harmonization in general is mandated. It does not aim to suggest an alternate view on the overall effects of IP on development.

[147] *See* Carsten Fink & Carlos A. P. Braga, *How Stronger Intellectual Property Rights affect International Trade Flows*, in *Intellectual Property and Development*, at 21 (Keith E. Maskus & Carsten Fink eds., 2005); *see also* Lall, *supra* note 142, at 9 (providing a good overview on the harmonization issue).

international IPRs – specifically stronger IP standards – is, there seems to exist a scholarly consensus on one issue: rent transfers.[148]

To illustrate this important issue, consider the impact of differing IP regimes on trade. As shown above, an innovative country will likely increase the export of IP-sensitive goods gradually to a country that constitutes an "imitation threat," the more IP standards become enforceable abroad. Thus, with increasing harmonization of IPRs, countries that can imitate the respective good will experience prima facie beneficial larger trade volumes,[149] which will remain largely unchanged for countries without such imitation skills.[150]

The IP exporters, mainly the United States, would in principle benefit from (further) harmonization and its resultant possibility of protecting their goods abroad.[151] At least in the short term, the southern "imitation threat" might experience losses, as he becomes a net importer of such goods and is exposed to increased market power of multinational corporations, which would now be able to charge supra-marginal prices abroad. The stronger the patents become, the larger is this effect. In principle, if considered in isolation,[152] it seems difficult to successfully challenge this point.

However, the case of GMOs is different. So far, the development of biotechnological downstream products and GMOs has been almost entirely confined to the North and its temperate climates. Most existing GMOs would not meet demand in developing countries because they simply would not grow. Therefore the immediate impact of strengthening the respective IPRs on prices and on profit flows would probably be very small, as there would be few tradable GMOs. But as soon as higher IP standards and the resultant increased profitability of such products lead to more useful GMOs

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[148] *See* Phillip McCalman, *Reaping What You Sow: An Empirical Analysis of International Patent Harmonization*, 55 J. Int'l Econ. 161 (2001); *see also* Abbott, *supra* note 5, at 501; Maskus, *supra* note 62, at 181; Fink & Braga, *supra* note 147, at 19; Anderfelt, *supra* note 61, at 127; CIPR Report, *supra* note 14, at 21; Tansey, *supra* note 49, at 4; Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History*, at 20 (2003); Matthews, *supra* note 78, at 122; *but see* Robert M. Sherwood, *Intellectual Property and Economic Development*, at 160 (1990).

[149] *See* Trebilcock & Howse, *supra* note 60, at 2 (arguing that trade liberalization and resultant larger trade volumes are in principle beneficial because they enable the importer to focus on areas where his comparative advantage lies).

[150] *See* Maskus, *supra* note 62, at 110-18.

[151] It would be very comforting but naïve to believe that the developed world urged for harmonized standards only (or mainly) for the greater good of enhancing global welfare, regardless of their own interests. One does not have to be particularly cynical to question whether such considerations were at all influential. In reality, regarding the strengthening of IPRs globally as "disguised US strategic trade policy" is probably closer to the truth. *Id*. at 181. However, even if augmenting domestic welfare has been the underlying purpose of the North's negotiators, there still might be beneficial "side effects" for the South.

[152] Potential advantages resulting from the patent law harmonization will be considered below.

designed for these regions, there might be increasing rent transfer if "northern" multinationals recognize the possibility of benefiting from such inventions, and of conducting the necessary research domestically.

But contrary to other areas such as pharmaceuticals, where there are markets in the South for drugs designed for the needs of the North, the only way to reap such profits in the case of GMOs is to create products specifically made for the South.[153] Therefore, the rent transfer, if it takes place at all, is inevitably offset (or at least partially compensated) by benefits resulting from the development of new, third-world specific, products. Only if the number of "orphan crops" (and other "orphan" organisms) was reduced, would substantial rent transfer occur.

Moreover, in the case of GMOs, every country qualifies as an "imitation threat" due to the inherent natural tendency of living organisms to reproduce. Therefore, if useful GMOs for a country exist abroad, trade in these goods will theoretically always increase with the harmonization of IP protection.

Nevertheless, the rent transfer argument is essential. Its significance, that is to say the short-term impact of harmonized IPRs, will mainly depend on whether the developing world would in fact become a net importer of specifically designed GMOs. If that is the case, welfare decreasing rent transfer could perhaps occur. It would remain to be seen if such effects could be balanced out by a larger number of innovative products, and their impact on welfare.

Other arguments raised against harmonization are less convincing. Additional costs for introducing and sustaining a functioning IP regime, for example, appears to be an argument of little persuasiveness in a post TRIPs world, where all members have to run such a system anyway.[154]

Further, stronger IPRs imposed on a country are said to make it more difficult to imitate innovative products, which would consequently inhibit the acquiring of new technological knowledge, and the protection of an "infant" industry until the point where it has become globally competitive.[155] Trebilcock and Howse suggest that a country whose strength is imitation should opt for weak standards, because this would be a domestically, and perhaps even a globally, efficient policy.[156] Arguably, it is first and foremost unfair to promote a society's progress through the exploitation of somebody else's inventions, and through shifting the monopoly costs that allow the inventor to recoup his investments on the consumers of this country.[157] Apart from such ethical considerations, it seems principally questionable whether such "pirated" knowledge can

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[153] *See* Barton, *supra* note 37, at 296.

[154] See CIPR Report, *supra* note 14, at 145-46.

[155] *Id*. at 24; *see also* Maskus, *supra* note 62, at 167; Sherwood, *supra* note 148, at 166; Lester C. Thurow, *Needed: A New System of Intellectual Property Rights*, Sept.-Oct. 1997 Harv. Bus. Rev., at 95 (arguing that imitation and copying are essential to "catch up").

[156] *See* Trebilcock & Howse, *supra* note 60, at 399 et seq.

[157] *But see id*. at 398.

ever be transformed into "skills required to innovate."[158] Moreover, it is doubtful whether foreign technology will be supplied to the same extent in the absence of legal protection,[159] and therefore, whether the potential benefits of imitating would not be outweighed by resulting trade distortions.[160]

Even if one regards these effects as ambiguous for a developing economy in general, this argument is particularly weak with respect to GMOs. As discussed extensively already, hardly any GMO that can grow in the tropics will be privately developed in the absence of protection. Thus, there will be little (private) innovation to imitate in the first place. But even if such products existed (e.g., due to sufficiently high standards in some countries), the GMO itself contains no potential for the acquisition of relevant knowledge through reverse engineering and the like. The imitators will not learn from imitation (i.e., by watching the organism grow and reproduce), and will not become innovative themselves. Further, literally everybody can reproduce GMOs. A domestic industry based on GMO "imitation" (i.e., reproduction that eventually becomes globally competitive) could never develop, as even this "imitation" would be immediately freely copied. It may be arguable to say that Korea's car imitation industry benefited from initially weak IP standards.[161] But it could have never developed if every Korean car sold could have been lawfully and almost costlessly reproduced. Even imitators must be able to charge a slightly supra-marginal price.

3.1.2. *The persuasiveness of pro-harmonization arguments in the GMO context*

The above alleged disadvantages are, in the case of IPR harmonization for GMOs, arguably almost negligible. Furthermore, the disadvantages that do exist are principally, at least to some extent offset by "dynamic" advantages. Three main benefits will be identified here,[162] which are particularly significant with regard to GMOs.

First, stronger IPRs provide more incentives for inventors, both locally and regionally. It is often argued that IP as an incentive for innovation does not work in the developing world, as these countries simply lack the "stock of local inventors."[163] Unquestionably, R&D capacities are generally disproportionately larger in the developed world. But contrary to many other areas such as pharmaceutical research, the differences

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[158] *See* Sherwood, *supra* note 148, at 167.

[159] *Id*. at 173; *see also* Lall, *supra* note 142, at 29.

[160] *See* Maskus, *supra* note 62, at 110-18.

[161] *See* Tansey, *supra* note 49, at 4-5; *see also* Trebilcock & Howse, *supra* note 60, at 398 (claiming that such a strategy benefited Japan); *but see* Sherwood, *supra* note 148, at 166.

[162] *See* Matthews, *supra* note 78, at 108. The decreased likelihood of trade sanctions will not be addressed here.

[163] *See, e.g.*, Matthews, *supra* note 78, at 110.

are smaller and a significant amount of sophisticated agricultural research has been conducted locally, mainly within public institutions, since the end of World War II.[164] So far, little has been achieved with regard to GMOs, but local scientific competence, or at least a basis for such, seems to exist.[165] And the picture slowly begins to change. Alliances between local researchers and multinational firms are emerging, conducting research towards GM rice and wheat for the developing world.[166]

A factor that would likely contribute to the further foundation of such collaborations is the role of IPRs in the creation and recognition of (intellectual) assets, which, again, is of particular relevance in the biotechnological sector.[167] Merges illustratively defines IPRs as the "crown jewels"[168] of many small firms. If entrepreneurs in the developing world would acquire these valuable assets, they would become more attractive partners, and more influential in a partnership. Cooperation would be the only way for international players to share in the profit from such local intellectual assets.

The importance of local incentives for research on new plant varieties apt for the tropics is underlined by Abbott;[169] analogous conclusions for the creation of GMOs can arguably be drawn. Therefore,

> "it must be recognized that biotechnology . . . will not evolve without IPRs, unless there is much more public sector research than seems plausible . . . IP protection is thus a necessary component of a global trade regime in a high technology era;"[170]

Investigating the implausibility of sufficiently large spending on public research is beyond the scope of this paper. Nevertheless, it is worth noting one convincing reason for this, elucidated by Scotchmer: IPR protection abroad encourages private investors to undertake research in products in order to earn profits *also* in foreign markets. As public sponsors are mainly concerned with domestic welfare, they spend too little overall. Therefore, "the expanded [IP] rights are a partial remedy to the fact that R&D spending is

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[164] *See* Barton, *supra* note 148, at 294; *see also* CIPR Report, *supra* note 14, at 60.

[165] *See* Tansey, *supra* note 50, at 20 (noting that "large developing countries such as India, for example, have a large pool of qualified scientists, which could form their own research-based agricultural enterprises once they are assured that their research output is protected.").

[166] *See* Barton, *supra* note 145, at 295.

[167] *See* R. Merges, *Intellectual Property Rights, Input Markets and the Value of Intangible Assets*, at 3 (1999), http://www.law.berkeley.edu/institutes/bclt/pubs/merges/iprights.pdf.

[168] *Id*. at 4.

[169] *See* Abbott, *supra* note 5, at 505.

[170] *See* Barton, *supra* note 145, at 296.

suboptimal in a fragmented world."[171]

Overall, the pace of progress would likely increase through private investment if incentives were raised and IPR-protected assets were created locally.[172] International IP protection is an essential prerequisite for sufficient innovation. This is even more so with regard to inventions with geographically confined applicability. Without the possibility of profits stemming from sales to other countries in that area, they will not be developed privately (to a satisfactory extent).

Second, stronger IP standards can encourage foreign direct investment. While the general ability of stronger IPRs to attract additional FDI must be regarded as ambiguous,[173] some empirical studies suggest that IP regimes have this effect in "Mansfield"-sectors,[174] where the industry relies heavily on IPRs due to simple reproducibility and the necessity of large investments in product development.[175] Biotechnology can be classified as such.

For existing products, weak IPR systems increase the risk of copying, reproduction or imitation. They also provide the IP owner with little ability to prevent a (potential) licensee from entering direct competition if he breaches the license. Therefore, should the respective firm aim to profit from a market with weak IPRs, it would prefer to establish local distributional systems for (irreproducible) end products, rather than invest in local production. FDI is thus to some extent replaced by exports.[176] As far as possible, this would also be the case for GMOs and derived products.

As for future research, the fact that the specific conditions (e.g., climate, soil) for which a new GMO will be invented are only found in the developing world provides a significant comparative cost advantage. It would require large efforts to artificially recreate similar environments in temperate climates, particularly if field trials are taking place. If foreign investors want to profit from market opportunities for transgenic

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[171] *See* Scotchmer, *supra* note 2.

[172] *See, e.g.*, K. E. Maskus, S. M. Dougherty & A. Mertha, *Intellectual Property and Economic Development in China*, in *Intellectual Property and Development*, at 295, 325 (K. E. Maskus & C. Fink eds., 2005).

[173] *See* Maskus *supra* note 62, at 119; Matthews, *supra* note 78, at 109; Correa, *supra* note 26, at 26; *see also* W. Lesser, *The Effects of TRIPs Mandated Intellectual Property on Economic Activities in Developing Countries* (2001), http://www.wipo.org/about-ip/en/studies/pdf/ssa_lesser_trips.pdf.

[174] *See* E. Mansfield, *Intellectual Property Protection, Foreign Direct Investment and Technology Transfer*, at 9 (IFC Discussion Paper No. 19, 1994), http://www.bvindecopi.gob.pe/colec/emansfield2.pdf.

[175] *See* B. M. Javorcik, *The Composition of Foreign Direct Investment and Protection of Intellectual Property Rights: Evidence from Transition Economies*, in *Intellectual Property and Development*, at 159 (K. E. Maskus & C. Fink eds., 2005) at 159; *see also* Lesser, *supra* note 173.

[176] Javorcik, *supra* note 175, at 136.

organisms in developing markets, this fact encourages them to direct their investments to these regions, and pursue the necessary research locally.

Third, effective IPRs can encourage technology transfer. Fink and Braga show that in order to reap benefits, even from radical biotechnological innovation, by marketing a downstream product, internationally active firms will rely on technology licensing with local firms, as these breakthrough inventions require adaptation to regional conditions. Adequate IPRs will arguably enforce such cooperation and increase the number of biotechnological research partnerships.[177] While other factors such as public support to strengthen local research capacities are at least equally important, effective patents must be regarded as essential. As shown above, firms will be reluctant to license valuable knowledge otherwise.

All the arguments made so far indicate that strengthening GMO patents would increase innovative activity, and consequently, the number of patent applications and awarded patents. The resulting publication of highly sophisticated technological knowledge would disseminate this information.[178] As mentioned above, a fairly advanced research framework focusing on traditional agricultural biotechnology already exists in many of these countries. What is perhaps currently lacking is the knowledge necessary for the creation of useful GMOs. But as soon as more GMO patents are published, local scientists should be able to appropriate some of this knowledge and become more inventive in this field themselves, ultimately without their northern partners.

Weighing the advantages and disadvantages with respect to IPR-protection for GMOs therefore leads to the unambiguous result that effective patents would be beneficial for developing economies in a post TRIPs world. For these reasons alone, steering towards Scylla, or more precisely, remaining in close vicinity to the danger of under-protection, does not seem to be a good idea.

3.2. *"Charybdis" – the drive towards GURTs*

In establishing a balanced IP regime, policy makers must be careful not to grant too powerful exclusive rights, as they would increase the deadweight loss without sufficient additional innovation. However, this danger appears to be rather insignificant in the context of internationally mandatory IP protection for GMOs. As shown above, not even countries (such as the United States) that employ the highest standards of biotech IPRs seem to exceed the ideal threshold of optimal patent strength. While some patenting developments might be controversial, the overall effect on innovative activity is doubtlessly beneficial.

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[177] C. Fink & C. A. P. Braga, *Technology Transfer in Agricultural Biotechnology: The Developing Countries Perspective*, in *Intellectual Property: Trade, Competition, and Sustainable Development*, at 409 (T. Cottier & P. Mavroidis eds., 2002).

[178] *See* D. Matthews, *Globalising Intellectual Property Rights*, 110 (2002); *see also* G. Tansey, *Food Security, Biotechnology and Intellectual Property*, at 20 (2002).

Needless to say, there is a theoretical possibility that even stronger standards may someday be adopted on an international level, but this seems highly implausible in light of developments so far. Moreover, if this did occur, the innovator's capability to appropriate would most likely remain within a welfare-enhancing margin[179] – as shown above, the optimal IPR appropriability level is arguably even higher than that of the United States today. Overly strong IPRs for GMOs can therefore hardly constitute "Charybdis" in this context;[180] despite that, many nations have a very sceptical attidude towards IP protection for transgenic organisms.[181] However, another hazard threatens the prospering of ongoing biotechnological innovation and the resultant beneficial impacts on developing economies.

Should private firms recognize the (tropical) third world as a promising market for new GMOs, but hesitate to invest due to the absence of effective protection, this might encourage the move towards more frequent use of GURTs. And should these technological means become more widespread and more sophisticated, the developing world might end up with stronger (technological) protection than is desirable. As shown above, GURTs potentially equip the inventor with a means to appropriate and prevent too much, resulting in detriments for ongoing research, too high prices for consumers and producers, and ultimately, detrimental consequences for overall welfare – in effect, these are the disadvantages of overly strong protection. Thus, in this context, the real "Charybdis" manifests itself in the probable consequences of a widespread use of GURTs.

Obviously, this is not to say that the existence of an effective IP system for GMOs prevents their development entirely. After all, the first "terminators" originated in the United States, a country awarding strong IP protection for GMOs. Perhaps almost all transgenic plants in the United States will soon contain "genetic switches" that provide the inventor with absolute control. Ultimately, it will be a question of experience once more. But a few things come to mind that seem to indicate a certain degree of substitutability between GURTs and efficient IPRs.

Opting for one of the protection methods appears to be a question of costs and profitability: if both options are available, the seed owner will ask whether technological

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[179] Sergio H. Lence et al., *Welfare Impacts of Property Rights in the Seed Industry* (2002), http://www.econ.iastate.edu/workshops/ispw/Sergio-Dermot-seed-paper.pdf.

[180] In Homer's Odyssey, Odysseus is advised by Circe to sail closer to Scylla, for Charybdis could drown his whole ship. In this "biotech odyssey," similar advice is given by many third world advocates who apparently conceive harmonized IPRs as "Charybdis" and portray them as inherently disadvantageous for poor countries. *See* Comm'n on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (2002), http://www.iprcommission.org/papers/text/final_report/reporthtmfinal.htm (suggesting limiting the patent scope as far as internationally permissible).

[181] Boniface Guwa Chidyausiku, *Art. 27.3(b) of the TRIPS Agreement: The Review Process and Developments at National and Regional Levels*, in *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*, at 101, 103 (Christophe Bellmann et al. eds., 2003) (highlighting the restrictive approach on biotech patents of the developing world).

or legal protection is cheaper and whether higher returns through self-policing enforcement and less leakage would justify the expense. While obtaining and enforcing patent protection is not cheap, it seems likely that GURTs will remain in the hands of a few firms for a considerable length of time. Licenses for "terminators" could be costly as well.

Furthermore, one can to some extent trust the self-regulating forces of the market. If both GURT and patent protected seeds are available, the latter are arguably of higher value for the potential purchaser because seed-saving and research (whether permitted or not) is possible.[182] Consequently, the seed owner that employs legal means might be able to charge a higher price per unit or to simply sell more, at least initially.

Clearly, much will depend on market and industry structure. But the availability of more options seems to inherently bolster competition between products. Thus, in the absence of legal protection, there will be hardly any GMOs available or they will be protected by GURTs. Providing patents could at least facilitate the creation of more diverse, and potentially more competitive markets for IPR-protected organisms.

For these reasons, steering towards Scylla (i.e., weak protection) may paradoxically lead to a tragic end in Charybdis. Adopting effective patent protection for GMOs however might be the only remedy available to avoid both dangers at the same time.

3.3. *Sailing safely between Scylla & Charybdis: multilateral harmonization as a navigation device*

As shown above, TRIPs does not achieve a high enough standard to provide sufficient incentives and to mitigate the move towards GURTs. In light of all these considerations, the question arises as to why (developing) countries do not adopt such standards unilaterally, and why international or multilateral action is needed. Expressed differently: why should multilateral action counter-intuitively be a more apt navigation device to sail safely through Scylla and Charybdis?

There are probably many factors that influence the prima facie detrimental behaviour of maintaining insufficient GMO protection. A salient aspect was emphasized above: TRIPs is perceived as part of a bargain, in which IP harmonization was the price to pay for more market access in other areas. Consequently, stronger IPRs are regarded as inherently disadvantageous for the developing world.[183] It seems that this perception leads to an almost automatic adoption of the minimum requirements, and the immediate

[182] If seed-saving is legally permitted, the higher value is obvious; but even if not, patent-protected seeds may still have a higher value as rights holders might be reluctant to sue infringing farmers. *See* Eran Binenbaum et al., *South-North Trade, Intellectual Property Jurisdictions and Freedom to Operate in Agricultural Research on Staple Crops*, at 26 (Env't and Prod. Tech. Div., Int'l Food Policy Research Inst., Discussion Paper No. 70, 2003), www.ifpri.org/divs/eptd/dp/papers/eptdp70.pdf.

[183] Correa, *supra* note 67.

rejection of IPRs as a tool of development in all fields. A case by case assessment, which would appear to be the more sensible approach, is hardly ever made.[184]

These considerations aside, there are additional reasons that deter countries from unilaterally stepping forward. Namely, whether or not IPRs have an incentive effect on R&D is primarily a question of market size.[185] In other words, whether or not investments in the creation of an intellectual product will be made depends mainly on ex ante expectations of the number of potential purchasers. Many developing countries probably do not have a sufficiently large market to provide satisfactory (ex ante) incentives.

One must agree with Taylor and Cayford's claim[186] that private actors only conduct biotechnological research that is targeted towards products for profitable markets. However, differing conclusions can be drawn from this fact. Rather than ruling out the creation of such markets and pointing to the shortcomings of the profit-orientated private sector, it appears necessary to investigate why such markets do not exist. As indicated above, there is no plausible other solution in sight that could constitute a remedy for the lagging R&D investment in orphan organisms.

Arguably, even large developing countries that perhaps have the potential of establishing such markets are caught in a "collective action problem" that to some extent resembles a prisoner's dilemma, an idea originally submitted by Sykes in the context of pharmaceuticals.[187]

Theoretically, if countries unilaterally strengthen their IP rights, they might be able to induce some additional research, but the global and regional effect on research would probably be modest due to the still comparatively small market size. Furthermore, other nations that do not introduce comparable standards might free ride on this country's R&D and appropriate the invention for themselves. Subsequently, the successful "imitating" would also result in a misallocation of the comparative advantage in producing the patented GMO. The firms that end up producing the GMO in the inventor's home country would find it difficult to compete with foreign firms because their foreign competition can sell the product abroad without having to pay the license fees required by the local system.

On top of that, the consumers in the country in which the invention is made would

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[184] *See* Oumar Niangado & Demba Kebe, *The Implications of Intellectual Property for Agricultural Research and Seed Production in West and Central Africa*, in *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*, at 127 (Christophe Bellmann et al. eds., 2003).

[185] J.H. Barton, *Intellectual Property, Biotechnology, and International Trade: Two Examples*, in *Intellectual Property: Trade, Competition, and Sustainable Development*, at 285, 295 (Thomas Cottier & Petros C. Mavroidis eds., 2003).

[186] Taylor & Cayford, *supra* note 10, at 334; *see also* Niangado & Kebe, *supra* note 184, at 129 (describing poverty and lack of resources for purchasing biotechnology products among African farmers).

[187] Sykes, *supra* note 63, at 65.

have to finance the necessary research entirely, as they are the only ones that would face supra-marginal prices. Moreover, the national policy makers might be deterred from introducing effective protection because this would deprive the country of imitation opportunities, in exchange for little additional research. As soon as effective patents are obtainable, free-riding on the research of other countries is no longer possible.

Even if only few such opportunities exist in practice, for reasons that were pointed out above, the perception of giving up these chances might influence policy choices. Ultimately, from a single country's perspective, the country might be better off without the overall beneficial standards if any other countries fail to adopt similar protection mechanisms.

Sykes argues that TRIPs was potentially an apt means to overcome such a collective action problem, an effect that has been allegedly diminished by the Doha Round and its clarification of the compulsory licensing provisions.[188] While scrutinizing the probability of substantially increased research for third world pharmaceuticals through stronger IPRs is beyond the scope of this paper, several factors indicate that Sykes' hypothesis is more convincing in the context of GMOs.

On the one hand, imitation (i.e., reproduction) is even easier with living organisms than with drugs. This exacerbates the prisoner's dilemma, as all concerned countries know about the simplicity of appropriating the other's invention. On the other hand, three aspects make successful tropics-specific research comparatively more likely in the case of GMOs than with drugs, thus also increasing the importance of overcoming this collective action problem.

Two of these aspects were mentioned above already. Contrary to the pharmaceutical sector, research capacities do exist, and tailor-made organisms are the only way to profit from the developing world's markets. A third point highlights the difference between these local markets for pharmaceuticals and for GMOs. Developing countries are often characterized by a rather disproportionate distribution of wealth and income,[189] and the percentage of people in these countries who are potentially capable of buying expensive patent protected drugs is often very small. This situation is exacerbated because these tropics-specific diseases seem to affect primarily poor people. Thus, manufacturers face convex demand curves, and will therefore only be able to sell either a small amount of their products for a high price, or will have to decrease their prices extraordinarily to sell substantially larger amounts.[190]

Therefore, even if the entire (tropical) developing world created one integrated market, it would remain doubtful whether this would lead to sufficiently large research incentives for pharmaceuticals. Were such a market for GMOs to exist, this desirable

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[188] *See* TRIPs, *supra* note 3, art. 31; World Trade Organization, Ministerial Declaration of 20 November 2001, WT/MIN(01)/DEC/2.

[189] *See, e.g.*, Branko Milanovic, *True World Income Distribution, 1988 and 1993: First Calculation Based on Household Surveys Alone*, 112 The Economic Journal 51 (2002).

[190] *See* A. Hollis, *Optional Rewards for New Drugs for Developing Countries*, at 4 (2005), http://www.who.int/entity/intellectualproperty/submissions/Submissions.AidanHollis.pdf.

outcome is much more probable, particularly as far as the agricultural sector is concerned.

> In contrast to medicines, there is the potential for companies to become attracted to crops that are widely grown in developing countries. The investment costs are correspondingly lower than for medical research, and the potential markets correspondingly larger. For instance rice, where the value of production in India alone exceeds that of the US maize market.[191]

Moreover, other than in the pharmaceutical sector, the purchaser of the marketed GMOs is frequently not the consumer of the end product, but a farmer, for example. Higher costs resulting from an investment in GM seed could therefore subsequently be externalized to the consumer, who, in many cases, would be located in the rich North.[192] That way, the rich North might effectively finance essential research for the South by doing what it does best: consumption.

Assisted by this indirect cost shifting, a harmonized market in the developing world might therefore be sufficiently profitable to induce the necessary research. The existence of "orphan diseases," despite fairly harmonized IPR standards for pharmaceuticals, does not necessarily mean that the problem of "orphan crops" cannot be overcome by stronger and harmonized patents.[193]

But, as shown above, unilateral movements towards more IP protection for GMOs are probably insufficient. In an increasingly globalized world, in which cross-border trade becomes easier, cheaper and faster with increasing pace, multilateral harmonization appears to be the only solution to this prisoner's dilemma.[194]

Investigating how such harmonization could be achieved in practice, would lead too far. Perhaps the review of Article 27.3(b) of TRIPs will lead to a surprising result and will create a sufficiently integrated market. However, a new treaty will probably be necessary, either within the forums of the WIPO or the WTO. Intuitively, an independent framework in which virtually all developing nations participate would be a superior solution, as it would not be conceived of as being imposed on the South by the North.

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[191] CIPR Report, *supra* note 14, at 64.

[192] Barton, *supra* note 145, at 296.

[193] *But see* Wright & Pardey, *supra* note 23, at 23 (arguing that this would be the case).

[194] *See also* Justine Pila, *Bound Futures: Patent Law and Modern Biotechnology*, 9 B.U. J. Sci. & Tech. L. 326, 370 (2003) (noting several other reasons that make a compelling case for harmonization in the field of biotechnology); Maskus, *supra* note 62, at 192.

CONCLUSION

Correa, exploring the scope of TRIPs obligations, notes: "Given the uncertain impact of patenting living matter, maximum flexibility seems in order."[195] This paper has challenged both claims made in this statement. First, it demonstrated that there is in fact little uncertainty as to the economic impact of patenting living matter – if biotechnological progress, and the creation of new GMOs are regarded as desirable, effective patent protection must be considered as an essential prerequisite for privately sponsored R&D.

However, such IPRs are not mandated by any international agreement, including, specifically, TRIPs. The "maximum flexibility" that seems in order according to Correa does exist, and the relevant provisions can be interpreted plausibly so that most biological material, except for (some) transgenic micro-organisms and a significant number of biological processes, would fall beyond mandatory protection. The possibility of introducing broad exceptions, and the fact that the agreement contains no rule concerning patent scope, must ultimately lead to the conclusion that no harmonization has in fact been achieved.

This outcome is not necessarily good news. To the contrary, it is at least arguable that the opposite to "maximum flexibility" – obligations containing fairly standardized effective GMO protection – would lead to more investment in private R&D targeted at the creation of badly needed tropics-specific GMOs through larger incentives for the local inventors, valuable intellectual assets, more FDI and facilitated technology transfer. It is rather implausible that these advantages would be offset by increased rent transfer or fewer chances of "learning by imitating." This is largely due to certain characteristics that distinguish GMOs from other IPR-protected products, most importantly the local confinement and the natural reproducibility of these products.

Moreover, protection that is too weak might lead to increasing reliance on GURTs, which permit too high a degree of appropriation, and which might inhibit continuing diverse research. Effective patents for GMOs, along with sufficiently harmonized markets, might constitute the only safe passage between the dangers of too weak IP protection and too strong technological protection, which were portrayed as Scylla and Charybdis.

To pursue this course, multilateral action is necessary, as developing countries face a collective action problem with regard to unilaterally raising the standards of GMO protection. This is because unilateral action cannot create a large enough market, and others can easily free ride on one country's efforts, which might lead to misallocation of resources and the shifting of the entire costs of research onto one country's purchasers. Raising IPR standards without common agreement might be futile, or even detrimental, in this context. Therefore, "maximum flexibility" really is not in order.

To the contrary: Multilateral or international agreements appear indeed to be the only solution to this predicament. International obligatory standards mandating reasonably strong and harmonized GMO patents are necessary to manoeuvre safely through Scylla and Charybdis.

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[195] Correa, *supra* note 26, at 22.