Chapter 12
Intellectual Property

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12.1 Introduction

Intellectual property (IP), broadly defined, is a series of privileges accorded to inventors and creators. These privileges are recognized through a series of international agreements that establish minimum standards. The most significant of these agreements is probably the World Trade Organization (WTO) *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS)[1] that binds WTO Member States to comply with a range of existing international IP agreements,[2] *and then* imposes minimum standards for copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout designs (topographies) of integrated circuits, and undisclosed information (TRIPS Articles 9–39). These IP privileges are generally recognized and enforced through national laws that are consistent with these international norms. The result is a patchwork of national laws, each attempting to articulate at least the minimum standards (albeit many are more generous—the so-called "TRIPS-plus") in the context of national and regional choices. The TRIPS standards adopted and applied by WTO Member States are then subject to WTO dispute resolution and penalties that include retaliatory trade sanctions where states have not implemented and applied their obligations to maintain TRIPS' minimum IP standards (TRIPS Articles 64). The WTO dispute resolution and sanction mechanism makes TRIPS one the few enforceable international laws, and hence its gravity in assessing the impacts of IP.

[1] Albeit there are others, such as, *International Union for the Protection of New Varieties of Plants* (plant variety rights), *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* (traditional knowledge), *International Treaty on Plant Genetic Resources for Food and Agriculture* (farmers' rights), and so on.

[2] These are the *Paris Convention for the Protection of Industrial Property*, the *Stockholm Act of the Paris Convention for the Protection of Industrial Property (1967)*, the *Berne Convention for the Protection of Literary and Artistic Works*, the *Paris Act of the Berne Convention for the Protection of Literary and Artistic Works (1971)*, the *International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations*, and the *Treaty on Intellectual Property in Respect of Integrated Circuits (1989)*: TRIPS Article 2.

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K. Ludlow et al. (eds.), *Socio-Economic Considerations in Biotechnology Regulation,* Natural Resource Management and Policy 37, DOI 10.1007/978-1-4614-9440-9_12,

IP is important to living modified organisms (LMOs) under the Cartagena Protocol on Biosafety (CPB) as many of these organisms are, or embody, inventions and creations that are protected by IP. For example, a genetically modified (GM) LMO might contain patent-protected gene constructs and sequences, be the product of a patent-protected process, be marketed using a trademark, and be associated with confidential information provided to satisfy regulatory standards in an importing country.

The consequence of IP is to grant exclusivity to the IP holder and exclude all others, preventing them from using or applying the product or process protected by IP. Thus, patent protected LMOs can only be used by the patent owner, or those licensed or authorized by the patent owner (e.g., TRIPS Article 28). All others will be subject to sanction (an account of profits and damages that can be up to treble damages in some jurisdictions) for using, applying, copying (making), importing, or otherwise infringing the IP owner's exclusive rights (e.g., TRIPS Article 28). The effect of the IP can be either to prevent others accessing and using the IP-protected product or process (such as using the patented LMO), or doing something as a consequence of the IP-protected product or process (such as importing the patented LMO). The result is that for the trade in LMOs under the CPB and TRIPS, there are potentially internationally contested inherent conflicts about IP protection, such as:

a. *Equality of access to genetic resources*—IP-protected genetic resources may not be available at a reasonable price. The result is that IP might limit access to a particular genetic resource or impose barriers to the uses of a particular genetic resource.
b. *Sharing the benefits from the accessed genetic resources*—IP may not adequately reward genetic-resource providers through royalties or preferred access to the IP-protected products or processes. In essence, the IP appropriates ownership of the genetic resource and inhibits the adequate sharing of the benefits that might flow from the exploitation of that genetic resource.
c. *Freedom to conduct research*—Key products and processes necessary for research may be IP protected. The result is that others wanting to conduct research might be limited in the research they might conduct and the commercialization of any outcomes of their research because of IP protections. This is likely to be particularly problematic where the IP protects and limits the uses of key research inputs and materials. The problem can be either limited access to IP-protected products or processes, or having to negotiate too many licenses to access and use a material (such as a "patent thicket").
d. *Freedom to adopt and apply technology*—Key products and processes necessary for exploiting the LMOs may be IP protected, including both the LMO itself and other products and processes, such as pesticides and herbicides. This includes the problems associated with transferring technology, and the know-how to enable the technology to be exploited.

e. *The increasing consolidation and monopolization of agriculture and food production (especially among seeds and chemical companies)*—The positioning of IP-protected products or processes into vertically integrated production and supply chains (especially where corporations have built their businesses around the exclusivity delivered by IP-protected products or processes) limiting supply and increasing price. This can be particularly problematic where there is not adequate competition on the market (and there is a lack of alternative substitutes).
f. *The terms and conditions by which IP-protected products and processes can be exploited*—The restrictive terms and conditions applying to users of IP-protected products or processes, especially onerous license agreements (such as maintaining records for 20 years) and the avoidance of exhaustion so that the purchaser never actually owns the purchased item. This raises particularly difficult problems for saving, reusing, selling, and exchanging seeds.
g. *Traditional knowledge and folklore*—Either the failure to take into account or address traditional knowledge and folklore in the discovery, research, and development and commercialization of IP-protected products and processes, or the deleterious effects LMOs might have on traditional knowledge and folklore, such as displacing traditional farming and cultural practices, and so on.

While the CPB does not specifically address IP, other than "confidential information" (Article 21), there is express recognition that "trade and environment agreements should be mutually supportive with a view to achieving sustainable development" and "this [CPB] shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements" (Preamble). Further, any "socio-economic considerations" taken into account in reaching decisions about importing or regulating LMOs under the CPB must be "consistent with their international obligations" (Article 26(1).[3] Thus, the CPB must be applied and implemented consistent with the Parties' other commitments to international IP agreements, and this specifically includes among others the WTO's TRIPS.

Thus, IP does have the potential to limit the CPB framework's reconciling of environmental and trade needs *and* any measures adopted under the aegis of the CPB that must be "consistent with their international obligations." Importantly though, the impact of IP is likely to be considerably reduced in practice as many countries, including those adopting and applying domestic IP arrangements, are not required to enforce IP *unless* the IP is expressly protected within that country. While some developed countries register and recognize large numbers of IP-protected products, processes, and creations, significant amounts of IP (particularly patents and plant variety rights) are not registered and protected in most developed and developing countries. IP remains, however, a significant limitation on the CPB.

[3] Noting also the Preamble: "Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development."

12.2 Methodologies

The IP issue in the context of the CPB is best framed as whether there are exemptions, exceptions, and flexibilities in the international IP agreements that might accommodate decisions involving socioeconomic considerations (SECs) made under the CPB. This contemplates IP as a grant recognized in national laws that is either extinguished or restricted where a SEC in a decision made under the CPB imposes on the IP by limiting the exclusive rights of the owner. Framed this way there are a range of exceptions and flexibilities that allow SECs to limit IP, and this in turn frames the possible content of those SECs. Those affecting patents and plant breeders' rights under TRIPS are considered here as they are likely to be the main IPs affecting LMOs.

A further critical distinction is also necessary. TRIPS generally provides for the grant of negative rights so that the privilege awarded is not to exploit or use a particular protected subject matter *but rather* to prevent certain acts with that subject matter, such as copying (making), using, offering for sale, selling, or importing—"This fundamental feature of [IP] protection inherently grants Members freedom to pursue legitimate public policy objectives since many measures to attain those public policy objectives lie outside the scope of [IP] and do not require an exception under the TRIPS Agreement" (European Communities 2005, (7.210)). This perspective justifies a range of laws applied to subject matters generally, independent of the IP, such as health and safety laws for medicines and devices. For example, the Australian *Therapeutic Goods Act 1989* (Cth) ss 41B-41MR regulates the safety and performance characteristics of medical devices preventing any devices, whether IP protected or otherwise, from being imported, exported, used, or supplied unless they satisfy various standards.

The WTO context of TRIPS is also important. Most WTO agreements (except TRIPS) are directed toward removing trade barriers setting limits on national regulation based on national treatment and non-discrimination. This allows regulation that does not go *above* the threshold set by the WTO agreements. Meanwhile TRIPS establishes and imposes minimum standards requiring regulation that does not go *below* the threshold set by TRIPS. The effect of this structural restraint in TRIPS is that there is little room for national differences about how to satisfy a minimum standard, contrary to the alternative that allows a range of measures up to the threshold. The norms for the minimum IP thresholds are generally well known and so provide little room for significant regulatory differences.[4]

Further, the kinds of privileges exercised by an IP owner are private interests albeit they have a broader public benefit (promoting innovation, creation, investment, and dissemination). This means, however, that governmental decisions about LMOs made under the CPB are affecting the private interests of an IP owner, and this is likely to be a third party to the governmental LMOs' decision under the CPB.

[4] Albeit TRIPS provides: "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice": TRIPS, Article 1(1).

In essence, the CPB decisions (and regulation) are imposed by governmental bodies setting a legal environment while the IP owners are private entities (persons and corporations) whose property interests are directly impacted by the CPB decisions (and regulation). This is significant because it means that the concessions being sought from IP owners under the CPB's SECs are generally being made by non-governmental IP owners, and the concession being made will be either a financial detriment (such as the loss of a royalty payment) or a commercial disadvantage (such as allowing competition).

The basic methodology is, therefore, to:

(1) Identify what IP is embodied in the LMO
(2) Identify who owns the IP embodied in the LMO
(3) Check whether the IP embodied in the LMO is enforceable in the jurisdiction
(4) Check whether the CPB's SECs will affect the IP embodied in the LMO

Only if the answer to the last question is "Yes" is there an issue about the conflict between the CPB and IP. This assessment of the methodologies suggests three avenues by which the CPB's SECs, as they relate to IP, might be addressed: (1) within the exemptions and exceptions in TRIPS; (2) within the flexibilities in TRIPS; and (3) the financial and technology transfer mechanisms in TRIPS and the *Convention on Biological Diversity* (CBD) to offset the effects and consequences of IP. Similar avenues might also be considered for other international IP agreement commitments. These avenues under TRIPS and the CBD are now considered in turn.

12.2.1 Exemptions and Exceptions in TRIPS: Articles 27, 30, and 31

The distinction between exemptions and exceptions is that the former does not require a patent be available for a subject matter (such as a plant or animal) at all, while the latter requires that patents for a particular subject matter might not be available according to the particular circumstances (such as particular microorganisms in a public health emergency). The scope of these exemptions and exceptions are available within the bounds of the TRIPS text. Unfortunately the text is not entirely clear and there are contested understandings about what may or may not be allowable. So while these exemptions and exceptions are theoretically possible their actual scope remains uncertain.

The express exemptions for patents in TRIPS Article 27 are available for *ordre public* or morality (Article 27(2)), diagnostic, therapeutic, and surgical methods for the treatment of humans or animals (Article 27(3)(a)), plants, and animals other than microorganisms and certain essentially biological processes (Article 27(3)(b)). Where patents are not available for plants then "an effective *sui generis* system or by any combination thereof" must be available. A generally accepted *sui generis* system is the *International Convention for the Protection of New Varieties of Plants* that provides a broad exemption for the "public interest" (Article 17(1)).

This Convention also provides exceptions for acts done privately and for non-commercial purposes, acts done for experimental purposes, and certain acts done for the purpose of breeding other varieties (Article 15).

A general and more limited exception is available in TRIPS Article 30 for patented inventions that satisfy the cumulative thresholds of not unreasonably conflicting with a normal exploitation of the patent and not unreasonably prejudicing the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. This is definitely an available, and not an illusory exception, although it is not a general basis for avoiding patents. This exception has been relied on, for example, to allow the making and using of the patent protected invention in gaining regulatory approvals for manufacturing and sale after the patent expired (the so-called "Bolar exception") (Canada—Patent Protection of Pharmaceutical Products 2000, (7.38)), but not for the manufacturing and stockpiling of a patent protected product in anticipation of a patent expiry (Canada—Patent Protection of Pharmaceutical Products 2000, (7.84)).

Another general exception is available in TRIPS Art 31 for laws allowing "other use of the subject matter of a patent without the authorization of the right holder," subject to respecting conditions and procedures aimed at protecting the "legitimate interests" of the rights holder. This is essentially a provision that allows for compulsory licensing for government and third-party uses. In other words, Members may determine the *grounds* for an award of a compulsory licence,[5] but must accord with the *conditions and procedures* required by TRIPS.[6] These are that each authorization is to be "considered on its…merits" and subject to review; that "efforts to obtain authorization on reasonable commercial terms and conditions" have been unsuccessful within a "reasonable…time"; the authorization has a limited "scope and duration"; the authorized use is not exclusive; the authorized use is not assignable; the authorized use is "predominantly for the supply of the domestic market"; and the authorized use may be terminated when the circumstances requiring authorization cease and there is adequate remuneration and this decision is reviewable (Article 31(a)–(j)). The issuing of authorizations for anticompetitive conduct is treated separately (Article 31(k)), and additional requirements are imposed for the proper working of another patent (dependent patents) (Article 31(l)).

12.2.2 Flexibilities in TRIPS: Articles 7 and 8

Within TRIPS, the main flexibility in dealing with socioeconomic questions is Art 8 that provides:

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary…to promote the public interest in sectors of vital import-

[5] This was confirmed in the Doha Declaration: WTO Ministerial Conference (2001), *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, (5(b)).

[6] These conditions and procedures are generally addressed in Article 31, although there may be other relevant conditions imposed by TRIPS such as national treatment (Article 3), most-favored nation treatment (Article 4), and so on.

ance to their socioeconomic and technological development, provided that such measures *are consistent with the provisions of this [TRIPS] Agreement*.
2. Appropriate measures, provided that they *are consistent with the provisions of this [TRIPS] Agreement*, may be needed to prevent … the resort to practices which … adversely affect the international transfer of technology (emphasis added).

The key limitation in these TRIPS provisions is the phrase "are consistent with the provisions of this [TRIPS] Agreement." This might be interpreted to mean that any measures adopted that limits TRIPS addressing socioeconomic factors must first satisfy the TRIPS minimum standards, in effect nullifying the apparent exceptions and flexibility provided by Article 8.[7] Alternatively, a narrower meaning might have been intended, and presumably this is the case as these words were intended to have some effect otherwise they would not have been included. The issue then is what does the term "consistent" mean? Or in the alternative, how inconsistent with the substantive parts of TRIPS (that is, the non-Art 8 parts) can a provision be before it passes the "not consistent" threshold, and is a breach of TRIPS? Unfortunately there is presently no definitive interpretation by a WTO dispute settlement panel or Appellate Body, albeit the existing decisions suggest Article 8 does allow "certain adjustments" but not "a renegotiation of the basic balance of [TRIPS]" (Canada—Patent Protection of Pharmaceutical Products 2000, (7.26)). Both the subsequent *Doha Ministerial Declaration* and the *Declaration on the TRIPS Agreement and Public Health* reinforce the importance of Article 8 (see WTO Ministerial Declaration 2001, (19); WTO Declaration 2001, (5)). The effect of these declarations on future interpretation is uncertain, albeit they will certainly justify some public health actions that are contrary to the non-Art 8 TRIPS provisions. Whether other clearly inconsistent measures are allowable seems unlikely given the panel and Appellate Body preference for the perspectives and expectations of IP holders (Okediji 2003, pp. 914–915). This analysis demonstrates, however, that there are credible avenues to assert a role for Art 8 in justifying flexibility in applying TRIPS.

Closely linked to the TRIPS main exception and flexibility in dealing with SECs are the objectives set out in Art 7 that provides:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

There appear to be six objectives: technological innovation; transfer and dissemination of technology; use of technological knowledge; the mutual advantage of producers and users; social and economic welfare; and a balance of rights and obligations. Together with the text of TRIPS' Preamble these objectives arguably apply to

[7] Some commentators consider this provision "is thus essentially a policy statement that explains the rationale for measures taken under Articles 30 (exceptions to rights conferred), 31 (other use without the authorization of the right holder) and 40 (control of anti-competitive practices]": Gervais 2008, p. 209.

a global interpretation of TRIPS and the measures implementing TRIPS in domestic laws. (For advocates of this proposition, albeit not universally accepted, see, Yusuf 2008, p. 14; Correa 2007, p. 104. Other proponents assert that these objectives are necessary to prevent the abuse of exemptions and exceptions: see, for example, UNCTAD-ICTSD 2005, p. 133). This means that in considering any particular apparent inconsistency between a domestic law or practice and TRIPS there needs to be an assessment taking into account the totality of the domestic arrangements. This perhaps suggests considerable potential to adopt measures that can be justified by a demonstrable social and economic welfare or balance of rights and obligations in a particular domestic regulatory setting. Importantly, both the *Doha Ministerial Declaration* and the *Declaration on the TRIPS Agreement and Public Health* reinforce the importance of Art 7 (WTO Ministerial Declaration 2001, (19); WTO Declaration, (5)). Again, the effect of these declarations on future interpretation is uncertain, albeit they will certainly justify some public health actions that are contrary to the non-Article 8 TRIPS provisions.

In short, there are avenues under TRIPS for SECs to be taken into account according to the flexibilities in TRIPS. This is particularly so where the regulation addresses how the IP will be exercised or exploited. More problematic and uncertain are regulations that might limit or conflict with the IP itself. In these circumstances, TRIPS may not be very flexible and will generally need to be complied with.

12.2.3 Offset the Effects and Consequences of IP using the Financial and Technology Transfer Mechanisms in TRIPS and the CBD

Where IP does pose a problem for the CPB then, there are potential mechanisms in the CPB, CBD, and TRIPS to ameliorate these problems. At this stage, these are postulated, and undoubtedly they will remain hotly contested, especially by those advocating the primacy of IP. Perhaps the most significant problem for the CPB will be where IP must be respected, but the IP is owned by a third party rather than a governmental entity, and requires compensation for the derogation of the IP as a consequence of the decision under the CPB. In these circumstances the CPB, CBD, and TRIPS do contemplate financial and technology transfer mechanisms, albeit the opportunity and scope will be contestable.

The CPB expressly provides that in addressing the financial resources necessary for the implementation of the CPB the provisions of CBD about financial resources are applicable (Article 28), and this includes the CBD Article 20(4):

> The extent to which developing country Parties will effectively implement their commitments under this [CBD] will depend on the effective implementation by developed country Parties of their commitments under this [CBD] related to financial resources and transfer of technology and will take fully into account the fact that economic and social development and eradication of poverty are the first and overriding priorities of the developing country Parties.

And Article 20(5):

> The Parties shall take full account of the specific needs and special situation of least developed countries in their actions with regard to funding and transfer of technology.

These CBD provisions suggest that for implementing the CPB there is an express obligation to consider financial and technology transfer issues and that this is the developed country Parties making concessions to the developing country Parties.[8] Further, the CBD's financial mechanisms expressly contemplate economic and social development as relevant objects.

Along similar lines, in addition to TRIPS Article 8 (set out above), Article 66(2) provides:

> Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

Following the Doha Ministerial Conference commitment in 2001[9] to "put in place a mechanism for ensuring the monitoring and full implementation of the (Art 66(2)) obligations" (WTO Ministerial Conference 2001, (11(2))), the TRIPS Council has implemented a scheme of annual reporting "on actions taken or planned in pursuance of their commitments under [Art 66(2)]" (Council for Trade-Related Aspects of Intellectual Property Rights 2003, (1)). This reporting addresses the legislative, policy, and regulatory framework for incentives, types of incentives, the entities providing the incentives and information about the functioning (efficiency and effectiveness) of the incentives (Council for Trade-Related Aspects of Intellectual Property Rights 2003, (3)). Within this broad remit the incentives to enterprises and institutions might well include financial and technology transfer mechanisms that address any conflicts between IP and the CPB.

12.3 Critical Assessment

The methodologies considered above essentially accept that in implementing SECs under the CPB there must be respect for IP. This assessment accepts that IP will almost certainly take a higher priority in the hierarchy of rights and obligations because of the CPB's express statement that it be applied and implemented "consistent with their international obligations" (Article 26(1)).[10] There are various exemptions and exceptions available under the IP agreements, albeit they are presently contest-

[8] There is recent interest under the CBD about effective access to and transfer of relevant technology: see Conference of the Parties to the CBD pp. 42 and 166–168.

[9] This commitment has been reiterated in the context of TRIPS and public health: see WTO General Council 2005, (6); WTO General Council 2003, (7).

[10] Noting also the Preamble: "Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development."

ed and have not been clearly articulated. While in practice these apparently onerous IP obligations are likely to be diminished because the international IP obligations often depend on domestic registration, and the like, there still remains a potential problem. Where there is a problem this is likely to be magnified because IP owners are generally third parties and not governmental entities that are the parties to the CPB decisions. This might be ameliorated, however, through a creative consideration of the financial and technology transfer mechanisms available under the CBP and other agreements.

12.4 International Arena

While the analysis here has focused on the WTO's TRIPS agreement there are numerous other international IP agreements. These include the *Paris Convention for the Protection of Industrial Property*, the *Stockholm Act of the Paris Convention for the Protection of Industrial Property*, the *Berne Convention for the Protection of Literary and Artistic Works*, the *Paris Act of the Berne Convention for the Protection of Literary and Artistic Works*, the *International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations*, the *Treaty on Intellectual Property in Respect of Integrated Circuits*, and so on. There are also agreements that extend, modify, or articulate further IP obligations such as the *International Union for the Protection of New Varieties of Plants* (plant variety rights), *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* (traditional knowledge), *International Treaty on Plant Genetic Resources for Food and Agriculture* (farmers' rights), and so on. Within this multiparty international IP domain, however, there are also further entrenched obligations under bilateral and regional trade agreements. These bilateral agreements are proliferating and often impose significantly higher IP obligations that the existing multiparty agreements. The effect in the international arena is that the particular IP landscape of each nation-state needs to be determined according to their particular commitments.

12.5 Administrative Consequences

Where decisions about SECs are being made the particular IP landscape needs to be considered. Presumably the IP content of the LMO and any related materials, processes, and so on, will need to be identified and the relevant owners determined. As IP is often owned by non-governmental third parties to the LMO decisions, the IP owners will need to be clearly identified and probably involved in the decision-making process. And where decisions adversely affect an IP owner's IP then

mechanisms of review and compensation will be required.[11] Presumably, IP could be identified through the importation application process under the CPB by asking questions on the application form about the kinds of IP embodied in the LMO.

12.6 Summary/Synthesis

- The CPB must be applied and implemented consistent with the Parties' other commitments to international IP agreements, and this specifically includes the WTO's TRIPS agreement.
- International IP agreements do not expressly exclude SECs.
- Where there are conflicts between the CPB and IP, there are various exemptions, exceptions, and flexibilities available under the IP agreements, albeit they are presently contested and have not been clearly articulated.
- Where IP is a problem for implementing SECs under the CPB this is likely to be magnified because IP owners are generally third parties and not governmental entities that are the parties to the CPB decisions.
- Any conflicts between the CPB and IP agreements might be ameliorated through a creative consideration of the financial and technology transfer mechanisms available under the CBP and other agreements.

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[11] See, for example, TRIPS, Article 41.

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