Chapter 4
Additional Mechanisms beyond Disclosure

I. Introduction

In Chapter 3, this handbook examined how disclosure requirements in the national patent legislation could potentially help act as an indicator for possible misappropriation for the national competent authority under the Nagoya Protocol and indigenous and local communities and related stakeholders, as well as to provide patent authorities with relevant information to make an informed decision on whether relevant patent criteria are met when a patent application has been filed with the national patent office and is being assessed for the potential grant of rights. A range of other mechanisms exist, though, that could potentially exclude the consideration of certain subject matter from patentability altogether, without proceeding to the question of whether patentability criteria are met, or which could be used as grounds to defeat or revoke a patent. These mechanisms are examined in this chapter.

From a strategic perspective, many of these patent law mechanisms can be classified as 'defensive', meaning that they are designed to prevent or reduce the misappropriation of genetic resources and associated traditional knowledge (TK) through the intellectual property (IP) system by others, rather than to use IP to secure benefits for the provider country or indigenous and local communities (ILCs) accruing from research done on genetic resources and related TK. Importantly, the mechanisms apply, through the national treatment principle, equally to foreigners and nationals of any given country. These patent law mechanisms are generally grounded on rationales that have developed over time, but with little consideration of Convention on Biological Diversity (CBD) or Nagoya Protocol objectives. Chapter 4 will discuss these mechanisms and their background so that users of this handbook are able to make informed decisions about how to shape their domestic legislation and negotiation strategies.

II. Life Forms and their Patentability

A. Biotechnology, GRs and Derivatives: Key Exclusions

National IP laws, appropriately tailored, may assist a country in addressing the situation where individuals seek to patent products based on genetic resources without having met CBD/Nagoya Protocol obligations. A first line of argument against those who seek such patents may be that the patent law cannot grant protection to the product in question, at least in the provider's jurisdiction. It is also important because stakeholders in provider countries need to be aware of the realistic range of possibilities when granting access to genetic resources and negotiating benefits (i.e., to what extent will it really be possible to obtain a patent over the fruits of the user's R&D for which benefits may be shared?).

The question of whether derivatives are subject matter covered by the Nagoya Protocol is discussed in Chapter 1. Unfortunately, the terminology used in the Protocol concerning genetic resources and their derivatives does not translate easily into the language used by IP practitioners. The language of the Protocol was drafted in a way that largely avoids linkages

to the IP system and is therefore difficult to utilize in clarifying IP-related ABS issues. Moreover, the IP law in this area is also quite complex.[111] From the perspective of patent law, many countries have traditionally excluded from patent protection naturally existing substances. This is permitted under the TRIPS Agreement for WTO Members, since Article 27.1 of TRIPS requires that patent protection be available only for *inventions* that otherwise meet patentability criteria, and not for *discoveries* of substances existing in nature. Article 27.3(b) of the TRIPS Agreement provides that plants and animals can also be excluded from patentability, but that some measure of patent protection must be available for micro-organisms.

Members are generally free to determine definitions for, or the scope of, the terms invention, discovery and micro-organism, respectively, as they are not defined under the TRIPS Agreement. Because countries have this flexibility in the implementation of Article 27 of the TRIPS Agreement, they often differ widely in the extent to which a substance found in nature needs to be changed, if at all, in order to be patentable. A number of countries, especially in Latin America, exclude from patentability the mere extraction or isolation of a naturally existing substance.[112] In these jurisdictions, the underlying biological material must have undergone a structural change in order to be patentable. With respect to micro-organisms, some countries such as Brazil have required that in order to be patentable, micro-organisms must have been genetically modified.[113] Under US[114], Japanese and EU practice, however, the process for isolating a substance existing in nature may qualify for patent protection; further, a process patent claim may include the underlying substance.[115] It should also be noted that the various approaches to define what is patentable have not been challenged in WTO dispute settlement to date.

The distinction, from a legal perspective, is that by removing certain genetic resources from patentable subject matter, there is no question of whether the claimed product or process meets the three patentability criteria of novelty, inventive step and industrial applicability. It remains in the public domain unless it is the subject of another exclusive right, such as plant variety protection or *sui generis* TK laws. IP law can therefore make it more difficult to (mis)appropriate certain genetic resources. National patent law could exclude from patentability mere discoveries, and ensure that some change in the underlying genetic resources must have taken place in order to proceed to the question of whether or not to grant a patent. This would render it impossible to appropriate plants and animals via patents as such[116], and remove the possibility of patenting the isolation or extraction of a naturally existing substance.[117] This approach would also, by definition, remove from patentability all

[111] The term 'derivatives' means something very different in patent law than it does under the CBD; it is a term of art used to describe a products that are similar to an originally patented product, but nevertheless not identical. In the case of medicines, for example, it could be used to describe a chemical entity with a slightly different chemical structure.
[112] See examples from Argentina, Brazil and the Andean Community. UNCTAD (2011b), pp. 48-49.
[113] The South Centre, V. II (2008), pp. 11-12.
[114] A US Supreme Court case is currently examining the question of whether gene sequences can be patented. See the discussion of the Myriad case below.
[115] Ibid. See also *Diamond v. Chakrabarty* 447 U.S. 303 (1980); Enforcement Standards for Substance Patents of Japan; and Article 3.2 of the European Directive on Biotechnological Inventions.
[116] Plants and animals as such can also be excluded from patentability wholesale under Article 27.3(b) of the TRIPS Agreement.
[117] The authors do not imply that extraction or isolation is not a laborious process that merits some type of compensation; the authors argue only that the patent system is not intended to provide a reward for activities that are closer to discoveries than inventions.

derivatives under the Nagoya Protocol, since by definition derivatives are naturally occurring biochemical compounds.

Commentary suggests that micro-organisms should be treated in a manner similar to plants and animals notwithstanding the requirement in Article 27.3(b) of the TRIPS Agreement that micro-organisms should remain patentable subject matter. There is general worldwide consensus that micro-organisms, which include fungi, bacteria and viruses (including those that can be classified as pathogens) as found in nature cannot be patented.[118]

While provider countries may adopt a bar for patentability along the lines of the preceding paragraph, this may not prevent an individual or company that bioprospects from seeking a patent over certain isolates and extracts where that is permitted.[119] As noted above, US, Japanese and EU law would currently allow genetic resources and derivatives which had been extracted and isolated, without any change to their structure, to be considered for patentability under certain circumstances, even where they are not patentable under provider country legislation. Moreover, patent laws should not prevent the patentability of a *bona fide* new invention that utilized an unchanged genetic resource. Even in such cases, disclosure could nonetheless be used to help assess, to some extent, the three criteria that must be met in order to grant a patent (see discussion of disclosure requirements in the previous chapter). In this regard, it should also be recalled that the question of mandatory disclosure of origin/source through a revision of Article 27.3(b) remains tabled at the WTO, although delegates do not appear to be any closer to agreement on this issue than they were when the proposal was first made in 2008. Further, in a best case scenario, where access to genetic resources has been provided to a user under MAT which include the appropriate sharing of benefits, providers may potentially even benefit where a *bona fide* user decides to seek commercialization of the fruits of his or her research in a jurisdiction of broad patentability standards.

Depending upon the level of sophistication of their R&D capacities, some provider countries may find that they can incentivize local firms to seek commercialization of the fruits of their research by allowing the patentability of isolates and extracts of micro-organisms. India, for example, has followed this approach.[120] Still relatively few developing countries that are home to rich biodiversity will be able to take advantage of the availability of patents over extracts and isolates of micro-organisms, though, and the simplicity of exclusion where the ability of the patent office to assess patent applications adequately is low may be a more practical TRIPS-compliant alternative of helping prevent misappropriation.

A final question relates to the status of genes and other sub-cellular components. R&D on the genetic code of the plants, animals and micro-organisms which have their origin in a provider country, as well as R&D into practical applications of that code, would be subject to applicable ABS requirements of the Nagoya Protocol, as this treaty applies to all such genetic resources. On the IP side, to the extent that a sub-cellular component is not an organism, there is no particular obligation in Article 27.3 of the TRIPS Agreement to provide any measure of protection for genes or sequences of genetic code.[121] In most jurisdictions, the genetic code of living things are generally regarded as a substance found in nature (hence, excludable from patentability). Yet, advances in genetic research are increasingly the subject of patent

[118] UNCTAD-ICTSD (2005), p. 392.
[119] South Centre V. II (2008), pp. 15-16.
[120] See Somasekhar (2005).
[121] UNCTAD-ICTSD (2005), p. 393.

applications in jurisdictions where much of that R&D is taking place. This is because the genetic code of living things, including humans, animals, plants and micro-organisms, can be mapped and isolated, and used in diagnosis and therapy. DNA can be synthesized from messenger RNA (cDNA). Jurisdictions where the fruits of genetic research are being patented argue that this takes the gene out of its naturally-existing environment, changes it and makes it patent-protectable.

But even in those jurisdictions that are permitting the patenting of genes, the status of what exactly is or is not patentable is subject to debate. In a recent case in the US, a District Court judgment decided to invalidate the patents on two isolated gene sequences that had been granted to Myriad Genetics, Inc. These two gene fragments are useful in the diagnosis of some hereditary forms of breast and ovarian cancer. A recent Court of Appeals for the Federal Circuit decision reversed the earlier 2010 District Court judgment and held that isolated gene fragments are potentially patentable. [122] The majority of the Court of Appeals argued that while genes themselves are products of nature, patents should continue to be granted to applicants who "isolate" nucleic acid sequences from their natural environment, sequence them, and identify functions and uses for those sequences in line with existing USPTO practice. The majority concluded that the isolation resulted in a change of molecular structure, even if it did not change the underlying genetic code of the isolated sequence. One judge dissented, however, and argued that mere isolation of the two BRCA gene sequences was not an invention, since there was no substantive change in the isolated gene from the larger gene sequence.[123] The US Supreme Court recently reversed the Court of Appeals decision, holding that the mere isolation of a gene, as in the case of the two BRCA genes, is not patentable.[124] The Supreme Court decision on the issue of the patentability of genetic code is likely to have an effect on practice not only in the US but elsewhere as well.

From the perspective of provider countries, keeping gene sequences of genetic resources from the country of origin off-patent is certainly one means to help prevent misappropriation. This is especially true for genetic resources that are potentially not covered by the Nagoya Protocol, including those that are already in the hands of user countries (i.e., pre-dating the CBD and/or the Nagoya Protocol). At the same time, as in the case of plants, animals and micro-organisms more generally, if there exists a material transfer agreement under MAT, where benefits are to be shared (as is required under the Protocol), then commercialization would potentially offer the possibility for the provider country stakeholders to gain from patenting.

Key Points

⇒ The Nagoya Protocol stipulates that the utilization of genetic resources as well as subsequent applications and commercialization are subject to benefit sharing obligations. The Protocol leaves it open to interpretation which substances or even which types of information generated from genetic resources through the application of biotechnology are subject to benefit sharing obligations.

[122] See, for example, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc et al.* (Case No 2010-1406, decided 29 July 2011 by the US Court of Appeals for the Federal Circuit.

[123] The dissenting judge's view is similar to the position taken by the European Patent Office (EPO) Technical Board of Appeal that while the diagnostic methods developed by Myriad are patentable, the underlying isolated gene in its normal or mutated form is not.

[124] *Association for Molecular Pathology et al. v. Myriad Genetics, Inc et al.* **(**Case No. 12-398, slip op, decided by the Supreme Court of the United States on 13 June 2013).

⇒ The TRIPS Agreement permits Members to exclude from patentability substances existing in nature, since they can be classified as discoveries, and not inventions. Plants, animals and micro-organisms in their natural form can therefore be excluded from patentability.

⇒ The TRIPS Agreement requires that some level of patent protection must be available for micro-organisms, such as viruses, bacteria, fungi, etc. Some countries have addressed this requirement by stipulating that some genetic change needs to have occurred in order for a micro-organism to be patentable. Other jurisdictions have been willing to entertain patent application claims for mere isolation or extraction.

⇒ Because genetics examines sub-cellular units, and micro-organisms are cellular, it falls outside the obligation relating to the patentability of micro-organisms under TRIPS Article 27.

⇒ IP law concerning the patentability of the fruits of genetic research is as yet evolving. There is little global consensus on what ought to be patentable. Key questions in these cases include whether the gene has been taken out of its naturally-existing environment; whether isolated gene sequences are patentable; and the extent to which such gene sequences need to be modified or applied in order to be patentable.

⇒ Exclusions from patentability will dispense with the need for patent offices to substantively examine an application. The result will be that the excluded item will be in the public domain unless covered by some other form of IP, at least in the provider country. This may be an attractive TRIPS-compliant alternative for developing countries that have little capacity to assess certain complex biotechnology patents.

B. Pathogens

Chapter 1 discussed the debate about whether pathogens are covered in under the Nagoya Protocol, and concluded that there did not appear to be any language in the text of the Protocol that would seem to exclude it. The link between pathogens under Article 8(b) of the Nagoya Protocol and IP surfaces when user country firms use the acquired pathogen to create vaccines and treatments for the diseases which they cause, and seek patents over the resulting medical product or process. For example, the Government of Indonesia decided in 2007 to withhold H5N1 virus samples from WHO's Collaborating Centres until a mechanism offered fairer terms for developing countries. Indonesia's action was initiated after it discovered that the sample viruses it had transferred to WHO Collaborating Centres were given to vaccine manufacturers without its knowledge or permission under material transfer agreements and patents had been granted to such manufacturers for the fruits of their research based on those samples.[125]

Article 8(b) of the Nagoya Protocol, which stipulates that Parties need to take due regard in the ABS legislation to emergency situations including those involving public health, could potentially provide a limited amount of relief in the event a user country firm uses a pathogen obtained from a provider country to create a vaccine that is then patented by that firm. Nothing would, for example, exclude the consideration by developing countries to grant the issuance of compulsory or government-use licenses to either import or produce the vaccines

[125] Shashikant (ed.) (2010), pp. 24 and 31.

locally, assuming that a patent exists over the vaccine in the provider country. National patent legislation would need to provide the legal underpinning for this eventuality, however. Specifically, compulsory and government-use licenses would need to be made available in order to address emergency situations. National ABS legislation should also include language that indicates that the access provided to pathogens under Article 8(b) must take into consideration the expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need. In order to make clear that the national ABS legislation has jurisdiction over such pathogens, there is nothing preventing Member States from stipulating that, notwithstanding the debate over whether the CBD and Nagoya Protocol cover pathogens, their ABS law covers all genetic resources, including pathogens.

A more difficult question is to determine the impact of the work done at the WHO on the sharing of virus pathogens on the Nagoya Protocol, and how developing countries should take this work on board in formulating a strategy to deal with the situation of demands made by user countries for access to pathogens found locally, as well as how this may affect the options available to developing countries in non-emergency situations.

At the May 2011 World Health Assembly, Member States adopted a resolution endorsing the report of the Open-Ended Working Group on Pandemic Influenza Preparedness on the sharing of influenza viruses and access to vaccines and other benefits, and the resulting 'Pandemic Influenza Preparedness Framework', which includes as annexes SMTAs for the sharing of pathogens with entities that are first, part of the WHO network for influenza monitoring, and second, between network entities and entities outside of that network.[126]

In the negotiations of the Open-Ended Working Group and at the 64th World Health Assembly (WHA) in May 2011 where the output of the Working Group was ultimately endorsed[127], government delegates largely avoided including any language in the draft SMTAs that would clarify the relationship between these SMTAs and the Nagoya Protocol. The concept of ABS so prevalent in the Nagoya Protocol is, nonetheless, also present in the two SMTAs, even in the absence of language directly linking the SMTAs with the Protocol. In the SMTA for the WHO network (SMTA1), recipients are obliged to actively seek the participation of scientists from the originating laboratories, especially those in developing countries, and participating entities are required to refrain from seeking any intellectual property (IP) protection over vaccines and other treatments made using the underlying materials.[128] Onward transfer under this SMTA to an entity outside the WHO network is permitted provided the outside entity agrees to be bound by the terms of the SMTA.

In the SMTA for contracts between WHO network entities and entities outside the WHO network (SMTA2), the recipient of the virus must commit to at least two benefit sharing options in exchange for access to the virus sample, which potentially includes royalty-free licenses to manufacturers in developing countries, creating a reserve for developing countries antiviral medicine in pandemic situations at affordable prices or donating 10% of vaccine production to WHO, among others.[129] Even if there was a conscious decision on the part of

[126] World Health Assembly Resolution 64.5 of 24 May 2011.
[127] Saez (2011).
[128] Assuming that pathogens are covered under the Nagoya Protocol, this requirement to refrain from patenting would be stricter than the standards as required by the Protocol.
[129] Ibid.

governments negotiating these instruments to avoid any reference to the Nagoya Protocol, it would make sense that the drafters would still wish to see these documents consistent with the Protocol, in the event the relationship between the work of the WHO and the Protocol were ever to be decided by a court of law. Both SMTA1 and SMTA2 are included in Annex II to this handbook.

However, while WHA Resolution 64.5 urges Member States to implement the Pandemic Influenza Preparedness Framework (which includes an endorsement of the SMTAs and stipulates the situations in which the SMTAs are to be used), unlike a binding treaty obligation, there is no means beyond general contract law to enforce compliance by a Member State or to ensure the use of and adherence to the terms of the SMTAs; countries and participating entities in the WHO Collaborating Centre network will, though, be bound by SMTA1. From a legal standpoint, it may therefore be prudent to consider the SMTAs as a contractual (as opposed to a treaty-based) safeguard against those that may seek to obtain IP protection over vaccines and other treatments produced using the underlying genetic materials (and related TK) without the permission of the country granting access, and recourse for violations of the SMTAs is, in principle, limited to the dispute resolution mechanism stipulated in these agreements. This is perhaps what was meant when Article 3*bis*(3) of the Nagoya Protocol requires that "[d]ue regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol", in so far as the negotiations of the WHO Working Group were still taking place during the Nagoya Protocol negotiations.

As a matter of strategy, developing countries which have to deal with issues of ABS over virus pathogens would be best advised to: 1) grant access to such pathogenic resources under the WHO network to avail of SMTA1, as this document grants the greatest measure of protection against the unauthorized patenting of products and processes developed from pathogens; and 2) review their ABS and IP laws to ensure that compulsory license and government-use license remedies are available under the second clause of Article 8(b) of the Protocol, i.e., in emergency outbreak situations. The latter will be necessary where, for one reason or another, access has to be granted to pathogens outside the WHO Collaboration Centre framework. In such cases, governments could cite the second clause of Article 8(b), as justification for negotiating a material transfer agreement with user firms for appropriate benefit sharing in emergency situations (perhaps by using SMTA2 as a template). In order to better ensure benefit sharing notwithstanding the debate over whether pathogens are covered under the CBD and NP in non-emergency cases, the national ABS law should make clear that the law is intended to govern issues related to access and benefit sharing for all genetic resources within national borders, including pathogens.

In other forums, discussions continue at the Geneva-based Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), which takes place under the auspices of the World Intellectual Property Organization (WIPO). Established in October 2000, this forum's mandate[130] is to shape an international *sui generis* regime for the protection of TK and traditional cultural expressions, as well as an IP regime that addresses the misappropriation of genetic resources. Discussions at the IGC have been examining disclosure requirements and the feasibility of databases under such an international

[130] See Decision 28 of the 38th WIPO General Assembly (2009). The mandate for this Committee was extended in 2011.

instrument(s), but have so far avoided the issue of how the evolving *sui generis* regime would interface with the CBD and the Nagoya Protocol, and how pathogens ought to be treated. At this stage, it is as yet unclear how the IGC discussion will shape the international regime for ABS and pathogens, and its implications on IP.

Key Points

⇒ There has been a longstanding debate among negotiators on whether the CBD and NP cover pathogens. Article 8(b) of the Nagoya Protocol, however, arguably requires Member States to take into consideration the need for expeditious access to pathogens in emergency situations and expeditious benefit-sharing arising out of the use of such genetic resources.

⇒ Where possible, developing countries should consider granting access to pandemic virus pathogens in cooperation with WHO Collaboration Centres using the SMTA1, as called for under WHA Resolution 64.5.

⇒ Developing countries should review their ABS and IP laws to ensure that compulsory license and government-use license remedies are available under the second clause of Article 8(b) of the Protocol, in emergency situations.

⇒ Where it is not possible to provide access to pathogens through WHO Collaboration Centres, developing countries should negotiate with the user country firm, possibly using SMTA2 as a template. In emergency situations, Article 8(b) of the Nagoya Protocol could be cited to obtain appropriate benefit sharing.

⇒ In non-emergency situations, access to pathogens should be made conditional on benefit sharing through national ABS legislation, which should make clear that the scope of domestic law includes ABS related to pathogens.

III. Limitations and Exceptions to IP Laws

A. The Research and Experimentation Exception for Patents and PBRs

Exceptions to patent law acknowledge the existence of a patent, but allow certain activities using the protected subject matter to take place notwithstanding an absence of permission by the patent holder. The research and experimentation exception in patent law is an exception to the right of a patent holder to be able to exclude others from the use of the patented subject matter if that subject matter is being used for certain research activities.[131] The effect of the exception is to shield scientists from liability when they conduct research using patented subject matter that falls under the exception without the permission of the patent holder. Most countries have included a research and experimentation exception in their national patent law.

Language from a World Trade Organization (WTO) dispute settlement case in 2000 perhaps captures the rationale behind such an exception best: "a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to

[131] UNCTAD-ICTSD (2005), pp. 437-38.

the public."[132] WTO Members have relied on this language to formulate explicit research exceptions in their domestic patent law under Article 30 of the TRIPS Agreement.[133]

Practices between countries vary, though, as to exactly what kind of research and experimentation actually falls under this exception. Some countries have extremely broad language that permits virtually all scientific and technological research activities, irrespective of how the fruits of that research may be used (for example, Brazil, the Bangui Agreement). Other countries attempt to distinguish between commercial and non-commercial research, excepting the latter but not the former (for example, Indonesia, Kenya, Lebanon). Still other countries make a distinction between research "with" a patented product or process and research "on" a patented product or process (for example, the continental European countries generally make an exception for research "on" a patented product or process but not on research "with" a patented product or process). There is therefore no uniform practice among the countries of the world. Moreover, the exact scope of the exception has not, to date, been the subject of WTO dispute settlement beyond the suggestive language in the EC-Canada case cited above.

It should be noted that IP regimes other than patents can also have a research and experimentation exception. Of particular relevance in the CBD context, is the area of plant variety protection, otherwise known as plant breeders' rights (PBRs). PBRs are a *sui generis* form of IP protection over new varieties of plants that meet certain criteria.[134] Article 15 of the 1991 International Convention for the Protection of New Varieties of Plants (UPOV), for instance, makes acts done for experimental purposes a mandatory exception to PBRs. UPOV permits free use of protected varieties by any breeder for the purpose of developing a new variety. Countries that have opted to have *sui generis* systems of PBRs outside the UPOV regime, such as Thailand, also include a statutory research exception in their PBR legislation.[135] Research exceptions can also be built into utility model legislation.

Arguably, a research and experimentation exception in the patent law is fully consistent with the Nagoya Protocol and supports certain provisions. Notably, Article 8(a) of the Protocol states that "[i]n the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall . . . [c]reate conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including though simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research." A potential conflict exists with PBR laws, however. PBR laws with a broad R&D exception allow a breeder to utilize genetic resources for developing new varieties, provided he already (legally) possesses those genetic resources.

It is important to note, however, that a research and experimentation exception in the national patent law will not eliminate the need for PIC under Nagoya compliant national ABS legislation in the event that someone seeks to access genetic resources for research purposes.

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[132] *Canada-Patent Protection of Pharmaceutical Products*, WT/DS114/R, 17 March 2000, para. 7.69.

[133] Article 30 of the TRIPS Agreement provides that "Members may provide limited exceptions to the exclusive rights conferred by patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner."

[134] The criteria for a plant variety to receive protection under PBR legislation are generally novelty, distinctiveness, uniformity and stability.

[135] See Section 33 of Thailand's Plant Varieties Protection Act, B.E. 2522 (1979), as amended.

Under Article 6(1) of the Protocol, "access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party." Utilization of genetic resources is further defined in Article 2 of the Protocol to mean research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined under the CBD. Unlike Article 8(a) of the Protocol, the PIC requirement makes no distinction between commercial and non-commercial research.

The interface of the provisions concerning R&D in the national patent law and national ABS legislation sets up an interesting situation. Patent holders are unable to prevent R&D activities involving their inventions that contain or are based on genetic resources, provided that R&D falls under the scope of the research and experimentation exception. Researchers are, however, not completely free to conduct that research without risk of legal liability as they may still be subject to PIC of the provider country when they seek to access those same genetic resources, subject only to the requirement that, under Article 8(a) of the Nagoya Protocol, simplified measures for access need to be available if the research is non-commercial.

This situation does not necessarily reflect an incompatibility of the two sets of laws. The patent holder has an economic incentive that may work against the development of technologies that could potentially render the subject invention obsolete. A research exception in the patent law helps to preserve some of the 'freedom to operate' and conduct such research in furtherance of the advancement of technical knowledge. The PIC requirement is the basic check against misappropriation. The economic dynamic of patent holders is not present in the case of PIC and provider countries. In fact, provider countries are interested in seeing genetic resources and associated TK become successful commercial products, provided the benefits accruing from those products are shared with the provider country and/or the indigenous communities.

Given that the treatment of the freedom to operate under these two sets of laws is compatible, how should countries structure their research and experimentation exception in the patent law? Before answering this question, it is important to consider a number of trends in R&D worldwide.

First, there is an increasing tendency for universities to seek patent protection over their research results as a consequence of certain national and university policies. A number of developing countries have passed legislation or are considering passing legislation that encourages the patenting of research results by universities. Such countries include India, Jordan, Malaysia and South Africa. These laws are often modelled at least in part on the US Bayh-Dole Act (1980), which, *inter ali*a, actively endorsed the practice of universities seeking patents, in an effort to bridge the gap between scientific research and commercialization.[136]

A second related trend is that there is an increased blurring of the lines between commercial and non-commercial research, with courts in certain common law countries such as the United Kingdom and the United States using this ambiguity to limit the scope of a research exception under patent law.[137] The increasing presence of public-private partnerships in research in

[136] See Sampat (2009).
[137] Adachi and Misati (2010).

areas such as biotechnology seems to have led to less clarity as to what constitutes commercial and non-commercial research. Courts in common law countries have generally not been favourable to arguments that universities, who are now encouraged to patent themselves, should be shielded from having to obtain the permission of patent holders in their research activities. A notable example is the US case of *Madey v. Duke University*, which in 2002 held that universities, which had previously relied on a wide research exception to conduct scientific research activities using patented subject matter without the consent of the patent holder based on their charters that commit them to non-profit objectives, could no longer rely on an exception to conduct such research where such research is in furtherance of the university's legitimate business interests.[138] While the US is not a Party to the CBD or the Nagoya Protocol at present, its court cases are still widely influential, and US universities conducting research are bound by the terms of the decision when they collaborate with international partners in scientific research.

These trends argue in favour of a relatively wide research exception if the objective is to preserve a relatively wide freedom to operate. Such an exception arguably need not distinguish between commercial and non-commercial research. It is increasingly becoming difficult to delineate between basic and applied research, as shown by the increasing trend to patenting the fruits of publicly funded university research under recent policies, partially as an incentive to encourage commercial actors to pick up the research with a view to eventual commercialization.

As noted above, researchers are still bound by the terms of the national ABS laws (which implement the Nagoya Protocol) and the requirement of PIC if they are accessing genetic resources of a provider country. Far from limiting the freedom to operate, however, the PIC requirement under the Protocol will act as a means to ensure that access to genetic resources for R&D purposes has taken on board the sharing of appropriate benefits for the provider country in the event of commercialization.

Key Points

⇒ The research and experimentation exception in patent law is an exception to IP rights that permits researchers to conduct research on a patented product or use a patented process without a license. The scope of what research and experimentation falls under this exception varies from jurisdiction to jurisdiction, however. Some jurisdictions permit a wide research exception, while others limit the exception to non-commercial research.

⇒ As a result partly of policies that encourage patenting of the fruits of university and other publicly funded research, it is becoming increasingly difficult to distinguish between what constitutes non-commercial and commercial research.

⇒ Research exceptions to patent law are generally seen as permitted under the TRIPS Agreement. According to a WTO Dispute Panel decision, it would frustrate the dissemination and advancement of technical knowledge, and the purpose of the disclosure requirement, if one were to allow the patent owner to prevent experimental use during the term of the patent.

[138] *Madey v. Duke University*, 307 F.3d 1351 (Fed.Cir. 2002), cert. denied 539 U.S. 958, 123 S.Ct. 2639, 156 L.Ed.2d 656 (2003).

⇒ Research exceptions need not be limited to patents; plant variety protection and utility model legislation may also build in research exceptions to the exclusive rights conferred.

⇒ A research and experimentation exception in the national patent law will not eliminate the need for PIC under Nagoya compliant national ABS legislation in the event that someone seeks to access genetic resources for research purposes.

⇒ The incentive of patent holders to try to prevent the emergence of competing technologies is not present in the case of PIC and provider countries. In fact, provider countries are interested in seeing genetic resources and associated TK become successful commercial products, provided the benefits accruing from those products are shared with the provider country and/or the indigenous communities.

B. The Medical Treatment Exception

Article 27.3(a) of the TRIPS Agreement permits Members that wish to do so to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. Many jurisdictions have chosen to incorporate a medical treatment exception in their patent law, albeit for varying reasons. The initial justification under the European Patent Convention (EPC) for the exclusion of methods of medical treatment was that methods of treatment are not subject to industrial application. The rationale had changed by 2000, when the EPC was being revised: here, medical methods are excluded from patent protection in the interests of public health.[139]

Developing countries have generally justified the inclusion of the exception in their patent law by claiming the need for local availability of treatment methods, and on moral grounds.[140] Other jurisdictions, such as the US and Australia, have opted not to make an exception to patentability for methods of medical treatment on the grounds that methods of treatment are no different from pharmaceuticals.[141] Ventose lists a number of other reasons why an exception to patent rights for methods of medical treatment may or may not be justified.[142] An interesting argument in favour of excluding medical treatment from the ambit of patentability is that patent protection for methods of medical treatment is "diametrically opposed" to "the Hippocratic Oath and its constituent fiduciary duties that bind them to act solely in the interests of their patients."[143] Moreover, the exclusion guarantees that the activities of physicians when they treat their patients are not hampered by patents.[144] A more cynical view of the historical evolution of the medical treatment exception is presented by Piper.[145]

The exclusion of methods of treatment from patent protection needs to be distinguished from the requirement under TRIPS to provide for the patentability of pharmaceutical products and the processes used to produce those pharmaceutical products (as noted elsewhere in the handbook, pharmaceutical products are no longer excludable under the TRIPS Agreement

[139] See Ventose (2011), p. 45.
[140] UNCTAD-ICTSD (2005), p. 384.
[141] Ibid.
[142] See Ventose (2011), Chapters 2 and 3.
[143] Ibid., p. 63. In this regard, the United States, under the 1996 Medical Procedures and Affordability Act, provides immunity to medical practitioners in suits relating to patents for methods of medical treatment.
[144] Ibid., p. vi.
[145] See Piper in Castle (ed.) (2009).

except for the LDCs). The distinction is that while drug X may be patentable provided it meets the three patentability criteria, and the industrial process to manufacture drug X may be patentable as a process patent, patent law exclusions for medical treatments would prevent the patentability of using drug X to treat condition Y. Likewise, a new vaccine may be patentable, but the procedure to administer that vaccine may not be patentable.[146]

The term "medical treatment" is not defined under the TRIPS Agreement, however, and there is an increasing grey area between pharmaceuticals and methods of medical treatment. Some medical technologies may defy a classification either as a pharmaceutical product or therapy, including, for example, certain gene therapies and genetic diagnostic testing technologies, or stem cell technologies.

The medical treatment exception is often used to prevent the patenting of new uses of known substances, for instance when an existing medicine is found to treat a condition for which it had not originally been intended.[147] In some countries, such as New Zealand and Switzerland, it is possible to try to circumvent the exception and to patent a new use of a known substance through a claim for patent protection over the use of a known drug method of manufacturing a product for treating an ailment.[148]

From the perspective of the CBD and Nagoya Protocol, there are two areas of particular relevance: the first is the issue of traditional medicine; and the second is the issue of genetically based medical technologies. With respect to the former, in the absence of a widely accepted definition of methods of treatment, there does not appear to be any reason why an exception to patent rights for such methods ought to extend only to methods of treatment as understood in Western medicine. A more difficult question, however, is delineating the boundaries of traditional medicine. Efforts exist in many developing countries to catalogue their traditional medicine practices. Some countries, such as China and India, have a far more regulated and codified system of traditional medicine than other developing countries, making it easier to define methods of treatment in the traditional medicine context. Of particular note is India's database of traditional medicines, which extends to well over 200,000 entries.[149] While developed partially as a means to help other countries assess prior art in cases where a disclosure in a patent application has triggered a case where the claimed invention has its origin in Indian traditional knowledge (see Chapter 3), jurisdictions that have incorporated a wide medical treatment exception in their patent law can also rely on this database to exclude medical treatments included in this database from patentability.

Many of the attempts to patent traditional medicines involve either cosmetic, health or pharmaceutical products and may not fall within the ambit of a 'method of treatment'.[150] But in many respects this is applying Western notions of medicine and health. From the perspective of a defensive CBD/Nagoya Protocol strategy, removing from patentability methods of treatment related to traditional medicine has the potential to go beyond treatments of known medical conditions in Western medicine and could incorporate notions of, for

[146] Administration of vaccines would in any event arguably fail for lack of novelty and inventive step even if patentable.
[147] Some countries explicitly provide for an exception from patentability of new uses of known substances, such as Article 21 of the Andean Community's Decision 486 (14 September 2000).
[148] See http://www.ajpietras.com/media.html (last accessed on 14 December 2011).
[149] See R Randeep, "India moves to protect traditional medicines from foreign patents - India fights to protect ancient treatments from Western pharmaceutical companies" in *The Guardian*, 22 February 2009 (accessed at http://www.guardian.co.uk/world/2009/feb/22/india-protect-traditional-medicines).
[150] Ibid. These include the attempt to patent products based on Indian turmeric and the neem tree.

example, preventive medicine and health. Chinese traditional medicine practice, including acupuncture, for example, places great emphasis on preventive medicine.[151] It is important to keep in mind, though, that exclusion of traditional medicine from patentability would not affect any protections granted to traditional medicine under TK laws.

As in other areas discussed in this handbook, a medical treatment exception contained in the provider country's patent legislation will only affect directly those patent applications under that law. It does not affect patentability in a foreign jurisdiction. But to the extent that a medical treatment exception is widely accepted in jurisdictions even in many developed countries, it would appear to be important that medical treatment be defined as broadly as possible under the domestic medical treatment exception in provider countries, to the extent that patent applications in foreign jurisdictions could potentially take that into consideration. Countries that have not done so may therefore wish to consider specifying in their legislation that the medical treatment exception extends also to traditional medicine.

The other area in which there is a potential interface between the medical treatment exception to patent law and the CBD/Nagoya Protocol is in the area of genetics and related therapies. There have been huge advances in gene-based therapies in recent years, due at least in part to successes in mapping the human genome. The interface occurs when patents are sought over therapies that have its origins in genetic resources that are covered by CBD/Nagoya-compliant legislation in provider countries. This potentially includes not only treatments derived from genetically manipulating plant and animal species (as in the case of plant-derived vaccines involving the introduction of a gene into a plant species to produce a vaccine or medicine), but also pathogens, a topic that is covered earlier, and which may be manipulated genetically in order to produce vaccines more conventionally.

From the perspective of the ABS stakeholder in the provider country, particular attention needs to be paid to the scope of the claim being made, and whether a medical treatment exception exists under the domestic patent law. In jurisdictions that exclude methods of treatment from patentability, while the medicines and vaccines used in treatment and the way in which they are industrially produced may in principle be potentially patentable, the modes through which those medical products are administered to patients could be excluded from the scope of patentability. The exclusion could be used to object to overbroad claims that cover the method of administration. Aside from patent law, there will still be a need to examine whether applicable ABS laws have been fully complied with.

Key Points

⇒ The TRIPS Agreement permits Members that wish to do so to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals. The EU and many developing countries exclude these methods from patentability, while the US, Australia and other countries permit the patentability of medical treatment methods.

⇒ The term "medical treatment" is not defined under the TRIPS Agreement and there is an increasing grey area between medicines and methods of medical treatment. Some medical technologies may defy a classification either as a pharmaceutical product or

[151] See Hillier and Jewel (1983), Chapter 2.

therapy, including, for example, certain gene therapies and genetic diagnostic testing technologies.

⇒ Countries are free to define medical treatment in their domestic laws to include traditional medicine. Countries that have not done so may wish to consider specifying in their legislation that the medical treatment exception extends also to traditional medicine.

⇒ Databases, such as the one set up by India to document their traditional knowledge, may help to define the contours of the medical treatment exclusion in domestic law, and serve as a reference point for user countries that likewise have such exclusion in their domestic patent legislation.

⇒ Patents can be sought over therapies that have its origins in genetic resources that are covered by CBD/Nagoya-compliant legislation in provider countries. This potentially includes not only treatments derived from genetically manipulating plant and animal species, but also pathogens. From the perspective of the ABS stakeholder in the provider country, particular attention needs to be paid to the scope of the claim being made, and whether a medical treatment exception exists under the domestic patent law.

C. The 'Clean Hands' Doctrine

As discussed in Chapter 3, there remains a debate over whether a mandatory disclosure of origin requirement that is enforced or includes a condition that obliges having complied with existing ABS legislation in provider and user countries as a pre-requisite for the granting of a patent that otherwise meets basic patentability criteria, is TRIPS compliant. Proponents of the idea that patent rights should not be granted when an applicant cannot affirmatively establish compliance ground their argument in the doctrine of 'clean hands'. According to the UK's IPR Commission's 2002 report on Integrating Intellectual Property Rights and Development Policy:

> "*The principle of equity dictates that a person should not be able to benefit from an IP right based on genetic resources or associated knowledge in contravention of any legislation governing access to that material. In such cases the burden should generally lie with the complainant to prove that the IP holder has acted improperly. However, a precursor for any action is knowledge of the wrong. It is to assist in this respect that we believe that a disclosure requirement of the type discussed above is necessary.*"[152]

The potential problems of a policy of not granting patents that otherwise meet TRIPS patentability criteria are covered in Chapter 3, and need not be repeated here. It suffices to say that if a country were to err on the safe side in this as yet unresolved debate, the patent office may require disclosure of origin and proof of legal provenance, but that this is relevant for the patent office only in so far as it is taken into consideration in the assessment, respectively, of novelty, inventive step and industrial application, or otherwise to determine whether the claimed invention covers patentable subject matter. This would not in any way, however, prevent any sanction for violation of ABS laws by the ABS authority in the country concerned.

[152] See Commission on Intellectual Property Rights (2002), chapter 4.

This may not be the end of the story with respect to the possibility to prevent would-be patent seekers who have not abided by applicable ABS laws, though. The 'clean hands' doctrine states that "equity will not grant relief to a party, who, as actor, seeks to set judicial machinery in motion and obtain some remedy, if such party in his prior conduct has violated conscience or good faith or other equitable principle."[153] 'Clean hands' is a judicial doctrine that traces its origin to US case law and other common law precedents.[154] While theoretically it may be possible to codify a 'clean hands' concept that nullifies a patent if applicable ABS laws had not been followed, this raises again the spectre of potential TRIPS non-compliance (i.e., does it add another requirement to obtain a patent?).

There are, though, ways in which a 'clean hands' doctrine could be applied so that there is little question as to TRIPS compatibility. A conservative approach consistent with TRIPS would be to invoke 'clean hands' in a lawsuit by ABS right holders who become aware of a problematic patent having already been granted. The two important criteria to underline here are first, that the patent has already been granted, and second, that the doctrine is the basis of a civil lawsuit and not an administrative proceeding such as in the course of an application for a patent. If the technology in question were still at the application stage, then the appropriate channel would in principle be to raise the issue of non-compliance with ABS in pre-grant oppositions, and the applicant would need to be given an opportunity to cure the non-compliance. In the absence of compliance with ABS laws even given the opportunity to do so, the patent may still be issued (so that there is no question of TRIPS consistency), but domestic ABS law would give ABS right holders the opportunity to file a suit in a court of law, pleading any range of remedies from non-enforcement of the patent, requiring that a share of royalties be given to the rights holder(s), compulsory licenses that permit the rights holder(s) to work the technology in question with the payment of an applicable royalty, compulsory cross- licenses[155], as well as damages.

Of these remedies, of particular note is the legal concept of non-enforcement of a patent. This concept is analogous to the situation of copyrights, where the enforcement of certain available remedies is distinguished from the existence of the copyright as such. The US, for example, has provisions within its copyright law which deny certain types of damages and fees for unregistered foreign copyright works. It was argued on behalf of the US, and accepted by WIPO, that the US registration provisions were compatible with the national treatment and formalities rules within the Berne Convention since the US registration requirement affects certain specific remedies rather than the ability to obtain redress at all. A number of commentators agree, stating that the Berne Convention, and hence the TRIPS Agreement and WIPO Treaties, do not prohibit formalities as a condition to certain types of remedies, licences, exemptions etc.[156] A similar doctrine could conceivably be applied to the case of

[153] Black's Law Dictionary definition (ed. 1983).
[154] The 'clean hands' doctrine has its origins in the US Supreme Court case *of Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488 (1942). Subsequent decisions have shaped the doctrine as it is practiced in the US courts today.
[155] This is a term that originates from the European Directive 98/44 on the Legal Protection of Biotechnological Inventions (passed by the European Parliament on 12 May 1998 and adopted by the Council and published on 30 July 1998). Article 12(2) of the Directive stipulates that where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention. A similar provision exists for plant breeders' rights (Article 12(1), Directive 98/44).
[156] See, for example, William Belanger, "U.S. Compliance with the Berne Convention", 3 *Geo. Mason Indep. L. Rev.* 373, 393 (1995); Final Report of the Ad Hoc Working Group on U.S. Adherence to the Berne Convention, reprinted in 10 *Colum.*-

non-compliance with underlying ABS laws in the case of patents, though this has not been tested to date under a WTO dispute resolution panel.

Going further, there may in certain specific cases even be room to argue in a civil lawsuit for the revocation of a patent in the event of non-compliance with ABS laws, or to prevent the receipt of certain patent applications that contain TK. Under a proposed amendment to New Zealand's Patent Law, inventions that use Maori TK without PIC are potentially in violation of public morality. A determination of violating public morality is made by the Commissioner for Intellectual Property upon the advice of a Maori Advisory Committee.[157] The determination enables the Commissioner to refuse an application or revoke an existing patent.[158] In order to ensure TRIPS compliance, each application invoking Maori TK is considered on a case-by-case basis and is designed to assess whether the patent application is consistent with Maori values. Public order and morality is a recognized exception to patent law under Article 27.2 of the TRIPS Agreement. Similar mechanisms could conceivably be devised for indigenous groups in other countries. It should be noted that the New Zealand legislation is not yet in place, however, and that, as is the case with clean hands in general this sort of mechanism has never been tested in WTO dispute settlement.

A similar argument was lodged in an opposition filed at the European Patent Office by the Alice Community by the African Center for Biosafety along with other interested parties, to certain patents that had been granted to Schwabe Pharmaceuticals in Germany over a method of producing extracts of two varieties of the *Pelargonium* plant. The plants were collected from the wild in the Eastern Cape region of South Africa by communities in the Alice region, from which extracts have traditionally been used to treat a variety of infections. Schwabe had obtained a patent over the extraction method for the manufacture of medicaments used to treat infections associated with HIV and AIDS. A preliminary opinion from the EPO[159] shows that the opposition that was filed that plead, among a number of other arguments, that the Schwabe patent should be rejected on grounds of public order and morality in so far as the patentee had not established compliance with PIC and MAT under the CBD. The analysis contained in the preliminary opinion, however, makes it clear that the EPO will not treat absence of the evidence of non-compliance with PIC and MAT as a *per se* violation of public order and morality. It is possible, states the preliminary opinion that a threat to the environment could potentially constitute a public order and morality rationale for an exception to patentability, but the text suggests that those moving to establish this argument must establish "seriously harm the environment or contravenes the generally accepted codes of conduct". This seems to be rooted, at least in part, because Article 53(a) of the European Patent Convention states that public order and morality cannot be used as a ground for non-patentability merely because it is prohibited by law or regulation in some or all of the contracting states, and must be examined on a case-by-case basis. In the end, the opposition claim was upheld and the patents revoked by the EPO on 26 January 2010 on alternate grounds, i.e., that it did not meet the inventive step criteria for patentability.

Under US legal precedents, patents may be invalidated or rendered unenforceable if it can be shown that the patentee intentionally misrepresented or omitted material facts during the

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VLA J.L. & Arts 513 (1986); Melville B. Nimmer & David Nimmer, Nimmer on Copyright §17.01(B) (2008). Nimmer & Nimmer, supra note 29, §17.01(B).

[157] A similar committee exists under New Zealand's Trademark Act.

[158] This is done through application of Section 17, Patent Act of New Zealand (1953, as amended).

[159] See European Patent Office document 02 777 223.5 of 14 July 2009.

patent application process.[160] While no US court case has voided a patent based on a failure to disclose facts related to source, origin or legal provenance as such, the intentional misrepresentation of facts to distinguish the subject matter with prior art, as well as an earlier court's finding that implied that the patentees had performed an experiment when in fact it had not, were upheld by the Federal Circuit in the 2003 case of *Hoffman-La Roche, Inc. v. Promega Corp*. This case concerned an enzyme that could be used in polymerase chain reaction - a process which generates copies of DNA, over which a patent had been granted. The application referred to DNA polymerase derived from Taq bacterium as prior art, and asserted that the subject matter enzyme was an advance over the prior art. Promega challenged the patent, arguing that certain assertions in the patent application were intentionally and materially misleading, and the District Court agreed. The Federal Circuit agreed with the findings of the District Court and remanded the case back to the District level to determine whether the appropriate remedy would be to invalidate or render unenforceable the patent. This case was settled between the parties thereafter. While this precedent leaves open the possibility to render unenforceable patents that fail to disclose material facts, the finding of intent is crucial, and is usually inferred from facts, including the wording of the patent application.

Key Points

⇒ The 'Clean Hands' doctrine states that "equity will not grant relief to a party, who, as actor, seeks to set judicial machinery in motion and obtain some remedy, if such party in his prior conduct has violated conscience or good faith or other equitable principle."

⇒ Clean hands could potentially be invoked in a lawsuit by ABS right holders who become aware of a problematic patent having already been granted. The two important criteria to underline are first, that the patent has already been granted and second, that the doctrine is the basis of a judicial proceeding.

⇒ Domestic ABS law could give ABS right holders the opportunity to file a suit in a court of law, pleading any range of remedies from non-enforcement or revocation of the patent, requiring that a share of royalties be given to the rights holder(s), compulsory licenses that permit the rights holder(s) to work the technology in question with the payment of an applicable royalty, compulsory cross- licenses, as well as damages.

⇒ In some cases, it may be difficult to establish an intent to mislead. Intent to mislead needs to be established from the facts surrounding each case.

⇒ A public order and morality argument could potentially be made to even revoke a patent, as in the case of draft New Zealand legislation.

D. Unfair Competition, Competition and Unjust Enrichment Based Theories

An alternative legal means to address the situation where an applicant attempts to obtain exclusive patent rights in the absence of compliance with applicable ABS laws is to justify

[160] See *Hoffman-La Roche, Inc. V. Promega Corp*., 323 F.3d 1534 (Fed. Cir. 2003).

refusal of the application or to revoke a patent utilizing the doctrine of unfair competition. Black's Law Dictionary explains unfair competition as follows:

> "*A term which may be applied generally to all dishonest or fraudulent rivalry in trade and commerce, but is particularly applied to the practice of endeavoring to substitute one's own goods or products in the markets for those of another, having an established reputation and extensive sale, by means of imitating or counterfeiting the name, title, size, shape, or distinctive peculiarities of the article, or the shape, color, label, wrapper, or general appearance of the package, or other such simulations, the imitation being carried far enough to mislead the general public or deceive an unwary purchaser, and yet not amounting to an absolute counterfeit or to the infringement of a trade-mark or trade-name. … As used in statute prohibiting unfair competition and defining the same as meaning and including 'unlawful, unfair or fraudulent business practice' 'unfair competition' is not confined to practices involving competitive injury but extends to practices resulting in injury to consumers.*"[161]

While often used to address situations of misleading marks or names, the doctrine also applies to patents and trade secrets. Under US practice, unfair competition is used for injunctive relief to prevent the importation of products that are covered by a patent in the US, but not abroad, as well as to prevent the importation of products using processes that are patented in the US, but not necessarily abroad.[162] Courts generally protect trade secrets under unfair competition laws to prevent the theft of something that the owner of the trade secret has made a reasonable effort to keep secret. It could be argued that seeking patent rights over a technology that has its origins in TK obtained in violation of PIC potentially amounts to 'stealing' and should be prohibited under unfair competition theory.

There are potential difficulties with this argument, though. TK may not fit neatly into any of the abovementioned cases. The authors are unaware of any instance in which non-compliance with ABS laws was used to invalidate a patent using unfair competition grounds. Moreover, TK may or may not be secret, and may not necessarily be considered a 'trade secret' in the strict legal sense of the term. If an indigenous group had allowed, for example, certain traditional medicine practices to be observed by an outsider, for example, that in the strict legal sense may be sufficient to deny trade secret protection. Moreover, in common law jurisdictions, the unfair competition doctrine is shaped by case law, which may limit the scope of a claim to those involving passing off and related deceptive practices. Finally, the rights conferred by ABS laws is as yet not well defined in many jurisdictions - and while it is clear that ABS laws require PIC and MAT, whether courts will interpret this as amounting to a property right in favour of indigenous groups remains to be seen.

Finally, unfair competition claims need to be distinguished from competition law claims. Unfair competition law addresses certain unfair commercial practices while competition legislation, as a general body of law, exists to act as a check on the abuse of IPRs, as envisaged in Articles 8 and 40 of the TRIPS Agreement. But these clauses generally act as a check on the exercise of granted rights in the context of a situation where the owner of the patent yields certain market power. Market concentration and power may be difficult to establish in the indigenous context, and while it would potentially become relevant perhaps in

[161] See Black's Law Dictionary (ed. 1983).
[162] See Blenko (1990) at http://www.tms.org/pubs/journals/jom/matters/matters-9010.html.

cases involving refusals to license, it is difficult to think of a situation where competition law could be successfully deployed to address situations of patent applications which have not complied with applicable ABS laws.

Aside from competition law and unfair competition theories, one could also theoretically frame a legal argument that those who have misappropriated resources, especially through obtaining IP rights, should not be allowed under an unjust enrichment theory. Unjust enrichment refers to a general principle that stipulates that "one person should not be permitted unjustly to enrich himself at the expense of another, but should be required to make restitution of or for property or benefits received, retained or appropriated, where it is just and equitable that such restitution be made, and where such action involves no violation or frustration of law or opposition to public policy, either directly or indirectly."[163] The theory is generally used in civil actions. While a provider could use the argument that a user patented an invention that utilized a genetic resource or associated TK without PIC or MAT, or in violation of an ABS agreement, one could argue that allowing the user to appropriate 100% of any benefits arising from that patent would amount to unjust enrichment. In a court of law, however, this strategy is also likely to entail arguments about the extent to which the original resource or TK contributed to the patented invention.

Key Points

⇒ Unfair competition theories generally exist to address certain deceptive trade practices, while competition law theories exist to address the abuse of market power.

⇒ The use of these theories to combat instances where there has been non-compliance with ABS laws may be limited, however, as it may be difficult to establish the legal requisites for these theories.

⇒ Apart from competition law, providers could attempt to frame arguments based on a theory of unjust enrichment.

VI. Conclusion

A variety of tools exist in patent law and related jurisprudence that can potentially help to address the problem of misappropriation. A first line of defence is to apply patent law to exclude the possibility of a would-be 'biopirate' from being able to obtain a patent. This can be done by arguing, for example, that the subject of the application is not patentable subject matter (i.e., not an invention.). As a second line of argument, one could try to establish that the criteria for patentability have not been met. Various exceptions to patent law also exist that shield users engaged in R&D activity and medical treatment. Patent authorities could, however, utilize those same arguments in the event that a domestic party sought to obtain a patent on an invention that utilizes a genetic resource or associated TK as well.

If a case must be litigated to defeat a patent held by a would-be 'biopirate', there are theories of equity that can be deployed to support the argument that a patent should be revoked or some remedy given to an aggrieved party. These theories include 'clean hands' and unjust

[163] Black's Law Dictionary definition (1983 ed.).

enrichment, among others. They could also include violation of the terms of a material transfer agreement (MTA), the subject of chapter 7.