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Plant, where are thou from?

- An analysis of the disclosure requirement of origin of genetic resources in patent applications

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Contents

Summary

In the last decades one of the main topics in the international intellectual property forum has been the biopiracy issue. Genetic resources[1] and traditional knowledge from developing nations are being misappropriated (i.e. biopiracy) by commercial actors in order to receive patent protection. Developments in genetics and biotechnology have intensified the controversy and attempts were initially sought in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[2] and the Convention on Biological Diversity (CBD)[3]. However, the discussions in the World Trade Organization (WTO) have been unsuccessful. There is only one solution that continuous to be discussed and it is the main topic of this thesis.

The purpose of the thesis is to examine if it is reasonable to impose a requirement to disclose the origin of the genetic resources in patent applications. In order to accomplish the purpose, five questions will be asked and answered. The questions surround what the motive is for such a requirement, the consequences or issues with it, other possible solutions, in what way the requirement should be introduced and if it should be mandatory. A legal dogmatic method will be used to answer the question formulations and to fulfil the purpose. In addition, a law and economics perspective as well as a law and politics perspective will be applied in the analysis. The initial chapters of the thesis present an introduction to patents and the two agreements. The proposed changes to the TRIPS Agreement are then reviewed in the fourth chapter. Possible complications and issues with the disclosure requirement and possible other solutions are finally addressed in the fifth and sixth chapter. Lastly, the thesis will be concluded by the analysis and the conclusion that it is reasonable to impose a requirement of disclosure of origin of genetic resources in patent applications.

[1] Genetic resources are genetic materials of plant, animal, microbial or other origin that contain functional units of heredity.
[2] Marrakesh, Morocco on the 15th of April 1994.
[3] Rio de Janeiro, Brazil on the 5th of June 1992.

Sammanfattning

Under de senaste årtiondena har en av de viktigaste frågorna i det internationella immaterialrättsliga forumet varit frågan om biopiratverksamheten. Genetiska resurser[4] samt inhemska kunskaper blir stulna från utvecklingsländer (i.e. biopiratverksamhet) av aktörer som vill tillskansa sig ett patentskydd. Kontroversen har intensifierats av utvecklingar i genetik och bioteknik. Ett försök till att lösa konflikten söktes först i TRIPS avtalet (Agreement on Trade-Related Aspects of Intellectual Property Rights)[5] och Biodiversitetskonventionen (the Convention on Biological Diversity)[6], men diskussionerna i Världshandelsorganisationen misslyckades. Dock finns det en lösning som kontinuerligt diskuteras och det är den som är det huvudsakliga ämnet för den här avhandlingen.

Syftet med avhandlingen är att undersöka om det är rimligt att införa ett krav på att patentsökare måste avslöja ursprunget till de genetiska resurserna som använts. För att uppfylla detta syfte ställs fem frågor. Frågorna består bl.a. av vad motivet är för ett sådant krav, vilka problem eller konsekvenser som finns, på vilket sätt kravet bör införas och om det bör vara tvingande. Den traditionella rättsdogmatiska metoden är dominerande men ett rättsekonomiskt och rättspolitiskt perspektiv anläggs i analysen. De två inledande kapitlen av avhandlingen introducerar de grundläggande patentkraven samt de två nämnda avtalen. I det fjärde kapitlet presenteras de föreslagna ändringarna i TRIPS avtalet. Därefter behandlas eventuella komplikationer och problem med ett krav på att avslöja ursprunget av genetiska resurser i det femte kapitlet. Andra möjliga lösningar presenteras sedan i det sjätte kapitlet. Till sist avslutas avhandlingen med en analys och slutsatsen att det är rimligt att införa ett krav på ett offentliggörande av ursprunget av genetiska resurser i patentansökningar.

[4] M.a.o. genetiskt material från växter, djur, mikroorganismer eller annat ursprung som innehåller enheter av arvsmassa.
[5] Marrakech, Marocko den 15:e april 1994, SÖ 1995:30.
[6] Rio de Janeiro, Brasilien den 5:e juni 1992, SÖ 1993:77.

Preface

This thesis symbolizes the end of my education at the law school in Lund. Before I present to you this thesis, I would like to thank the people that have made the experience easier, happier and better. First and foremost, I would like to thank my mother, father and brother for always being there and for helping me whenever I needed them. They pushed me during those times when I felt as if I could not make it and made me realize my true potential. Nemogu se vam dovoljno zahvaliti i volim vas puno, vasa ćerka i sestra.

The friends I have made during these years have also given me lots of laughs and support. I would especially like to thank my friend, Sabina Anne Co for helping me with the thesis by reviewing it and helping me find my mistakes. Another person that has helped me with this thesis is lecturer Peter Gottschalk. I would like to thank him for taking his time to discuss this thesis and for giving me great advises and tips.

Finally, I would like to give my thanks to my supervisor, Hans Henrik Lidgard for guiding me throughout this final work. Thank you for teaching me different tricks and tips and for taking your time to help me.

Thank you all, because without you this would not have been possible.

Värnamo, Sweden
16th of March 2016
Emina Cehaja

Abbreviations

ACTA	Anti-Counterfeiting Trade Agreement
ABS	Access and Benefit Sharing
CBD	the Convention on Biological Diversity
GR	Genetic Resources
ICC	International Chamber of Commerce
ICTSD	International Centre for Trade and Sustainable Development
IGC	the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IPR	Intellectual Property Rights
LDCs	Least Developing Countries
PCT	the Patent Cooperation Treaty
TK	Traditional Knowledge
TRIPS	the Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCTAD	The United Nations Conference on Trade and Development
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1 Introduction

1.1 Background

Intellectual property was first mentioned as early as 500 B.C.E. The first known protection of intellectual property was that of the granting of yearlong monopolies on culinary delights to chefs in the Greek colony of Sybaris. There have been a lot of changes since then. Intellectual property is still generally defined as a non-physical property that is the product of original thought. In the same way, there are still laws that protect intellectual property and the interests of the inventor through the assignment and enforcement of legal rights to produce and control physical realizations of the intellectual property.[7] One of the reasons why these laws and statutes continue to be enforced is to advocate the economic and moral rights of the inventor in their inventions but also to uphold the right of the public to access the inventions. The other motive is to deliberately promote creativity, the distribution and application of the ideas whilst at the same time promoting fair trade in hopes of a positive effect on economic and social development.[8]

In order to unify the outlook on the protection and regulation of intellectual property around the world, multiple treaties and agreements have been generated through the years. One of the more inclusive agreements is the one administered by the World Trade Organization (WTO), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[9]. The agreement provides minimum standards of protection for every category of

[7] Moore, Adam & Himma, Ken: "*Intellectual Property*", The Stanford Encyclopedia of Philosophy (Winter 2014 Edition), from: http://plato.stanford.edu/archives/win2014/entries/intellectual-property, on the 25th of January 2016.
[8] World Intellectual Property Organization (WIPO): "*WIPO Intellectual Property Handbook: Policy, Law and Use*", WIPO Publication No. 489(E), Second Edition, 2004, from: http://www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch1.pdf, on the 13th of March 2016, p. 3.
[9] Marrakesh, Morocco on the 15th of April 1994.

intellectual property rights (IPR).[10] All in all, the main purpose of the TRIPS Agreement is to unify IPR systems around the world under a universal set of rules whilst at the same time tackling the problems of IPR infringements and international piracy.[11]

Even though the TRIPS Agreement is the most inclusive agreement it fails to address the issues that the Convention on Biological Diversity (CBD)[12] focuses on, i.e. the conservation of biodiversity and the sustainable use of genetic resources. Unlike the TRIPS Agreement, the CBD is a convention that is administered by the United Nations. The multilateral treaty entered into force approximately two years before the TRIPS Agreement, on the 29th of December 1993. The inspiration for the Convention arose from the increasing interest to sustainable development around the world.[13]

Although both the TRIPS Agreement and the CBD were adopted in the 1990s they have become more disputed in recent years. One of the reasons is the fact that there has been a rise in the demand of intellectual property protection, protection for traditional forms of creativity and innovation. These demands stem mainly from indigenous people, local communities and governments in developing nations that are the source of these types of intellectual property and traditional knowledge (TK).[14] At the centre of this controversy are the matters concerning biopiracy.[15] The act of biopiracy is taking and commercially misusing genetic resources, particularly through

[10] World Trade Organization (WTO): "*Overview: the Trips Agreement*", from: https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm#standards, on the 29th of January 2016.
[11] World Health Organization (WHO): "*Trade, foreign policy, diplomacy and health: Trade-Related Aspects of Intellectual Property Rights (TRIPS)*", from: http://www.who.int/trade/glossary/story091/en/, on the 29th of January 2016.
[12] Rio de Janeiro, Brazil on the 5th of June 1992.
[13] United Nations Secretariat of the Convention on Biological Diversity: "*History of the Convention*", from: https://www.cbd.int/history/, on the 29th of January 2016.
[14] Traditional knowledge is all types of knowledge, skills and practices that are passed on and developed from generation to generation in a community. For more information see http://www.wipo.int/tk/en/tk/; WIPO: "*Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions*", 2015, from: http://www.wipo.int/edocs/pubdocs/en/tk/933/wipo_pub_933.pdf, on the 1st of March 2016.
[15] Carr, Jonathan: "*Agreements that divide: TRIPS VS. CBD and proposals for mandatory disclosure of source and origin of genetic resources in patent applications*", Journal of Transnational Law & Policy, Vol. 18:1, 2008, p. 132.

the acquirement of patents, without compensating the country or community of origin.[16] The developments in genetics and biotechnology have further fuelled this international controversy. On one side of this controversy are the developing countries. They fear that through the patenting of biological resources, their most valuable equity is transferred to grand corporations that are from the more wealthy and industrialized nations of the world. In opposition, the more developed countries view is that the protection of intellectual property is not only beneficial but also essential for there to be further advancements in science, technology and global economics. Through the years the hostility between the two standpoints have evolved greatly.[17]

An attempt to dissolve the issues of each party was sought in the two international agreements, the TRIPS Agreement and the CBD. However, the attempt merely broadened the rift.[18] Multiple attempts at resolving the conflicting interests have been made, however, only one solution has been heavily disputed. This solution or proposition is the main topic of this thesis.

1.2 Purpose

The purpose of this graduate thesis is to examine if it is reasonable or appropriate to impose a requirement of disclosure of origin of genetic resources in patents. In order to be able to discuss and fulfil this purpose a number of question formulations are needed. The following questions will be answered trough this thesis:

- What is the motive behind a requirement of disclosure of origin of genetic resources in patented technologies?
- Are there any consequences or issues with this requirement and if so what are they?
- Are there other steps that need to or could be taken?
- How should such a requirement be introduced?

[16] Oxford University Press: "*Oxford Dictionaries*" from: http://www.oxforddictionaries.com/definition/english/biopiracy, on the 29th of January 2016.
[17] Carr op. cit. p. 132.
[18] Ibid.

- Should Members be required to abide such a requirement?

1.3 Method & Material

In this subsection, the researcher would like to address how the aforementioned questions and the purpose of the study will be fulfilled. The main method that will be used in this graduate thesis is the traditional legal dogmatic method. The main body of this thesis could be defined as the "descriptive section"[19]. In the section the mentioned agreements, regulations, preparatory work and doctrine will be presented in accordance with the legal dogmatic method in order to establish the current state of the law. The legislation in this area is of great significance and that is one of the reasons why this thesis will to a great extent be based on the law. Aside from the regulations, the subject has also been dissected in dissertations, articles and academic journals etc., which are relevant when applying such a method.[20]

In the analysis, a couple of different perspectives will be used. One of them is a critical perspective. The facts and statements made in the main body will be scrutinized thoroughly in the analysis. Both positive and negative aspects will be brought up on both sides of the spectrum, the opposing as well as the supporting side, in order to ascertain whether or not a disclosure requirement would be in compliance with the agreements. Still, in order to draw more legitimate and correct conclusions of the repercussions of a requirement of disclosure and thus whether it is a reasonable and appropriate regulation, there is a need to incorporate two more perspectives.

One of the two perspectives that will be applied in the analysis is a law and economics perspective. The outcome of the legal dogmatic method will be tested to see if the result is economically legitimate and reasonable. In other

[19] Lidgard, Hans Henrik et.al.: "*Methods in legal research*", (as provided by the author), p. 2.
[20] One of the most detailed and comprehensive is: "*Agreements that divide: TRIPS VS. CBD and proposals for mandatory disclosure of source and origin of genetic resources in patent applications*" by Jonathan Carr. For more information see footnote 16.

words the general national economical effects that are found will be tested against the results from the judicial analysis. No abstract economic principles, theories or models will be used. Moreover, common sense and statistics will be used to make a more in-depth discussion.

The other perspective that will be used in the analysis is the law and politics perspective. Similar to the recently mentioned perspective, it will be used to test if the results from the legal analysis are legitimate. In the analysis the interests that lie behind the new requirement and the political consequences as well as the relevance of the different concerns will be discussed. Thus, the purpose of the regulations (both the existing and the proposed) will be examined as well as the interests that are protected by such a system. In the end, the results of the legal dogmatic method and the findings from the law and politics perspective will be compared in order to determine if the requirement is politically legitimate and necessary. The different perspectives and the results of them will be compared and analysed in order to reach a legitimate and correct conclusion on whether or not to impose a requirement of disclosure of the origin of genetic resources (i.e. the disclosure requirement) in the patent legislation.

As to the material that will be used it will mainly consist of the two international agreements that have already been mentioned, the CBD and the TRIPS Agreement. As a supplement, the Nagoya Protocol will also be referred to as well as the different proposals to amendments that have been given. Some preparatory work and doctrine will be used in order to give a more comprehensive and complete review. Different documents and information will be used from the two international organizations, the WTO and the World Intellectual Property Organization (WIPO). Furthermore, the thesis will also bring light to informative and relevant articles both from academic journals and from other sources. The majority of the articles have been published in different journals e.g. the Law, Environment and Development Journal, the International Law & Management Review, Journal of Transnational Law & Policy and the Boston College International

and Comparative Law Review. All used sources have been evaluated and assessed as valid and reliable. Finally, as already mentioned this thesis will rely upon the laws and regulations and doctrine as there is no existing case law on the subject.

1.4 Research aspects

As mentioned above, the conflicts between the CBD and the TRIPS Agreement have been discussed for a long time, in terms of the biopiracy issue. The proposal of a disclosure requirement has also been discussed for many years, by Nuno Pires de Carvalho, Dominic Keating and Begoña Venero. However, there have been some new developments in recent years and the question has once again become a hot issue. This is one of the reasons why the disclosure requirement needs to be revisited in a more recent and updated manner.

1.5 Delimitations

The main theme of the thesis is genetic resources, the TRIPS Agreement, the CBD and the disclosure requirement. As presented the subject of this thesis is definite and specific. However, both the CBD and the TRIPS Agreement are international agreements and contain various regulations as well as other issues and delimitations are needed. The first delimitation concerns the agreements. There will neither be an extensive presentation nor a historical passage of the agreements, as it would fall outside of the purpose of the thesis and it would be counterproductive.

There are a couple of subjects that are important in connection to the disclosure requirement. One of the subjects is biopiracy. Although it is important in connection to the requirement, it falls outside of the purpose and question formulations to present and discuss biopiracy on its own. The main reason is that it is neither productive nor efficient and the main purpose would be lost through such a presentation. Other subjects that are relevant but are not considered are plant breeders' rights and farmers' rights.

Even though they are closely related, it still falls out of the purpose and it is not productive to review it.

Initially, traditional knowledge was supposed to be delimitated because it rarely fulfils the novelty criterion in patent law, as TK is often of old kind. In addition, in countries that require a written original draft, the TK can almost never be patentable. Other solutions need to be sought in those situations and that is the reason why the disclosure requirement is to some extent insignificant in relation to TK. However, TK is closely related to the origin of the disclosure requirement and the discussions have always centred on both genetic resources and TK. That is the reason why TK is referenced to the extent it is needed in the work. However, the focus will remain on genetic resources and the disclosure requirement.

Access and Benefit Sharing (ABS)[21] is another closely related subject that will be mentioned in this thesis. An in-depth explanation or review will however not be made. It is referenced as a background for the discussion and as a consequence to the disclosure requirement.

1.6 Outline

After the introduction, a general patent presentation will follow that references the relevant provisions in the TRIPS Agreement. To be more specific, the second chapter will present a review of the requirements for a patentable invention. After the presentation of the relevant articles in the TRIPS Agreement a presentation of the purpose of the agreement and a correlation to the already mentioned articles will be made. Aside from the review of the TRIPS Agreement, the relevant provisions in the CBD and the Nagoya protocol will also be presented in the third chapter.

[21] Access and benefit sharing describes the way in which genetic resources can be accessed and how the benefits that are a result from their use are shared between the users (countries or people) and the providers (the countries or people that provide the genetic resources).

Henceforth, the fourth chapter will introduce the proposed requirement of disclosure. The chapter reviews the background behind the disclosure requirement and the different proposals that have been communicated to the TRIPS Council. Following the presentation of the requirement, the fifth chapter addresses the consequences and issues with a requirement of disclosure of origin. The consequences and issues are those of economical, judicial and political significance. The last part of the main body, the sixth chapter, elaborates on other types of solutions to the issue that the requirement of disclosure aims to solve, i.e. contracts, databases and a WIPO administered mechanism.

The presented material will then be analysed. The requirement, the issues and the alternative solutions are all weighed against one another in the seventh chapter of this thesis. The chapter will also feature a discussion that is viewed from the different perspectives already mentioned in the method and material chapter above.

Finally, in the last chapter the questions will be answered and conclusions will be drawn from the discussion presented in the analysis.

2 An introduction to patents

In the following chapter a small introduction to patents will be presented. The first subchapter presents the requirements that need to be fulfilled in order for an invention to receive patent protection. First, the main article of TRIPS Agreement, Article 27, is presented and later under the last of the five subheadings Article 29 is introduced, as the first four are drawn from Article 27. The second chapter defines the rights that are conferred, in order to give a broader and more full understanding of the patent system and the implications of a patent.

2.1 Patent requirements

The TRIPS Agreement sets the minimum standards regarding the requirements for obtaining patent protection. Daniel C.K. Chow and Edward Lee, both Professors of Law, divide the requirements into five areas[22]: 2.1.1 Subject matter, 2.1.2 Industrial applicability or Utility, 2.1.3 Novelty, 2.1.4 Inventive step, and 2.1.5 Enablement. The first four requirements are found in Article 27, whilst the fifth is found in Article 29 of the TRIPS Agreement (see Supplement A).

2.1.1 Subject matter

The subject matter is defined very broadly in Article 27, as it states that "any inventions, whether products or processes, in all fields of technology", "without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced" are available for patent protection. However, Members have a right to omit certain inventions from patents in accordance with Article 27(2) and (3). Exceptions that are necessary to protect ordre public or morality are accepted under specific circumstances in the case that the omission is not motivated solely due to the fact that their law prohibits such exploitation (Article 27(2)). In other

[22] Chow, Daniel C. K. & Lee, Edward: "*International intellectual property: problems, cases, and materials*", 2. ed., Thomson/West, St. Paul, Minn., 2012, p. 313.

words, ethical or moral concerns are required, as is exemplified by the European Unions exclusion of human embryos due to pressing ethical and moral concerns. Following, Article 27(3) states that surgical, medical, and therapeutic methods can all be omitted as patentable subject matter, as well as, plants and animals that are not microorganisms. On the other hand, plant varieties need to be protected through patents or through a *sui generis* protection.[23]

2.1.2 Industrial applicability or Utility

One of the five requirements for patentability is that the invention needs to be able to be industrially applicable. The requirement is also known as the utility requirement. Due to the varied implementation by Members, there has been an insertion of a footnote in the TRIPS Agreement. It states that the terms are to be viewed as synonymous with the word useful. However, it has been a disputed fact[24] that the terms "industrial applicability" and "utility" are at all synonymous as the scope of the individual terms differs between Members.[25]

Nevertheless, the definition of industrial applicability is that an invention is considered industrially applicable if it can be used or made in any industry, including agriculture. The invention needs to be able to be applied for practical purposes, i.e. it cannot only be theoretical. The term "industry" is to be interpreted in the widest way possible. Therefore, the meaning of "industrial applicability" is the application of the invention through technical means on a particular scale. On the other hand, in order for an invention to have utility the applicant must have affirmed that the invention is useful for any practical purpose. In other words, it must have a specific and substantial utility and a person that has ordinary skills in the art[26] must deem the declaration credible.[27]

[23] Chow & Lee op. cit. p. 314f.
[24] E.g. see WIPO Standing Committee on the Law of Patents, SCP/9/5, 17th of March 2005.
[25] Chow & Lee op. cit. p. 351.
[26] A "person with ordinary skills in the art" is a skilled practitioner in the relevant field of technology, who has average knowledge and ability and is aware of what was common

2.1.3 Novelty

The most essential requirement is that an invention has to be new or consist of enough novelty to certify for a patent.[28] What defines whether an invention is novel is if it is not included in any prior art. Consequently, the definition of "prior art" is that it is all the knowledge of the relevant application that has existed before the filing date or the priority date.[29]

Similar to the industrial applicability requirement, there are two different interpretations of this requirement. The main difference is that one side, as affirmed in the European Patent Convention, has no geographical limitation on prior art whilst the other side supports a novelty requirement that is restricted by geography. The main supporter of the geographical limitations on novelty has previously been the U.S., however, their standards of novelty have been changed to be more like the European.[30] Another dissimilarity in the definition of prior art is that in many countries any information made public in any form, e.g. oral or written, is a form of prior art. However, a few consider only written disclosures as prior art. In addition, it has been established that it is not admissible for a patent examiner to connect multiple different prior arts when examining the novelty of an invention.[31]

2.1.4 Inventive step

Article 27 of the TRIPS Agreement also requires an invention to consist of an "inventive step". Similar to the industrial applicability criterion it is highlighted that the inventive step is to be seen as equivalent to the term non-obvious. On the other hand, the logic and concept behind the requirement is similar to the logic behind novelty. In other words, the

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general knowledge in the art at the relevant date. For more see: http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_3.htm.

[27] WIPO: "*WIPO-MOST Intermediate Training Course on Practical Intellectual Property Issues in Business: Topic 2: Patents*", WIPO/IP/BIS/GE/03/2, Geneva, November 10-14, 2003, p. 4.

[28] Chow & Lee op. cit. p. 355.

[29] The priority date is the date of filing of the first patent application; WIPO/IP/BIS/GE/03/2, p. 4.

[30] Chow & Lee op. cit. p. 355.

[31] WIPO/IP/BIS/GE/03/2, p. 4f.

requirement prevents the granting of patents for inventions that are already known to society.[32] Prior art is therefore reviewed in the assessment, as the inventive step criterion requires the invention to not be obvious to a person with ordinary skills in the art. It is not enough that the invention is new; the divergence must be considerable and fundamental to the invention.[33] For example, an invention that has never been made before can still fail to fulfil the criterion due to it being obvious to a person that has ordinary skills in the art. The motive behind the criterion is that an old or an obvious invention does not contribute to the state of the art or to innovation.[34] In conclusion, protection should not be given to any invention that a person with ordinary skills in the art can identify as an obvious result of prior art/s.[35]

2.1.5 Enablement - *Article 29 of the TRIPS*

The last requirement that needs to be fulfilled is the enablement and the disclosure of the invention in the patent application, which is asserted in Article 29 of the TRIPS Agreement (see Supplement A). According to the article, Members must demand an applicant to disclose the invention in a way that is adequately clear and exhaustive so that a person with skills in the art can execute the invention.[36] A person skilled in the art should be able to use the invention without unnecessary experimentation.[37] The purpose of this requirement stems back to fundamental patent law. Sufficiently disclosing the invention in the application is important as it distributes knowledge to the public, which would have otherwise been kept secret, in exchange for patent protection.[38]

An option is also given to countries to instead demand the petitioner to present the best way to execute the invention that is known to him or her at

[32] Chow & Lee op. cit. p. 376.
[33] WIPO/IP/BIS/GE/03/2, p. 5.
[34] Chow & Lee op. cit. p. 376.
[35] WIPO/IP/BIS/GE/03/2, p. 5.
[36] The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Article 29(1).
[37] WIPO/IP/BIS/GE/03/2, p. 5.
[38] Chow & Lee op. cit. p. 387f.

either the filing date or at the priority date. Members can also require an applicant to give information on other foreign applications and grants according to Article 29(2) of the TRIPS Agreement.[39]

Finally, the enablement criterion differs from the other four criteria, as it is more of a procedural or administrative requirement and not so much a substantive requirement.[40]

2.2 The rights that are conferred - *Article 28 of the TRIPS*

A provision regarding what exclusive rights countries must provide inventors with under patent law was missing for a long time until it was dealt with through the adoption of Article 28 of the TRIPS Agreement.[41] After a patentee acquires a patent, he or she has the exclusive right to determine who is allowed to use his or her invention. In other words, the patentee can stop others from "making, using, offering for sale, selling, or importing[42] for these purposes" his or her patented invention if they do not have an authorization. The same rights apply to corresponding products and processes. Furthermore, the patentee always has the right to assign, transfer or license his patent to whomever he or she likes.[43]

In conclusion, the exclusive right that a patentee receives has two functions, namely to protect against infringement and to provide the possibility of authorizing or licensing the right to anyone. National laws in most countries provide few exceptions to these exclusive rights.[44]

[39] Chow & Lee op. cit. p. 388.
[40] Ibid. p. 387.
[41] Ibid. p. 401.
[42] This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provision of Article 6.
[43] The TRIPS Agreement Article 28.
[44] WIPO/IP/BIS/GE/03/2, p. 7f.

Summary

To summarize this chapter, there are requirements that need to be met in order for an inventor to receive a patent for his or her invention. There are five requirements, specifically subject matter, industrial applicability, novelty, inventive step and enablement. The criteria are of high standards as an inventor receives a monopoly on the market of that particular product or process for the next 20 years. In their own way, each requirement serves its purpose and eliminates the potential existence of “bad patents”.

3 Introducing the two agreements

The purpose of the chapter is to introduce the two main agreements, the Convention on Biological Diversity (CBD) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Underlying aims and objectives will be presented in order to give a full understanding of the agreements. As the main articles of the TRIPS Agreement have already been presented, this chapter will connect them with the goals presented here. On the other hand, a more comprehensive introduction to the CBD will be made, introducing both the aims of the agreement and the relevant articles.

3.1 The TRIPS Agreement – *Aims and Objectives*

The preamble of the TRIPS Agreement states that the aspiration with the agreement is to reduce hinderances and distortions on international trade. At the same time, there is a need to advocate for a more effective and sufficient protection of IPR. On the other hand, the measures and procedures that are used to enforce the rights cannot obstruct lawful trade.[45] As mentioned in the introduction, the TRIPS Agreement requires WTO Members only to meet the minimum standard of protection and enforcement of IPR. It does not hinder them to adopt a more far-reaching regulation.[46] The main purpose of the TRIPS Agreement, which was also mentioned in the introduction, is to unify IPR systems around the world under a universal set of rules whilst at the same time tackling the problems of IPR infringements and international piracy.[47]

However, the TRIPS Agreement also has other objectives and principles that need to be considered. Precise and important objectives and principles,

[45] The TRIPS Agreement's Preamble.
[46] The TRIPS Agreement Article 1.
[47] WHO op. cit.

that play a substantial part in the implementation and interpretation of the Agreement, are laid down in Articles 7 and 8.[48] Through the enforcement and protection of IPR there should be a "promotion of technological innovation", but also a transfer and distribution of the technology to "producers and users of technological knowledge". The distribution should be done in a way that is "conducive to social and economical welfare", while balancing rights and obligations between parties.[49] Article 8.1 provides the Members with a right to implement regulations to protect their public health and nutrition, but also the opportunity to "promote the public interest in sectors of vital importance to their socio-economic and technological development", if they are in conformance with the Agreements provisions.[50] Suitable measures to prevent abuse of IPR or practices that restrain and affect international transfer of technology in an unreasonable and adverse way may be needed according to Article 8.2.[51] An international transfer of technology may be needed to provide least developing countries (LDCs) with new skills, knowledge and technologies. LDCs can develop the knowledge into new inventions. In addition, the developed countries have an obligation, in Article 66.2 of the TRIPS Agreement, to provide incentives for the transfer of technology.[52]

All the principles, aims, objectives and purposes of the TRIPS Agreement are to be considered thoroughly in the implementation and interpretation of the Agreement. It is therefore troubling that developing countries have recognized that only one side of the Agreement's objectives are being conveyed, the ones concerning the protection of "technology assets", whilst the transferring of technology and the active promotion of "developmental interests" are practically being ignored.[53]

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[48] Yu, Peter K., "*The Objectives and Principles of the TRIPS Agreement*", Houston Law Review, Vol. 46, pp. 797-1046, 2009, p. 981.
[49] The TRIPS Agreement Article 7.
[50] The TRIPS Agreement Article 8.1.
[51] The TRIPS Agreement Article 8.2.
[52] The TRIPS Agreement Article 66.2.
[53] The United Nations Conference on Trade and Development (UNCTAD)- International Centre for Trade and Sustainable Development (ICTSD): "*Resource Book on TRIPS and Development*", Cambridge University Press, Cambridge, 2005, p. 119.

3.2 The Convention on Biological Diversity

In early June 1992, during the United Nations Conference on Environment and Development (the Rio "Earth Summit") the Convention on Biological Diversity was opened for signature. As was mentioned in the introduction, the CBD is a multilateral treaty that is administered by the UN, i.e. not the WTO.[54]

3.2.1 Aims, objectives and leading principles

The CBD was initially heavily influenced of the growing threat to ecosystems and species. Due to the growing extinction of species, caused by human activities, communities around the world became more interested in sustainable development, which in turn also inspired the Convention. In a way the CBD therefore symbolizes a big step forward in both the preservation of biological diversity and the tenable use of its element, but also the fair and impartial sharing of the benefits (ABS) that arise from the genetic resources.[55] On the other hand, the CBD also brought another very important development. After the Convention, genetic resources were considered as property of the state, i.e. they were no longer a free resource, as will be explained in the second subchapter of the fifth chapter of the thesis.[56]

In the first article of the CBD, the three main objectives guiding the interpretation and implementation of the agreement are set forth. The first objective to be sought after is the conservation of biological diversity. Furthermore, a more sustainable use of the components of biological diversity needs to be pursued. The final objective mentioned in the article is that there is a need to find a fair and impartial sharing of the benefits that arise from the usage of genetic resources (GR). These objectives need to be

[54] United Nations Secretariat of the Convention on Biological Diversity: "*History of the Convention*".
[55] Ibid.
[56] West, Simon: "*Institutionalised Exclusion: The Political Economy of Benefit Sharing and Intellectual Property*", 8/1 Law, Environment and Development Journal p. 19, 2012, p. 26.

fulfilled in a way that allows appropriate access to GR and appropriate transfer of technologies. At the same time, the actions need to consider all the rights to the relevant resources and technologies and that the actors are sponsored by appropriate funds.[57]

Besides the objectives, a few principles need to be taken into account when interpreting the Convention and its articles. Emulating the Charter of the United Nations and the principles of international law, the signing parties of the Convention have a sovereign right to utilize their resources in accordance with their own environmental policies. On the other hand, they also have a responsibility to guarantee that the environments of other states or areas outside the limits of national jurisdiction are not damaged by activities in their own jurisdiction or control.[58]

3.2.2 Article 15 of the CBD

Article 15 of the CBD is one of the more important and relevant articles to be reviewed in context to this thesis. The article regulates the access to GR. Firstly, it affirms the countries sovereign rights over their natural resources and the national government's rights to regulate access to GR through national legislation. The parties should also try to establish conditions that facilitate access to GR, which in turn are used in an environmentally reasonable way by other parties. In their pursuit, the implemented restrictions should not go against the objectives set forth in the CBD. Following the assertion, a more detailed regulation is set down where the GR that are provided by a contracting party are said to be only those attained from the countries of origin of such resources or by other parties that have attained them in conformance with the Convention.[59]

In the cases where access is granted, it should be on commonly agreed terms and under this provision. The access should also be subject to prior informed consent if the party that provides the GR has not requested

[57] The Convention on Biological Diversity (CBD) Article 1, (see Supplement A).
[58] The CBD Article 3.
[59] The CBD Article 15(1)-(3).

otherwise. Beside the obligation of prior consent, the contracting party also has an obligation to try to develop and carry out scientific research using the GR as a base with the participation of the party providing the GR. Nonetheless, the last provision in the article states that each party "shall take legislative, administrative or policy measures" in order to share the results of research and development and the benefits that arise from the commercial utilization of the GR, in an impartial and fair way. The sharing shall be done on commonly agreed terms and conditions.[60]

3.2.3 Article 16 of the CBD

Not far from the previous article, Article 16 of the CBD regulates the access to and transfers of technology. In its first provision, it affirms the importance of access and transfer especially in regards to the objectives of the Convention (see Supplement A). At the same time, it urges the parties to transfer technologies, which are important for the conservation and sustainable use of biological diversity, or make use of the GR in a way that does not cause any significant damage to the environment. Furthermore, the transfer and access to technology should be provided in a fair and most favourable way.[61]

Additional actions need to be taken according to the third provision in the Article. Contracting parties need to take either legislative, administrative or policy measures with the purpose of giving the parties access to and transfer of technology on commonly agreed terms. This includes technologies that are protected by patents or other IPR. The same actions should also be taken so that the private sector assists in the access to joint development and the transfer of technology to the benefit of the governmental institutions and private sector of the developing countries. In the last provision of the article, the contracting parties are reminded that patents and other IPR shall, in

[60] The CBD Article 15(4) - (7).
[61] The CBD Article 16(1) - (2).

regard to national legislation and international law, be supportive of and not counter to the objectives of the CBD.[62]

3.2.4 The Nagoya Protocol

Aside from the articles in the Convention, there are also a number of protocols that have been produced since the entry into force of the Convention. "The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity" (The Nagoya Protocol) is the most recent one and the most relevant to this thesis. It is a supplementary agreement to the CBD that entered into force on the 12th of October 2014. The agreement provides a transparent legal framework that also implements one of the three already mentioned objectives of the CBD. It implements the fair and equitable sharing of benefits that arise from the use of GR. Thereby the Agreement assists in the conservation and sustainable use of biodiversity.[63]

One of the subjects that were discussed during the negotiations of the Nagoya Protocol was the disclosure requirement. Although it was heatedly discussed in the initial rounds the discussions died down. In the end, the mandatory disclosure requirement in the state issuing the patent using GR was not included in the Protocol.[64]

Summary

This chapter has shown the different objectives and purposes of both the CBD and the TRIPS Agreement. On one hand, the TRIPS Agreement sets forth a very intellectual property protection oriented legislation where the

[62] The CBD Article 16(3) - (5).
[63] United Nations Secretariat of the Convention on Biological Diversity: "*About the Nagoya Protocol*", https://www.cbd.int/abs/about/default.shtml/, on the 31st of March 2016.
[64] Kamau, Evanson Chege et al.: "*The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community*?", 6/3 Law, Environment and Development Journal, p. 246, 2010, available at http://www.lead-journal.org/content/10246.pdf, p. 257.

protection of technological assets are highlighted whilst the transferring of technology are ignored. On the other hand, the CBD brings forth a more environmentally protective regulation, promoting access to GR and the transferring of technology and resources. Both have different aims, yet they do not contradict one another. They can be conformed to meet both the interests highlighted in the TRIPS Agreement but also the ones in the CBD.

4 The proposed changes

Through this chapter the proposed changes by WTO Members will be presented. First and foremost a general overview will be presented of the origin and motive for the new proposal. It is then followed by the proposals for changes in the TRIPS Agreement under the subchapter "Amendments of the TRIPS", which in turn is divided into the different proposals that have been put forward.

4.1 The background behind the proposed patent requirement

The outset of the proposed requirement springs essentially from Article 27.3(b) of the TRIPS Agreement. The article allows Members to exclude plants and animals that are not microorganisms and all biological process other than non-biological and microbiological processes. It also prescribes that the Members shall provide protection for new plant varieties. The last sentence of Article 27.3(b) obliges the Members to revise the Article after 4 years following the entry into force of the WTO Agreement.[65] At the end of 1998 a decision was made to review the Article.[66]

During the primary stages of the discussion, it was decided that the relationship between the TRIPS Agreement and the CBD should be looked upon and that attention should be given to the protection of TK and folklore. These discussions progressed into discussions on the disclosure of origin of biological material and associated TK.[67] The idea of a disclosure

[65] The TRIPS Agreement Article 27.3(b).
[66] WTO Council for Trade- Related Aspects of Intellectual Property Rights: "*Review of the provisions of Article 27.3(b)*", IP/C/W/273/Rev.1, 2003.
[67] WTO: "*TRIPS: Reviews, Article 27.3(B) and related issues: Background and the current situation*", from:
https://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm, on the 1st of March 2016.

requirement was mainly derived from Article 15 of the CBD, which establishes the terms of access to GR.[68]

The initial conceptual discussions of the disclosure requirement were, on the other hand, very much influenced by the Andean Community[69] regime on access to genetic resources. In the beginning, the suggested disclosure requirement was viewed very sceptically, but with time it garnered more interest especially by experts and policy makers. Likewise, there have been representatives of indigenous peoples organisations that have endorsed the idea, especially concerning TK. It is their belief that the requirement has potential, as a tool, to prevent misappropriation of knowledge and practices that are used by these communities, but also to conserve and sustainably use the biodiversity in these countries.[70]

Another presented reason behind the will to introduce a disclosure requirement is due to two facts. Developing countries are paying high prizes for products that are being re-introduced in their own countries but that are made from their own regional resources. At the same time, these countries do not have the means to use the intellectual property framework to protect their own indigenous and local resources and knowledge from being pirated and copied.[71]

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[68] Gollin, Michael A.: *Feasibility of national requirements for disclosure of origin*, in: Ed. Chouchena-Rojas, Martha et al., "Disclosure Requirements: Ensuring mutual supportiveness between the WTO TRIPS Agreement and the CBD", IUCN, Gland, Switzerland and Cambridge, UK and ICTSD, Geneva, Switzerland, 2005, p. 21.

[69] The Andean Community is a customs union consisting of the countries Peru, Ecuador, Colombia and Bolivia. They were influenced by the Andean Community Decision 391 on a Common Regime on Access to Genetic Resources.

[70] Chouchena-Rojas, Martha et al., "*Disclosure Requirements: Ensuring mutual supportiveness between the WTO TRIPS Agreement and the CBD*", IUCN, Gland, Switzerland and Cambridge, UK and ICTSD, Geneva, Switzerland, 2005, p. 9.

[71] Ewens, Lara E., "*Seed Wars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds*", 23 Boston College International and Comparative Law Review 285 (2000), from: http://lawdigitalcommons.bc.edu/iclr/vol23/iss2/6/, on the 1st of March 2016.

4.2 Amendments of the TRIPS

To come to terms with the ”unfairness”[72] in the use of GR a disclosure requirement has been proposed multiple times. In the following, the most elevated and discussed proposals will be presented.

4.2.1 The original proposal

On the 24th of June 2002 Brazil presented a communication on behalf of the delegation of ten countries[73]. It is this communication that contains the first proposal for a disclosure requirement, i.e. the original proposal. The introduction of the communication emphasizes that the Doha Ministerial Declaration[74] had found that the relationship between the TRIPS Agreement and the CBD needed to be analysed. This was due to the belief of developing countries that there was incoherence between the two agreements and that the incoherence needed to be dealt with through a modification of the TRIPS Agreement. Through the modification, the agreements would both support and promote a sustainable use of resources.[75]

An important aspect that needs to be ensured, in order to obtain coherence between the agreements, is that the patenting of plants, animals or microorganisms does not conflict or contradict the regulations in the CBD. The provisions that are implied are the ones stating the sovereignty over the Members' own GR, the regulation on the objectives of benefit sharing and prior informed consent, and lastly the provision on the protection of TK.[76]

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[72] From the outlook of developing countries.
[73] China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe.
[74] It is a declaration from 2001, of the Fourth Ministerial Conference in Doha, Qatar, and it provides the mandate for negotiations on a range of subjects, and other work including issues concerning the implementation of the present agreements. The negotiations take place in the Trade Negotiations Committee and its subsidiaries.
[75] WTO Council for Trade- Related Aspects of Intellectual Property Rights: "*The relationship between the TRIPS Agreement and the Convention on biological diversity and the protection of traditional knowledge*", IP/C/W/356, 2002, p.1 & 3.
[76] Ibid. p. 5.

Considering all these prospects, the proposal is then finally presented in the last section of the communication (see Supplement B for the excerpt). The Trade Negotiations Committee[77] should decide that the TRIPS Agreement needs to be modified to determine that Members should demand applicants, for patents relating to biological materials or TK, to disclose "the source and country of origin of the biological resource and of the traditional knowledge used in the invention", in order to acquire patent rights. The applicant also needs to provide "evidence of prior informed consent" and "evidence of fair and equitable benefit sharing" before being granted a patent.[78]

Requiring applicants to disclose and provide evidence is according to the proposal a more cost-effective method to create an accepted solution to stop biopiracy than to drive national resources into costly legal processes for the annulment of patents that consist of illegal GR. Furthermore, an introduction would not be more troublesome to implement than the other requirements in the already existing patent application process. All in all, the modification would equip governments, investors, traditional communities and researchers with a more predictable environment. At the same time it would promote research and development in biotechnology in the developing nations. The regulation would then embody the objective of the TRIPS Agreement to advocate for technological innovation but also for the distribution and transfer of technology.[79]

4.2.2 The second submission

After several papers and submissions from developing countries another submission was made by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand and Venezuela. In the submission the original proposal from June 2002 is commented as well as the papers and submissions following it. The reason behind the submission is that the

[77] The Trade Negotiations Committee is a committee that operates under the authority of the General Council. It was set up to establish subsidiary negotiating bodies to deal with individual negotiating subjects.
[78] IP/C/W/356, p. 5.
[79] Ibid. p. 6.

countries would like to emphasize and strengthen the main arguments to introduce a regulation like the one in the original proposal. On the other hand, the purposes of the proposed provision are many. First and foremost, it would reduce the occurrence of bad patents. Secondly, it would help countries in the tracking of the GR. Thirdly, the provision would help patent offices with conforming the inventive step in an invention in a more effective manner. Lastly, it would ensure the compliance with these countries national laws on prior informed consent and fair and equitable benefit sharing.[80]

In the submission, the countries correspond to the counterarguments, made by many, that they should pursue legal remedies under own patent laws or under the laws of the country that has granted the patent. To them, seeking legal remedies in multiple jurisdictions and under international laws is not economically possible, as it is both complicated and costly. Another argument that has been raised is that the provision would not be in coherence with the principle of non-discrimination between different fields of technology in the TRIPS Agreement. The principle states discrimination is present if the novelty, inventiveness and usefulness criteria are applied diversely in different fields of technology. On the other hand, the processes for granting patents are often different depending on which field of technology they belong to. The requirements in the proposed provision only facilitates in making the assessment of patentability more accurate. It would therefore assist in the confirmation of whether or not the applicant did in fact invent the claimed invention in the patent application or if s/he discovered it in nature or acquired it from traditional culture. The novelty and inventive step requirements would be assessed better and more precisely.[81]

[80] WTO Council for Trade- Related Aspects of Intellectual Property Rights: "*The relationship between the TRIPS Agreement and the Convention on biological diversity and the protection of traditional knowledge*", IP/C/W/403, 2003, p. 1ff.
[81] Ibid. p. 2ff.

One of the main counterarguments that have been put forward has been that an additional condition on patentability would constitute an unnecessary burden. On this note, it is stated in the submission that the research and knowledge around and behind the product is at the applicant's disposal. Obviously, information on compliance with national laws of where the biological resources were acquired and the TK would be among this material. It is therefore a reasonable procedure to require the applicant to submit this material that is in his possession. Another disputable condition has been whether or not the provision should have an implication if it is not followed. If there are no consequences, e.g. a revocation of a patent in the case of the applicant presenting false information, the requirements would be ineffective and only a decorum.[82]

4.2.3 The African group proposal

The African group[83] presented their communication on the 26th of June 2003, with the purpose of assisting in the finalization of the long-lasting problems with the review of Article 27.3(b) of the TRIPS Agreement. Overall, the communication has a good disposition as it addresses the issues that need to be solved in areas where there are possible agreements in views and in areas without a common understanding. Although a lot of the same aspects as in the last communication are mentioned the African group note new aspects. Through the protection of GR and TK, which originate from developing countries, poverty can be addressed. Equity and due recognition for the keepers of the GR and TK are also important matters.[84]

In the communication, the African group explain the reason why a solution is sought in the WTO and the TRIPS Agreement and not in other institutions and multilateral agreements. One of the reasons is that there will be no effective protection of GR and TK unless there is an instrument in the

[82] IP/C/W/403, p. 4f.
[83] A coalition formed in the WTO consisting of all African WTO Members. A full list can be found in Supplement B.
[84] WTO Council for Trade- Related Aspects of Intellectual Property Rights: "*Taking forward the review of Article 27.3(b) of the TRIPS Agreement*", IP/C/W/404, 2003, p. 1ff.

TRIPS Agreement. The WTO has its own way of functioning as the rights and obligations of Members are defined and breaches of obligations are dealt with. That is the reason why the solution to the misappropriation of GR and TK, through patenting, needs to be undertaken under obligations that are enforceable under the WTO.[85]

Concerning the disclosure requirement, the African Group presents a different proposal (see Supplement B). The group agrees that through a disclosure requirement misappropriation of GR and TK can be prevented and prohibited. However, Article 29 of the TRIPS Agreement is, according to the group, more suitable for regulating the requirements for all relevant patent applications. The requirements for equity, disclosure of origin of GR and TK, and the display of conformity with relevant domestic procedures would instead be incorporated in a third paragraph of the article (see Supplement B).[86]

4.2.4 The Peruvian proposal

In the beginning of June 2005, Peru submitted a communication where they presented their view on the relationship between the TRIPS Agreement and the CBD in the aspect of Article 27.3(b). Although there has been a lot of progress since the first proposal, it can be noted in the submission that countries are still split on the inclusion of a disclosure requirement. The reason is that countries are divided into the different versions of requirements: a voluntary requirement, a more limited one that only includes disclosure of origin and a mandatory inclusion.[87]

But, still there is a need for a disclosure requirement. There is an economic motive, as both GR and TK are essential to guarantee the potential of their commercial utilization and industrialization. In the communication, Peru

[85] IP/C/W/404, p. 2 & 5.
[86] Ibid. p. 6.
[87] WTO Council for Trade- Related Aspects of Intellectual Property Rights: "*Article 27.3(b), relationship between the TRIPS Agreement and the CBD and protection of traditional knowledge and folklore*", IP/C/W/447, 2005, p. 1 & 5.

also refers to a worldwide study from 1999, where the annual market value of GR, which were used in biotechnology, the pharmaceutical industry, crop protection and bioremediation, were calculated to ca. 500-800 billion U.S. dollars[88]. The legal aspects are another reason, as the legal system would be more corresponding and less "bad patents" would be granted. Furthermore, the rights and belief of indigenous people need too be respected. Finally, the political reasons are also important, as countries need to protect their interest in regards to their sovereign rights over resources in their territory.[89]

The Peruvian proposal differs from the previous proposals (see Supplement B). An insertion, in the form of an additional letter under paragraph 3 of Article 27 of the TRIPS Agreement, is proposed. Members have, according to the paragraph, a right to exclude products or processes from patentability if they do not fulfil certain requirements. Products or processes that do not have prior informed consent, an agreement on fair and equitable sharing of benefits, and that do not comply with national and international law can be excluded. Moreover, Members have, in the new proposal, the right to introduce domestic legislations that correspond with principles and obligations set forth in the CBD. The disclosure requirement, on the other hand, is to some extent neglected. The proposal suggests an amendment of Article 29(1) where Members are required, where it is suitable, to include a "disclosure of origin and legal provenance". Legal penalties are, according to the proposal, to be decided by each country in their domestic regulations.[90]

However, to some extent Peru also recognizes that even if all their requests were recognized there would still be problems with illegal and unauthorized use of GR and TK.[91]

[88] IP/C/W/447, p. 3.
[89] Ibid. p. 5.
[90] Ibid. p. 13f.
[91] Ibid. p. 5.

4.2.5 The Norweigan proposal

At a TRIPS Council meeting in June 2006 Norway presented their view on the amendment of the TRIPS Agreement. It was their belief that the two Agreements could and should be implemented in a supportive way. A disclosure requirement would improve the interaction between the treaties. Furthermore, it would also facilitate in the patent process, as it would guarantee that the novelty criterion is met, which is inline with the fundamental intentions and principles set forth in the patent system. The disclosure of origin would also simplify the enforcement of each Member's rights to their GR. The provisions on prior informed consent and benefit sharing would therefore also be more effective. In addition, Article 16.5 of the CBD would then also be given effect, as IPR would then be supportive of the objectives of the CBD.[92]

Although agreeing with other Members that a disclosure requirement should be introduced, Norway believes that some key principles need to be taken into consideration when outlining the obligation (see Supplement B). The obligation should require patent applications to contain the information of the supplier country but also the country of origin if it is known. In the event that the applicant refuses or is unable to disclose this information to the patent office, the application should be stopped if s/he has had a chance to disclose it. However, remedies outside of the patent system should be used if the applicant gives wrong or insufficient information. Contrary to other proposals, the misleading or withholding of information should, therefore not affect the validity of the patent. Finally, the disclosure requirement would be applicable to all types of patent applications international, regional and national.[93]

[92] WTO General Council for Trade Negotiations Committee Council for Trade- Related Aspects of Intellectual Property Rights: "*The relationship between the TRIPS Agreement, the Convention on Biological Diversity and the protection of traditional knowledge; Amending the TRIPS Agreement to introduce an obligation to disclose the origin of genetic resources and traditional knowledge in patent applications*", IP/C/W/473, 2006, p. 1.
[93] Ibid. p. 2.

To summarize their point of view, Norway gives a proposal on how to incorporate the key principles into a new article in the TRIPS Agreement, Article 29*bis*. According to Norway, the new mandatory obligation to disclose should be connected to the patent application. However, it should not be a substantive patent criterion[94]. Instead, appropriate and effective sanctions outside of the patent system should be provided and patent applications without the required information should not be processed.[95]

4.2.6 The latest proposal

Following the proposal from Norway, the delegation of India circulated a communication, IP/C/W/474, in the TRIPS Council in July 2006. Since then, the proposal has been discussed and the latest version that has been put forth of that same proposal is one from the 19th of April 2011 (see Supplement B).[96]

In the latest proposal, the Members have included a preface where many principles and aspects are noted, reaffirmed and recalled. Most of them have already been mentioned under other proposals. However, the most important assertion is that Members acknowledge that the disclosure requirement needs to be incorporated into patent applications. The inclusion will, according to the proposal, not only prevent the exploitation of GR but also the granting of erroneous patents. At the same time, the disclosure requirement will increase the transparency in the patent system. Due to those reasons and due to the disclosure requirement in Article 29 of the TRIPS Agreement being incomplete without a disclosure of origin requirement, the TRIPS Agreement needs to be amended through the insertion of Article 29*bis*.[97]

[94] A substantive patent criterion needs to be met for the patent to be held valid.
[95] IP/C/W/473, p. 3.
[96] WTO Trade Negotiations Committee: "*Draft decision to enhance mutual supportiveness between the TRIPS Agreement and the Convention on Biological Diversity*", TN/C/W/59, 2011, p. 1.
[97] Ibid. p. 2.

The proposed Article 29*bis* requires Members to take into consideration the objectives, definitions and principles in the TRIPS Agreement and the CBD as well as the Nagoya Protocol, when they establish a mutually supportive relationship between the TRIPS Agreement and the CBD. Regarding the disclosure requirement, the Article requires patent applicants to disclose the country and the source in that country that provides the GR and the TK. The requirement should only be applied if the invention includes the use of GR and/or TK. An appropriate, effective and proportionate system should be established to control breaches of the requirement. A patent application should therefore not be processed if the disclosure requirement is not followed. If an already granted patent is found to not have followed the requirement the applicant should be reprimanded. Administrative sanctions, criminal sanctions or fines and compensations for damages should be introduced as consequences for such behaviour.[98]

Summary

In conclusion, the reasons for the many discussions and proposals for a disclosure requirement in the TRIPS Agreement are that the countries rich in biodiversity wish to prevent the misappropriation of both GR and TK, but also to find a more sustainable way of using these resources. Viewing all the different proposals dissimilarities are obvious but there are also similarities in the way the requirement is formulated. Finally, it is clear that a settlement or solution has not been found as the discussions are still on going.

[98] TN/C/W/59, p. 2f.

5 Repercussions, issues and other aspects of the proposal

Between the different proposals, a strong opposition has been shown to an amendment of the TRIPS Agreement, mostly from developed countries. The discussions have been held many times in the TRIPS Council and numerous communications have been presented. In the communications, the opposing parties have brought forward legal issues and complications with an introduction of a disclosure requirement that cannot in their opinion be overlooked. Furthermore, political aspects that need to be considered have been introduced but also the economical repercussions of a disclosure requirement.

5.1 Legal issues

An oppositional position towards the proposal has mainly come from the United States and Japan. One of the first arguments that were presented stated, as has been mentioned before, that the disclosure requirement would not be in coherence with the principle of non-discrimination between different fields of technology. The view was that the requirement was arranged to be applied only for inventions that involved GR.[99] Another Article that Japan claims is violated by the addition of a disclosure requirement is Article 62.1 of the TRIPS Agreement.[100] The Article allows Members to require, as a condition for acquiring or maintaining IPR, compliance with procedures and formalities that are reasonable.[101]

On the other hand, the U.S. have in their communications underlined that a new patent requirement would disturb the careful balance in the patent

[99] Ni, Kuei-jung: "*The incorporation of the CBD mandate on access and benefit-sharing into TRIPS regime: an appraisal of the appeal of developing countries with rich genetic resources*", 1 Asian Journal of WTO & International Health Law & Policy 433, 2006, p. 448.
[100] WTO Council for Trade-Related Aspects of Intellectual Property Rights: "*Minutes of Meeting: Held in the Centre William Rappard from 27 to 30 November and 6 December 2000*", IP/C/M/29, 2001, p. 56.
[101] The TRIPS Agreement Article 62.1.

system. The patent system is set up with an underlying incentive for inventors to initiate and accomplish demanding and costly research and progress with the reward of an exclusive right to hinder others from utilizing the patented invention for a specific time. It is this balance between incentive and protection that the U.S. believes will be disturbed if the new disclosure requirement is amended.[102] On the other hand, the International Chamber of Commerce's (ICC) ABS Task Force go further by claiming that the balance will not only risk to be disturbed but a disclosure requirement will deter innovation. Innovation is not in anyway encouraged by a requirement to disclose the origin of the GR connected to the invention.[103] In other words, legal assurance is needed in order for there to be an incentive to invent.

An additional argument brought forth by the U.S. is that disclosing the source and origin does not, in their view, tackle the concerns of developing countries. The requirement will not prevent erroneously granted patents, as it would be of little value in the process of determining prior art, "inventorship", obviousness and novelty.[104] An example of this is the Turmeric Case[105]. Even though the origin of the GR was disclosed in the Turmeric Case it did not hinder an erroneous patent from being issued.[106]

Besides the aforementioned principal and theoretical issues with the proposed provision there are two more practical issues with the implementation that have been brought forward. The first issue is that it is difficult to ascertain the exact origin and source of GR.[107] Numerous resources are indigenous to one country but are often both sold and grown in

[102] WTO Council for Trade- Related Aspects of Intellectual Property Rights: "*Article 27.3(b), relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore*", IP/C/W/469, 2006, p. 8.
[103] International Chamber of Commerce's (ICC) Task Force on Access and Benefit-Sharing: "*Access and Benefit Sharing: Special Disclosure Requirements in Patent Applications*", Document number: 212-11/7, 25th of May 2005, p. 6.
[104] IP/C/W/469, p. 7.
[105] A patent was issued in the U.S. for the Turmeric, a tropical herb grown in Eastern India. The patent was later revoked, as it did not fulfil the five patent criterions. The Turmeric had been used in the same way for a long period in India.
[106] IP/C/W/469, p. 7.
[107] Carr op. cit. p. 145.

many countries all over the world. If not, they are often sold as raw materials with the purpose to gain a prompt profit.[108] Another issue that will emerge with the implementation of the new requirement is that it will put an undue burden on both patent offices and patent applicants.[109] Supporting a demanding solution will according to the U.S. not solve the problems.[110]

Overall, the argument is that the objectives will not be accomplished through the insertion of a disclosure requirement.[111] Instead the incorporation of an untested requirement would lead to legal uncertainty.[112] Therefore, the U.S. is of the opinion that the requirement, if accepted, would not only supress innovation but it would also weaken the patent system.[113]

5.2 Political aspects

During previous decades, the prevailing principle was that all GR were a part of the "common heritage of mankind" and that they could be used without any restrictions.[114] A political discord between the North and South[115], among other things, led to the "common heritage of mankind" being replaced by state sovereignty.[116] The developing countries had long argued for a change in the negotiations of the CBD. The common heritage principle was, in their view, a version of colonialism. Developed countries were free to utilize their GR without charge.[117] Through the commencement

[108] IP/C/W/469, p. 4.
[109] WTO Council for Trade- Related Aspects of Intellectual Property Rights: "*Article 27.3(b), relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore*", IP/C/W/449, 2005, p. 8.
[110] IP/C/W/469, p. 4.
[111] Ibid. p. 9.
[112] WTO Council for Trade- Related Aspects of Intellectual Property Rights: "*Article 27.3(b), relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore*", IP/C/W/434, 2004, p. 4 footnote 7.
[113] IP/C/W/469, p. 9.
[114] Keating, Dominic: "*Access to Genetic Resources and Equitable Benefit Sharing Through a New Disclosure Requirement in the Patent System: An Issue in Search of a Forum*", 87 Journal of the Patent & Trademark Office Society 525, 2005, p. 530.
[115] i.e. developed and developing countries.
[116] West op. cit. p. 26.
[117] Keating op. cit. p. 530.

of the CBD, the sovereign rights over natural resources were since then under each country's discretion.[118]

In a similar way, there is now a dissonance on whether or not the disclosure requirement should be incorporated into the TRIPS Agreement or solved in another forum. Among the developed countries, the U.S. has emphasized the need to solve the issue in another forum or in another way through cooperation between countries. The reason why the provision should be under a separate regulatory system is because it is outside of the scope of the TRIPS Agreement.[119] Issues of misappropriation of GR are not, in their view, issues to be regulated or enforced through patent law.[120] Nuno Pires de Carvalho, author and acting director of the Intellectual Property and Competition Policy Division (WIPO), argues further by claiming that it is unreasonable to incorporate such a provision into the TRIPS Agreement. One of the reasons is that the provision stems from a treaty that is outside of the scope of the WTO. In addition, the provision would force Members that have not signed or enforced the CBD to follow it.[121]

On another note, the U.S. also argues that most of these countries have none or few clearly defined national systems that monitor the consummation of GR.[122] In order to achieve their declared objectives, developing countries should instead enact national rules or solutions that are tailored to their actual needs and that meet their practical concerns. Thus, the issues need to be addressed internally before an international solution is sought.[123] During the years, numerous countries[124] have adopted different versions of the

[118] West op. cit. p. 26.
[119] IP/C/W/469, p. 2.
[120] IP/C/W/434, p. 6f.
[121] Carvalho, Nuno Pires de: "*The TRIPS Regime of Patents and Test Data*", 4. ed., 2014, p. 373.
[122] IP/C/W/469, p. 2.
[123] IP/C/W/434, p. 2.
[124] The Andean Community, Belgium, Brazil, China, Costa Rica, Cuba, Denmark, Egypt, European Union, Germany, India, Italy, Kyrgyzstan, Norway, Peru, Philippines, Romania, South Africa, Sweden, Switzerland; see footnote 125 for the full document with a compilation of each nation's regulation.

disclosure requirement into their national regulations.[125] One of the countries that have adopted a disclosure requirement is Costa Rica. However, the implementation of the substantial requirement has not been simple. The patent offices have frequently relied on external substantive examiners and patent office's lawyers to complete the formal exam. According to Jorge Cabrera Medaglia, professor and legal adviser of the National Biodiversity Institute, the issues are so profound that the legal texts need to be revised.[126] Senior research fellow at the Fridtjof Nansen Institute, Morten Walløe Tvedt, and author, Tomme Young, have also researched the different disclosure requirements. Their research has shown many limitations and problems with such a system. One of the issues concerns the continuous ambiguity. The Norwegian provision is used as an example to illustrate that their use of terminology is inclusive. Thousands of patent applications would need to be examined each year under this provision. Other observations, made by the two authors, are that the disclosed information is not verified and the source countries are not contacted. Furthermore, the disclosure requirement does not create rights for the source country and no benefit-sharing obligation is conferred on the user.[127] Nevertheless, the issues are being observed and the more practical aspects and implementation of the disclosure requirements in national legislations are still at the starting point. It is recognized that legal adjustments may be needed in order to make the requirement functional.[128]

Lastly, developing countries need to consider the difficulties in changing a WTO-agreement. The TRIPS Agreement can only be amended if the WTO Members reach an agreement. The first and only time the WTO Members

[125] WIPO: "*Disclosure Requirement Table*" from: http://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf, on the 12th of March 2016.
[126] Medaglia, Jorge Cabrera: "*The Disclosure of Origin Requirement in Central America: Legal Texts, Practical Experience and Implementation Challenges*", in: ICTSD, Issue Paper No. 3, June 2010, p. 10 & 15.
[127] Tvedt, Morten Walløe & Young, Tomme: "*Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*", IUCN Environmental Policy and Law Paper No. 67/2, 2007, p. 35.
[128] Muller, Manuel Ruiz: "*Disclosure of Origin and Legal Provenance: The Experience and Implementation Process in South America*", in: ICTSD Policy Brief Number 7, June 2010, p. 5.

approved a change was on the 6th of December 2005 and it concerned compulsory licensing. However, an actual change or amendment of the TRIPS Agreement has not been made. The reason is that two thirds of the WTO's Members have to accept the change in order for the changes to be included into the TRIPS Agreement. At the time of writing, 67 out of 162 WTO Members have accepted the change and the deadline has been extended to the 31st of December 2017.[129] The Anti-Counterfeiting Trade Agreement (ACTA)[130] is another example that illustrates the difficulties in changing the TRIPS Agreement. Members had initially tried to incorporate measures that combat counterfeiting and piracy into the TRIPS Agreement. However, the attempts were unsuccessful and the ACTA was established. The difficulties, disagreements and frustration with the lack of progress in the TRIPS Council were the main reasons why the countries abandoned a TRIPS amendment and tried to shop forums (i.e. forum shopping).[131]

5.3 The economical repercussions

Apart from the already mentioned legal and political issues and aspects, some attention has also been given to the possible economical and to some extent social repercussion of the proposed amendment. The ICC has emphasized that three major sectors that are operating in modern biotechnology research may be influenced by the adoption of the disclosure requirement. One of the three sectors is the agricultural sector, due to it mainly consisting of the use of GR that have been acclimatized for ages. The industrial biotechnology sector may also be influenced, as it heavily relies on microbial resources and the development of products that can facilitate in the discovery of rare characteristics, but it also facilitates in "the

[129] WTO: "*Intellectual Property: TRIPS and Public Health: Members accepting amendment of the TRIPS Agreement*", from: https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm, on the 14th of March 2016.

[130] Tokyo, Japan on the 1st of October 2011; ACTA is a multinational treaty that aims to establish an international legal framework that targets counterfeiting and piracy. To this day the Agreement has not entered into force. For more information see: http://www.inta.org/Advocacy/Pages/AntiCounterfeitingTradeAgreement.aspx.

[131] Matthews, Duncan & Žikovská, Petra: "*The Rise and Fall of the Anti-Counterfeiting Trade Agreement (ACTA): Lessons for the European Union*", International Review of Intellectual Property and Competition Law (ICC), Volume 44, Issue 6, 2013, p. 633f.

substitution of renewable resources for energy and other natural resource factors of production".[132]

The final sector that may be influenced is the pharmaceutical sector.[133] As has been mentioned earlier, the introduction of a disclosure requirement would affect the incentive to invent in a negative way. The incentive mechanism in the patent system is crucial for advocating and encouraging research and development.[134] If the balance of the patent system is disturbed it would also affect the risks of investing and developing a commercially successful product.[135] In other words, the investments would decline. At the same time, the investments made into newly developed companies in the biotechnological sector would be affected.[136] Another repercussion, would be that the research invested into both the pharmaceutical and biotechnological field would decrease.[137] It is the research that results into new inventions, which in turn improve our existence, through better medicines.[138] The losses of new pharmaceuticals have been estimated to circa 150 to 200. However, the final cost would be over $144 billion by the year of 2025.[139] Some of the repercussions have already been revealed, according to the ICC. Due to the uncertainties concerning the access to GR, the pharmaceutical sector has started to rely heavily on synthetic molecules instead of natural products.[140]

[132] ICC's Task Force on Access and Benefit-Sharing op. cit. p. 4.
[133] Ibid. p. 4.
[134] IP/C/W/469, p. 5.
[135] Ibid. p. 9.
[136] Curci, Jonathan, "*The new challenges to the international patentability of biotechnology: legal relations between the WTO Treaty on Trade-Related Aspects of Intellectual Property Rights and the Convention on Biological Diversity*", 2 International Law & Management Review 1 2005-2006, 2005, p. 41.
[137] Wolfe, Timothy A. & Zycher, Benjamin: "*Biotechnological and Pharmaceutical Research and Development Investment Under a Patent-Based Access and Benefit-Sharing Regime*", Pacific Research Institute, San Francisco, May 2005, p. 5.
[138] IP/C/W/469, p. 5.
[139] Wolfe & Zycher op. cit. p. 15.
[140] ICC's Task Force on Access and Benefit-Sharing op. cit. p. 4.

Summary

A large number of issues and repercussions have been presented in this chapter. In addition, there are also political aspects that affect not only the decision-making but also the consequences of that decision. The truth is that neither side actually knows the factual results; they are all estimates and assessments.

6 Other solutions?

Members of the TRIPS Agreement have through the years presented numerous suggestions and proposals. Some of them have had the purpose of finding a better solution than the disclosure requirement. The sixth chapter of this thesis presents, in a concise manner, the different solutions that have been brought to the TRIPS Council.

6.1 A contract-based system

The most argued possible substitution for the disclosure requirement has through the years been a contract-based system. The system would be based on contracts between involved parties, i.e. countries with GR and companies or other parties that wish to acquire the GR. Through the contracts, benefit sharing can be established but also other rights and obligations can be regulated. Developing countries can therefore efficiently control their GR and ensure that the benefits are shared. A disclosure requirement could be incorporated into the contract.[141]

However, developing countries have stated that the contracts would not fulfil the goal of stalling the issuance of a patent that is based on knowledge or information from another country. The contract-based system would also be ineffective as the parties are often of greatly unequal bargaining power.[142] Developing countries have also stated that even though the system is perfected it would still not be able to guarantee the effectiveness and mandatory enforcement that is present in international law.[143]

[141] IP/C/W/434, p. 2 & 5f.
[142] IP/C/W/403, p. 5.
[143] WTO Council for Trade- Related Aspects of Intellectual Property Rights: "*The relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge*", IP/C/W/459, 2005, p. 5.

6.2 Databases

Another proposed replacement for the disclosure requirement has been organized and searchable databases. The databases would hold information on GR and would be available all over the world. Thus, allowing patent examiners to use them while screening patent applications. The examinations could therefore be improved, as relevant prior art would be discovered more easily.[144] Instead of providing "hints" to information, like the disclosure requirement, the databases would present the information immediately.[145]

Nevertheless, databases have many limitations. Developing countries have therefore stated that databases should only be used as a complement to the disclosure requirement.[146] There are limitations in the amount of documentation of TK, due to the knowledge's "vast breath and depth".[147] But there are also limitations in the form of language barriers and in the form of knowledge that is not documented or documented in the local language. Lastly, the proposal is also questioned in its appropriateness, as TK would no longer be confidential if it was submitted into these databases.[148]

6.3 A WIPO administered mechanism

During the negotiations in the TRIPS Council, Members have expressed their support of finding a solution in another forum. For instance, the U.S. has emphasized and reminded the TRIPS Council that they support WIPOs efforts to integrate prior art connected to GR and TK into the international patent system.[149] At the same time, Canada and Australia have stated that they would rather discuss the topic in the WIPO Intergovernmental

[144] IP/C/W/434, p. 7.
[145] IP/C/W/469, p. 6.
[146] IP/C/W/403, p. 5.
[147] WTO Council for Trade- Related Aspects of Intellectual Property Rights: "*Minutes of Meeting: Held in the Centre William Rappard from 17 to 19 September 2002*", IP/C/M/37/Add.1, 2002, p. 60f.
[148] IP/C/W/403, p. 5.
[149] IP/C/W/469, p. 7.

Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).[150] The latter has also been done and the process has since the 2010 Nagoya Protocol intensified. The latest session at the IGC was held between the 15th and 19th of February 2016. Much of the discussions were centred on a possible disclosure of origin requirement. Still the U.S., EU and others (mostly first world countries) are resisting a disclosure requirement. The reason is that they believe that intellectual property and the patent system should not be used to assure conformity with other laws and regulations.[151] As the negotiations fell through, the 30th session has been scheduled for the 30th of May to the 3rd of June 2016.[152]

Prior to the discussions in the IGC, countries tried to attain a disclosure requirement in the Patent Cooperation Treaty (PCT)[153]. Like the TRIPS Agreement Members have sought to amend the PCT to include either essentially the same proposed provision or a more formal requirement.[154] However, towards the end of the PCT Reform Phase and after several years of work and proposals the disclosure requirement fell out. Nevertheless, a review of the PCT is still likely to happen in the future according to WIPOs Deputy Director General Francis Gurry.[155]

Despite progress in different international forums, e.g. WIPO, the WTO is still the most important and appropriate forum, for developing nations, to discuss the disclosure requirement. The progress in the WTO should be supported as developed countries could still choose to avoid signing an apparatus, under WIPO, that implements the disclosure requirement. Thus, the main purpose would not be fulfilled, as a mandatory requirement at an

[150] Carvalho op. cit. p. 373.
[151] ICTSD: "*After Hiatus, WIPO IGC Resumes with Intense Debate over Genetic Resources, Disclosure*", in: Bridges Volume 20, Number 7, from: http://www.ictsd.org/bridges-news/bridges/news/after-hiatus-wipo-igc-resumes-with-intense-debate-over-genetic-resources, on the 1st of March 2016.
[152] WIPO: "*IGC: What is Happening Now*", from: http://www.wipo.int/tk/en/igc/snapshot.html, on the 1st of March 2016.
[153] Washington DC, U.S.A. on the 19th of June 1970.
[154] Carr op. cit. p. 132.
[155] New, William: "*WIPO PCT Reform Ends As Swiss Disclosure Proposal Suspended*", from: http://www.ip-watch.org/2007/04/30/wipo-pct-reform-ends-as-swiss-disclosure-proposal-suspended/, on the 1st of March 2016.

international level would be lost. On the other hand, the WTO Members would be legally bound to implement a disclosure requirement if the TRIPS Agreement was amended.[156]

Summary

Overall, there have been plenty proposals on different instruments and systems that could either be implemented or amended to fulfil the same purpose/s as the disclosure requirement. Unfortunately, none have yet succeeded in pleasing both sides' expectations, wishes and goals.

[156] Venero, Begoña: *Addressing the disclosure requirement at the international level: the role of the TRIPS agreement*, in: Ed. Chouchena-Rojas, Martha et al., "Disclosure Requirements: Ensuring mutual supportiveness between the WTO TRIPS Agreement and the CBD", IUCN, Gland, Switzerland and Cambridge, UK and ICTSD, Geneva, Switzerland, 2005, p. 31.

7 Analysis

During the last decades the interest in mother earth and her resources has escalated. At the same time great developments have been made in genetics and biotechnology, which in turn has increased the interest even more. With the increased attention to GR, developing countries have spoken out and demanded that the misappropriation of "their" resources should be stopped and prevented. Throughout this essay, the most debated solution has been presented and the time has come to discuss the question formulations and to finally fulfil the purpose of this thesis. In other words, the final two chapters will determine if it is reasonable to impose a requirement of disclosure of origin of GR in patents.

7.1 Question 1: *What is the motive?*

The starting point of the inclusion of a disclosure of origin of GR was the revision of Article 27.3(b) of the TRIPS Agreement. As was mentioned in the fourth chapter of this thesis, it was decided that the relationship between the TRIPS Agreement and the CBD should be analysed. During the discussions the requirement of disclosing the origin of biological material and associated TK, was brought up and it has since then been discussed heavily.

Within the different proposals, multiple motives and purposes have been defined. The most recited purpose is that the biodiversity rich countries wish to prevent the misappropriation, i.e. biopiracy, of both GR and TK and to find a more sustainable way of using these resources. Another motive that has been mentioned numerous times is that the TRIPS Agreement and the CBD need to be implemented in a supportive way and that the interaction between the two needs to be improved. Even though they maybe constitute the general motive, there are numerous reasons to why developing countries would benefit from a disclosure requirement.

Developing countries do not have the means or power to through the use of the intellectual property framework protect their local resources and the rights and knowledge of indigenous people. Through the disclosure requirement they would receive an effective protection of GR and TK without a charge. At the same time, the sovereignty that was established through the replacement of the "common heritage of mankind" would be reaffirmed in a new forum. Besides the purpose of reaffirming sovereignty, the amendment would also, as was mentioned earlier, promote research and development in biotechnology.

Another aspect that has been brought forward as a motive for the amendment is that developing nations wish to guarantee the potential of the GR's and TK's commercial utilization and industrialization. In addition, these countries are also paying a high prize for products that are made from their own regional resources.

Nevertheless, the developing countries have presented that the requirement would also have the motive to facilitate in the patent process by assuring that the novelty criterion and the inventive step are met. The requirement would also reduce the occurrence of bad patents and simplify the enforcement of each Member's rights to their GR.

Lastly, throughout the thesis numerous purposes have been presented. All of them can be categorized in political, economical or judicial motives. The most persistent motives presented by the developing nations have been that they wish to stop the exploitation of GR, the granting of erroneous patents while at the same time increasing transparency in the patent system. Even though, there maybe some hidden agendas, such as the desire to stop being seen as colonies and the desire to obtain pecuniary gains, the now mentioned motives seem in my opinion more important for developing countries.

7.2 Question 2: *What are the consequences and issues?*

On another note, some of the already mentioned motives for the proposed regulation could also be seen as possible positive consequences. The GR would be used in a more sustainable way and the misappropriation would stop. At the same time, a protection of the rights and knowledge of indigenous people and the GR could be established. In addition, the developing countries would receive an opportunity to develop and evolve into more successful and thriving nations in all areas due to the additional incomes and benefit sharing. In other words, this would be possible with the disclosure requirement, as developing nations would be able to track and claim sharing of benefits arising from their GR.

Even though developing nations have claimed that the disclosure requirement would also put an end to the granting of erroneous patents and that it would increase transparency in the patent system, developed countries have found great legal issues and problems with the provision. Developed countries have claimed that the provision is not in coherence with the principle of non-discrimination between different fields of technology in the TRIPS Agreement and that it is not a reasonable procedure or formality. These issues are not in my opinion obstacles for the disclosure requirement. The principle is not applicable, as the three criterion are not applied in a diversely manner in different fields of technology. The requirement would only assist in the assessments of the three criterions in the specific field. Concerning the reasonability of the disclosure requirement, I find that it is reasonable to require patent applicants to disclose the origin of the GR that they have used in their invention. Moreover, it would also not be an unnecessary or undue burden on patent offices nor patent applicants. The applicant has at his or her disposal all the research and knowledge around and behind his or her product and the information on the origin of the GR would obviously be among the material. Similarly, the patent offices would also only be required to analyse and scrutinize whether or not the applicant

has fulfilled the five patent requirements described in the second chapter of this thesis. However, while scrutinizing the application they would need to take into consideration the origin of the GR used. Issues concerning difficulties in affirming the origin of the GR are inconceivable, as in this day and time sellers and distributors are required to disclose the origin of their products (mainly considering import and export laws). This is unless the GR have been unlawfully attained, which would explain the difficulties.

An additional possible consequence that has been presented is that the careful balance in the patent system, between incentives and protection, would be disturbed with a new patent requirement and that the action would create a legal uncertainty. It has further been argued that the innovation will also deter and less research and developments will be done. Consequently, leading to an investment decline as the risks of investing will increase and the research will decrease. In conclusion, developed nations have argued that the final consequence will be that circa 150 to 200 drugs and $144 billion will be lost. Several attempts have been made to verify or contradict these numbers. However, no material has been found that either supports or opposes the statistics. Interestingly, the proposed amendment of the TRIPS Agreement, if introduced, may still potentially have a detrimental effect on the economy, even if there is no factual basis for the claims.

Nonetheless, the numbers are only estimates and assessments of, in the view of developed nations, possible repercussions based on their interpretation of the disclosure requirement. However, if the requirement is treated as an extension, supplement or complement to the novelty and inventive step requirements, the possibility of those consequences becomes impossible. A disclosure requirement would only assist in confirming the invention's originality in order to eliminate the possibility of a prior art. Conclusively, the mentioned actions of the pharmaceutical sector have not shown the consequences to an inclusion of a disclosure requirement. Instead, they demonstrate the complexity and the uncertainty of the subject, but also that a correct interpretation is needed.

Lastly, it has been argued that the TRIPS Agreement is not an agreement that can be easily amended. The ACTA and compulsory licensing have been presented as examples of the difficulties. Although it is hard to amend the TRIPS Agreement, I believe that the problem and the debate will not subside. The biopiracy issue and the troubles concerning GR are not disappearing. Even though the WTO Members are disagreeing, it is my view that the disclosure requirement will be adopted in the future as there are no better nor suitable options, as will be discussed in the following subchapter.

7.3 Question 3: *Are there other steps?*

Other steps or alternative solutions have during the many sessions been proposed. One of the alternative routes that developed countries have proposed is that the issues should be solved in another forum or through cooperation between countries. The motive has been that the issues are outside of the scope of the TRIPS Agreement. However, taking into consideration, the already mentioned, Article 7 and 8 of the TRIPS Agreement and the fact that the main purpose of the Agreement is to not only unify the IPR systems but also to tackle problems of IPR infringements and international piracy, it is hard to see why these issues would fall outside of the scope. Countries would therefore not be following a treaty that they did not sign. Instead they would follow the TRIPS Agreement by tackling the biopiracy issue.

Nevertheless, attempts have been made in another forum (WIPO). The issue has been discussed in both the IGC and the PCT. In the IGC, developed countries continue to focus on the same problems and issues with the proposal. At the same time, the developing nations are not willing to compromise and are standing their ground. That is the reason why an agreement is remote in the IGC (the PCT discussion have already been abandoned).

Another proposed step that developing countries need to take is that they should establish a clearly defined national system that monitors the use of GR. Through the development of tailored national rules that meet the developing nations' needs the issues would be solved internally before addressing them internationally. Although it is a reasonable argument at first hand, considerations need to be taken to not only the economical and political situation in theses nations but also the fact that numerous countries do not have an intellectual property system that functions. It is therefore unreasonable to demand nations, without the ability, to establish a full system that protects their sovereign rights. Furthermore, the Costa Rican disclosure requirement is a perfect example of that fact. Vague provisions and difficulties in the practical implementation, have led to significant uncertainties and a system that is over-loaded. Both Tvedt and Young have recognized the issues and consequences of an ambiguous provision. Countries are not able to implement and adopt regulations that are as effective, precise and applicable as an international provision.

Equivalently, biopiracy will not be solved by the use of contract-based systems. One of the reasons is that the parties entering into these contracts are of non-equal bargaining strength. The final contracts would therefore be less substantial and more in line with the view of developing nations. In addition, the contract-based system would not provide the same effectiveness and mandatory enforcement. Even if some enforcement could be sought the developing nations would not have the legal or economical strength to argue their rights.

Finally, it has also been suggested that organised and searchable databases could replace the disclosure requirement. Patent examiners could use databases in order to improve the screening process and discover more relevant prior art. However, there would be no obligation to use the databases and the origin of the GR would not matter. In other words, the databases would not help prevent biopiracy. Instead, databases would be an exceptional complement or tool to the disclosure requirement.

7.4 Question 4 & 5: *How should it be introduced? Should Members be required to abide?*

Following the previous chapter's conclusion that none of the proposed substitutions for the disclosure requirement are as suitable, the first remark to be made is that there is a reason why a disclosure requirement should be adopted. Contrarily to the views of developing nations, the disclosure requirement will be of significance in the patent system but also in the efforts to stop biopiracy. The determination of prior art, obviousness, novelty and the inventive step will be aided by the requirement as it will i.a. disclose possible prior arts in other nations.

The next question to be answered is in what way such a disclosure requirement should be introduced. In the fourth chapter of this thesis several proposals were reviewed. The different requirements that have been proposed can be characterised in to three different requirements: a voluntary requirements, a more limited one that only includes disclosure of origin and a mandatory inclusion requirement. It is hard to evaluate and determine which of the different proposals is the closest to the best solution and the prime example. However, a solution is needed and compromises need to be made on both sides. The Norwegian proposal is the closest to a compromise between the developing and developed countries. The proposal requires a disclosure of origin of GR to be made, but it is not sanctioned with a possible revocation of the patent. Instead, the applicant would be punished either through criminal or administrative penalties. In order to appease developing nations, my proposal, would be to include a mandatory re-examination of the patent. If a patent holder is found to not have abided the rule or found to have withheld information, the patent offices should re-exam the patent. The purpose of the regulation would be to review whether or not the five elementary patent requirements are still fulfilled. However, the proposal is only a suggestion, the requirement should in my view have serious repercussions if it is not followed.

The discussed requirement should be introduce in the TRIPS Agreement, as the WTO is the most important and appropriate forum for this issue. The reason being that the WTO Members would be legally bound to implement the disclosure requirement if the Agreement was amended. Without a mandatory implementation of the disclosure requirement the issues raised would not and cannot be resolved, as this thesis has shown.

8 Conclusions

This thesis commenced with a purpose and five question all revolving around a disclosure of origin of genetic resources requirement. The first of these questions to be analysed and answered was what the motive is for including the requirement. Different nations have presented various purposes behind the requirement. However, the most persistent motive is that developing nations wish to put an end to the exploitation of their resources. Even though developed countries believe that there are possible consequences or issues with the proposal, my view is that the requirement is not being interpreted in the right way. The disclosure requirement if implemented would not disturb the patent system nor would it be inconsistent with the TRIPS Agreement. In other words, the possible consequences or issues with the requirement are non-existent. Instead, the resistance stems mainly from the fact that developing nations still consider GR as free resources. Countries need to join forces and develop a disclosure requirement that suits both sides. Although the disclosure requirement needs to be implemented in the TRIPS Agreement the discussions and sessions in the IGC should not be deserted, i.e. one does not exclude the other. To finally answer my last questions, I believe that a balance is needed. The wishes or desires of both developing and developed nations need to be considered. Nevertheless, the proposal that is accepted still needs to be mandatory and Members should be required to abide the requirement. In conclusion, the thesis has shown that it is reasonable and appropriate to impose a requirement of disclosure of origin of GR in patents.

The discussions and sessions throughout these decades have been many and it may seem that they have brought nothing with them. Au contraire, the discussions have helped in determining the common grounds among the Members. Hopefully and probably a disclosure of origin of GR requirement will be introduced in the future and another step will be made towards stopping biopiracy. The question is not how it is when.

Supplement A

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The preamble

Members,

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;

Recognizing, to this end, the need for new rules and disciplines concerning:

(a) the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions;

(b) the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;

(c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;

(d) the provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments; and

(e) transitional arrangements aiming at the fullest participation in the results of the negotiations;

Recognizing the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods;

Recognizing that intellectual property rights are private rights;

Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base;

Emphasizing the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures;

Desiring to establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (referred to in this Agreement as "WIPO") as well as other relevant international organizations;

Hereby agree as follows:

Article 1

Nature and Scope of Obligations

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

2. For the purposes of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.

3. Members shall accord the treatment provided for in this Agreement to the nationals of other Members.[157] In respect of the relevant intellectual property right, the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the WTO Members of those conventions.[158] Any Member availing itself of the possibilities provided in paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights (the "Council for TRIPS").

[157] When "nationals" are referred to in this Agreement, they shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

[158] In this Agreement, "Paris Convention" refers to the Paris Convention for the Protection of Industrial Property; "Paris Convention (1967)" refers to the Stockholm Act of this Convention of 14 July 1967. "Berne Convention" refers to the Berne Convention for the Protection of Literary and Artistic Works; "Berne Convention (1971)" refers to the Paris Act of this Convention of 24 July 1971. "Rome Convention" refers to the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome on 26 October 1961. "Treaty on Intellectual Property in Respect of Integrated Circuits" (IPIC Treaty) refers to the Treaty on Intellectual Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989. "WTO Agreement" refers to the Agreement Establishing the WTO.

Article 7

Objectives

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.

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

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

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[159] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

[159] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing[160] for these purposes that product:

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Article 66

Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a

[160] This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provision of Article 6.

viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. 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.

The Convention on Biological Diversity (CBD)

Article 1

Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Article 3

Principle

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Article15

Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

2. Each Contracting Party shall endeavour to create renditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in. such Contracting Parties.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16

Access to and Transfer of Technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

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

through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1. 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Supplement B

The Original Proposal

In this connection, it is proposed that the TRIPS Council recommends to the Trade Negotiations Committee that it takes a decision to the effect that the TRIPS Agreement should be amended in order to provide that Members shall require that an applicant for a patent relating to biological materials or to traditional knowledge shall provide, as a condition to acquiring patent rights:

> (i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention;
>
> (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes;
>
> (iii) evidence of fair and equitable benefit sharing under the relevant national regimes.[161]

The African Group

The African group consists of the following WTO members (43):

Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cabo Verde, Central African Rep., Chad, Congo, Congo (Democratic Rep.), Côte d'Ivoire, Djibouti, Egypt, Gabon, Gambia, Ghana, Guinea, Guinea Bissau, Kenya, Lesotho, Madagascar, Malawi, Mali, Mauritania, Mauritius, Morocco, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Seychelles, Sierra Leone, South Africa, Swaziland, Tanzania, Togo, Tunisia, Uganda, Zambia, Zimbabwe.[162]

The African Group proposal of a disclosure requirement

The Group suggests that Article 29 be modified by adding the following as paragraph 3:

> "3. Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin."[163]

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[161] IP/C/W/356, p. 5.
[162] WTO: "Groups in the negotiations", from: https://www.wto.org/english/tratop_e/dda_e/negotiating_groups_e.htm, on the 1st of March 2016.
[163] IP/C/W/404, p. 6.

The Peruvian Proposal

Specifically, Peru proposes an amendment to Article 27 of the TRIPS Agreement in the form of a further exception to patentability, with the following wording [Members may also exclude from patentability]:

> "(c) products or processes which directly or indirectly include genetic resources or traditional knowledge obtained in the absence of compliance with international and national legislation on the subject, including failure to obtain the prior informed consent of the country of origin or the community concerned and failure to reach agreement on conditions for the fair and equitable sharing of benefits arising from their use.
>
> Nothing in TRIPS shall prevent Members from adopting enforcement measures in their domestic legislation, in accordance with the principles and obligations enshrined in the Convention on Biological Diversity".

Peru also proposes an amendment to Article 29(1), consisting in the addition of a paragraph which expressly provides as follows:

> "Where appropriate, Members shall require the disclosure of origin and legal provenance in the patent applications to be submitted ".[164]

The Norwegian Proposal

Key principles for a disclosure obligation

Norway is of the opinion that such a disclosure obligation should be based on the following key principles:

1. A binding international obligation should be introduced to include information on the supplier country (and the country of origin, if known and different) of genetic resources and traditional knowledge in patent applications. The supplier country (or country of origin, if relevant) of traditional knowledge must be disclosed even if the traditional knowledge has no connection with genetic resources. If the national law of the supplier country or country of origin requires consent for access to genetic resources or traditional knowledge, the disclosure obligation must also encompass a duty to state whether such consent has been given. If the country of origin is unknown, that fact must be disclosed.
2. The disclosure obligation should apply to all patent applications (international, regional and national).[165]

[164] IP/C/W/447, p. 13f.

3. If the applicant is unable or refuses to give information despite having had an opportunity to do so, the application should not be allowed to proceed.
4. If it is subsequently discovered that incorrect or incomplete information has been given, this should not affect the validity of the granted patent, but should be penalised in an effective and proportionate way outside the patent system.
5. A simple notification system should be introduced, under which patent offices send all declarations of origin they receive to the CBD Clearing-House Mechanism.[166]

The Latest Proposal

Members,

Bearing in mind the principles, objectives and definitions of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement), of the Convention on Biological Diversity (CBD), and of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol);

Reaffirming that States have sovereign rights over their own biological resources[167];

Stressing the need for the TRIPS Agreement and the CBD to be implemented in a manner which is mutually supportive and does not run counter to their respective objectives[168];

Recalling that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the CBD[169];

Stressing the need to ensure that the utilization of genetic resources and/or associated traditional knowledge must comply with the access and benefit-sharing legislation of the Member providing genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a Member that has acquired the genetic resources in accordance with the CBD;

Noting that Article 17 of the Nagoya Protocol establishes that Parties shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources, including designating effective check-points to collect or receive, as appropriate,

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[165] The specific provisions of the disclosure obligation should be fully compatible with the International Treaty on Plant Genetic Resources for Food and Agriculture and the Multilateral System established under it.
[166] IP/C/W/473, p. 2.
[167] Paragraph 4 of the Preamble of the CBD.
[168] Article 16.5 of the CBD and Article 4 of the Nagoya Protocol dealing with "Relationship with International Agreements and Instruments".
[169] Article 1 of the CBD.

relevant information regarding the utilization of genetic resources at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization;

Noting the extensive discussions in the Council for TRIPS and under the aegis of the Director-General on the introduction into the TRIPS Agreement of a mandatory requirement for the disclosure of origin of genetic resources and/or associated traditional knowledge used in inventions for which intellectual property rights are applied for;

Recognizing that the disclosure requirement in Article 29 of the TRIPS Agreement is incomplete without the disclosure of origin of genetic resources and/or associated traditional knowledge;

Acknowledging that a legal obligation establishing such a mandatory disclosure requirement in patent applications will contribute to prevent both misappropriation of genetic resources and the grant of erroneous patents and also enhance transparency about the utilization of genetic resources and/or associated traditional knowledge;

Decide to amend the TRIPS Agreement by inserting a new Article as follows:

Article 29bis

Disclosure of Origin of Genetic Resources and/or Associated Traditional Knowledge

For the purposes of establishing a mutually supportive relationship between this Agreement and the Convention on Biological Diversity, Members shall have regard to the objectives, definitions and principles of this Agreement, the Convention on Biological Diversity, and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, in particular its provisions on prior informed consent for access and fair and equitable benefit sharing.

Where the subject matter of a patent application involves utilization of genetic resources[170] and/or associated traditional knowledge, Members shall require applicants to disclose: (i) the country providing such resources, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD; and, (ii) the source[171] in the country providing the genetic resources and/or associated traditional knowledge. Members shall also require that

[170] As mentioned in Article 2 of the CBD, "Genetic resources" means genetic material of actual or potential value and "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.
[171] Including details of whom in the providing country such resources were obtained from.

applicants provide a copy of an Internationally Recognized Certificate of Compliance[172] (IRCC). If an IRCC is not applicable in the providing country, the applicant should provide relevant information regarding compliance with prior informed consent and access and fair and equitable benefit sharing as required by the national legislation of the country providing the genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD.

Members shall publish the information disclosed in accordance with paragraph 2 of this Article jointly with the publication of the application or the grant of patent, whichever is made first.

Members shall put in place appropriate, effective and proportionate measures so as to permit effective action against the non-compliance with the obligations set out in paragraph 2 of this Article. Patent applications shall not be processed without completion of the disclosure obligations set out in paragraph 2 of this Article.

If it is discovered after the grant of a patent that the applicant failed to disclose the information set out in paragraph 2 of this Article, or submitted false and fraudulent information, or it is demonstrated by the evidence that the access and utilization of genetic resources and/or associated traditional knowledge violated the relevant national legislation of the country providing genetic resources and/or associated traditional knowledge, that is, the country of origin of such resources or a country that has acquired the genetic resources and/or associated traditional knowledge in accordance with the CBD, Members shall impose sanctions, which may include administrative sanctions, criminal sanctions, fines and adequate compensation for damages. Members may take other measures and sanctions, including revocation, against the violation of the obligations set out in paragraph 2.[173]

[172] Article 17.3 of the Nagoya Protocol states that "An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent". Article 17.4 states the minimum information that shall be contained in the IRCC when such information is not confidential.

[173] TN/C/W/59, p. 1ff.

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