

Human Rights and TRIPS Exclusion and Exception Provisions

Hans Morten Haugen

Diakonhjemmet University College

The Agreement on Trade-Related Aspects at Intellectual Property Rights contains several provisions that both allow for exclusion from patentability, as well as exceptions from the exercise of the rights of the patent holder. With the exception of the first part of article 30, none of these have until now been clarified by the World Trade Organization's (WTO's) dispute-settlement system. Based on an in-depth analysis of a number of these TRIPS provisions, the article identifies whether and how human rights provisions, as well as more overall human rights principles, can be applied in order to strengthen and confer legitimacy to these exclusion and exception provisions. While there is general agreement of the weight of human rights, there is more disagreement on the relevance of human rights, primarily due to the general wording of human rights provisions. Without undertaking a full analysis of the relevant human rights provisions, the article finds that human rights also do provide guidance in negotiations and enforcement of intellectual property rights. An analysis of the prospects for taking into account human rights within the dispute-settlement system and in the political bodies of the WTO is also conducted.

Keywords ICESCR; TRIPS; food; human rights

Human rights, including economic, social and cultural human rights, do in principle prevail over intellectual property rights (Cullet, 2003; Haugen, 2007a; Pauwelyn, 2003a, p. 491; Pauwelyn, 2005; Yu, 2007, pp. 1092–3). As the enforcement provisions of human rights are generally weaker than those found under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), however, intellectual property disputes raising human rights concerns are not necessarily solved for the benefit of the protection of human rights.

To assess the potential role of human rights in the intellectual property rights sphere, this article will analyze human rights in the context of the TRIPS Agreement's exclusion and exception provisions. Most of these provisions have not been clarified by the World Trade Organization's (WTO's) dispute-settlement system, and they have not been interpreted in any systematic way from a human rights perspective.

This article seeks to answer the following two questions, with a particular emphasis on the TRIPS Agreement provisions on patent protection. First, to what extent can human rights contribute to clarify the scope of these provisions? Second, to what extent can human rights be protected by the actual application of these provisions?

By focusing on examples from patenting over seeds and plants, the exclusion provisions of the TRIPS Agreement, which raise environmental concerns, are given

particular attention. Patenting that raises human rights concerns relating to food plants and wild plants have received less attention compared with patenting in the field of medicines. As will hopefully be shown, these concerns are also relevant.

The first section provides an overview of the relevant provisions. Then the exclusion provisions and the exception provisions will be analyzed in each section. An overall assessment of human rights in the WTO will then be given before the article concludes.

Overview of the Provisions

No less than five substantive provisions of part II, section 5 of the TRIPS Agreement (“Patents”), give a basis for either preventing the granting of or limiting the enjoyment of the exclusive rights. These are:

- Article 27.2, allowing for exclusion from patentability inventions whose commercial exploitation must be prevented in order 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 the prohibition of the exploitation is necessary to protect these above-mentioned purposes, and that the exclusion is not made merely because the exploitation is prohibited by their law.¹
- Article 27.3, allows for excluding plants and animals as such from patentability, as well as essentially biological processes for the production of plants and animals. Moreover, plant varieties can be excluded from patent protection, provided that plant varieties are protected by an “effective *sui generis* system”.²
- Article 30, allowing the limited exceptions on the enjoyment of patent rights, provided that the “exceptions shall not unreasonably conflict with a normal exploitation of the protected material”, and “shall not unreasonably prejudice the legitimate interests of right holders, taking account of the legitimate interests of third parties”.³
- Article 31, identifying six situations when compulsory licenses can be granted:
 - the right holder refuses others to obtain authorization for use (article 31(b));
 - emergency and extreme urgency (article 31(b));
 - public non-commercial use (article 31(b));
 - anti-competitive use (article 31(k));
 - dependent patent (article 31(l)); and
 - to produce pharmaceutical products for export to eligible states only (article 31bis).⁴
- Article 32, listing no requirement for the revocation or forfeiture of patents, only that the right holder shall have “an opportunity for judicial review” of any such decision.⁵ Hence, public interest considerations, and not only abuse of patent rights, can be a basis for limiting the exercise of the rights.

In addition to these substantive provisions, one must also add three articles in part 1 of the TRIPS Agreement: article 6 (“Exhaustion”), saying that the state is

free to apply the principle of international exhaustion of intellectual property rights; article 7 (“Objectives”); and 8 (“Principles”). The Doha Declaration on the TRIPS Agreement and Public Health states in paragraph 5(a) that each provision of the TRIPS Agreement shall be read in light of the object and purpose of the agreement as expressed, in particular, in its objectives and principles (WTO, 2001a). Article 8 states that important public measures can be taken, but only if “these are consistent with the provisions of this Agreement”.

We see that all these provisions have strict requirements for their applications. Hence, it cannot be expected that these provisions can be applied generally, or without any criticism or objection. At the same time, the fact that these provisions are included in the TRIPS Agreement gives a relatively strong basis for stating that the TRIPS Agreement contains a relatively broad basis for ensuring the rights of others than the patent holders. The role of human rights provisions in identifying the scope and applicability of these exclusion and exception provisions has not been tested, until now, but several authors have written about human rights in the context of the TRIPS Agreement (Abbott, 2007; Cohn, 2001; Cornides, 2004; Drahos, 1999; Helfer, 2004; Rott, 2002).

Among the paragraphs identified above, the emphasis will be on article 27.2, which is an exclusion provision, and article 30 and article 32, which are exception provisions. Particularly, the latter of these has been given limited attention in both the academic literature and in the reviews of national implementation undertaken by the TRIPS council.

Article 31 on compulsory licenses has been extensively analyzed elsewhere, including the rapid compulsory license measures by the authorities of the United States of America (US), faced with the threat of anthrax in 2001 (Abbott, 2002, pp. 486–8; for more general information, see Consumer Project on Technology (CPT), 2008; for a CPT letter regarding compulsory licenses of the Rocher-patented medicine tamiflu in the context of avian influenza, see CPT, 2006). It must be noted that the TRIPS Agreement allows compulsory licenses also “in cases of public noncommercial use” as read from article 31(b), and the most advanced industrialized states have provisions allowing for the granting of compulsory licenses without any delay.⁶ Developing countries should make sure that they have adequate compulsory license provisions in their national legislation, similar to those found in the legislation of industrialized states.

The Four Bases for Exclusion from Patentability Under Article 27.2

This section will analyze the scope of this provision, in order to find out which requirements must be met in order to exclude an invention from patentability, keeping in mind that every exclusion must be thoroughly justified. First, it will be identified how many bases there are for excluding certain inventions from patentability. Second, there will be a clarification of the terms *ordre public* and morality.

Third, there will be a clarification of the phrases “protect human or plant life or health”, and “avoid serious prejudices to the environment”.

Initially, it will be clarified whether article 27.2 establishes four bases for excluding certain inventions, or whether there are only two bases, and then two examples of these two bases. The term “including” preceding the phrase “protect human, animal or plant life or health or to avoid serious prejudice to the environment” might qualify this latter phrase.

On the one hand, the term “including” could imply that this phrase is *subject* to either *ordre public* or morality. Stated differently, the term “including” implies that the phrase does not represent an individual basis for exclusion, but that it merely serves to exemplify what might fall under one of the two categories of *ordre public* or morality. On the other hand, it has been confirmed since the first report issued by the WTO Appellate Body that the interpreter shall give meaning and effect to all terms of a treaty.⁷ Therefore, it is initially found that the phrase “protect human, animal or plant life or health or to avoid serious prejudice to the environment” implies that the scope of article 27.2 is wider than what it would have been if this latter element of the provision was not included.

In order to test this clarification, there will be an analysis of the jurisprudence developed in relation to the treaty that contains a provision most similar to article 27.2 of the TRIPS Agreement. The wording of article 27.2 is *based* on the European Patent Convention (EPC), article 53(a).⁸ This paragraph has never been found by any organ of the European Patent Office (EPO) to justify an exclusion from patentability (see Dutfield, 2003, p. 161; Llewelyn, 1995, p. 506; Llewelyn, 2005; Moufang, 1998).⁹

There are, however, certain differences between article 27.2 of the TRIPS Agreement and article 53(a) of the EPC. First, the former is explicitly on “exclusion from patentability”, while the latter is on “exceptions to patentability”. Second, article 27.2 of the TRIPS Agreement lists more reasons for exclusions, by adding the phrase “including to protect human, animal or plant life or health or to avoid serious prejudice to the environment” after “*ordre public* and morality”. Third, article 53(a) of the EPC includes the term “publication”, and does not require the “exploitation” to be commercial. Of these three differences, the second is interesting to study in more detail. In line with what was found above, it will be examined whether the TRIPS Agreement’s exclusion from patentability (“protect human, animal or plant life or health or to avoid serious prejudice to the environment”) implies that article 27.2 of the TRIPS Agreement applies to more situations compared with article 53(a) of the EPC.

The terms “morality” and “*ordre public*” do not in themselves include environmental concerns. The phrase “seriously prejudice the environment” is, however, found by the Technical Board of Appeal of the EPO to *fall within the scope of article 53(a)*, by stating: “... article 53(a) EPC constitutes a bar to patentability for inventions the exploitation of which is likely to seriously prejudice the environment”.¹⁰ The EPO has still not explicitly recognized “protect human, animal or plant life or health” as a legitimate exception.

An author has found that these two environmental bases for exclusion represent merely a “specification” of the terms “morality” and “*ordre public*” (van Overwalle, 2005, p. 221). It must be acknowledged that the term “including” preceding the environmental phrases in the wording of article 27.2 of the TRIPS Agreement gives a certain reason for caution. While the two environmental bases do not necessarily extend the scope of the terms “morality” and “*ordre public*”, the inclusion of the two phrases “seriously prejudice the environment” and “protect human, animal or plant life or health” must be understood to represent distinct and additional bases for exclusion from patentability.

Therefore, article 27.2 of the TRIPS Agreement has a slightly wider scope than article 53(a) of the EPC. This emphasis on environmental concerns in the TRIPS Agreement is also confirmed by the preamble of the WTO Agreement (“protect and preserve the environment”), which can be applied when interpreting article 27.2.¹¹

Summing up the analysis on the number of bases contained in the TRIPS Agreement, article 27.2, the analysis of the jurisprudence of the EPO does not directly counter the finding made above that the environmental elements of article 27.2 of the TRIPS Agreement imply that the scope of this provision is wider. There is no jurisprudence, however, which seeks to clarify whether the phrase “protect human or plant life or health” applies to more situations than the phrase “avoid serious prejudice to the environment”.

The second issue identified above relates to the scope of the terms *ordre public* and morality. *Ordre public* was deliberately chosen instead of “public order”, as the former relates more directly to public policy and its application is stricter (Gervais, 2003, p. 222). A general understanding is that *ordre public* refers to the “... basic and fundamental values of a domestic legal system, encompassing values that are moral, economic or political” (United Nations High Commissioner for Human Rights, 2005, p. 10). Morality tends to be more related to the given culture in a certain country or region. Concepts of morality might differ between distinct cultures within a country. Another distinction is that “... *ordre public* refers to legal principles which touch upon the essential interests of the state, whereas the concept of morality encloses extra-legal norms based on prevailing public values” (Van Overwalle, 2005, p. 221).

An intellectual property law author notes that the exclusion provisions of *ordre public* and morality are given little emphasis in intellectual property law assessments (Llewelyn, 2005, pp. 39–43). As the application of these two exclusion provisions has not been clarified in the context of the TRIPS Agreement, well-founded hypothetical examples of public policy concerns that might fall within the scope of article 27.2 will now be given.

Regarding the possible application of either *ordre public* or morality as a basis for excluding an invention from patentability, the possible application of article 27.2 on inventions relevant in the field of food production could extend to the *possible* introduction of “genetic use restriction technology” (GURT), also called “terminator technology” and “sterile seeds”. Even though several patents on

GURT have been granted, such seeds are currently not available on the market. Some find that such inventions would fall under the exclusion provision of article 27.2 (Crucible Croup, 2001, p. 37). It seems reasonable to state that a plant that does not have the ability to reproduce, because of the insertion of a particular gene, is contrary to the morality in many communities, not only in “traditional” communities. Therefore, an exclusion from patentability is one possibility, but a decision by the relevant regulatory authority is more appropriate, as this is done by the body with the specific mandate and relevant competence.

We will now turn to the third issue regarding the bases for exclusion from patentability, namely the phrases “protect human, animal or plant life or health or to avoid serious prejudice to the environment” of article 27.2 of the TRIPS Agreement. It has already been found above that this formulation provides a broader basis for excluding an invention from patentability than what is implied in the terms “*ordre public* and morality”. At the same time, as has been shown by the EPO in the *Plant Genetic System* case referred to above, environmental considerations can be included in both *ordre public* and morality.

In the context of this article, addressing plants, the effects relating to human beings and to plants are considered more important than the effects relating to animals. Hence, the analysis below will be on the phrase “protect human and plant life or health”.

Moreover, the phrase “serious prejudice” establishes a rather high threshold for being applied as a basis for an exclusion from patentability, particularly by the term “serious”. This term indicates that the negative impacts resulting from the commercial exploitation of the invention must be substantial. There is no similar requirement with regard to the phrase “protect life or health”. Therefore, it is found that there is a lower threshold for excluding an invention from patentability if this is necessary to prevent commercial exploitation in order to “protect human or plant life or health”, than to “avoid serious prejudice to the environment”.

The term “plant life or health” is relevant in the context of this article. Also, the protection of plant life *can* be a basis for excluding GURT or non-self-reproducing technology from patentability. The same reasoning applies to plant varieties. Article 2.2 of the 1978 version of the International Convention for the Protection of New Varieties of Plants (UPOV 1978)—which is a provision not found in national legislation or legal decisions—reads:

Each member State of the Union may limit the application of this Convention within a genus or species to varieties with a particular manner of reproduction or multiplication, or a certain end-use.

The same reasoning as was applied regarding GURT can also be applied in this context. Hence, it is not considered to be necessary to elaborate in more detail about this; therefore, an effective *sui generis* system does not prevent states from including provisions saying that GURT can be excluded.

A definitive conclusion regarding this situation is difficult to give, as the scope of article 27.2 is narrow, but nevertheless slightly wider than article 53(a) of the EPC, and as article 27.2 of the TRIPS Agreement has not been clarified in the dispute-settlement system.

Requirements to be Fulfilled for Article 27.2 to Apply

A comprehensive understanding of article 27.2 can only be achieved by a precise understanding of the requirements that must be fulfilled for this paragraph to be justifiably applied.

There are three conditions on the application of article 27.2. These must be met if the exclusion from patentability shall be justified. First, the exclusion relates to one of the substantive purposes of protection (*ordre public*, morality, human, animal or plant life or health, and avoid serious prejudice to the environment). Second, the exclusion is *necessary* to prevent commercial exploitation in order to protect these purposes. This second requirement can also be clarified in light of article 8.1, which also includes a necessity requirement. Third, the exclusion is *not* made merely because the exploitation is prohibited by law of the state. These conditions indicate a rather high threshold for applying article 27.2.

Below, the requirements of “necessity” and “exclusion is not made merely because the exploitation is prohibited by their law” will be clarified.

The WTO’s dispute-settlement system has not clarified the term “necessity” in the TRIPS Agreement. Its clarification of the same term under General Agreement on Tariffs and Trade (GATT) might, however, provide important guidance. When clarifying the preamble of article XX of GATT 1994, a panel stated: “It was not the necessity of the policy goal that was to be examined [but] . . . whether these inconsistent measures were necessary to reach the policy goal” (WTO, 1996, paragraph 6.22).

In another report, the Appellate Body found that when assessing a trade-restrictive measure, “the importance of the common interests or values protected by that law or regulation” must be taken into account (WTO, 2000a, paragraph 164). Moreover, the Appellate Body said, “It is not open to doubt that Members of the WTO have the right to determine for themselves the level of enforcement of their WTO-consistent laws and regulations” (WTO, 2000a, paragraph 176). This must be considered to give a certain deference to national law. The WTO jurisprudence also says that if less trade-restrictive measures are available, and these are equally effective as more trade-restrictive measures in reaching the policy goal, these less trade-restrictive measures shall be chosen, but if no other measures are available, the trade-restricting measure is justified (WTO, 2001b, paragraph 174).

Article 27.2, however, must also be read in light of, *inter alia*, article 8.1 of the TRIPS Agreement (WTO, 2001a, paragraph 5(a)). If there are no alternative measures that would achieve the same end (including leaving the decision to the regulatory authorities), article 27.2 may be applied, provided that the other

requirements are met. This view is partly challenged by an author who states that provided that it is necessary to exclude an invention from commercial exploitation, ways other than excluding from patentability should be chosen if such alternatives are available (Pires de Carvalho, 2005, p. 210).

The phrase “exclusion is not made merely because the exploitation is prohibited by their law” has not been clarified by the WTO dispute-settlement system. This element of article 27.2 is included in order to prevent national legislation from being used in an inappropriate way. To identify the meaning of this phrase, two alternative interpretations are introduced. First, when an exclusion from patentability is justified based on *ordre public* and morality, it is to be determined by the relevant WTO body alone, without assessing the national legal provisions. Second, the national legislation is given considerable weight in determining whether the exclusion from patentability is justified, but it is not the only element of relevance to the process of finding whether article 27.2 applies in a particular situation. Deference to national law is an established principle in the WTO (Davey, 2003; Pauwelyn, 2003b). This also applies to the sensitive issues of *ordre public* and morality.

This indicates that the two requirements of necessity and “exclusion is not made merely because the exploitation is prohibited by their law” *can* be subject to a certain deference by the WTO system. At the same time, the wording of article 27.2 implies that it has a limited application.

Human Rights Provisions and Principles in the Context of Article 27.2

There will now be an assessment of human rights provisions and principles of relevance in the context of article 27.2. Of particular relevance in the context of this thesis is whether human rights principles, or interests protected by human rights provisions can be part of—and strengthen—one of the “exclusion from patentability” bases. This can take place through the reference to specific human rights principles or provisions, also in the adoption of an “effective *sui generis* system” for the protection of new varieties of plants. Plant varieties will be analyzed later in this section.

Article 27.2 of the TRIPS Agreement includes several phrases that are relevant in a human rights context. Any interpretation of this provision is to be based on “any relevant rules of international law applicable in the relations between the parties”, as stated in the Vienna Convention on the Law of Treaties, article 31.3(c). Such rules of international law cannot *a priori* exclude human rights provisions.

In addition to the substantive provisions, there are seven recognized human rights principles that are of considerable importance in order to understand how human rights are to be implemented.¹² The first of these principles, namely human dignity, has been elaborated by another author (Petersmann, 2007, pp. 267–8). The focus in this article will be only on substantive human rights provisions, in particular as they relate to food plants and wild plants.

Based on the need to protect the human rights of persons who depend on access to food, it will be analyzed whether these rights can contribute to an application of article 27.2, which is found to be justifiable by the dispute-settlement system. *More specifically, can the right to adequate food strengthen the basis for the exclusion from patentability, based on article 27.2 of the TRIPS Agreement?* It must be noted that there are several human rights provisions that are relevant in the context of exclusions, such as the human right to continued access to natural resources, and the human right to enjoy the benefits of scientific applications and its progress.¹³ Three examples will be provided below: one situation characterized by lack of food, one situation characterized by uncontrolled spread of transgenic food plants through pollen and one situation where both the patented product as well as the patenting *per se* goes against the deep-held value system of a community.

Initially, it must be emphasized that with regard to the right to adequate food, there are obligations on the three levels of respect (non-interference), protect (prevent other from interfering) and fulfill (facilitate and eventually provide). The wording of the Covenant gives states a certain margin of discretion, but at the same time, there are specific terms (“fundamental”, “ensure” and “shall take measures”) of article 11 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), that indicate that the states are under relatively strong obligations as imposed by the right to food.¹⁴ Moreover, there is an obligation to “take steps . . . to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means”, as recognized in the general obligation provision of the ICESCR.¹⁵

The first relevant situation regarding food and plant variety protection is that there is actually a lack of food of such magnitude that health, life and *ordre public* are threatened. One *could* foresee a situation where the number of hungry people is high and increasing, where non-protected plants are being replaced by protected plant varieties, and where the plant varieties are owned by actors who are not able to provide such varieties in adequate quality or quantity. Also, when the protected varieties do not contain GURT, this represents a serious situation. Hence, in such situations, there are several possibilities, including measures taken by the regulatory authorities.

Food riots and other consequences resulting from lack of food can, as a consequence, result in the “public order” being threatened, but there is a higher threshold to claim that the *ordre public* is threatened. An “effective *sui generis* system” that does not build strictly on TRIPS Agreement terms is possible, hence giving more possibilities for the exclusion from patentability. Therefore, an exclusion provision in an “effective *sui generis* system” can include the term “public order”. Such provisions that deviate from the TRIPS Agreement might be questioned by the TRIPS Council, but can be justified by references to articles 7, 8, 27.1¹⁶ and 30. If “public order” is included as a ground for exclusion, food accessibility can fall within the scope of this provision. At the same time, the *exception* provisions might also be applicable, and can be as relevant at the *exclusion* provisions in order to combat hunger.

A second situation that *might* arise is the adventitious spread of plants into adjacent fields or into the wild. This can no longer be considered as merely hypothetical and speculative, in particular with regard to transgenic plants, which are potentially dominant over other plants in a different manner than plant varieties. Such spread could have consequences for the health of the other plants. This might negatively affect ordinary cultivation of traditional plants while the transgenic plants are being removed, and hence have implications for the right to food. Finally, the issue of lack of biological diversity, resulting from the growing or uncontrolled spread, is also a concern with regard to the right to food.

Hence, there might be situations where plant health is a legitimate concern that could provide for the exclusion of plant variety protection under an effective *sui generis* system. At the same time, the regulatory authorities are probably more appropriate in deciding that a plant variety shall not be released, due to the undesired consequences.

The third situation applies to a practice of both genetic engineering and patenting that goes against the “morality” of a community.

Acceptability: there are higher requirements for stating that an invention relating to food plant is contrary to the *morality* of a society or a community, compared with the requirements for stating that such an invention is not *culturally acceptable* (United Nations, 2000a, paragraph 11). At the same time, cultural *acceptability* can give meaning in order to define what morality might constitute. Hence, it cannot be disregarded that it can be found that an invention relating to food plant and that is considered to be culturally unacceptable by the population can be contrary to morality. As already indicated, the patenting of a plant that is not able to reproduce, through GURT, is one example. To determine that an invention is contrary to morality, both hard evidence from natural and social science disciplines, as well as evidence relating to deep-held and widely shared public values, are relevant.

Cultural life: the most specific human rights regarding cultural life, broadly understood, are found in article 15.1(a) of the ICESCR and article 27 of the International Covenant on Civil and Political Rights (ICCPR). Can an invention relating to a food plant adversely affect the possibility to enjoy these human rights to the extent that it is justified to exclude this invention from patentability? To provide an example, a situation can be characterized by the existence of a very important or sacred plant, that has been subject to attempts of patenting by outsiders. Moreover, these plants are of fundamental importance for the cultural life of the community. Even when these plants might be available for the community, the mere knowledge that someone else is controlling this plant in a modified form can be abhorrent.

This situation, creating such a level of tensions between local communities and foreign collectors and researchers, is likely. It must be noted, however, that the basis is the morality in the community where the patent application is examined, more specifically whether cultural participation is affected in this community, and not the

morality in the community, that keeps the original resource. The morality requirement is met only if the patenting goes against the morality in the first community. Hence, it must be considered that there is a high threshold for taking into account human rights relating to cultural life in order to clarify the term “morality”. This context is hence less relevant than a context characterized by patenting of material containing GURT.

The article will now analyze the protection of plant varieties. All WTO members are under an obligation to provide protection by patents or by an “effective *sui generis* system”. There can be no doubt that such an “effective system” can be based on treaties by which the state is bound. Moreover, such a system does not primarily have to be based on the UPOV Convention, which does not include strong public interest provisions, but rather on the TRIPS Agreement, which is the first intellectual property treaty that explicitly states that social welfare and technology transfers are objectives.¹⁷

The argument for why human rights might be included in an exclusions provision, preventing the commercial exploitation of a protected plant variety, is that such exploitation adversely affects the *access to and distribution of propagating material and food produced by this material*. Such a situation will make the enjoyment of the right to food more difficult. Can an “effective *sui generis* system” potentially include exclusion provisions, that state that plant variety rights may not be granted if such an exclusion is necessary to allow distribution of food (accessibility) in order to ensure the realization of the right to food?¹⁸ The phrase “protect nutrition” in the TRIPS Agreement, article 8.1 confirms that states can take measures for this purpose, as long as the substantive requirements in section 5, part II, are met.

In conclusion, it is found that principles and substantive provisions regulating human rights, including the right to food, are not generally possible to exclude in the context of exclusion provisions established in accordance with the TRIPS Agreement. They are also relevant in the context of provisions establishing an “effective *sui generis* system” for the protection of plant varieties.

Whether these human rights provisions can play any role in a clarification of relevant provisions of the TRIPS Agreement by the dispute-settlement system of the WTO¹⁹ will be analyzed later in the article. At this stage, it is sufficient to observe that human rights treaties must be acknowledged to contain general wording, hence giving a certain margin of appreciation in the implementation of human rights treaties. On the other hand, in any clarification or interpretation that relates to subject matter that is regulated by human rights treaties, the importance of the interests that human rights seek to protect implies that human rights cannot be ignored (Haugen, 2007a; Marceau, 2002; Pauwelyn, 2003a, p. 491).

The Scope of Article 30 as an Exception Provision

All three requirements of national patent legislation identified by article 30²⁰ raise interesting questions of interpretation. One panel report has analyzed the scope of

these requirements, emphasizing that "... Article 30's very existence amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments" (WTO, 2000b, paragraph 7.26).

As this panel report is a result of a dispute initiated by the European Communities (EC), it might come as a surprise that the position of the EC with regard to the applicability of article 30 is much more nuanced in another document. After more or less quoting the above statement from the panel, the EC continues:

The provisions of Article 30 should be fully respected, and be read in light of Article 7 and 8 They should not be interpreted as allowing for any substantial or unjustified curtailment of patent rights. However, the EC and their member States are not in principle opposed to exceptions being made, for example, for purposes of research . . . (WTO, 2001c, paragraph 14)

Hence, there can be situations where it is legitimate to limit the enjoyment of the rights recognized in article 28, but article 30 has only been interpreted to allow for limited exceptions, based on economic considerations. In addition to the first requirement that the exceptions must be limited, this panel identified, with regard to the second and the third requirement, that the crucial issue is whether patent owners are able to "... extract economic value from their patent" (WTO, 2000b, paragraph 7.56) and "... claim a "legitimate interest" in the economic benefits . . ." (WTO, 2000b, paragraph 7.61).

The third requirement of article 30 includes the terms "third parties" and "legitimate interests". While the latter has been clarified (WTO, 2000b, paragraph 7.60 through 7.83), the former has not been appropriately clarified. Each of them will now be analyzed.

Third Parties

With the caution that must be exercised when seeking to clarify an element of a multilateral trade agreement that has not been clarified by the WTO's dispute-settlement system, the term "third parties" will be interpreted. Will only commercial competitors to the patent owner be understood as third parties, or will the users of the patented products or processes also be understood as third parties? To provide one example from the field of agriculture, are farmers third parties who may hold legitimate interests that are to be taken into account?

The panel in *Canada—Pharmaceuticals* did not correct the EC's view that the use of the term "third parties" only refers to other patent owners (WTO, 2000b, paragraph 7.62). Canada held that "... general societal interests . . . were within the ambit of the term "third parties" . . ." (WTO, 2000b, paragraph 7.67). Based on the principle of judicial economy, however, clarification of the term "third parties" was not considered necessary, as the clarification of the term "legitimate interest" resulted in the finding that all the three requirements of article 30 were met in favor of Canada. As none of

the parties to this dispute made an appeal, the Appellate Body was not given an opportunity to uphold, modify or reverse the findings of this panel.

There are three relevant arguments derived from this. First, this panel did not explicitly state that the term “third parties” *must* be understood *only* as other patent owners. Second, it never argued *against* the Canadian position that “general societal interests” are within the ambit of the term “third parties”. Third, the principle of judicial economy implies that an elaborate understanding of the term “third party” was not necessary for understanding the term “legitimate interests”, which was the crucial term in the dispute.

No WTO body has therefore challenged the position that general societal interests can be taken into account within the term “third party”. That the interests of third parties are to be taken into account is also in compliance with the object and purpose of the TRIPS Agreement, which are expressed, *inter alia*, in articles 7 and 8. Two recognized authors state regarding intellectual property and the conduct of public and social policy: “. . . states cannot be presumed to have surrendered sovereign police and welfare powers in the course of intellectual property standard setting . . .” (Maskus and Reichman, 2004, p. 307; see also Abbott, 2002, p. 488). Public interests in general and farmers’ interests in particular fall within the “legitimate interests of third parties”, which can be taken into account when identifying the scope of the legitimate exceptions.

Legitimate Interests

It will now be examined whether there are any principles of the report in *Canada—Pharmaceuticals* that are relevant for the purpose of this thesis, addressing the agricultural sector. This panel primarily analyzed whether “legitimate interests” is a wider concept than “legal interests”, and concluded in the affirmative (WTO, 2000b, paragraph 7.73). The panel, however, confirmed that the scope of article 30 cannot be extended too far (WTO, 2000b, paragraph 7.82). The report has been criticized because it errs in applying the non-discriminatory principle on exception provisions (see Howse, 2000; see also Haugen, 2007b, p. 108).

The legitimate interests of the right holder shall not be prejudiced, and the legitimate interests of third parties shall be taken account of. The report that has dealt most extensively with the scope of article 30 confirms that the public interest shall not be disregarded. As this dispute appeared between two industrialized states, such public interest considerations must also be given emphasis in the context of TRIPS implementation in developing states.

Can Article 32 on Revocation or Forfeiture be Applied as a Public Interests Provision?

In an analysis of the very short text of article 32,²¹ it is actually more interesting to analyze what the text does not include. The text is seemingly easy to interpret, namely that a judicial review possibility shall be available in order to challenge any revocation or forfeiture decision. Revocation can take place if it is found that the conditions for

granting the patent were later found not to be met. Forfeiture can take place in situations of abuse of a patent or failure to pay the requested patent fees.

The *travaux préparatoires* are of a certain interest, however. In the negotiations, two unsuccessful proposals were made: first, a US proposal to limit revocation to cases of lack of fulfillment of the substantive patent eligibility criteria, and second, an EC proposal that a patent cannot be revoked on grounds of non-working (Gervais, 2003, p. 254; see also Watal, 1999, p. 115). We see that there was no proposal trying to limit the possibility to decide on a forfeiture of a patent, which could be understood to imply that such an action is less controversial.

Moreover, article 32 must be understood in the context of the treaties incorporated into the TRIPS Agreement, primarily the Paris Convention for the Protection of Industrial Property (Paris Convention). Finally, similar to article 30, the crucial issue in this analysis of article 32 is whether it is possible to include public interest provisions in the revoking of patents.

Based on article 2.1 of the TRIPS Agreement, stating that “Members shall comply” with the Paris Convention, article 32 of the TRIPS Agreement will be analyzed by also including provisions from the Paris Convention, primarily article 5A(3):

Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

Article 5A(4) of the Paris Convention regulates compulsory licenses.

A recognized guide to the Paris Convention—to which all WTO members must comply—finds, however, that this Convention does not rule out revocation or forfeiture of a patent based on *public interest*, and not merely *abuse* of patents (Bodenhausen, 1968, p. 70). This is confirmed by Watal, stating that that *if public interests, and not abuse* is the basis, “. . . the conditions and time limits of Article 5A do not apply” (Watal, 1999, p. 111).

This is a reading of article 32 that is not shared by all. An opposing view comes from Pires de Carvalho (2005, p. 376). The wording of article 32 makes it clear that this article primarily seeks to enable the holder of a right that has been revoked or forfeited to challenge this decision. In other words, the right holder shall have available judicial mechanisms to defend a patent once it is granted, and subsequently forfeited or revoked.²²

However, as industrialized states failed in their efforts to have a very limited basis for forfeiture or revocation of a patent, the TRIPS Agreement explicitly does not determine the basis upon which such decisions could be made. The state would have a stronger position if it can be proven that some form of abuse is involved in the exercise of the patent.

A state facing a situation where a patent is preventing the adequate access to life-saving goods and where abuse of the patent is proven could forfeit the patent on reasons of public interests. Alternatively, the state has to comply with the procedural requirements of article 5A(3) of the Paris Convention, saying that there must be 2 years from the grant of the first compulsory license to the start of proceedings to revoke or forfeit a patent. In urgent situations, a state that is desperately seeking access to life-saving goods cannot wait for 2 years.²³

Forfeiture of a patent based on strong public interests considerations can be done under circumstances where the grant of a compulsory license is insufficient to mitigate the situation that has made it necessary in the first place to take such measures in the public interest. This forfeiture of the patent must be found to be the most appropriate measure under the circumstance in order to reach a given policy goal.

It is therefore found that article 32 of the TRIPS Agreement does not specify any basis for making revocation or forfeiture decisions, despite the attempts from industrialized states. Any forfeiture decision based on public interest considerations would, however, be easier to defend if it can be proven that abuse of the patent by the right holder has contributed to the critical situation. Hence, article 32 can also be considered to be an exception provision under part II of the TRIPS Agreement allowing for the consideration of public interests, which might include protection of human rights.

Human Rights in the Patent Exception Provisions

Are human rights provisions or principles legitimately interpreted as falling within the public exception provisions that have been found to apply to both article 30 and article 32? The same reasoning developed with regard to article 30 and 32 will also apply to article 31, as the purpose of all these three provisions must be termed to ensure wider access to patented goods, while also taking into consideration the impact for the patent holder and the long-term effects on the development on new products.

Human rights “derive from the inherent dignity of the human person”,²⁴ and establish an absolute minimum standard for the protection of a dignified life for every human being, with a particular emphasis on the most marginalized and vulnerable among them. These rights shall be exercised without discrimination of any kind. While the single patent examiner might have difficulties in providing for decisions that aim at ensuring the human rights of everyone, including the most vulnerable, the drafting of intellectual property rights treaties must include provisions that ensure that the rights of individuals and the interests of the community are appropriately balanced with the rights of the patent rights holders. The TRIPS Agreement allows for adopting legislation, which, including exceptions provisions, for instance legislation that exempts “innocent bystanders” from liability for patent infringements, allows compulsory licenses without any strict procedural require-

ments in cases of public, non-commercial use, and allows for revocation and forfeiture provisions that provide a sufficiently wide basis for making appropriate decisions. The right holder's expectations and the predictability of the patent system can be taken into account without sacrificing the wider community interests.

Moreover, the rights of minorities and peoples are protected under human rights treaties. Minorities "shall not be denied the right, in community with the other members of their group, to enjoy their own culture".²⁵ Any measure, including decisions relating to intellectual property rights protection that makes it more difficult for a minority community to enjoy their culture is problematic from a human rights perspective. Legislation should secure a swift and not too burdensome procedure for challenging allegedly wrongfully granted patents, including an internal review procedure, so that patent offices themselves can revoke patents, without a burdensome administrative or court procedure (Llewelyn, 2004, p. 158). People, including indigenous peoples, have rights over their natural wealth and resources. Moreover, both the ICESCR and the ICCPR state: "In no case may a people be deprived of its own means of subsistence".²⁶ Also, this provision, which sets out a collective right, and not an individual right, must be taken into account when drafting patent legislation, and when granting individual patents. An appropriate system for the protection of the traditional knowledge of local communities and indigenous peoples could be adopted, based on this provision and article 15.1(c) of the ICESCR (Cullet, 2007, p. 425–9).²⁷

Finally, the states that have ratified the ICESCR are under an obligation to take steps "... to the maximum of its available resources with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means".²⁸ If these "steps" or "appropriate means" are being impeded by the provisions of the TRIPS Agreement, there is a need to assess whether the state has made use of all of the exception provisions of the TRIPS Agreement, and whether there are more provisions that can be applied in order to balance the obligations of the ICESCR better with the obligations of the TRIPS Agreement.

The interests protected by the two treaties must be considered to differ. There is general agreement that the interests protected by human rights treaties represent a "vital matter" (International Law Commission, 1967, p. 217, paragraph 13). Moreover, the interests protected by intellectual property treaties are established by means of instrumental treaties in order to serve higher societal objectives. As stated by the British Commission on Intellectual Property Rights: "We therefore consider that an IP right is best viewed as one of the means by which nations and societies can help to promote the fulfilment of human economic and social rights" (Commission on Intellectual Property Rights, 2002, p. 6).

In addition to the individual rights protected by the human rights treaties, there are certain provisions that address the interests of the society at large. As an example, see the provisions on limitations in the ICESCR, saying that if the enjoyment of human rights is to be justifiably limited, this can only be done

according to law, according to the nature of the human rights and “. . . solely for the purpose of promoting the general welfare in a democratic society”.²⁹

This provision, saying that the enjoyment of human rights can only be justifiably limited if all three criteria of article 4 are met, implies that it is perceived to be a positive relationship between human rights enjoyment and the general welfare of the society. Hence, human rights provisions can be part of the public interest considerations, and give legitimacy to these. As was also found with regard to the exclusion and exception provision of the TRIPS Agreement, however, there are strict requirements for the application of these provisions.

It therefore seems reasonable to concur with an author who states that the right of the state to make use of an exception under the TRIPS Agreement can represent an obligation for the state under ICESCR, in order to be able to comply with obligations imposed by both treaties (Petersmann, 2005, p. 354, n. 29). The same author observes: “. . . the WTO jurisprudence has not yet clarified the impact of human rights (e.g. to human health and food) on the interpretation of, for example, intellectual property rights guaranteed in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights . . .” (Petersmann, 2002, p. 634). He continues: “GATT and WTO jurisprudence has so far hardly ever challenged the sovereign right of GATT and WTO Member states to protect the human rights of their citizens through internal and international social rules . . . if procedural due process requirements have been met” (Petersmann, 2002, p. 637). We will now analyze the relationship between state obligations under human rights treaties and obligations imposed by the WTO more in detail.

Human Rights in the WTO

There is a lack of explicit human rights references in the TRIPS Agreement. This, however, does not imply that human rights are possible to ignore in the context of formulating and enforcing legislation seeking to comply with the TRIPS Agreement. An author addresses three contexts where the WTO could encounter human rights: first, human rights are introduced in order to support trade-restricting arguments; second, if and when general trade restrictions in the form of sanctions can justifiably be imposed due to a state's gross and systematic human rights violations; third, to what extent human rights protection is weakened due to the obligation to comply with obligations imposed by the WTO (Clapham, 2006, p. 165; see also Harrison, 2007, referring to the first as cooperation-based and compliance-based measures, respectively, and the second as confidentiality-based measures). The emphasis in this article, and also in this section, will be on the first of these contexts.

Regarding the impact of implementation of the agreements under the WTO on human rights realization, the general observation is that a state—in order to comply with its other obligations—must make maximum use of the exceptions that the TRIPS Agreement allows for.

Different authors have different views on what role human rights can play in the context of the TRIPS Agreement. One recognized intellectual property rights author says: “The human rights side of the TRIPS dialogue . . . may in the longer term have significant effect” (Abbott, 2002, p. 476). Another author—who has a generally positive view on the role human rights can play—says that “. . . human rights per se offer little guidance in defining complex regulatory issues” (Cottier, 2007, p. 303) and that “. . . human rights, once identified, need to be translated into economic regulations” (Cottier, 2007, p. 303).

The position of the present author leans toward the former of these two authors, but not unconditionally. The recognized human rights are already identified, even if there might be disagreements on the scope of certain of the recognized human rights. Moreover, human rights do give guidance, also in the context of interpreting and managing intellectual property rights (Brown, 2005, p. 512; Brown, 2006, p. 613). In this context, however, it must be observed that Helfer warns against an “intellectual property balancing paradigm” that he sees developing in the European Court of Human Rights, arguing rather for a “rule of law paradigm” strictly addressing “. . . arbitrary government conduct” (Helfer, 2008, p. 51).

If one addresses the dispute-settlement system of the WTO, there is general agreement that because the covered agreements must be clarified in light of public international law, human rights are to be taken into account in the dispute-settlement system. To “take into account” is stronger than “take into consideration”, but obviously weaker than “apply” (Sands, 1998, p. 103). A proper clarification by the dispute-settlement system—which is not considered an interpretation;³⁰—must also take into account other relevant treaties also, but an interpreter can only “apply as law” treaties under its jurisdiction (for this position, see Marceau, 2002, pp. 786, 795 and 804; *contra*, see Pauwelyn, 2003a, p. 263, pp. 465–72; Pauwelyn, 2005, pp. 212–8). Therefore, the human rights are of specific importance in the dispute-settlement system, and can be taken into account in any clarification of the “covered agreements”.

Four explanations can be given for the limited role of human rights in the context of the WTO, both the less demanding act of “referring to” and the more demanding act of “taking into account”. First, with regard to the political bodies of the WTO, there is concern among certain groups of states to include human rights in the WTO deliberations. The opposition comes from different states regarding different treaties. WTO member states considered to be developing countries are eager to see human rights provisions in the fields of intellectual property and services only, and held that human rights applied on trade in goods allows for protectionism, and keeping their good off relevant markets. The reasoning among industrialized states is totally opposite, and they are reluctant to introduce human rights in policy areas of trade other than trade in goods. With a decision-making based on consensus, any state can reject a reference to a human rights provision or principle.

To illustrate, one document referring to substantive ICESCR provisions only included this reference in the preambular paragraph. The paragraph reads:

... the obligation to protect and promote the fundamental human rights to life and the enjoyment of the highest attainable standard of physical and mental health, including the prevention, treatment and control of epidemic, endemic, occupational and other diseases and the creation of conditions which would assure to all medical service and medical attention in the event of sickness, as affirmed in the International Covenant on Economic, Social and Cultural Rights (WTO, 2001d, preambular, paragraph 3)

The human rights reference was not included in later versions of the declaration on the TRIPS Agreement and Public Health (WTO, 2001a).

Also in documents where a broad range of implicit human rights concerns are raised, human rights provisions are not explicitly applied. As an example, see a statement before the TRIPS Council by Bangladesh:

... the patent provisions of TRIPS allowed countries to recognize monopoly rights over individual genes and their characteristics, which negated farmers' rights over seeds and propagating material with such genes and characteristics, reduced genetic diversity, made crops more vulnerable to pest attacks and has raised the costs of seeds and agricultural inputs to unaffordable levels for poor farmers. (WTO, 2004, p. 20, paragraph 102)³¹

Similar concerns are identified in a document by the United Nations High Commissioner for Human Rights (2001), within specific human rights provisions.³² This document, applying the term "impact" in its title, tends to express a relatively general concern, and cannot be said to represent a specific assessment of the TRIPS Agreement in the context of human rights. The document from the High Commissioner for Human Rights is rather seeking to clarify incompatible provisions and indicate how the different provisions of the respective treaties can be implemented to avoid conflict. For a comprehensive analysis on the relationship between the TRIPS Agreement and human rights, see Haugen (2007c).

A second explanation for the infrequent references to human rights provisions in the context of the WTO is to be found in a document from the UN High Commissioner for Human Rights: "... human rights might be associated too closely with trade restrictions. This could work against the wider objective of human rights approaches to trade and development, which place the realization of human rights among the objectives of trade rules" (United Nations High Commissioner for Human Rights, 2005, p. 15). Other UN documents have applied a more conciliatory approach when assessing the relationship between human rights and the international trade regime.³³

A third explanation can be derived from an earlier, more general document, where the High Commissioner identifies the following elements in a “human rights approach to trade”: respecting the principle of *non-discrimination*; promoting popular *participation*; using human rights *impact* assessments and consultations with individuals and communities to guide trade rule and policy making; promoting progressive liberalization of trade to *promote the progressive realization of human rights*; promoting *accountability*; ensuring corporate social *responsibility*; and encouraging international *cooperation and assistance* (United Nations High Commissioner for Human Rights, 2003, pp. 4–5).

All these terms are important for serving the same public interests that the realization of the recognized human rights seeks to achieve. These broad principles are, however, not always easy to apply by the dispute-settlement system, which is mandated to clarify the covered agreements in accordance with customary rules of interpretation of public international law.

The fourth and last explanation for the infrequent references to human rights provisions in the context of the WTO focuses on the composition of staff and delegations at the WTO. Even if it must be acknowledged that several of those who have led the academic debate on the relationship between trade and human rights are either working in the WTO (Marceau) or used to work there (Pauwelyn, Petersmann), there must be said to be a lack of competence regarding human rights among negotiators and lawyers dealing with international trade law.

Human rights are, however, infrequently introduced in the clarification made by the dispute-settlement system. While the reports have made references to human rights provisions,³⁴ human rights provisions have not been substantively taken into account. Human rights provisions are not referred to in the political forays, such as the Ministerial Conference, or in reviews taking place in the different councils.

There is no evidence that human rights *per se*, including economic, social and cultural rights, are directly ignored in the WTO. As an example, the Appellate Body has stressed that the assessment of risks must take place “. . . in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die” (WTO, 1998, paragraph 187). The fact that human rights treaties and the provisions contained therein have a “constitutional” nature, which implies that these treaties prevail over ordinary contract-based treaties, is not challenged. The challenge is to identify a correct and proper use of human rights provisions in treaty formulation, in the adoption of legislation nationally and in the proper taking into account done by the dispute-settlement system. Human rights represent relevant rules of international law, which are to be taken into account in treaty interpretation, in accordance with the Vienna Convention on the Law of Treaties, article 31.3(c). A criterion for the taking into account of such a “rule” outside of the WTO is that the non-WTO provision “. . . may be evidence of specific international relevance” (Marceau, 2002, p. 782).

Conclusion

This article has analyzed whether there is a possibility to take into account human rights principles and provisions under both the exclusion provisions and the exception provisions of the TRIPS Agreement, and whether the political and monitoring bodies of the WTO are prepared to include references more comprehensively. The article has also briefly addressed the extent to which states can include references to human rights in their national legislation while at the same time being in compliance with the TRIPS Agreement.

Initially, it must be observed that, compared with the human rights provisions analysed in this article, the provisions of the TRIPS Agreement are both more relevant in the WTO context, more specific regarding the subject matter it protects, and more specific with regard to how the rights are enforced. At the same time, substantive human rights provisions give more guidance on both technology intellectual property and regulatory policies than claimed by some authors (see Cottier, 2007). When adopting public measures, including in the field of patent protection, public authorities cannot be prevented from assessing how these measures contribute towards the fulfillment of basic human rights, such as the right to adequate food and the right to the highest attainable standard of health, and adopt their measures in a way that takes into account all the legal obligations of the state.

To conclude more specifically with regard to the various provisions of the TRIPS Agreement analyzed above, the fact that several of the provisions have not been clarified in the dispute-settlement system gives reason for caution. Bearing in mind this uncertainty—which also extends to the lack of clarification of the phrase “third party” of article 30—some conclusions will now be drawn.

In the context of article 27.2, appropriately implemented measures imply that the measures are applied in a non-discriminatory manner, that they are necessary to reach a legitimate policy objective and that they are based on a well-founded assessment of what is implied by international obligations imposed by other treaties to which the state is bound. It cannot be excluded that human rights obligations can be taken into account in order to contribute to the clarification of the exclusion provisions of article 27.2.

In the context of articles 30 and 32, appropriately implemented measures must also be justified by referring to the public considerations and the prevailing public interest involved in arguments for increased availability of products that are normally available only on the terms determined by the patent holder. The overall social and technology policies of a state cannot be set aside by the obligations imposed by the TRIPS Agreement.

Therefore, it is reasonable to expect that in the hypothetical case of a dispute relating to subject matter regulated by the TRIPS Agreement, which is also relating to human rights provisions contained in the ICESCR, there might be a certain deferral to national public policy, particularly if the dispute involves human rights protection, which relates to the right to life. Both the right to the highest attainable

standard of health (ICESCR, article 12) and the right to adequate food and freedom from hunger (ICESCR, article 11) come to mind. The outcome of a dispute, however, is not given even in such cases, even if human rights in principle prevail over intellectual property rights, as observed initially and in later sections of this article. Such deferral must be expected even more if a developing state is a party to the dispute.

When implementing the TRIPS Agreement nationally, the process requirements regarding the TRIPS Agreement should generally be complied with. The states, however, must be aware of the possibilities for flexible implementation that exist in the TRIPS Agreement, in order to ensure a better compliance with all obligations. As an example, industrialized states like the US have legislation allowing for flexible approaches in the area of compulsory licenses regarding public, non-commercial use. We have also seen, however, that there is a high threshold for applying human rights provisions in implementation reviews and negotiations in the WTO. In the context of the TRIPS Agreement, it is the developing state that has been most actively pursuing human rights arguments. Those arguments should not be alien for industrialized states, either.

About the author

Hans Morten Haugen, Associate Professor at Diakonhjemmet University College, PO Box 184, Vindern, 0319 Oslo, Norway; e-mail: haugen@diakonhjemmet.no

Hans Morten Haugen was awarded a Ph.D. Degree in Law in 2006 at the University of Oslo with the dissertation *The Right to Food and the TRIPS Agreement: With a Particular Emphasis on Developing Countries' Measures for Food Production and Distribution*, published by Martinus Nijhoff Publishers in 2007 (Raoul Wallenberg Institute Human Rights Library, Vol. 30). The work was undertaken while he was a member of the International Project on the Right to Food in Development (IPRFD) at the Norwegian Centre for Human Rights. Four of his articles appear in *The Journal of World Intellectual Property* and one of his most recent articles is 'Human rights and technology—a conflictual relationship? Assessing private research and the right to adequate food' in (2008) *Journal of Human Rights*, 7(3), 224–44.

Notes

- 1 The full text of article 27.2 of the TRIPS Agreement (“Patentable Subject Matter”) reads:

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.

- 2 The full text of article 27.3(b) of the TRIPS Agreement (“Patentable Subject Matter”) reads:

Members may also exclude from patentability: . . . plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, 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.

- 3 The full text of article 30 of the TRIPS Agreement (“Exceptions to Rights Conferred”) reads:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

- 4 Article 31*bis* was included in the TRIPS Agreement by the decision of 6 December 2005 (see WT/L/641).

- 5 The full text of article 32 of the TRIPS Agreement (“Revocation/Forfeiture”) reads: “An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available”.

- 6 As an example, the US legislation allows in 28 USC 1498 for the issuing of compulsory licenses concerning uses of patents (section a), copyrights (section b) or plant variety certificates (section d), when the use is by or for the government of the US.

- 7 The Appellate Body said: “An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or nullity” (WTO, 1996, p. 23); an accompanying footnote 45 refers to two International Court of Justice decisions, one International Law Commission report and three international law textbooks supporting this view.

- 8 The full text of article 53(a) of the EPC reads:

European patents shall not be granted in respect of . . . inventions the publication or exploitation of which would be contrary to “*ordre public*” or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

- 9 Article 53(a) has been invoked several times, of which three involve plants: T 0320/87 (Lubrizol Genetics Inc., OJEPO 1990, p. 71), T 0356/93 (Plant Genetic System NV, OJEPO 1995, p. 345) and G 0001/98 (Transgenic Plant/Novartis II, OJEPO 2000, p. 111). In T 0356/93, the Technical Board of Appeal (TBA) analyzed both the concepts of “morality” and “*ordre public*”, in paragraph 17 and 18, respectively. With regard to

morality, plant biotechnology was found in paragraph 17.1 to be no "... more contrary to morality than traditional selective breeding ..." and that the crucial issue was the "... destructive use of these techniques" (*ibid.*). When examining the "*ordre public*" exception, the TBA found that article 53(a) "... constitutes a bar to patentability for inventions the exploitation of which is likely to seriously prejudice the environment" (paragraph 18). The TBA concluded that "... it would be unjustified to deny a patent under Article 53(a) EPC merely on the basis of possible, not yet conclusively-documented hazards" (paragraph 18.7). The EPO Guidelines state with regard to article 53(a) that this paragraph applies to "... invention so abhorrent that the grant of patent rights would be inconceivable". See also V0008/94, 1994 OJEP0 1995, p. 388, paragraph 6.2.1. For an alternative position, referring to national courts, see ECJ's reasoning in paragraphs 37–9 of C-377/98, *Kingdom of the Netherlands v European Parliament and Council of the European Union*, [2000] ECR I-6229.

- 10 T 0356/93; OJEP0 1995, p. 345, paragraph 18.
- 11 Not even the EU Commission Directive 98/44 includes strong environmental principles, but is referring to the TRIPS Agreement, article 27.2 in recital, paragraph 36; see also paragraphs 37–9. The position that a genuine and sufficiently serious threat to the environment falls within *ordre public* is confirmed by Advocate General Jacobs in the ECJ case C-377/98, Order of 14 June 2001, paragraph 109.
- 12 These are dignity, non-discrimination, rule of law, participation, empowerment, accountability and transparency (see Food and Agricultural Organization, 2007).
- 13 An exceptions and limitations provision can be based on human rights principles and provisions, including the rights of peoples over their natural resources, including the prohibition against the deprivation of such resources (article 1.2 of the Covenant—see *infra* n. 26); the obligations relating to research; and the right to enjoy the benefits of scientific progress (article 11.2(a) and article 15.1(b) of the Covenant).
- 14 The term "ensure" is found in article 11.1 of the ICESCR. The full text of article 11.2(a) of the ICESCR reads:

The States Parties to the present Covenant, recognizing the fundamental right of everyone to be free from hunger, shall take, individually and through international co-operation, the measures, including specific programmes, which are needed: ... To improve methods of production, conservation and distribution of food by making full use of technical and scientific knowledge, by disseminating knowledge of the principles of nutrition and by developing or reforming agrarian systems in such a way as to achieve the most efficient development and utilization of natural resources.

- 15 The full text of article 2.1 of the ICESCR reads:

Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.

- 16 The panel observed in WTO (2000b), paragraph 7.92: “Article 27 does not prohibit *bona fide* exceptions to deal with problems that exist only in certain product areas”.
- 17 The agreement by the which the World Intellectual Property Organization (WIPO) became a specialized agency of the United Nations uses similar language, stating in article 1 that WIPO is responsible for “. . . facilitating transfer of technology . . . in order to accelerate economic social and cultural development” (United Nations, 1975).
- 18 The term “ensure the realization” is taken from article 11.1 of the ICESCR.
- 19 In the WTO, the Ministerial Conference and the General Council shall have the “exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements” (agreement establishing the WTO, article IX:2), while the mandate of the WTO dispute-settlement system is to “clarify the existing provisions of those agreements” (Dispute Settlement Understanding, article 3.2).
- 20 See *supra* n. 3.
- 21 See *supra* n. 5.
- 22 In this context, note two paragraphs of the TRIPS Agreement, article 41 (“General obligations”):
 2. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays. . . .
 5. It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. . . .”
- 23 See in this context the observations on compulsory licenses for public, non-commercial use as acknowledged in the TRIPS Agreement, article 31(b) in n. 6, and accompanying text.
- 24 Third preambular paragraph to the ICESCR and the ICCPR.
- 25 The full text of article 27 of the ICCPR reads:

In those States in which ethnic, religious or linguistic minorities exist, persons belonging to such minorities shall not be denied the right, in community with the other members of their group, to enjoy their own culture, to profess and practise their own religion, or to use their own language.
- 26 The full text of joint article 1.2 of ICESCR and ICCPR reads:

All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic co-operation, based upon the principle of mutual benefit, and international law. In no case may a people be deprived of its own means of subsistence.
- 27 The full text of article 15.1(c) of the ICESCR reads:

The States Parties to the present Covenant recognize the right of everyone ... [t]o benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

The relationship between this paragraph and the other paragraphs of article 15.1 (the right “to take part in cultural life” and the right “to enjoy the benefits of scientific progress and its applications”) is “... mutually reinforcing and reciprocally limitative” (United Nations, 2006, paragraph 4). The fact that the paragraph is closely linked to and “... dependent on the enjoyment of other human rights ...” other provisions of the ICESCR and the ICCPR (United Nations, 2006) is obvious, as all human rights are interdependent and interrelated (United Nations, 1993, paragraph 5).

28 See *supra* n. 15.

29 The full text of article 4 of the ICESCR reads:

The State Parties to the present Covenant recognize that in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only to such limitations as are determined by law, only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.

30 See *supra* n. 19 for a distinction.

31 We see that while the emerging legal concept of farmers’ rights is included in the statement by Bangladesh (farmers’s rights are recognized in the 2001 International Treaty on Plant Genetic Resources for Food and Agriculture, article 9), nothing is mentioned about the right to adequate food or other human rights in this paragraph or other paragraphs.

32 Five paragraphs (22–6) refer to the “fundamental differences of approach” between the promotion and protection of human rights, on the one hand, and the rights covered by the TRIPS Agreement, on the other: (1) in TRIPS, the various links with the subject matter of human rights are expressed in terms of exceptions to the rule; (2) TRIPS does not establish the content of the responsibilities of the intellectual property rights holders to balance the exercise of the rights; (3) TRIPS obligates to provide protection for all forms of technology, which impacts on states’ ability to decide on development strategies; (4) TRIPS promotes the protection of modern forms of technology in industrialized countries, but does not necessarily benefit potential innovators in developing countries; (5) TRIPS does not acknowledge the protection of the cultural heritage and technology of local communities and indigenous peoples.

33 In United Nations (2000b, p. 4, paragraph 14), the United Nations Secretary-General identifies the following points of potential convergence between trade and human rights: first, common objectives found in both trade and human rights treaties, such as increased living standards; second, the emphasis on non-discrimination in both human rights and trade treaties; and third, the emphasis on preferential treatment of developing countries in these treaties. The latter, saying that developing countries are treated differently from other countries, does actually only apply to economic rights for non-nationals; see ICESCR, article 2.3.

- 34 The most comprehensive assessment of state obligations relating to human rights (health and labor rights) was undertaken in WTO, 2003, paragraphs 7.180–7.210.

References

- Abbott, F. (2002) 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', *Journal of International Economic Law*, 5(2), 469–505.
- Abbott, F. (2007) 'Patents, Biotechnology and Human Rights: The Preservation of Biodiverse Resources for Future Generations', in F. Francioni (ed.), *Biotechnologies and International Human Rights*. Hart Publishing, Oxford, pp. 315–31.
- Bodenhausen, G. H. C. (1968) *Guide to the Application of the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967*. United International Bureaux for the Protection of Intellectual Property (BIRPI), Geneva.
- Brown, A. E. L. (2005) 'Socially Responsible Intellectual Property: A Solution?', *SCRIPT-ed* [online], 2(4), 485–513. Available at (<http://www.law.ed.ac.uk/ahrc/script-ed/vol2-4/csr.asp>) [Accessed February 2008].
- Brown, A. E. L. (2006) 'Human Rights: In the Real World', *Journal of Intellectual Property Law and Practice*, 1(9), 603–13.
- Clapham, A. (2006) *Human Rights Obligations of Non-State Actors*. Oxford University Press, Oxford.
- Cohn, M. (2001) 'The World Trade Organization: Elevating Property Interests above Human Rights', *Georgia Journal of International and Comparative Law*, 29(3), 427–40.
- Commission on Intellectual Property Rights (2002) *Integrating Intellectual Rights and Development Policy*. Commission on Intellectual Property Rights, London.
- Consumer Project on Technology (2006) *Avian Influenza. Letter Dated 8 March 2006 to EU Commissioners Kyprianou and Mandelson* [online]. Consumer Project on Technology, Washington, DC. Available at (<http://www.cptech.org/ip/health/tamiflu/cptech03082006.doc>) [Accessed February 2008].
- Consumer Project on Technology (2008) *Health Care and Intellectual Property: Compulsory Licensing* [online]. Consumer Project on Technology, Washington, DC. Available at (<http://www.cptech.org/ip/health/cl/>) [Accessed February 2008].
- Cornides, J. (2004) 'Human Rights and Intellectual Property: Conflict or Convergence?', *Journal of World Intellectual Property*, 7(2), 135–67.
- Cottier, T. (2007) 'Genetic Engineering, Trade and Human Rights', in F. Francioni (ed.), *Biotechnologies and International Human Rights*. Hart Publishing, Oxford, pp. 275–313.
- Crucible Croup (2001) *Seeding Solutions*, Vol I. International Development Resource Center/Dag Hammarskjöld Foundation/International Plant Genetic Resource Centre, Ottawa/Stockholm/Rome.
- Cullet, P. (2003) 'Patents and Health in Developing Countries', in J. Hatchard and A. Perry-Kessaris (eds), *Law and Development: Facing Complexity in the 21st Century: Essays in Honour of Peter Slinn*. Cavendish, London, pp. 78–96.
- Cullet, P. (2007) 'Human Rights and Intellectual Property in the TRIPS Era', *Human Rights Quarterly*, 29(2), 403–30.
- Davey, W. J. (2003) 'Has the WTO Dispute Settlement System Exceeded its Authority? A Consideration of Deference Shown by the System to Member Governments' Decisions

- and Its Use of Issue-Avoidance Techniques', in T. Cottier and P. Mavroidis (eds), *The Role of the Judge in International Trade Regulation: Experience and Lessons for the WTO*. University of Michigan Press, Ann Arbor, MI, pp. 43–79.
- Drahos, P. (1999) 'Intellectual Property and Human Rights', *Intellectual Property Quarterly*, 3(3), 349–71.
- Dutfield, G. (2003) *Intellectual Property Rights and the Life Science Industries: A 20th Century History*. Ashgate, Aldershot.
- Food and Agricultural Organization (2007) *Focus on the rights to food: Right to food and indigenous peoples* [online]. Food and Agricultural Organization, Rome. Available at http://www.fao.org/righttofood/wfd/pdf2007/focus_indigenous_eng.pdf [Accessed February 2008].
- Gervais, D. (2003) *The TRIPS Agreement: Drafting History and Analysis*, 2nd edition. Sweet and Maxwell, London.
- Harrison, J. (2007) *The Human Rights Impact of the World Trade Organization*. Hart, Portland, OR.
- Haugen, H. M. (2007a) 'The Nature of Social Human Rights Treaties and Standard-Setting WTO Treaties: A Question of Hierarchy?', *Nordic Journal of International Law*, 76(4), 435–64.
- Haugen, H. M. (2007b) 'Patent Rights and Human Rights: Exploring their Relationships', *Journal of World Intellectual Property*, 2(10), 97–124.
- Haugen, H. M. (2007c) *The Right to Food and the TRIPS Agreement—With a Particular Emphasis on Developing Countries' Measures for Food Production and Distribution (Raoul Wallenberg Institute Human Rights Library Vol. 30)*. Martinus Nijhoff Publishers, Leiden.
- Helfer, L. R. (2004) 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking', *Yale Journal of International Law*, 29(1), 1–83.
- Helfer, L. R. (2008) 'The New Innovation Frontier? Intellectual Property and the European Court of Human Rights', *Harvard International Law Journal*, 49(1), 1–52.
- Howse, R. (2000) 'The Canadian Generic Medicines Panel—A Dangerous Precedent in Dangerous Times', *Journal of World Intellectual Property*, 3(4), 493–508.
- International Law Commission (1967) *Yearbook of the International Law Commission 1966*, Vol. II. United Nations, New York.
- Llewelyn, M. (1995) 'Article 53 Revisited', *European Intellectual Property Review*, 17(10), 506–11.
- Llewelyn, M. (2004) 'From GATT to G.A.T.T.: Fifty Years of European Bio-IP, Part II', *Bio-Science Law Review*, 6(4), 142–62.
- Llewelyn, M. (2005) 'Schrodinger's Cat: An Observation on Modern Patent Law', in P. Drahos (ed.), *Death of Patents, Perspectives on Intellectual Property Law and Policy*. Vol. 11. Lawtext Publishing, Witney, pp. 11–66.
- Marceau, G. (2002) 'WTO Dispute Settlement and Human Rights', *European Journal of International Law*, 4(13), 753–814.
- Maskus, K. and Reichman, J. H. (2004) 'The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods', *Journal of International Economic Law*, 7(2), 279–320.

- Moufang, R. (1998) 'The Concept of Ordre Public and Morality in Patent Law', in G. van Overwalle (ed.), *Patent Law, Ethics and Biotechnology*. Bruylant, Brussels, pp. 65–77.
- Pauwelyn, J. (2003a) *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law*, Cambridge Studies in International and Comparative Law. Cambridge University Press, Cambridge, UK.
- Pauwelyn, J. (2003b) 'Does the WTO Stand for "Deference to" or "Interference with" National Health Authorities When Applying the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement)?', in T. Cottier and P. Mavroidis (eds), *The Role of the Judge in International Trade Regulation: Experience and Lessons for the WTO*. University of Michigan Press, Ann Arbor, MI, pp. 175–92.
- Pauwelyn, J. (2005) 'Human Rights in WTO Dispute Settlement', in T. Cottier, J. Pauwelyn and E. Bürgi (eds), *Human Rights and International Trade*. Oxford University Press, Oxford, pp. 205–31.
- Petersmann, E.-U. (2002) 'Time for a United Nations "Global Compact" for integrating Human Rights into the Law of Worldwide Organizations: Lessons From European Integration', *European Journal of International Law*, 13(3), 621–50.
- Petersmann, E.-U. (2005) 'Introduction', *Journal of International Economic Law*, 8(2), 347–62.
- Petersmann, E.-U. (2007) 'Biotechnology, Human Rights and International Economic Law', in F. Francioni (ed.), *Biotechnologies and International Human Rights*. Hart Publishing, Oxford, pp. 229–73.
- Pires de Carvalho, N. (2005) *The TRIPS Regime of Patent Rights*, 2nd edition. Kluwer Law International, The Hague.
- Rott, P. (2002) *Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen*, Schriftenreihe des Zentrums für Europäische Rechtspolitik an der Universität Bremen (ZERP). Nomos Verlagsgesellschaft, Baden-Baden.
- Sands, P. (1998) 'Treaty, Custom and the Cross-Fertilization of International Law', *Yale Journal of Human Rights and Development*, 1(1), 85–105.
- United Nations (1975) *Agreement between the United Nations and the World Intellectual Property Organization*, UN General Assembly Resolution 3346(XXX), Annex of 17 December 1975.
- United Nations (1993) *Vienna Declaration and Programme of Action* (A/CONF.157/23).
- United Nations (2000a) *General Comment No. 12 on the Right to Adequate Food* (UN doc. E/2000/22), pp. 102–10.
- United Nations (2000b) *Globalization and its Impact on the Full Enjoyment of all Human Rights, Report of the Secretary-General* (A/55/342).
- United Nations (2006) *General Comment No. 17 (2005): The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of which he or she is the Author (Article 15, Paragraph 1 (c), of the Covenant)* (E/C.12/GC/17).
- United Nations High Commissioner for Human Rights (2001) *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, Report from the High Commissioner* (E/CN.4/Sub.2/2001/13).
- United Nations High Commissioner for Human Rights (2003) *Human Rights and Trade, Report to 5TH WTO Ministerial Conference, Cancún, Mexico 10–14 September 2003*

- [online]. Available at <www.unhchr.ch/html/menu2/trade/cancunfinal.doc> [Accessed February 2008].
- United Nations High Commissioner for Human Rights (2005) *Human Rights and World Trade Agreements: Using General Exception Clauses to Protect Human Rights*. Office of the High Commissioner for Human Rights, Geneva.
- van Overwalle, G. (2005) 'Legal and Ethical Aspects of Bio-Patenting: Critical Analysis of the EU Biotechnology Directive', in P. Drahos (ed.), *Death of Patents, Perspectives on Intellectual Property Law and Policy*, Vol. 11. Lawtext Publishing, Witney, pp. 212–27.
- Watal, J. (1999) 'Implementing the TRIPS Agreement on Patents: Optimal Legislative Strategies for Developing Countries', in O. Lippert (ed.), *Competitive Strategies for the Protection of Intellectual Property*. Fraser Institute, Vancouver, pp. 105–23.
- World Trade Organization (1996) *US—Gasoline, Report of the Panel (WT/DS2/AB/R)*.
- World Trade Organization (1998) *EC—Hormones, Report of the Appellate Body (WT/DS26/AB/R [parallel case: WT/DS48/AB/R])*.
- World Trade Organization (2000a) *Korea—Beef, Report of the Appellate Body (WT/DS161/AB/R)*.
- World Trade Organization (2000b) *Canada—Pharmaceuticals, Report of the Panel (WT/DS114/R)*.
- World Trade Organization (2001a) *Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/W/2)*.
- World Trade Organization (2001b) *EC—Asbestos, Report of the Appellate Body (WT/DS135/AB/R)*.
- World Trade Organization (2001c) *The Relationship between the Provisions of the TRIPS Agreement and Access to Medicines*, Communication from the European Communities and their Member States (IP/C/W/280).
- World Trade Organization (2001d) *Proposal: Draft Ministerial Declaration: Proposal from a Group of Developing Countries (IP/C/W/312)*.
- World Trade Organization (2003) *EC—Tariff preferences, Report of the Panel (WT/DS246/R)*.
- World Trade Organization (2004) *Council for Trade-Related Aspects of Intellectual Property Rights—Minutes of Meeting*, 18 November 2003 (IP/C/M/42).
- Yu, P. K. (2007) 'Reconceptualizing Intellectual Property Interests in a Human Rights Framework', *University of California Davis Law Review*, 40(3), 1039–1149.