Does TRIPS allow for prohibition of gene patents?

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Content

Summary

National or regional patent law can prohibit Gene patents without getting in conflict with the TRIPS agreement of the WTO. Possible legal solutions can be chosen by the approach of defining inventiveness, by limiting the scope of patents or by applying criteria of morality and public order. The debate about gene patents can be a promising entry point for further necessary amendments in international patent law to meet better the requirements of modern society.

1. Introduction:

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets internationally binding standards in patent law. These standards are a matter of controversial debate in several areas. One controversy is about so called 'life patents' that are covering gene sequences, microorganisms, plants, animals and human gene sequences. While since the 1980s, thousands of patents on genetic resources and living matter have been granted in industrialized countries (such as US, EU, Japan, Australia and others) controversies are still going on. One hot topic is the patentability of seeds and farm animals[1].

1 www.no-patents-on-seeds.org

Another focus emerged in the context of the patentability of (human) gene sequences. Especially in the US and Australia this has been a major issue within the last years, while in Europe the debate already started around 1998-2004, when the EU patent Directive 98/44EC was adopted by the EU member states.

While in the 1990ies patents on gene sequences were backed to some extent by industry, legal experts and political decision makers, the situation has been changed since that. More and more articles, reports and opinions were published showing concerns that gene patents are hampering innovation much more than fostering new applications and that DNA sequences as found in nature should not be seen as patentable inventions (REF). Meanwhile in the US and Australia some legal initiatives were started to exclude gene sequences from patentability. In this context, the question arises if TRIPS would allow such a prohibition.

In this context, the TRIPS Agreement is the most relevant international regulation. While also WIPO and the member states of the Convention on Biological Diversity (CBD) were debating about patents on genetic resources, the TRIPS Agreement is the only one that requires patents to be granted in all fields of technology. Thus, in the case of national or regional legislation to exclude gene patents, the TRIPS Agreement is the multilateral system that has to be obeyed.

2. TRIPS and Patents

The TRIPS Agreement deals with intellectual property rights in general and sets standards e.g. for copyright and trademarks. While Section 1 and Articles 1-8 deal with basic principles, Section Five and Articles 27-34 of the TRIPS agreement are dealing specifically with patents (see full wording of the Articles in the Annex). A short overview is given in the following table.

Table 1: Tabled overview on specific patent provisions of the TRIPS Agreement

Article	Provisions
Article 1-8	General provisions and basic principles
Article 27 (1)	Patents shall be granted in all fields of technology, if the concerned matter is inventive (or 'non-obvious') and capable of industrial application (or 'useful').
Article 27 (2)	Patents can be denied for moral reasons.
Article 27 (3)	Patents can also be denied for diagnostic, therapeutic and surgical methods for the treatment of humans or animals; plants and animals and essentially biological processes for the production of plants

	or animals.
Article 28	Patents confer on its owner exclusive rights to prevent others from making, using, offering for sale, selling, or importing
Article 29	A patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art
Article 30	Exceptions to the rights conferred have to be limited and should not conflict with a normal exploitation of the patent
Article 31	Rules are set for usage of the patent without the authorization of the patent holder
Article 32	An opportunity for any decision to revoke a patent shall be available.
Article 33	The protection shall be given for a period of twenty years.
Article 34	Burden of proof in cases of litigation

In regard of a prohibition of gene patents Article 27 is the most relevant. The other Articles deal with provisions that are relevant in case patents are granted.

3. Framing the debate

While most of the discussions about gene patents are emerging in context of DNA derived from humans the underlying problem is broader and quite complex for several reasons:

The biological function of a gene is not only defined by a piece of DNA, but also by gene regulation and its cellular context. It should be kept in mind that

- Identical DNA sequences can occur in different species, while having other biological functions.
- Within a single organism, some DNA sequences can have several hundred biological functions depending on the system of gene regulation. This is especially relevant for genomes in multicellular and complex organisms with gene splicing.

The complexity of gene sequences has been revealed especially after accomplishing the human genome project around the year 2000[2]. However, current practice of patent offices in the US and the EU does not take into account these basic scientific findings. Patent law still presumes a physical entity between the structure of a DNA and the function of a gene. In result the first who

2 See for example: Pearson,H. 2006, Nature 441, What is a Gene? Pages 399-401

discovers a DNA sequence can claim a patent monopoly on all downstream usages of its biological functions, the known and even those being unknown at the time of the patent application. This kind of patent protection for a product is derived from the field of chemical compounds and is called 'absolute' patent protection, means all possible usage is covered by the patent that claims the new product (in this case a DNA sequence).

Many problems and criticisms of current practice in gene patenting are stemming from the enormous scope of absolute patent protection that does not fit to the complexity of biological gene functions. For example, already in the 90s there was a heated debate about a patent on a gene sequence that was granted before it was known that this DNA and its protein are of certain value for combating HIV[3].

The scope of the gene patents can even cover whole organisms: Plants and animals inheriting patented DNA sequences also can fall under the scope of the patent. Even if the gene sequence is not isolated and transferred by genetic engineering, a patent on an whole organism (such as a plant) can be derived from the occurrence of particular gene sequence that for example is used as a tool in marker assisted breeding for plants and animals (REF). This problem does not occur in humans, but it is closely related to the issue of gene patents and their broad scope. It is argued that plant breeding and world food security can be negatively affected by these patents (REF).

There are other areas besides the human genome that needs to be considered: For example, there are controversial debates about patents on gene sequences derived from microorganisms and especially pathogens such as viruses causing HIV, SARS and hepatitis or bacteria such as staphylococcus. It was argued that in these cases patent protection can hamper the development of antibiotics, vaccines and blood tests (REF).

When it comes to debate the impact of TRIPS and possible interpretations of its provisions, the scope of the patent and its potential negative impact on health system and food security are quite relevant. This issue is examined in the next paragraph.

4. TRIPS and gene patents

The most relevant provision in the TRIPS Agreement is Article 27. Its full wording is given in the Annex. For the issue discussed herein the following passages are crucial:

Article 27 **Patentable Subject Matter**

3 Science, Vol 275, 28.2.1997 S. 1263

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

2. Members may exclude from patentability inventions (…) to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment (…).

3. Members may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. (…)

Further, Article 8 (1) from the "general provisions and basic principles" of the TRIPS Agreement should be taken into account:

***Article 8*, Principles**

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

TRIPS does allow the exclusion for patents in plants and animals but does not foresee any other exclusions in the area of living matter such as DNA sequences. Therefore, some observers are of the opinion that these patents cannot be excluded by national or regional legislation. The argument emphasized by those experts is that patents shall be granted in all fields of technology without discrimination and therefore also patents on gene sequences have to be issued.

The interpretation as explored in this short paper does not follow this argumentation. On the opposite, it shows that there is some flexibility in the provisions of the TRIPS Agreement that can be used to exclude gene patents from patentability. Especially recent developments in European Patent legislation are useful to exemplify the legal situation. There are three issues that shall be discussed in this context:

1. invention versus discovery
2. scope of patents

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

3. ordre public and morality

4.1 invention versus discovery

TRIPS does not give a definition for the criteria of an invention. It is up to the member states of the WTO and their patent offices to decide what kind of technical features are fulfilling the requirement of becoming an invention.

On the one hand it has to be taken into account that current patent law considers the fact that a material already exists in nature not as an sufficient argument to exclude it from patentability: If a substance found in nature has to be isolated from its surroundings to make it available and therefore it is necessary to apply technical processes for obtaining it, the substance might be considered an invention. It can be true if the substance shows some surprising technical features that cannot be predicted form its known properties. On the other hand, if the process for obtaining it, cannot be considered a significant technical problem and a substance does also not reveal unexpected technical features it is a discovery and therefore not patentable. There is no clear cut between an inventive process and something that is considered to be obvious. The distinction between might even be changed by patent offices. For example the European Patent Office follows a line for 'raising the bar' for inventiveness and therefore is rejecting a growing number of patent applications.

In any case, the decision which technical features are considered to fulfill inventiveness is not fixed by the TRIPS Agreement but by national or regional laws. There is already considerable difference between member states of the WTO regarding the question what can be considered as an patentable invention: For example, in the US business methods and software developments are considered as inventions, while Europe refuses such patents. The European Patent Convention (EPC) for example in Article 52 (2) excludes several matters as being not patentable:

> "The following in particular shall not be regarded as inventions (…):
> (a) discoveries, scientific theories and mathematical methods;
> (b) aesthetic creations
> (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers.
> (d) presentations of information."

Adding DNA sequences to this list would be justified since (at least nowadays) the process for isolating DNA sequences is not inventive. Thus (natural occurring) gene sequences (and their variations) can be regarded just as an

example for discoveries that in general cannot be patented. This approach was chosen by the US court dealing with the case of Myriad´s patent on breast cancer genes (REF).

As mentioned, some experts are of the opinion that refusing patents on gene sequences would be a discrimination of a particular field of technology. This argument cannot be accepted. As long as DNA sequences in general are being regarded as a discovery and not an invention, this exclusion from patentability is not directed to particular fields of technology such as pharmaceuticals or diagnostic applications. On the opposite, it also would concern plant and animal breeding and the area of microorganisms, no matter in which field of technology they get used. Such an exclusion in patent law only would concern a specific tool but not a field of technology. It particular it also does not exclude patents on biotechnological inventions that are based on the usage of genetic material, like pharmaceuticals. Thus defining DNA sequences as non-patentable discoveries should be regarded as being in line with the provisions of the TRIPS Agreement.

4.2. scope of patents

The scope of patents is also not defined by TRIPS Agreement and leaves significant room for interpretation of the member states of the WTO. In this context the particular, it should be discussed, if a patent on a gene sequence only can cover particular technical applications or if the principle of absolute patent protection is applied.

Similar as in the case of patentable inventions, considerable differences also have been emerged between Europe and the US concerning the scope of patents. For example, especially France but also Germany have implemented the European Patent Directive 98/44 EC by reducing the scope of patents being granted on human gene sequences to specific applications.

The French Intellectual Property Code states[5]:

Article L 611-18 of the IP Code
:

> “The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. Only an invention constituting a technical application of a function of an element of the human body may be protected by a patent. This protection shall cover the element of the human body only to the extent necessary to the realisation and the exploitation of this particular use. Such use must be disclosed

5 http://195.83.177.9/code/liste.phtml?lang=uk&c=36&r=2566

in the patent application in a concrete and precise manner. The following, in particular, shall be considered unpatentable:

a) processes for cloning of human beings;

b) processes for modifying the germ line genetic identity of

human beings;

c) uses of human embryos for industrial or commercial purposes;

d) total or partial sequences of a gene as such"

Article L 613-2-1 of the IP Code
:

"The scope of a claim concerning a gene sequence shall be confined to the part of such sequence that is directly related to the specific function disclosed concretely in the description. The rights created by the delivery of a patent including a gene sequence may not be called upon against a later claim on the same sequence if this claim satisfies the requirements of Article L 611-18 and if it discloses any other particular application of this sequence."

Therefore, even within the EU, different standards are applied. As it is mentioned in a resolution of the European Parliament from October 2005:

"whereas the Directive allows the patenting of human DNA only in connection with a function, but it is unclear whether a patent on DNA covers only the application in this function or whether other functions are also covered by the patent" [6]

Also relevant is a recent decision of the European Court of Justice that comes to the conclusion, that the scope of Monsanto´s patent on genetically engineered herbicide tolerant soybeans is restricted to soybeans in only as far as the function of herbicide tolerance is still of relevance. The ECJ comes to the conclusion if a patented DNA sequence is present in a product like soybean meal where it can no longer perform the specific function for which this DNA sequence was patented, the scope of the patent is restricted (C-428/08). This effectively establishes a purpose-bound protection for gene sequences rather than an absolute protection. The ECJ specifically investigated and confirmed that this finding is in compliance with the TRIPS Agreement.

Concerning the aim to exclude gene sequences from patentability, the limiting of the scope of gene patents can serve as a solution to some extent: It might be possible to avoid patents on the gene sequence and only allow for patents of

6 European Parliament resolution on patents for biotechnological inventions, 25. October 2005, P6_TA(2005)0407

particular technical functions. This kind of regulation will render less legal clarity than using the argument of inventiveness (see above) and might trigger litigation cases, but it can be a starting point to abandon absolute patent protection on gene sequences.

4.3 ordre public and morality

TRIPS also does not give a definition of moral reasons or of ordre public that allows the rejection of patents. Another recent case at the European Court of Justice shows (not decided yet finally), there is considerable flexibility for member states of the WTO to exclude particular inventions for moral reasons from patentability. In a case about a patent on human stem cells, the general attorney of the court came to the conclusion that European Patent Law is excluding these inventions as far as they are based on industrial use of human embryos or claim totipotent embryonic cells as an invention that can develop to a human being (C-34/2010).

Similar as shown in the context of inventiveness and the scope of patents, there is a considerable difference between the use of the morality clause in patent law in Europe and the US. Article 6 of the European Patent Directive (98/44 EC) gives a non exhaustive lists of inventions that are excluded for reasons of public ordre and morality that are in line with the TRIPS Agreement but are not applied within the US:

> Article 6
>
> 1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
>
> 2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
>
> (a) processes for cloning human beings;
>
> (b) processes for modifying the germ line genetic identity of human beings;
>
> (c) uses of human embryos for industrial or commercial purposes;
>
> (d) processes for modifying the genetic identity of animals, which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Concerning gene sequences there is mounting evidence in the health sector that these patents are in contradiction to the interests of patients and doctors. Further, the monopolization of genetic resources in the context of plant and animal breeding is matter of growing concern in Europe, development countries and also the US. This development is also reflected by the view of several

observers. For example, Andrews already explained in 2002[7]:

> "The Trade-Related Intellectual Property Rights (TRIPS) agreement of the World Trade Organization, promulgated in 1995, requires all of its international signatories to agree to provide a 20-year intellectual property protection for inventions (including those that are related to health care). Nevertheless, even TRIPS highlights how public health should be given greater weight than the commercial concerns of patentees. Article 27 of TRIPS specifically allows governments to exclude diagnostic, therapeutic or surgical methods from patentability. It also allows them to deny patentability of a particular invention to protect human life or health. Article 8 of TRIPS allows governments to take public health concerns into consideration in their national intellectual property laws, and Article 31 allows governments to ignore health-care patents in certain situations and to grant compulsory licenses (see next section) to third parties to produce a generic version of a health-care product. Under TRIPS, patents can be ignored in a public health emergency."

In conclusion, the TRIPS Agreement with its provisions of Art 8 and Art 27, (2) and (3) can be seen as an entry point for a broader interpretation of morality and ordre public, also taking into account socio-economic concerns. This could be used by member states of the WTO to come up with regulations to exclude patents on genetic resources for not only technical reasons (like inventiveness) but also including reasons of ordre public an morality. This approach will need further explorations but could help to develop a modern patent law that very general is much more balanced concerning the interests of civil society and less biased towards the interests of industry. Thus, the debate about gene patents sequences can become a starting point for crucial amendments needed in international patent law to meet better the socio-economic interests of modern society.

5. Conclusion

As the comparison between patent law in Europe and the US shows, there is significant flexibility in interpreting the TRIPS agreement. The three issues as discussed, inventiveness, scope of patent protection and morality reasons can be used to exclude gene patents. To avoid any allegation of possible discrimination, the exclusion of gene patents should not be restricted to particular medical applications, but cover all kind of genetic material.

The need for clear regulation in this context emerges from a better understanding of the complexity of biological functions of gene sequences and the mounting evidence that gene patents can impact research and development in the area of medical purposes and plant and animal breeding negatively.

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The recent discussion about gene patents should be seen as an opportunity to start a process of amending patent law with a better balance in the interest for modern society where innovation to an large extent is no longer based on exclusive IP rights, but on systems of open source.

ANNEX: Wording of TRIPS Agreement

SECTION 5: PATENTS

Article 27 Patentable Subject Matter

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

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

3. Members may also exclude from patentability:

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

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

Article 28 Rights Conferred

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

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing[9] for these purposes that product;

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

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

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

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

Article 29 Conditions on Patent Applicants

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

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

Article 30 Exceptions to Rights Conferred

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.

Article 31 Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[10] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances that led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each

10 "Other use" refers to use other than that allowed under Article 30.

case, taking into account the economic value of the authorization;
(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions that led to such authorization are likely to recur;
(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
(ii) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and
(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 32 Revocation/Forfeiture

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Article 33 Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.[11]

Article 34 Process Patents: Burden of Proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;
(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to

11 It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.