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Patents on Plants -
Swedish Patent Act
(1967:837) in Compliance with
International Obligations?

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Summary

Many concerns regarding the possibility to patent various forms of lives have been raised in the debate regarding patents. One of the issues for focus in the debate has been the gradual shifting in where to draw the line between a discovery and an invention, specifically when patents on plants are concerned.

The main issue examined in this thesis is whether or not Swedish Patent Act (1967:837) is in compliance with some of Sweden's international obligations regarding patents on plants. The international obligations that have been examined are Article 27 in the TRIPs Agreement and the EC Directive 98/44/EC on Legal Protection of Biotechnological Inventions.

Many changes have recently been enforced and it will take time to properly evaluate the result of the chosen international approach to patent. Nevertheless, it is an exciting time where the law has to be able to adopt and adjust more rapidly than ever, in order to keep up with the fast development within research.

Preface

I would like to take the opportunity to express my gratitude to my family who has supported me strongly through the various phases a writer of a thesis is going through. Thank you for believing in what I was doing and that I one day would finalise my work.

I would especially like to thank you Ms. Maria Bideke for her fantastic support and her never-ending patience, as well as for the help in proof reading the thesis. Ms. Bideke also provided me with the strength I needed in order to finalise the work. Without Ms. Bideke's piece of good advice, as well as encouragement, I would not have accomplished my degree.

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Abbreviations

AG	Advocate General
EC	European Community
EU	European Union
GATT	General Agreement on Tariffs and Trade
PL	Patentlagen (1967:837)
TRIPs	Trade Related Aspects on Intellectual Property Rights
WTO	World Trade Organization

1 Introduction

The idea that one could patent and consequently own life, for example plants or separate genes and gene sequences in animals, plants or human beings, was up until the beginning of the 20th century completely unfamiliar with the Western world.¹ However, after decades of powerful development within the area of intellectual property rights, World Trade Organisation (hereinafter referred to as WTO) was founded in 1995 and the somewhat controversial agreement called Trade Related Aspects on Intellectual Property Rights (hereinafter referred to as the TRIPs Agreement) was adopted.

Article 27 of the TRIPs Agreement deals with the issues of patentability or non-patentability of plant and animal inventions, as well as the protection of plant varieties. The thesis will focus on the relation between article 27 in TRIPs and its effect on European Community (hereinafter referred to as EC) law, and its effects on Swedish Patent Law.

Since the European Communities² is a member of WTO itself, it is bound to take action in order to ensure that EC law complies with the WTO Agreements.³ As the TRIPs Agreement was established, it gave power to the already ongoing debate within the EC about the need for harmonisation within the field of the legal protection for biotechnological inventions. In accordance with the legal undertaking of the TRIPs agreement, the EC started to develop and design a new Directive.

Finally, after many years of debate, the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions was adopted. Consequently, the adoption of the Directive 98/44/EC, as well as Sweden's own obligations towards WTO, created the urgent need for changes in Sweden's national legislation. The legal changes proposed by Sweden's Government entered into force in May 1, 2004⁴. Yet, the question whether or not the suggested changes is enough to actually make Swedish Patent Law comply with the TRIPs agreement, remains open.

1.1 Purpose

The purpose of the thesis is to examine Article 27 in the TRIPs Agreement and its effect and influence on EC law, and consequently Swedish Law, focusing on patenting of plants. The issue at stake is whether or not the

¹ Trebilcock M. J. and Howse R. (2000), *The Regulation of International Trade*, Routledge, London and New York, p.307.

² The European Community is, for legal reasons, known as the European Communities in WTO matters.

³ http://www.wto.org/english/thewto_e/countries_e/european_communities_e.htm. 22/04/04.

⁴ SOU 2003/04:55, p.2.

Swedish Patent Act (1967:837), after the amendments and adjustments implemented in May 2004, is complying with the international obligations regarding patents on plants, more specifically Article 27 in TRIPs Agreement and the Directive 98/44 on Legal Protection of Biotechnological Inventions.

1.2 Limitations

The international legal system for intellectual property rights consists of a very complex structure. Therefore, it has to be emphasised that this is no attempt to cover all aspects of the topic, since it would be far too extensive for the thesis.

A relevant topic in relation to the patenting of plants is the plant breeder's right.⁵ However, this will be left out, even though it is interacting with the changes demanded by article 27 in TRIPs, since it would broaden the topic further than intended.

Neither Paris, Berne, Rome nor Washington conventions will be examined further, even though the TRIPs is based on them and also works as a supplement to the very same conventions. It is, however, of no relevance to the specific questions about to be answered in this thesis and will subsequently be left out.

1.3 Method and Material

In order to find answers to the questions stated above, the research has been conducted by examining traditional law sources, and articles on the topics concerned. International law, EC law, as well as national Swedish law constitute the frames for the research. As far as EC law is concerned, relevant case law has also been examined. When searching for sources of information, internet has been a tool of major importance, as well as an important resource independently.

1.4 Disposition of the Essay

Firstly, the TRIPs Agreement will be presented together with a brief introduction to WTO and its history. This will be followed by a more in-depth study of the TRIPs agreement, with special focus on Article 27. Secondly, the EC Directive 98/44/EC will be explored and the articles with relevance to Article 27 will be thoroughly discussed.

⁵ Malmer P. (1999), 'TRIPs avtal privatiserarmänsklighetens gen-skafferi', *Inga givna vinster om WTO, världshandeln och utvecklingen i världen*, Forum Syd, p.75-80.

Thereafter, the Swedish patent law and consequently, the suggested changes because of the impact of WTO's TRIPs agreement, as well as the Directive 98/44/EC on Legal Protection of Biotechnological Inventions, will be examined. Finally, an analysis of whether or not the Swedish Patent Act (1967:837) is complying with Sweden's international obligations as far as patenting of plants are concerned, will be conducted.

2 The TRIPs Agreement

In order to research whether the Swedish Patent Act (1967:837) complies with Article 27, as far as patenting of plants are concerned, it is of major importance to clarify if, and to what extent, a plant can be patented under the TRIPs Agreement. This will be presented below.

This section will start by defining what a patent is, as well as explaining briefly some of the reasons as to why we have patent regulations. This will be followed by a brief presentation of WTO and its history, which is important for the full understanding of the TRIPs Agreement. Finally, the TRIPs Agreement and its content and construction will be discussed, with special focus on Article 27.

2.1 Definition of Patent and its Purposes

Patent can be defined as an exclusive right, given to the inventor of new products and techniques, to the profit of the investments and research- and development costs for a limited period of time.⁶

Patent regulations can be considered to be a way of balancing interests between 'development and research' on the one hand, and 'public interest' on the other. Patent can be described as a contract, which is set up between a society and an inventor. To give an incitement for innovation, the government of a society is enforcing the contract. If the inventor is not being encouraged by being given a remuneration, in that that others will be allowed to freely copy their work, no one would probably be willing to invest their money to come up with new ideas, which subsequently society could benefit from. The remuneration consist of a patent, which will give the inventor an exclusive market right for a certain number of years. However, it can be argued that intellectual property rights sometimes can give rise to an undermining of the access to certain products that are fundamental for the public good.⁷

2.2 The World Trade Organization

In order to understand the TRIPs agreement, it is of great importance to be aware of WTO's construction and history. Therefore, the aim of this section is to give a brief introduction to how WTO was created, and also provide information about the agreements, upon which the WTO is based on.

⁶ Forum Syd (November 2001), *Fokus på Världshandeln: TRIPS – kontroversiellt patentavtal inom WTO*, p.1.

⁷ Oxfam GB (February 2001), *Patent Injustice: How World Trade Rules Threaten the Health of Poor People*, p.31.

2.2.1 From GATT to the WTO

The General Agreement on Tariffs and Trade (hereinafter called GATT) was enforced in 1948. The purpose of the Agreement was mainly to prevent protectionism, which was considered to be one of the reasons, as to why the Second World War erupted. The GATT was finally signed by 23 countries.¹

After a few decades the regulations had turned into a complex system of different rules and agreements. When the Member Countries started to negotiate about agreements concerning trading with services and intellectual property, the complexity demanded new institutional frames. The WTO became the new regular Organization, which replaced the previous, provisory role of the GATT. The WTO started to act 1 January 1995.⁸

2.2.2 The WTO at Present

The WTO has got 148 Member Countries⁹ and all together they account for more than 90% of the world trade.¹⁰

Decisions are made by all the Member Countries and usually by consensus. It is also an option to make decision by a majority vote, but this has never been used in the WTO and was very rare under the GATT. The agreements in the WTO have been ratified by all the Member Countries' parliaments.¹¹

The WTO Agreement is an umbrella agreement, which establishes the structure of WTO. The Agreement is not only including GATT of 1997, but also many other agreements, such as the TRIPs. The Member States have to subscribe to the agreements, even though there are a few exceptions. As a member of the WTO, the Member Countries have to commit themselves to the TRIPs Agreement and its provisions.¹²

2.3 The TRIPs Agreement

As some of the industrialised countries in the European Union and United States have faced increasing competition from some of the newly industrialised countries from Asia and Latin America, domestic policies in trading issues have become focus for increased attention. It is often claimed that the newly industrialised countries stick to policies, which are of unfairly disadvantage to American or European trading interests. Subsequently, intellectual property rights have become a very prominent issue on the trading agenda.¹³

⁸ Kleen P. (1996), *Världshandelns spelregler*, SNS Förlag, Stockholm, p.10.

⁹ As at 13 October 2004.

¹⁰ www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm, 15/10/2004.

¹¹ www.wto.org/english/thewto_e/whatis_e/tif_e/org3_e.htm, 15/10/2004.

¹² Trebilcock M. J. and Howse R. (2000), p.25.

¹³ *ibid*, p.307.

The Uruguay Round introduced, for the first time in history of the GATT, negotiations on multilateral level on intellectual property rights that are trade related. It was argued that the TRIPs Agreement became included as a part of the Final Act of the Round, under pressure of the industrialised countries. The TRIPs sets minimum standards on copyright, trademarks, patents among others. The Agreement is based on, and also works as a supplement to the Paris, Berne, Rome and Washington conventions. Subsequently, the TRIPs Agreement has not got a completely autonomous role, but provides an extra protection for intellectual property rights. The agreement treats availability of rights, as well as the enforcement of them. Whilst the members cannot choose to set a lower standard of protection on issues covered by the Agreement, than the standard given in therein, they cannot be forced to set a higher standard, to provide a more extensive protection.¹⁴

The TRIPs was, not amazingly, considered to be highly controversial for several reasons. Firstly, there was already an existing international regime of intellectual property rules within the World Intellectual Property Organisation (WIPO). Secondly, one of the overarching aims of the WTO is to liberalise trade. Limitations on the intellectual property area, which gives monopoly to a certain manufacturer, creates trade restrictions.¹⁵

Many developing countries have shorter period of time of patent protection than most developed countries. Consequently, domestic, imitated products often dominate the market in developing countries. This could lead to a potential loss of foreign sale by the original producer who financed the innovation. Additionally, the enforcement of patent protection in many developing countries has been considered to lack in transparency, legal security, as well as certainty. Furthermore, some of the governments in developing countries are tolerating production and sale of pirate products and/or appropriation of trademarks and symbols, which have no connection to the original product.¹⁶

Given this background with the huge gap between the developed and developing countries' point of views regarding intellectual property rights, it is understandable that the TRIPs Agreement has been heavily debated ever since it was adopted in 1995¹⁷.

2.3.1 The TRIPs Construction and its Content

The TRIPs Agreement contains detailed provisions on what rights and standards that will be granted under intellectual property law. The TRIPs is based on the same basic principles as several of the WTO Agreements,

¹⁴ Correa M. C. (2000), *Intellectual Property Rights, the WTO and Developing Countries*, London and New York, p.1-2.

¹⁵ Wallach L. and Sforza M. (1999), *Whose Trade Organisation?*, Public Citizen, Washington D.C., p.102.

¹⁶ Trebilcock and Howse (2000), p.307.

¹⁷ *ibid*, p.307.

which are defined in the GATT agreement. Among those are the principles of ‘most-favoured-nation’¹⁸ and ‘national treatment’¹⁹, which are not only found in the GATT Agreement, but also in the TRIPs Agreement itself. The national treatment principle is discussed in TRIPs Article 3, while the most-favoured-nation-clause is discussed in article 4 in the TRIPs. These principles are of relevance to this thesis, since they constitute a fundamental base for patent legislation to prevent discrimination among the Member Countries in the WTO. Therefore, they will be briefly presented below.

Under the principle of ‘most-favoured-nation’, the members have agreed to that any more favourable concessions negotiated with a third party will be extended to each other as well. That means that if there are certain advantages given to one country, the same advantages will have to be given to all WTO Member Countries. The article addresses the issues of discrimination by members amongst foreign exporters²⁰.

The principle of ‘national treatment’ basically means that foreigners must be treated in the same way as nationals. The Article is designed to constrain another form of discrimination, than article III in the GATT. It is aiming for those situations where a member adopts internal or domestic policies, which will favour domestic producers and subsequently put other producers in an unfavourable position. There are important exceptions to these fundamental principles in the GATT, as well as the TRIPs, however, it is of no relevance to analyse this further.²¹

Furthermore, the Agreement contains detailed provisions on how the rights are going to be enforced, and there are sanctions and remedies available for cases where Member Countries violate the Agreement. The interesting approach in international intellectual property rights is that disputes concerning implementation, as well as interpretation of the TRIPs Agreement can be brought in front of a panel. The panel will make statements regarding the dispute and if those are not complied with, trade sanctions may occur as a result.²²

The responsibility for enforcing the Agreement in the Member Countries is mainly with the legislators and the governments in the Member Country but also with the courts. The politically responsible bodies shall implement the regulations. The role of the court is to make sure that the regulations are being enforced properly.²³

¹⁸ GATT, article I.

¹⁹ GATT, Article III.

²⁰ Trebilcock and Howse (2000), p.29.

²¹ *ibid.*

²² Article 64 TRIPs, art.XXII and art.XXIII GATT 1994.

²³ Ministry for Foreign Affairs Sweden (2000), *Trade Relations and Intellectual Property Rights in the Baltic Sea Region*, Nordstedts Tryckeri AB, Stockholm, p.36.

2.3.2 General Information on Article 27 in the TRIPs Agreement

According to Article 27.1 in TRIPs, a product or a process must be made available for patent if it is new, involves an inventive step and is capable of industrial application. A patent, according to the TRIPs Agreement, provides for a total monopoly for the patented product or process for a minimum period of time of 20 years²⁴. In accordance with Article 27 in the TRIPs, Member Countries have to include micro-organisms and micro-biological processes in the patent protection regulations. However, it can be argued where to draw the line between biological processes and micro biological processes, which makes it hard to define what each of them involve. Moreover, the line between micro- organisms and other forms of lives does not appear to be very clear.

Article 27 in the TRIPs Agreement provides that:

“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.* 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 and 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. 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.

* For the purpose 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.”²⁵

Generally, article 27(1) in the TRIPs Agreement provides the criteria to be fulfilled in order for a subject to be patentable. Article 27(2) and 27(3) are dealing with situations where a Member Country has the possibility to exclude certain inventions from patentability. The patentable subjects

²⁴ Article 33, the TRIPs Agreement.

²⁵ Article 27, the TRIPs Agreement.

include products, as well as processes, and they generally cover all fields of technology²⁶. Each section of Article 27 will be discussed further below.

2.3.3 TRIPs Agreement Article 27(1)

Article 27(1) in the TRIPs Agreement constitutes the main rule and provides that any invention, which fulfil the requirements of being new, involving an inventive step and is capable of industrial application, should be available for patent. Furthermore, article 27(1) in the TRIPs Agreement states that patents are to be available and that patent rights should be enjoyable, regardless of the place of the invention, field of technology and whether the product was imported or locally produced.

Since the thesis is focusing on possibilities to grant patent for plants, it is of great interest to discuss whether or not biological material can be considered to fall within the definition of a discovery or within a patentable invention. It is difficult how to define discovery and invention, and subsequently, where the line should be drawn between the two. This can be considered to be depending on that different legal systems are not using the same definitions. Furthermore, the definitions have changed considerably over time. One of the issues that has been raised, is to what extent it should be possible to grant a patent regarding biological materials, which is something already existing in nature.²⁷

The scope of what an invention includes has been broadened, especially in developing countries since the 1980s, in order to include biological material. However, some of the developing countries have interpreted the concept of invention more strictly. It can be argued that both interpretations are complying with TRIPs, however, with different implications depending on what approach chosen.²⁸ A number of factors such as economy, legal and ethical aspects are to be taken into consideration when a Member Country is deciding on how to define the meaning of 'invention'.²⁹

2.3.4 TRIPs Agreement Article 27(2) and 27(3)

Exceptions from the main rule in article 27(1) are presented in article 27(2), as well as in article 27(3) in the TRIPs. According to article 27(2) in the TRIPs members of WTO are under certain circumstances entitled to exclude inventions from patentability. This is acceptable when the measure is taken in order to protect 'ordre public or morality'. This includes protection of human, animal or plant life, as well as health. An exclusion from patentability is according to Article 27(2) is also acceptable if it is done to avoid serious damage to the environment. However, the exclusion from

²⁶ http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm, 27/2/2004.

²⁷ Correa C. M. (2000), p.52.

²⁸ *ibid.*

²⁹ *ibid*, p.54.

patentability would not be justifiable if it was only due to the fact that the exploitation is prohibited by the Member State's law.

27(2) TRIPs states, as shown above, that there is a possibility for any WTO Member Country to exclude certain products or processes from patentability in domestic laws because of 'ordre public or morality'. A significant flexibility is left to the WTO Member Countries to interpret and define the concept of 'ordre public and morality'.³⁰

As stated above, article 27(3) provides facts about what members may exclude from patentability. Article 27(3) (a) is aiming for diagnostic, therapeutic and surgical methods for the treatment of humans, as well as animals. Hence, more interesting for this thesis is article 27(3) (b), where exclusion is allowed for 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. In the last part of the article, a sub-clause states that the Members are obliged to provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.

Article 27(3) (b) allows WTO Member Countries to exclude plants from patentability. The legal, economic, as well as ethical implications of allowing patents on e.g. plants have had Member Countries to interpret the possibilities to make exceptions from patent broadly.³¹

2.4 Conclusion

A patent is a monopoly, granted to a producer for a product or process for a certain number of years. According to TRIPs, Article 27(1), the invention has to fulfil the requirements of being new, involving an inventive step, as well as being capable of industrial application, in order to be patentable. It can be argued whether or not biological materials can be considered to fall within the scope of being an invention, since it is something already pre-existing in nature.

TRIPs Article 27(2), as well as Article 27(3), provides for the possibility for the WTO Member Countries to exclude certain areas from patentability. This can be accepted this action is taken in order to protect ordre public or morality, or to protect diagnostic, therapeutic and surgical methods for treatment of human and animals. Article 27(3) (b) opens up for the possibility to exclude plants from patentability, that are not non-biological or microbiological processes. However, where to draw the line between biological and non-biological processes is not very clear. Moreover, this is also the case when trying to determine what is included in a microbiological process and what is not.

³⁰ Correa, C. M. (2000), p.62.

³¹ *ibid*, p.67.

Article 27(3) (b) creates an obligation for the Member Countries to provide for the protection of plant varieties. The Article opens up for different solutions, such as either provide patents or an effective sui generis system or to combine the two of them in order to obtain efficient protection for plant varieties.

The research conducted in this descriptive section is aiming for a clarification as to what extent, if at all, a patent for plants can be granted under Article 27 TRIPs. This will be discussed further in the analysis. Whether or not the Swedish Patent Act (1967:837) is complying with TRIPs Article 27 regarding possibilities for patenting plants, will also be further examined in the analysis.

3 Directive 98/44/EC on Legal Protection of Biotechnological Inventions

On July 6, 1998, the European Parliament and the Council of the European Union adopted the EC Directive 98/44/EC on the Legal Protection of Biotechnological Inventions.³² The Directive was incorporated into Swedish law in May 2004³³ and is expected to implement a harmonisation of the patent field within Europe.³⁴

This section is aiming to clarify to what extent, if at all, a patent for plants can be granted under the Directive 98/44/EC. In order to understand if Swedish Patent law complies with the Directive 98/44/EC regarding patenting of plants, this section is of major importance. This issue will be further discussed in the analysis.

Firstly, general information on the Directive 98/44/EC will be presented. Secondly, the relevant articles in the Directive in relation to plant protection will be discussed. This will be followed by a presentation of the relevant case law, with focus on the case C-377/98, where the Netherlands applied for an annulment of the Directive 98/44/EC on Legal Protection of Biotechnological Inventions.

3.1 Introduction to Directive 98/44/EC

The recital 12 in the preamble of the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, states that the European Community and its Member States have signed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). The Agreement has entered into force and, subsequently, the EC has to provide for that patent protection must be guaranteed for products and processes in all areas of technology.³⁵ As explained previously, the European Communities is an independent member of WTO, and is therefore bound to make sure that its rules and regulations correspond to the agreements developed by WTO.³⁶

The main objective of Directive 98/44/EC is to increase the protection of biotechnology and genetic engineering by harmonising the internal market, since it is considered to be of major importance for the Community's future

³² Preamble of the Directive 98/44/EC, p.1.

³³ Lag (2004:159) om ändring i patentlagen (1967:837).

³⁴ Prop. 2003/04:55, p. 37.

³⁵ Recital p.12, the preamble 98/44/EC.

³⁶ http://www.wto.org/english/thewto_e/countries_e/european_communities_e.htm. 22/04/04.

industrial development.³⁷ There is a fear that uncoordinated development of the national laws within the European Union could lead to a decrease in the incentives to trade, and consequently prevent industrial development.³⁸

The Directive was debated for around ten years in the European Parliament, as well as in the Council of the European Union, before it was finally adopted in July 6, 1998. As of October 7, 2002, only 6 member countries had implemented the Directive 98/44/EC into their own national law (Denmark, Finland, Ireland, Great Britain, Greece and Spain).³⁹ Sweden's Parliament just recently⁴⁰ adopted new regulations in order to fulfil its obligations as an EU Member State, and subsequently comply with the Directive.

The Directive does not demand the national patent law to be replaced by specific regulations in order to obtain the level of protection needed for biotechnological inventions. The Directive provides certain principles regarding the patentability of biological material, more specifically regarding where to draw the line between discovery and invention. The chosen construction is aiming for giving the national legislation the primary role for determining the protection within this field.⁴¹

3.2 Relevant Articles in Directive 98/44/EC

Article 1(1) in Directive 98/44/EC stipulates that the EU Member States have an obligation to provide for patent protection for biotechnological inventions. It is also emphasised in Article 1(2) that obligations the EU Member States have in relation to the TRIPs Agreement shall not be affected by Directive 98/44/EC. Consequently, the EU Member States shall interpret and implement the Directive in a way, which is consistent with the TRIPs Agreement.⁴²

3.2.1 Patentable Subjects

Article 3(1) in 98/44/EC stipulates that inventions that are new, involves an inventive step and are capable of industrial application shall be available for patent. Furthermore, this is also valid when the product consists of "biological material or a process by means of which biological material is produced, processed or used"⁴³.

³⁷ Recital Preamble of 98/44/EC, (1).

³⁸ Recital Preamble of 98/44/EC, (7).

³⁹ <http://europa.eu.int/scadplus/printversion/sv/lvb/126026a.htm>, 19/04/04.

⁴⁰ The Directive 98/44/EC was implemented in the Swedish Patent Act (1967:837) on 1 May 2004, in accordance with "Lag (2004:159) om ändringar i patentlagen (1967:837).

⁴¹ Prop. 2003/04:55, p. 38.

⁴² Article 1(1) and 1(2), 98/44/EC.

⁴³ Article 3(1), 98/44/EC.

Article 3(2) stipulates that:

“Biological material which is isolated from its natural environment or produced by means of technical process may be the subject of an invention even if it previously occurred in nature.”⁴⁴

Thereby it can be argued that the Directive 98/44/EC states that patent can be granted for inventions despite the fact that they consist of biological material e.g. plants, that already exists in nature.⁴⁵

Article 4(1) and 4(2) provides:

- “1. The following shall not be patentable:
- (a) plant and animal varieties;
 - (b) essentially biological processes for the production of plants and animals.
2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.”⁴⁶

Article 6(1) provides that inventions shall not be patentable when the commercial exploitation would be contrary to ordre public or morality. However, exceptions for this shall not be accepted only because they are restricted in any way or prohibited by national laws or regulations.

3.3 Case C-377/98

The Case C-377/98 Kingdom of the Netherlands v. European Parliament and Council of the European Union, is relevant to this thesis since the Court’s Judgement provides interpretation of certain articles in the Directive. The statement of AG Jacobs is also of great relevance, since it constitutes the base for the Court’s decision. On this basis, it is possible to analyse whether or not plants are considered patentable under Directive 98/44/EC. More clearly, the case is of major importance in order to understand what obligations arise from the Directive and moreover to provide an understanding for the reasons as to why the Directive was heavily debated.

The case C-377/98 derives from a request for the annulment of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. As already stated many Member Countries in the European Union considered the Directive to take too extensive measures and wanted the Directive to be annulled. The parties applying for an annulment were the Kingdom of the Netherlands, the Italian Republic and the Kingdom of Norway.

The parties based their reasoning for an annulment on six various grounds. It was claimed that article 100a of the Treaty was the incorrect legal basis

⁴⁴ Article 3(2), Directive 98/44/EC.

⁴⁵ Koktvedgaard M. and Levin M., (2002), *Lärobok i immaterialrätt*, Elanders Gotab, Stockholm, p. 232.

⁴⁶ Article 4(1) and 4(2), Directive 98/44/EC.

for the Directive. They also stated that the Directive constituted a breach of the principle of subsidiarity, as well as a breach of the principle of legal certainty. Furthermore, it was claimed that the Directive was in breach of obligations in international law and that it was in breach with the fundamental right to respect for human dignity. Finally, it was stated that the Directive was in breach of procedural rules in the adoption of the Commission's proposal.

The main focus in this case, relevant to this thesis is the fourth ground in the appeal. The fourth ground is stating that the Directive would be in breach with international obligations, such as TRIPs among others⁴⁷.

From the parties in favour of an annulment it was argued that Article 27(3)(b) of the TRIPs Agreement allows Member States not to grant a patent for plants and animals other than micro-organisms, whereas the Directive does not provide this possibility for the Member States.

AG Jacobs stated that the TRIPs Article 27(3)(b) provides the possibility for WTO Members to exclude a wide range of subjects from patentability. The Community, as an independent member of the WTO, decided to exclude only part of that wide range as provided for in Article 4(1). Consequently, the Community is only using an option available to exercise its rights, still in accordance with TRIPs Article 27(3)(b).⁴⁸

Finally, the Court's position was that the Directive does not provide the options available in the TRIPs. In the TRIPs the WTO Member States have a possibility to exclude plants and animals, with exceptions for micro-organisms from patentability, whereas the EU Member States do not have this possibility in accordance with the Directive. However, the approach chosen in Article 4 in the Directive is in compliance with the TRIPs. It is possible for some WTO Member States to adopt another point of view in respect of how to interpret the application of the agreement.⁴⁹

The Court states in its reasoning that the interpretation of this ground should not be considered to be a "direct breach by the Community of its international obligations, as at an obligation imposed on the Member States by the Directive to breach their own obligations under international law, while the Directive itself claims not to affect those obligations".⁵⁰

⁴⁷ E.g. Convention on Biological Diversity, European Patent Convention etc.

⁴⁸ <http://curia.eu.int/cgi-bin/gettext.pl?lang=en&num=79989385C19980377&doc=...>
19/4/2004, recital 154 in the Opinion of Advocate General Jacobs, delivered on 14 June 2001.

⁴⁹ <http://www.curia.eu.int/jurisp/cgi-bin/gettext.pl?lang=sv&num=79988990C19980377...>
26/3/26.

⁵⁰ <http://curia.eu.int/jurisp/cgi-bin/gettext.pl?lang=en&num=79988990C19980377&doc=...>
19/4/2004, recital 55 in the Judgement of the Court, 9 October 2001.

3.4 Conclusion

In 1998, the European Parliament and the Council of the European Union adopted the Directive 98/44/EC on Legal Protection of Biotechnological Inventions. The Community itself is an independent member of the WTO, and consequently the EC has to make sure that the rules and regulations developed regarding patents have to comply with the TRIPs. The main objective of Directive 98/44/EC is to increase protection of biotechnology, as well as genetic engineering, by harmonising the internal market.

Article 3(1) provides for that patent should be available for inventions that fulfil the requirements of being new, involving an inventive step and are capable of industrial application. This is also valid when a product consists of biological material. According to 3(2), even biological material that has been isolated from the natural environment or produced by a technical process can be considered to be an invention, even if it occurred in nature earlier. Therefore, it can be argued that patents for plants can be granted under the Directive 98/44/EC, despite the fact that they were pre-existing in nature.

According to Article 6(1) exceptions from patentability for an invention due to the fact that the commercial exploitation would be contrary to ordre public or morality can be accepted. However, it is not permitted to make an exception from patentability only because it would be in breach with domestic law or regulation.

The case C-377/98 where the Netherlands on several grounds requested the annulment of the Directive 98/44/EC, illustrates how controversial the Directive was considered to be. The case is important, since it defines how to interpret several of the articles in the Directive. One reason brought forward was that the Directive 98/44/EC would infringe on the EU Member States obligations in relation to TRIPs. The Court's final judgement was that the TRIPs provides for the possibility for the WTO Member States to exclude plants and animals, with exception of micro-organisms, from patentability. The EU Member States do not have this option of choice in the Directive. However, the approach chosen in Article 4 is in compliance with the TRIPs and there is nothing in the TRIPs Agreement preventing WTO Member States from adopting another view on how the TRIPs should be applied in this regard.

The issue whether or not Swedish Patent Act (1967:837), is in compliance with the Directive regarding patent on plants, will be discussed in the analysis.

4 The Swedish Law

This section aims to give the reader a brief description of what subjects are patentable under the Swedish Patent Act (1967:837) (hereinafter referred to as PL, Patentlagen). Furthermore, it aims to explore under what conditions, if at all, patent for plants can be granted. This is of great importance in order to understand if PL is complying with 27.3 (b) in TRIPs, as well as with 98/44/EC regarding patents for plants.

Firstly, a brief section about the implementation of the Directive 98/44/EC into Swedish Law will be presented. Secondly, the relevant sections in PL will be discussed.

4.1 Implementation of the Directive 98/44/EC into Swedish Law

The Directive 98/44/EC on Legal Protection of Biotechnological Inventions should have been implemented into Swedish law in July 2000. However, providing patent protection for biotechnological inventions is a very controversial issue and the topic has been heavily debated all over Europe and, subsequently, the implementation process has been prolonged.⁵¹

The Swedish Government presented their suggestions for changes in the Proposition 2003/04:55 in order to make PL comply with the Directive 98/44/EC.⁵² From the Government it was argued that the law already complied with the Directive 98/44/EC before the suggested changes came into force. However, the Government claimed that the changes were necessary in order to clarify the limits and borders for patenting of genes and gene-sequences.⁵³ Sweden implemented the Directive 98/44/EC on Legal Protection of Biotechnological Inventions on 1 May 2004.⁵⁴

4.2 Swedish Patent Act (1967:837)

In the Nordic patent tradition, patentable subjects were to be found in the lifeless technique and not in biological processes. This tradition is also supported by the demand for the general, but not explicit, demand that an invention should be possible to reproduce. The definition of being 'possible to reproduce' is when you can bring about or recreate an identical phenomenon in a desirable number. It has to be well defined and be within the scope of the human possible at the technical stadium for the time of the

⁵¹ <http://www.nir.nu/aktuellt.asp?ID=231>, 2/4/2004.

⁵² Ibid.

⁵³ http://www.regeringen.se/galactica/service=irnews/action=obj_show?c_obj_id=56182, 6/4/2004.

⁵⁴ Lag (2004:159) om ändring i Patentlagen (1967:837).

application. As far as living organisms are concerned, it is not normally possible.⁵⁵

4.2.1 Patentable Subjects

One section of major importance to this thesis is to be found in PL 1:1 a §:

“1 a § Patent meddelas inte på växtsorter eller djurraser. Patent kan dock meddelas på en uppfinning som avser växter eller djur, om uppfinningens genomförbarhet inte är tekniskt begränsad till en viss växtsort eller djurras. Vad som avses med växtsort framgår av 1 kap 3 § växtförädlarrättslagen (1997:306).

Patent meddelas inte på ett väsentligen biologiskt förfarande för framställning av växter eller djur. Med väsentligen biologiskt förfarande för framställning av växter eller djur avses ett förfarande som i sin helhet består i naturliga företeelser, som korsning eller urval. Patent kan dock meddelas på en uppfinning som avser ett mikrobiologiskt förfarande eller ett annat tekniskt förfarande eller ett genom ett sådant förfarande framställt alster. Med mikrobiologiskt förfarande avses ett förfarande som utförs på mikrobiologiskt material eller genom vilket sådant material används eller framställs.

En uppfinning kan vara patenterbar även om den avser ett alster som består av eller innehåller biologiskt material eller ett förfarande genom vilket biologiskt material framställs, bearbetas eller används. Ett biologiskt material som isoleras från sin naturliga miljö, eller framställs genom ett tekniskt förfarande, kan vara föremål för en uppfinning även om det redan förekommer i naturen. Biologiskt material omfattar material som innehåller genetisk information som kan reproducera sig självt eller kan reproduceras i ett biologiskt system.”⁵⁶

PL 1:1 §, first paragraph, provides the basic criteria to be fulfilled in order for a subject to be patentable. This section states that you can obtain patent for an invention only after an application, given that the invention is capable of industrial application. PL 1:1 §, second paragraph point 1, is explaining that if it is only a matter of a discovery, scientific theory or a mathematical method, this cannot in itself constitute an invention⁵⁷.

PL 1:1 a §, paragraph one stipulates that an invention concerning plants or animals can be patentable, as long as the invention's feasibility is not technically limited to one specific plant variety. Furthermore, the same section is making an exception from patentability for plant varieties. The reason as to why the plant varieties are excluded from patentability is probably since they are protected under the plant breeder's right.⁵⁸

PL 1:1 a §, third paragraph, first sentence provides that an invention is patentable, even if it concerns an invention consisting of biological material or concerns a process where biological material is being produced or used in the process. Furthermore, it is pointed out in PL 1:1 a §, third paragraph, second sentence, that biological material can be considered to be an invention despite the fact that it is pre-existing in nature, or is being produced by a technical process. Before this was introduced to Swedish

⁵⁵ Kockvedgaard M. and Levin M., (2002), p. 230.

⁵⁶ PL 1:1 a §.

⁵⁷ PL 1:1 §, second paragraph, no.1.

⁵⁸ Prop. 2003/04:55, p. 26.

Patent Act (1967:837) requests were circulated to various parties in order to get comments on the planned changes. In their answers some of them pointed out that by introducing this, where to draw the line between invention and discovery would be changed radically. Some also opposed to the idea, claiming that it would be unethical to allow patent for the use of something, which is pre-existing in nature, e.g. a natural existing gene-sequence.⁵⁹ However, if one just discover a natural existing biological material, e.g. a gene sequence, is not enough in order to be able to patent the sequence. Nevertheless, you could possibly obtain a patent for the natural existing material if it has an area of use that makes the invention a technical solution of a problem.⁶⁰

This point of view is also confirmed in the proposal to the Parliament, where it is stated that it is possible to obtain patent for biological material. In order for patent to be available, the invention still has to fulfil the general requirements of being new, involving an inventive step and being capable of industrial or professional application. However, this is not expressed explicitly in the PL. Where to draw the line between invention and discovery is decided by the industrial application of the material. The example provided is medical use or application. At this point it can be considered to be a technical solution of a problem, and subsequently, an invention that is patentable.⁶¹

In accordance with PL 1:1 c §, first paragraph, first sentence, patent cannot be granted for an invention, where the professional use would be contrary to 'ordre public or morality'⁶². However, the exploitation must not be considered to be contrary ordre public or morals, only because it is forbidden in the legislation.⁶³

4.3 Conclusion

Sweden implemented the Directive 98/44/EC on Legal Protection of Biotechnological on 1 May 2004. The Swedish Government claimed that the laws already complied with the Directive, however, the changes enforced were considered necessary due to the need for a clarification of the limits and boarders for patenting of genes and gene-sequences.

PL 1:1 § second paragraph is stating that an invention is patentable after an application has been handed in, and as long as the invention is capable of industrial application. This is followed by an enumeration of various examples that are not patentable. One example is that if it is only a matter of a discovery, the invention should not be possible to obtain patent for.

⁵⁹ Prop.2003/04:55, p.60-61.

⁶⁰ Prop. 2003/04:55, p. 51-52.

⁶¹ Prop.2003704:55, p.61.

⁶² 'allmän ordning eller goda seder'.

⁶³ PL 1:1 c §, second paragraph.

PL 1:1 a §, third paragraph, first sentence states that an invention is patentable, even if it concerns an invention consisting of biological material or relates to a process where biological material is being produced or used in the process. PL 1:1 a §, third paragraph, second sentence, provides that biological material can be considered to be an invention. This is the case even if the 'invention' is pre-existing in nature, or is produced in a technical process.

The conclusion of a long reasoning regarding the patentability or the non-patentability for inventions that are pre-existing in nature, and consequently consist of biological material, is that if certain criteria are fulfilled it is possible to obtain patent for biological material. The invention has to be new, involve an inventive step and has to be capable of industrial application, even though this is not stated explicitly in the PL.

There is a possibility in accordance with PL 1:1 c §, first paragraph, first sentence to make exceptions from patentability if the exploitation of the invention would be contrary to ordre public or morality. However, it is not possible to make an exception only because it is forbidden in laws or regulations.

Whether the Swedish Patent Act (1967:837) is in compliance with Article 27 in the TRIPs, as well as with the Directive 98/44/EC, will be examined in the analysis.

5 Analysis

The TRIPs Agreement has put immense pressure on its Member States to make patentability of plants available for patents. The EU, as an independent member to WTO, has created specific frames for its Member Countries in order to harmonise the internal market, regarding patents for plants. This, in effect, has created limitations for the Swedish construction of Patent Law. The effect for Swedish Patent law might not be considered to be revolutionary, but nevertheless, a big change in the patent system.

My aim for the thesis was to identify the effects of Article 27.3(b) of the TRIPs for Swedish Patent Law, thereby having to examine the EC Law and Directive 98/44/EC. More specifically my aim was to identify if Swedish Law in respect of patents for plants complies with the TRIPs, as well as with the EC Directive 98/44/EC.

Firstly, I will analyse to what extent patents can be granted for plants under Article 27 in the TRIPs Agreement. Secondly, I will analyse to what extent patents for plants can be granted under Directive 98/44/EC on Legal Protection of Biotechnological Inventions. Thereafter, I will examine to what extent patents for plants can be granted under the Swedish Patent Act (1967:837). Finally, I will analyse whether the Swedish Patent Act (1967:837) is in compliance with Sweden's international obligations, as mentioned above, regarding patents on plants.

The main rule in the TRIPs Agreement in accordance with Article 27.1 in the TRIPs, is that patent should be available within all fields of technology, provided that the requirements of novelty, inventive step and industrial application are fulfilled. The main issue here is to determine whether or not biological material, already existing in nature, is to be included within the concept of invention. As mentioned previously, there is plenty of room for the WTO Member Countries to interpret the concept of invention, since there is no definition of 'invention' available in TRIPs. This opens up for the possibility to allow patents for plants.

The exceptions from the main rule presented above are stated in 27(2) and 27(3) in TRIPs. 27(2) provides that it is possible to exclude inventions from patentability that are contrary to ordre public or morality. 27(3) states that it is possible to exclude plants and animals, other than micro-organisms, from patentability. Thereby the conclusion can be drawn that it is possible to exclude plants from patentability.

The TRIPs Agreement gives the WTO Member States a freedom of choice regarding their approach to patent for plants. The conclusion is that it is possible under the TRIPs Agreement to grant patent for plants, even though they are pre-existing in nature.

The Directive 98/44/EC on Legal Protection of Biotechnological Inventions came about as an effect of the TRIPs Agreement. The European Communities is a WTO Member itself. Therefore, the EC is obliged to make sure that its rules and regulations that are developed are complying with the TRIPs. The Directive was developed in order to harmonise the internal market. It was argued that if it was left to the EU Member States to interpret the TRIPs independently, too many different regulations regarding patent could be developed, and consequently create trade obstacles on the internal market.

The approach chosen was that several of the concepts used in the TRIPs were later on carefully defined in the Directive, and directions on how to interpret certain Articles, were sharply determined in the Case C-377/98. Consequently, the EC Member States were not left much of a choice for how to interpret certain concepts, as far as patents for plants were concerned.

A patent shall be granted under the Directive, in accordance with Article 3(1) if the invention concerned is new, involves an inventive step and is capable of industrial application. According to Article 3(2), this is also the case when a product consists of biological material, which has been isolated from the natural environment or produced by a technical process, despite the fact that it occurred in nature previously. Therefore, it opens up for the possibility to grant patent for plants that patents under Directive 98/44/EC, despite the fact that they were pre-existing in nature.

The Case C-377/98, the parties in favour of an annulment argued that Article 27(3)(b) of the TRIPs Agreement allows Member States not to grant a patent for plants and animals other than micro-organisms, whereas the Directive does not provide this possibility for the Member States. However, the Court's position was that this is the situation, but the approach chosen in Article 4 in the Directive is still in compliance with TRIPs. Article 4(2) provides that "Invention which concerns plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety."

The Directive also provides an option of excluding inventions from patentability in Article 6(1) if the commercial exploitation is contrary to ordre public or morality.

My interpretation is that patents for plants can be granted under the Directive, even if the biological material was pre-existing in nature. However, the technical feasibility is not allowed to confine on plant variety.

The gradual adjustment of Swedish legislation to TRIPs has been an ongoing process since 1995. The implementation of the Directive 98/44/EC was enforced 1 May 2004. Due to the fact that the changes were enforced rather recently, it is hard to predict what the future results of these changes will be. Nevertheless, the question now to be examined is if the Swedish

Patent Act (1967:837) is in compliance with Article 27 in the TRIPs, as well as with Directive 98/44/EC, regarding granting patent for plants.

Sweden is a member of the WTO and is therefore obliged to comply with the TRIPs Agreement. The European Communities is also a member of WTO and has to make sure its rules and regulations comply with the TRIPs Agreement. It was argued that leaving the implementation of the TRIPs Agreement completely up to the various EC Member States, would create too many various approach and thereby possibly create trading obstacles in the long run. Therefore, it was preferred to develop a new Directive in order to facilitate the trade on the internal market. Consequently, Sweden has, as a member of the WTO, as well as being a Member Country in the EC, implemented changes in the national legislation in order to comply with the international obligations as set out in TRIPs and in Directive 98/44/EC.

The TRIPs Agreement sets out certain principles and frames for how the WTO Member States shall act regarding their national legislation for patents. The Directive 98/44/EC clarifies for the EU Member States how to interpret certain 'concepts'.

The Swedish Patent Act (1967:837), as well as other legislation on the area, provides for that patent on biological materials, e.g. plants can be granted if some general requirements are fulfilled. The invention has to be new, involve an inventive step, as well as being capable of industrial application. There is also a possibility to exclude invention from patentability if it is contrary to order public or morality in accordance with PL 1:1 c §, first paragraph, first sentence.

PL 1:1 a §, third paragraph, first sentence provides that an invention is patentable, also if the invention consists of biological material or relates to a process where biological material is being produced or used in the process. PL 1:1 a §, third paragraph, second sentence, it is stipulated that biological material can be considered to be an invention. This is the case even if the 'invention' is pre-existing in nature, or is produced in a technical process.

The interesting issue now is whether or not the Swedish Patent Act (1967:837) is in compliance with Article 27 TRIPs and the Directive regarding patents for plants.

Since Sweden is a member of WTO, as well as the EC, Sweden has an obligation to comply with the rules provided from both institutions. The TRIPs has a wide construction, giving the WTO Member Countries options on how to approach the issue of patentability for plants. In TRIPs the Member States can provide patents for plants if they wish to do so. They can also choose to make exceptions from the patentability for plants. However, the Directive has a more narrow construction and does not provide the same possibility as TRIPs. The Directive does not open up for the possibility to exclude plants from patentability, which means that the EC Member States

have to open up for the possibility to grant patent for plants and other inventions including biological material.

I consider that there can be a conflict situation between the Directive and TRIPs in this respect. This issue was brought in front of a court in Case C-377/98, and the result was that the Court could not see a conflict between the Directive and TRIPs regarding the more narrow limitations given in the Directive. The Court's position was that there was nothing in the TRIPs that states that it is forbidden to make a more narrow interpretation and the Directive is therefore still in compliance with the TRIPs. However, even if there would be a conflict in this issue, strictly looking at the construction of TRIPs Agreement and the Directive, there is little doubt that WTO would take any action. WTO is in favour of strong patent protection rules and regulations and from that point of view, there is no conflict of interest.

Given this background, it would be a difficult situation if there were a conflict, since Sweden has obligations to both parties involved. Especially so, since it can be argued which one should be given the priority.

Assuming that the court made an adequate decision and consequently, there is no conflict between TRIPs and the Directive in this respect, Swedish Patent Law (1967:837) can be considered to be in compliance with its international obligations, TRIPs and the Directive. It is possible to obtain patent for plants, even if they did exist in nature already. This means that Swedish law is providing for the option demanded by the Directive.

Regarding the possibility to exclude inventions from patent if it is contrary to ordre public or morality, TRIPs and the Directive are using the same construction. Sweden's law and legislation is complying with the international obligation in this respect. Some have questioned if it is moral and ethical to actually be able to patent material that are already pre-existing in nature. Generally, it cannot be possible to exclude patents for plants by using this argument. It is defined as an explicit demand in the Directive to provide for that patent for plants are available and I think it is questionable when to use this section at all in order to obtain an exception. Even more so when it is stating that it is not possible to use this escape-clause only because it is stated in law. Normally laws are used to encourage certain behaviour among the country's inhabitants. This also includes moral. It is doubtful to have a clause, which looks feasible on paper, but not particularly useful in reality.

It is important to bear in mind that the effects of the Directive will take time to evaluate, since we are still not able to see the full effects of its construction and Sweden just implemented the Directive. Since the changes are so recent, there is no case law on the area yet, even though I am convinced it will not take too long before we will see cases coming up.

Generally, I consider Swedish Patent Act (1967:837) to be in compliance with its international obligations in relation to Article 27 in TRIPs and the Directive 98/44/EC regarding patents for plants.

One reason as to why the topic has been heavily debated is probably ethical and moral aspects, as well as legal difficulties. Nevertheless, the protection for biotechnological inventions has never been as much in the focus for debate. The rapid changes within this field of technology will more than likely create the need for additional legal changes within the near future. Nonetheless, keeping the legislation up to date will be of great importance in order to prevent a poor development where the industry will take advantage of the situation where the legislation is not being updated.

6 Conclusions

The aim of the thesis was to examine and determine whether or not Swedish Patent Act (1967:837) is in compliance with international obligations, such as TRIPs Article 27, as well as Directive 98/44/EC, in respect of patenting of plants.

TRIPs Article 27(1) provides for that an invention is patentable if it is new, involves an inventive step and is capable of industrial application. This can include biological material. Article 27(2), as well as Article 27(3) stipulates that certain areas can be excluded from patentability. Article 27(3) (b) opens up for the possibility to make exceptions for patent on plants. TRIPs leave it up to the WTO Member States to decide what should be considered to be an invention, since this is not defined in the TRIPs.

The Directive 98/44/EC was created as an effect of the TRIPs Agreement. The European Communities is an independent member in the WTO and is therefore obliged to make sure that the rules and regulations that are developed are complying with the obligations relating to WTO. The Directive was created to harmonise the patent regulation within the EC. The EC was afraid that leaving the interpretation to its Member Countries would create too many various systems for patent protection for biotechnological inventions, which possibly could create legal, as well as trade implications, and consequently the Directive was created.

Article 3(1) in the Directive 98/44/EC states that patent should be available for inventions that are new, involves an inventive step and are capable of industrial application. In the same article it is expressed that this should also be the case if a product consists of biological materials. Article 3(2) stipulates that if a biological material is isolated from its natural environment, or produced by means of technical process may be considered an invention, where a patent can be obtained, even if it previously occurred in nature. Furthermore, Article 4(2) stipulates that inventions where plants are concerned shall be granted patent if the technical feasibility of the invention is not confined to a particular plant or animal variety.

The Directive 98/44/EC was implemented into Swedish law 1 May 2004. Swedish Patent Act (1967:837) provides that patent for inventions including biological material e.g. plants can be granted if some general requirements are fulfilled. The invention has to be new, involve an inventive step, as well as being capable of industrial application.

In accordance with PL 1:1 a §, third paragraph, first sentence, an invention is patentable, even if it consists of biological material or relates to processes where biological material is being produced or used in the process. PL 1:1 a §, third paragraph, second sentence, states that biological material can be

considered to be an invention. This is the case even if the ‘invention’ is pre-existing in nature, or is produced in a technical process.

The construction of when to provide for patent protection in the Directive is stricter than TRIPs. TRIPs let the WTO Member States to choose whether or not to exclude plants from patentability. This possibility is not provided in the Directive 98/44/EC. The Directive demands the EC Member States to make it possible to patent plants. One could argue that the Directive is not in compliance with the TRIPs, and that there is a conflict between TRIPs and the Directive. This would create implications for Sweden, which is a country with international obligations to follow the TRIPs, as well as the Directive 98/44/EC.

The TRIPs and the Directive 98/44/EC opens up for a possibility to exclude certain inventions from patentability if it is contrary to ordre public or morality. Sweden’s law and legislation provides this possibility and is in this respect in compliance with the international obligations mentioned above. However, it can be questioned in what situation this section can be used at all, since a country is not allowed to make exceptions from patentability for plants only because it is prohibited in law or regulations. Normally, the laws are used for this purpose, to make people act in a certain way because of moral or other ethical aspects. Therefore, the practical value of this clause can be questioned.

Ethical and moral aspects, as well as legal implications are probably the main reasons as to why the topic has been so much in focus for debate recently. The technical development within the field of biotechnology is keeping a fast pace at the moment. The laws and regulations within this field are likely to face implications in keeping up with the fast development. The future will show the results of the TRIPs, Directive 98/44/EC and its effect and real impact on Swedish Patent Act (1967:837).

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