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Compulsory Patent Licensing:
A minor case study.

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Preface

I am indebted to Håkan Olsson, Niklas Loman, Carsten Rose and Bodil Sjöberg for their time and answering my many questions.

Hans Henrik Lidgard, thank you for your patience.

Timo Minssen, godspeed!

Librarians, I salute you!

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Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
AIPLAQJ	AIPLA Quarterly Journal
Am. J. Hum. Genet.	American Journal of Human Genetics
BRCA	Breast Cancer
CMH	Commission on Macroeconomics and Health
Colum. L. Rev.	Columbia Law Review
CPTech	Consumer Project on Technology
DS	Departement Serien(Memorandum)
ECJ	European Court of Justice
ECR	European Court Reports
EEC	European Economic Community
E.g.	Exempli gratia (for example)
EIPR	European Intellectual Property Review
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FEDCBJ	Federal Circuit Bar Journal
Fordham Int'l L.J.	Fordham International Law Journal
GATT	General Agreement on Tariffs and Trade
HGP	Human Genome Project
HHS	U.S. Department of Health and Human Services
Ill. L. Rev.	University of Illinois Law Review
J. Pat. & Trademark off. Soc'y	Journal of the Patent Office Society
Notre Dame L. Rev.	Notre Dame Law Review
Nw. J. Int'l L. & Bus.	Northwestern Journal of International Law and Business
NIR	Nordiskt Immateriellt Rättsskydd
NU	Nordisk Utredningsserie
Patentlagen (1967:837)	Swedish Patent Law
Prop	Proposition
Tenn. L. Rev.	Tennessee Law Review
TRIPS	Trade Related Aspects of Intellectual Property Rights
UCC	Universal Copyright Convention
Va. L. Rev.	Virginia Law Journal
WTO	World Trade Organisation
Yale L.J.	Yale Law Journal

1 Introduction

1.1 Background

The patent right institution was created in order to stimulate research and development. It is, however not the only incentive to such activity. Other stimuli to research and development are the competitive market forces and the freedom which comes with academic tenure. Patent rights are property rights granted with the aim to fulfil the public goal of economic prosperity. It is a means to stimulate technological development and the total welfare of a country, so is publicly funded academic research.

However strong, patent rights are not unlimited. Amongst other limitations, patent grants are limited in time and some third party uses are allowed even during the patent period. Another limitation is compulsory patent licensing. A compulsory license is an *ex ante* limitation, a limitation of the patent right once it has been issued.

The technology that has been considered to boost economic development has changed over the years and not all has lived up to expectations. The present focus is set on biotechnology which is a science not always considered to be subject to patenting, but is today. It used to be a domain of mostly publicly funded university researchers but now is increasingly a field for private experimentation and the discoveries are privatised through patents rather than entering the public domain through instant publishing. There are those who claim that the patents are strangling the development as a whole in biology related areas but foremost it is a development at the expense of the freedom of the publicly funded university researcher.

1.2 The Case

An article by Dr. Håkan Olsson from 1999 is one of many testimonies of this development. He describes how biotechnological research threatens to be increasingly sensitive to patent strategic considerations and is limited by the patent policy of private corporations. A culture of sharing to the benefit of expanded knowledge is crumbling in the hunt for market shares.

Patent rights restrain his academic freedom. As a solution he advocates compulsory licensing of the patents he is dependent on in his academic enterprise. In an article¹ he mentions the European patent EP0705903. Which is owned by Myriad Genetics Inc, an American enterprise.

¹ Håkan Olsson; *Kommersialiseringen av gener – patent på bröstcansergener pilotfall*, 96 Läkartidningen 37, p. 3920, 1999 (Olsson 1999). An English version of this article can be found in Lundin, S., Åkesson, L. (eds.) ; *Gene Technology and Economy*, p. 42-51, Malmö, 2002 (Olsson 2002).

1.3 Purpose

The purpose of this thesis is to explore whether Dr. Håkan Olsson can turn to one of the limitations of patent law in order to re-establish his academic freedom. Will Dr. Håkan Olsson be successful with an application for a compulsory license of patent number EP0705903?

1.4 Method

This is an enquiry of law. With the conflict at hand as point of departure, will the presentation ascertain the law as it currently stands and then solve the case in point. The method used to ascertain the law as it currently stands is teleological. The choice of method springs from the fact that interpretative case law concerning the rules of compulsory patent licensing is scarce. The current rules in Swedish patent law have never been subject to judicial interpretation.

The teleological method of interpretation demands the fulfilment of the purpose of the law. The rules of compulsory licensing constitute a limitation of the patent protection. In order to give an assessment as complete as possible, both the purpose of patent protection and the rules of compulsory license will be explored.

The search for the purposes of the rules applied will be conducted in compliance with the doctrine of the sources of the norm as proposed by Alexander Peczenik in *Vad är rätt?*². This is a doctrine which leaves the possibility to regard proposals for future legislative acts.

Patent law is an institution deeply rooted in international conventions which will be reflected in the sources of law explored. The international treaties are accounted for extensively since they are of relevance when interpreting the Swedish rules on the topic.

The reference to U.S. law in section 5.2.2 should not mislead the reader to believe that this is a comparative study. I only wish to point out a possible source of inspiration to Article 31 of the TRIPS agreement, nothing else.

1.5 Disposition

The disposition is as follows. Firstly there is a more detailed presentation of the parties and the situation at hand. The teleological method holds that the law be interpreted in accordance with the purpose of the law. The purpose of patent protection is sorted out through the examination of patent theory. Secondly the international sources of Compulsory licensing are presented,

² Alexander Peczenik: *Vad är rätt?*, Fritzes, Göteborg 1995.

followed by the purpose of this institution. Finally there is a survey of relevant Swedish law.

The answer to the enquiry will be examined in the section entitled Analysis and provided in the chapter named Conclusion.

1.6 Limitations

Prof. Hans Henrik Lidgard has commented³ on Prof. Håkan Olsson's article. In his article, Prof. Lidgard makes an inventory of the legal problems and possible solutions to Prof. Olsson's dilemma. In his account of possible solutions, Prof. Lidgard discusses two of the general exceptions to the sole right of the patentee in Swedish Patent Law: non-commercial use⁴, experimental use⁵. He also treats two of many limitations of the patent right: competition law⁶ and compulsory patent licensing⁷. From Prof. Lidgard's article it is evident that patenting of genes, human or not, poses some very interesting questions, not least the ethical aspect.

This thesis will only deal with compulsory patent licensing and takes its starting point in Prof. Lidgard's account of the case at hand.

Compulsory patent licensing is not only a patent law institution, it is also a competition law sanction. I will account for compulsory licensing as a remedy for anti-competitive behaviour, but I will not make a thorough competition law analysis of the case at hand.

When treating the Swedish patent legislation, I will only consider the present patent law from 1967.

The law is stated as of June 30, 2004.

1.7 The state of the art

Compulsory patent licensing is for the most part mentioned in surveys on patent law. The institute is often accounted for but very seldom what purposes it serves. More interesting are the articles published on the subject, mostly in North American reviews and journals.

These are not numerous but can be said to have their origin in two different events. First, the internal debate as to whether the United States of America should introduce a general statutory compulsory licensing scheme.⁸ That is

³ Hans Henrik Lidgard: Hindrar Europeiska patent svensk cancerforskning?, Festschrift till Ulf Bernitz, Europarättslig Tidskrift, 2001, p. 105.

⁴ Ibidem p. 104.

⁵ Ibidem p. 114.

⁶ Ibidem pp. 119-121.

⁷ Ibidem pp. 117-119.

⁸ See e.g. Cole M. Fauver; *Compulsory patent licensing in the United States: an idea whose time has come*, 8 Nw. J. Int'l L. & Bus. 666 (1988), Mark W. Lauroesch; *General compulsory licensing in the United States: good in theory, but not necessary in practise*, 6 Santa Clara Computer & High Tech. L.J. 41 (1990-1991), Gianna Julian-Arnold; *International compulsory licensing: the rationales and the reality*, 33 IDEA: J.L. & Tech.

rules of compulsory licensing in the general patent law, United States Code Title 35 – Patents. The second source is comments on the developments in international law, lately the creation and interpretation of the WTO⁹ TRIPS agreement¹⁰ adopted in Marrakech in 1994.¹¹

Worth mentioning are also the numerous comments on the so-called Magill-case of the European Court of Justice.¹² This is a competition law case and concerns the duty to deal doctrine. The debate caused by this case treats compulsory licensing of patents as an competition law remedy. There is also an American debate on this subject, but it is outside the scope of this presentation.

Articles treating the Paris Convention are for the most part by European writers.¹³ They are informative and treat the law as it stands as for compulsory licensing of patents. Not having any general statute on compulsory licensing of patents, American authors take a stand either for or against compulsory licensing. For the most part are they rather hostile towards involuntary patent licensing. Many times they reflect the right holders' perspective in the domestic legislative debate or the development in the TRIPS and Doha negotiations.

However, what most American writers seems to have overlooked is that even though the American patent law does not contain any rules concerning compulsory licensing the American legal system does have other acts, doctrines and institutions that have the very same effect.

Furthermore, the rules of involuntary licensing in the TRIPS agreement, in which the United States of America is a participant, are to a very great extent modelled upon this countries own domestic experience.¹⁴

349, Alan M. Fisch; *Compulsory licensing of pharmaceutical patents: an unreasonable solution to an unfortunate problem*, 34 Jurimetrics J 295-315 (1994), Joseph A. Yosick; *Compulsory patent licensing for efficient use of inventions*, 5 Ill. L. Rev. 1275 (2001).

⁹ World Trade Organisation.

¹⁰ Trade Related Aspects of Intellectual Property Rights, Annex 1C of the WTO agreement.

¹¹ See e.g. Markus Nolff; Compulsory licensing in view of the WTO ministerial conference declaration on the TRIPS agreement and public health, 84 J. Pat & Trademark Off. Soc'y 133 and Sara M. Ford; *Compulsory licensing provisions under the TRIPS agreement: balancing pills and patents*, 15 AM. U. Int'l. L. Rev 941.

¹² Joined Cases C-241 and 242/91P, Radio Telefis Eireann (RTE) and Independent Television Publications Ltd. (ITP) v. Commission [1995] ECR I-743. See e.g. Thomas C. Vinje; *The final Word on Magill*; 6 EIPR 297 [1995] and John Temple Lang; *Defining legitimate competition: companies duties to supply competitors and access to essential facilities*, 18 Fordham Int'l L.J. 437.

¹³ See e.g. Klaus Pfanner; *Compulsory licensing of patents: survey and recent trends*, NIR vol. 54 1985 p. 1. For an article on the Swedish rules of compulsory patent see Berndt Godenhielm; *Tvångslicensbestämmelserna i 1967 års patentlag*, NIR 1979 p. 231.

¹⁴ See text accompanying footnotes 167-181.

2 Myriad Genetics v H. Olsson

2.1 Parties

2.1.1 Prof. Håkan Olsson

M.D. Håkan Olsson is a professor of oncology at the University of Lund, Sweden. The Department of Oncology is part of the Department of Medicine, within the Faculty of Medicine, Lund University Hospital. He is also the head physician and director of clinical research and medical studies.

The objective of Prof. Olsson's research is to find environmental and genetic risk factors in, amongst others, breast cancer patients. The genetic factors investigated include monogenic syndromes as BRCA1 and BRCA2. His research is based on his patients and the screening of their blood.

Both Lund University Hospital as a health care provider¹⁵ and Prof. Olsson¹⁶ being a consultant are obliged by law to give a patient individual information about available methods of examination, care and treatment. They are also obliged to inform the patient on the state of his or her health.

If Prof. Olsson, in his research, makes a scientific finding which is patentable, he alone can file for a patent and will be the proprietor of the patent right.¹⁷

2.1.2 Myriad Genetics, Inc.

Myriad Genetics, Inc. is a corporation in the state of Delaware having its principal business office in Salt Lake City, Utah (U.S.A.). It is a private entity focused on the discovery and commercialisation of genes involved in major common disorders, including cancer. Myriad Genetics was founded by the Harvard scientist Walter Gilbert together with Mark Skolnick from the University of Utah in the early 1990:s. Myriad genetics primary sells diagnostic and therapeutic services and products based on cancer related genes.¹⁸

¹⁵ 2b § Health and nursing law (1982:763) (Hälso- och SjukvårdsLAG (1982:763)).

¹⁶ 2 § chapter 2, Law (1998:531) about professional health care and nursing (Lag (1998:531) om yrkesverksamhet på hälso- och sjukvårdens område).

¹⁷ 1 § second passage Law (1949:345) about the right to employee's inventions (Lag (1949:345) om rätten till arbetstagares uppfinningar) *e contrario*.

¹⁸ www.myriad.com (last visited 2004-06-30).

Mark Skolnick was the first to clone the BRCA1 gene in 1994¹⁹. He patented the method of isolating and detecting the human breast and ovarian cancer predisposing gene BRCA1, a process now owned by Myriad Genetics. However, it was not a one-man job. The research behind this discovery was a co-operation between Myriad Genetics, the University of Utah (Salt Lake City, U.S.A.), McGill University (Montreal, Canada), Lilly Research Laboratories (Indianapolis, U.S.A.) and The National Institute of Environmental Health Sciences (Triangle Park, U.S.A.).

The project was also supported by grants from the National Institutes of Health (Bethesda, U.S.A.), the National Cancer Institute of Canada (Toronto, Canada), the Canadian Genetic Diseases Network (Vancouver, Canada) and the Cedars Cancer Institute of the Royal Victoria Hospital (Montreal, Canada).²⁰

In 1995, the researchers at Myriad also came out first in a very tight race for priority for the mapping of the BRCA2 gene. Myriad Genetics filed a patent application on the process to diagnose a predisposition to breast cancer through screening of the BRCA2 gene just one day before Mike Stratton and his team at the Institute of Cancer Research in Sutton, Surrey, had an article published in *Nature*²¹ on the exact same findings.²²

Mike Stratton and his researchers were part of the Human Genome Project (HGP) with the aim to map the whole human genome. The HGP was an international project started in 1990 and completed in 2003²³. It was funded by altruistic means, both private and public. Altruistic is used in the sense that the sponsors did not require property rights in the results in exchange for financial support.

Myriad Genetics has more than one patent in the knowledge surrounding the two BRCA genes. The company is the applicant and owner of four European patents in processes regarding the BRCA1²⁴ gene and one in the BRCA2 gene²⁵.

Mike Stratton and his team at Myriad Genetics are, however, not the only ones who have done research in this particular area and are not the only ones with property rights in this knowledge. Another American private

¹⁹ Miki Y, Swensen J, Shattuck-Eidens D, Futreal PA, Harshman K, Tavtigian S et al.; *A strong candidate for Breast and Ovarian Cancer Susceptibility Gene BRCA1*, *Science* 1994; 226 (5182): 66-71.

²⁰ Ibidem p. 71, note 52.

²¹ R. Wooster et al., “Identification of the breast cancer susceptibility gene BRCA2”, *Nature*, vol. 378, 1995, pp. 789-92.

²² Sulston, John, Ferry, Georgina; *The common thread*, Great Britain 2002, p. 141.

²³ See e.g. www.ornl.gov/sci/techresources/Human_Genome/project/50yr.shtml (last visited 2004-06-30) for more information about the HGP project.

²⁴ WO9927075 (EP19980960334) based on USPAT 6,030,832, EP0705903 (based on USPAT 5,693,473 and USPAT 5,709,999), EP0699754 and EP0705902 (the two latter based on USPAT 5,747,282, USPAT 5,753,441 and USPAT 5,710,001).

²⁵ EP0785216 (USPAT 5,837,492).

company, OncorMed, is applicant for another five European patents issued in processes relating to the two BRCA genes²⁶.

Myriad Genetics sued OncorMed for infringement of Myriad Genetics United States Patent No. 5,709,999.²⁷ The case was settled and gave Myriad Genetics an exclusive license to use OncorMed's BRCA 1&2 patents in exchange for undisclosed fees²⁸.

A rudimentary search in the patent database of the European Patent Office will produce no less than twenty-four (24) different applicants (Myriad Genetics and OncorMed included) divided among forty-four (44) different patents issued on processes related to the two BRCA genes.²⁹

In 1996 Myriad Genetics introduced the BRCAnalysis® genetic test for susceptibility to breast and ovarian cancer. Backed with its patent rights, Myriad Genetics is threatening to take legal action against any laboratory that is using either gene to carry out breast cancer screening.³⁰ All screening of the BRCA- genes for susceptibility to breast and ovarian cancer in the U.S.A. is today performed by or with approval from Myriad Genetics in exchange for a fee.

2.2 Draft agreement.

In September 1999, Myriad Genetics offered Lund University Hospital a license for the use of Myriad Genetics patented processes regarding the BRCA1 and 2 genes.³¹ The license grants the non-exclusive right to perform analysis of BRCA1 and BRCA2 for the purpose of determining breast and ovarian cancer risk by testing for a previously known mutation, within the territory of Sweden.

Even if the licensee is authorised to develop and sell testing services for the BRCA1&2 genes he is not allowed to perform a full sequence analysis of the two genes. That is a privilege Myriad Genetics reserves for itself.

Thus when an oncologist at the University Hospital of Lund is to determine whether a patient has cancer due to a mutation in either the BRCA1 or 2

²⁶ WO9915704 (BRCA1&2), WO9915701 (BRCA2), EP0994946 (BRCA2), WO9805677 (BRCA1), EP0820526 (BRCA1). Patent number WO9727560 might also be of relevance since it covers a method "of determining hereditary cancer patterns presenting in cancer family histories".

²⁷ US. Patent no. 5,709,999, Linked breast and ovarian cancer susceptibility gene. Press release 1/20/98, www.myriad.com (last visited 2004-06-30).

²⁸ Press release 5/18/98, www.myriad.com (last visited 2004-06-30).

²⁹ The search was conducted in the European Patent Office online patent database at www.espacenet.com, 2003-04-16. The search resulted from a request of patents mentioning "BRCA1" or "BRCA2" in their abstract, giving a total amount of forty-four (44) patents divided upon twenty-four (24) applicants. For the full list of patents and applicants, see supplement A.

³⁰ Sulston and Ferry, p.142.

³¹ Draft license agreement on file with the director of the Department of Oncology, Carsten Rose, Lund University Hospital.

gene, the oncologist can not perform that sequence analysis in Lund, but must send a blood specimen (or extracted DNA) to Myriad Genetics in Utah to have the analysis done there for him.

To obtain a license, Myriad Genetics first demands a down payment, a one time non-refundable sum of \$US 15,000.³² The royalty for each test performed is a minimum of \$US 50. This price includes screening of “a specimen from a single individual that detects up to a total of five known mutations”³³. A test from a single patient that “detects between a total of six and twenty known mutations”³⁴ costs \$US 150³⁵. Apart from the down payment the prices correspond to Lund University Hospitals internal costs for doing the screening themselves.³⁶

Myriad Genetics has guaranteed not to conduct any research on the specimens provided by the licensee.³⁷

Myriad Genetics charges no testing fees for non-commercial³⁸ research.³⁹ However, the company reserves the right to decide what constitutes non-commercial or basic research where testing services are to be performed of charge. In Article three (3.3) there is a non-exhaustive enumeration of factors to be considered by Myriad Genetics in such a decision.

These factors are;

- whether the tests are conducted pursuant to a research plan having a well defined hypothesis,
- whether the research plan and the results of the research are subject to peer review,
- whether the study is of limited duration,
- whether the tests are paid for by insurance or grants,
- whether the tests are conducted as part of the general health service of the country,
- the number of patients involved,
- whether the tests are conducted to determine the prevalence of mutations and
- whether the results of the tests are returned to the patient for clinical management.

Furthermore, the Draft Agreement obliges the licensee to communicate every improvement in the course of developing or selling testing services including any novel BRCA1 or BRCA2 mutation. If the licensee obtains a patent covering an improvement, the licensee shall grant Myriad Genetics, or its designee, a royalty-free, exclusive right and license to make, use and sell any improvement outside the territory of Sweden. If the licensee does

³² Draft Agreement, Article Three (3.1).

³³ Draft Agreement, Article Three (3.2).

³⁴ Ibidem.

³⁵ Ibidem.

³⁶ Interview with Prof. Håkan Olsson, 2002-09-24.

³⁷ Draft Agreement, Article Two (2.3).

³⁸ The agreement speaks of testing services” performed for *bona fide* research purposes”.

³⁹ Draft Agreement, Article Three (3.3).

not choose to apply for a patent for a patentable improvement the licensee shall according to the Draft Agreement, provide Myriad Genetics with such a possibility.⁴⁰

2.3 Conflict

In an article from 1999⁴¹ Prof. Olsson express great concern regarding the patentability and commercialisation of human genes. His objections to this development are mainly three.

First, patenting favours researchers performing the last step in cloning at the expense of the researchers publishing the findings which make the cloning possible.⁴²

Second, in order to be profitable, only common diseases will be aided by commercial gene-technology. Hospitals and universities will be left with research in the field of rarer diseases with less commercial potential.⁴³

Third, he sees the transparent research community as closing in upon itself in the fear of relinquishing news-damaging material in the quest for patents.⁴⁴

Prof. Olsson also points out a more far-fetched risk with sending blood samples abroad. The Swedish population is ethically fairly homogeneous. Therefore foreign countries can through studies of genetic polymorphism, in theory, create biochemical weapons aimed at the Swedish population.⁴⁵

As for his own institution, he is worried that Myriad Genetics exertion of their patent rights will damage the competence for routine screening and practices surrounding breast and ovarian cancer research. These practices have been established over a long period of time to the benefit of patients, financed with taxpayers money.⁴⁶

Employees at Myriad Genetics conduct research and publish their findings. Not surprisingly, Prof. Olsson regards Myriad Genetics as competitors for academic esteem. In order to be relieved of claims for royalties and be able to conduct his testing himself, Prof. Olsson must put his research on display for Myriad Genetics, something that he is not very keen on doing.⁴⁷

⁴⁰ Draft Agreement, Article Two (2.2) and Article Six (6.1).

⁴¹ Håkan Olsson; *Kommersialiseringen av gener – patent på bröstcansergener pilotfall*, 96 Läkartidningen 37, p. 3920, 1999 (Olsson 1999). An English version of this article can be found in Lundin, S., Åkesson, L. (eds.) ; *Gene Technology and Economy*, p. 42-51, Malmö, 2002 (Olsson 2002).

⁴² Olsson (1999) p. 3920 and Olsson (2002) p. 44.

⁴³ Olsson (1999) p. 3921 and Olsson (2002) p. 44.

⁴⁴ Ibidem.

⁴⁵ Olsson (1999) p. 3923 and Olsson (2002) p. 46-47. This objection to Myriad Genetics claims or its patents will not be explored further. As Prof. Olsson says himself, it is a far-fetched possibility and there are other rules both in and outside the Swedish patent law treating warfare patents, namely 48 § patentlagen (1967:837) and Law (1971:1078) about defence inventions (Lag (1971:1078) om försvarsuppförningar).

⁴⁶ Interview with Prof. Håkan Olsson, 2002-09-24.

⁴⁷ Ibidem.

Furthermore, even if Prof. Olsson chooses to keep his research to himself, he is reluctant to send away high-risk blood and pay for a job he is capable of doing himself.⁴⁸

A promise not to conduct research on the specimens is inadequate in the face of his helping a commercial entity to build up a blood bank at his own expense, not only financially but potentially also academically. There is no way to control whether Myriad lives up to its promise or not.⁴⁹

Also, Swedish rules on research ethics demand that the patient is entitled to see the results of a test which might make all testing in Lund, royalty-based, clinical testing in the meaning of the Draft Agreement, article 3.3.⁵⁰

Finally, Prof. Olsson strongly disapproves of the fact that Myriad Genetics does not only exercise its sole right to its current patents but also demands the commercialisation of future improvements made by him and his colleagues in the technology at hand.⁵¹

Prof. Olsson suggests compulsory patent licensing as the solution to his problems⁵². This way screening would be kept on a national level and his own research under his own control. In his English article he mentions Myriad Genetics patent EP0705903⁵³. It is a method patent⁵⁴ and the personnel at the Department of Oncology in Lund possess the know-how to exploit it.

Myriad Genetics holds three other patents valid in Sweden on methods regarding the BRCA1 gene⁵⁵ and one regarding the BRCA2 gene⁵⁶. The patent mentioned in Håkan Olsson's article and EP07059902 are being subjected to an opposition procedure at the European Patent Office initiated by a number of non-profit making organisations⁵⁷.

⁴⁸ Olsson (1999) p. 3923 and Olsson (2002) p. 49.

⁴⁹ Olsson (1999) p. 3921 and Olsson (2002) p. 46.

⁵⁰ Interview with Prof. Håkan Olsson, 2002-09-24.

⁵¹ Interview with Prof. Håkan Olsson, 2002-09-24. Draft Agreement, Article Two (2.2) and Article Six (6.1).

⁵² Olsson (1999) p. 3923 and Olsson (2002) p. 48 .

⁵³ EP0705903 “In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene”. Olsson 2002.

⁵⁴ The abstract speaks of an invention that “relates to methods and materials used to isolate and detect a human breast and ovarian cancer gene BRCA1, some mutant alleles of which cause susceptibility to cancer, in particular breast and ovarian cancer. More specifically, the invention relates to germline mutations in the BRCA1 gene and their use in the diagnosis of predisposition to breast and ovarian cancer. The present invention further relates to somatic mutations in the BRCA1 gene in human breast and ovarian cancer and their use in the diagnosis and prognosis of human breast and ovarian cancer.”

⁵⁵ EP0705902, EP0699754 and WO9927075

⁵⁶ EP0785216

⁵⁷ Bundesministerium für Soziale Sicherheit und Generationen, (AT) (EP0705902); Belgian Society of Human Genetics, Genetic Dpt. Hopital Erasme – IJLB (BE) (EP0705902); Sozialdemokratische Partei der Schweiz (CH) (EP0705902); Greenpeace (CH) (EP0705902); Greenpeace (DE) (EP0705903); Institut Curie (FR) (EP0705903 and EP0705902); Assistance publique-hopital de Paris (FR) (EP0705903 and EP0705902); Institut Gustave Roussy-Igr (FR) (EP0705903 and EP0705902); De Staat der Nederlanden Minister van Volksgezondheid (NL) (EP0705903, EP0705902); Vereniging van Stichtingen Klinische Genetica (NL) (EP0705903).

3 Congruency and conflicts between the functions of the patent system and the norms of science⁵⁸

3.1 Norms of Science

Sociologist Robert K. Merton has in his writings⁵⁹ identified the norms and incentives that guide the behaviour of scientists. Merton suggests that “the institutional goal if science is the extension of certified knowledge”⁶⁰. This is a goal reached through empirical research. He also presents four interrelated norms which support both the end and the means of science; “universalism”, “communism”, “disinterestedness” and “organised scepticism”.

Universalism means that the veracity of a scientific finding is to be judged with objective criteria. Who made the finding or where it was made should not be taken into consideration when evaluating a scientific finding.⁶¹

The norm of “Communism” concerns the cumulative aspects of research. Scientists collaborate and they build upon what others have found before them. Today’s scientists draw on previous learning. Present discoveries will be used by and should be dedicated to the research community as a whole.⁶² Disinterestedness refers to the fact that scientific claims should be based on empirical truth. The role of a scientist is to advance knowledge, therefore he should not present false claims in order to enhance deviating personal preferences or goals.⁶³

Organised scepticism means that nothing should be regarded as true unless it has been subjected to empirical scrutiny.⁶⁴

A number of the parties above also opposed to Myriad Genetics patent EP0699754 (Method for diagnosing a predisposition for breast and ovarian cancer[1996/10]). This latter patent was revoked on 18 May 2004, see http://www.european-patent-office.org/news/pressrel/2004_05_18_e.htm (last visited 2004-06-30).

⁵⁸ This section draws heavily upon Rebecca S. Eisenberg’s article; *Proprietary rights and the norms of science in biotechnology research*, 97 Yale L.J. 177.

⁵⁹ His most influential articles have been re published in “*The sociology of science*.” Edited by Norman W. Storer, 1973 Chicago.

⁶⁰ Robert K Merton; *The normative structure of science* in *The sociology of science*, Ibidem p. 270.

⁶¹ Ibidem p. 270-273.

⁶² Ibidem p. 273-275.

⁶³ Ibidem p. 275-277.

⁶⁴ Ibidem p. 277-278.

The reward structure of science fortifies these norms. The gaining of esteem for originality on the part of colleges is the premium of every scientist. The institutional goal of science is the advancement of knowledge. Knowledge advances through original contribution. Original contributions to the common stock of knowledge are rewarded with professional recognition.⁶⁵ No one deserves the esteem of his peers unless his findings have survived the organised scepticism of his colleges. The norm of disinterestedness is thus enforced through the ambition to be recognised for originality. However, in order to be recognised, one has to submit one's findings to the scrutiny of others and do it before someone else beats you to it. The quest for originality also reinforces the norm of Community.⁶⁶

3.2 Patent Law

A patent is a legal right issued by a government to an inventor for a fixed number of years⁶⁷. The patent is issued for an invention. An invention is an idea that solves a certain problem.⁶⁸ The patent right is exclusive and the proprietor⁶⁹ can exclude anyone else from making, selling or using⁷⁰ the patented invention during the patent period.

The patent system is highly formalistic and the patent right is obtained through application. The application must meet a number of formal and material standards. Among other things, it must contain a description of the invention.⁷¹ The scope of the protection sought must be defined in certain claims⁷² and the application must hold a summary of the invention⁷³. All this is so that the subject matter of the sole right is accessible to "a person skilled in the art",⁷⁴.

⁶⁵ Robert K. Merton; *Priorities in scientific discovery* in *The sociology of science*, supra note 31 at p. 293.

⁶⁶ Robert K. Merton; *Behaviour patterns of scientists* in *The sociology of science*, supra note 31 at p. 332.

⁶⁷ Article 33, the TRIPS agreement stipulates that the patent term "shall not end before the expiration of a period of twenty years counted from the filing date." Twenty years is now a widely accepted patent term. COM (2000) 412 final, Article 27. 1.a and 4 chapter 40 § patentlagen (1967:837).

⁶⁸ Not all inventions are inventions from a patent law perspective. Discoveries, scientific theories and mathematical methods, aesthetic creations, schemes, rules and methods for performing mental acts, playing games or doing business, presentations of information, methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are non-patentable inventions. EPC, Article 52 and 1 chapter 1 § second passage, point 1-4 patentlagen (1967:837).

⁶⁹ A patent is applied for and granted to the inventor/s or someone assigned by the inventor, EPC, Article 60, 17, 43 §§ PL. There exist specific rules if the inventor is an employee. EPC, Article 60 and Law (1949:345) about the right to employee's inventions (Lag (1949:345) om rätten till arbetstagares uppfinningar.).

⁷⁰EPC, Article 64 and 1 chapter 3 § patentlagen (1967:837).

⁷¹EPC Article 78 (b) and 2 chapter 8 § second passage patentlagen (1967:837).

⁷²EPC, Article 78 (c) and Article 84. 2 chapter 8 § second passage patentlagen (1967:837).

⁷³EPC, Article 78 (e) and Article 85. 2 chapter 8§ third passage patentlagen (1967:837).

⁷⁴EPC, Article 83 and 2 chapter 8 § second passage patentlagen (1967:837).

In order to obtain a patent the invention must be new⁷⁵, industrially applicable and involve an inventive step.⁷⁶ It must also fall within the patentable subject matter.⁷⁷

What falls within the patentable subject matter is subject to the will of the legislator, the demand of the inventive community⁷⁸ and the practice of the patent office. The patent office operates through legal doctrine in its administrative process⁷⁹. It applies general patent law and is guided by administrative rules and international patent tradition⁸⁰.

General patent law is adopted in a fairly broad language to be interpreted on a case-by-case basis. Specific laws treating certain patentable subject matters are more of a way to adjust administrative or legal outcomes to political ambitions or a new technological development.

The patent application is made public eighteen months after it is filed in order for third parties to oppose the protection claimed.⁸¹ When the patent is granted it is published in specific patent registers open to the public.⁸²

Once issued the patent confers a property right. The patentee can explore it exclusively, transfer it as a whole or license it in part for a royalty.⁸³ It is thus up to the patentee to decide which suits him best.

When the patent has expired, anyone can not only learn what the innovator has accomplished but also make use of it freely.

3.3 Summary

Patent law and scientific norms are to some extent congruent with one and another. They both encourage priority of innovation and dissemination of new discoveries. The scientist publishes promptly in order to gain recognition for his original claim. In his article the scientist must argue for his claim so that he can be rendered both priority and originality in the sceptical eyes of the scientific community.

The patent applicant must in a description show that he has developed a new, useful invention in order to be granted a patent by the Patent and

⁷⁵EPO, Article 52 (1) and Article 54 and 1 chapter 2 § 1st passage patentlagen (1967:837).

⁷⁶EPO, Article 52 (1) and Article 57. 1 chapter 1 § 1st passage patentlagen (1967:837).

⁷⁷EPO, Article 52 (1) and Article 56. 1 chapter 2 § 1st passage patentlagen (1967:837).

⁷⁸Nelson, Richard R.; "An evolutionary theory of economic change", Harvard University Press 1982, p. 393.

⁷⁹Dam, Kenneth W; *The economic underpinnings of patent law*, Journal of Legal Studies, vol. 23, January 1994 p. 248.

⁸⁰Koktvedgaard, Mogens, Levin, Marianne; *Lärobok i immaterialrätt*, Uppлага 6:1, Stockholm 2000, p. 181.

⁸¹EPC Article 93 and 99. 2 chapter 22 and 24 §§ 2nd passage patentlagen (1967:837).

⁸²EPC, Article 127 and 1 chapter 22 § first passage patentlagen (1967:837).

⁸³EPC, 4th chapter IV, Articles 71-74 and 43-44 §§ patentlagen (1967:837).

Trademark Office. The patent application is made public 18 months after the application has been made⁸⁴.

The eighteen month delay shows that there are some differences in the timing of when the disclosure was made.

A scientist motivated by collegial esteem may publish earlier than a scientist filing for a patent. An article describing a finding to the peers of the author is very likely to be damaging in the patent application process and thus preclude a patent. The patent applicant does therefore not publish his discoveries until after the patent application has been filed. However, a scientific, recognisable, discovery may very well need further experimentation before it is a patentable innovation.⁸⁵

Therefore the gap may be greater than eighteen months between a publication motivated by the norms of science and an article by a scientist with the ambition to patent his discoveries.

The real clash between the two systems lies in the effect of publication. Until publication both the scientist and the patent applicant keep their projects secret. However, when the scientist publishes, the knowledge is no longer exclusive to him. It is dedicated to the scientific community, free for anyone to use and build upon.

But the exclusivity held by the patenting scientist survives public disclosure through the issuance of a patent for a maximum of another twenty years. The latter might be able to collect the rewards of both the scientific structure and the intellectual property system, not only for his present achievement but for subsequent research as well.

With a patent, a scientist can let others use the protected knowledge free or for a royalty, on a exclusive or non-exclusive basis. But he can also prevent anyone else from using his patented findings.

He might not use it himself, so-called patent suppression, or he could use it exclusively. With one or several patents, a scientist can disrupt ongoing and future concurring research projects and might be able to preserve future claims of priority and originality for himself.

⁸⁴ 2 chapter 22 § patentlagen (1967:837).

⁸⁵ Eisenberg p. 216.

4 Patent theory

4.1 The Theories

In striving to establish the purpose of the patent right, I will turn to the theories on intellectual property. There exist many theories on intellectual property in general. The theories on patents are fewer, but are still numerous.

One way to sort the theories on intellectual property is by analysing the ends they try to fulfil. Four different purposes can be distinguished; (1) the natural law duty of a state to respect and protect man's natural right to the fruits of his labour, (2) the utilitarian maximisation of net social welfare, (3) the satisfaction of fundamental human needs and (4) the achievement of a just and attractive culture.⁸⁶

The theories on patents are commonly presented in the chronological order in which they appear in the patent polemic⁸⁷. The most accounted for can be classified among the first two groups of theories of intellectual property mentioned above.

The only one from the labour theory group of theories that still purports some actuality is The Reward Theory⁸⁸, probably because of its sensitivity to economic interpretations. It is the only non-utilitarian theory described here.

4.1.1.1 The Reward Theory

A basic premise in The Reward Theory is that if man renders society a service, justice requires society to compensate him accordingly. Society is therefore morally obligated to reward its inventors in proportion to the usefulness of their inventions to society. Commensurate awards are thought to be effected through the exclusive, monopoly-like, patent rights of their inventions⁸⁹.

4.1.1.2 Patent-Induced Theory

The “monopoly-profit-incentive” thesis supposes that inventions will not be sufficiently commercialised if inventors or /and investors only can expect the profits of a competitive market. Profit expectations are increased through the possibility of monopoly pricing. Patent grants are therefore the

⁸⁶ Fisher, William; *Theories of Intellectual Property*, in New essays in the legal and political theory of property (Munzer, S., ed.), Cambridge, 2001.

⁸⁷ See Machlup, pp. 20-25, Penrose, pp. 19-42 and Oddi, pp 273-284.

⁸⁸ The Reward Theory can be distinguished into two separate theories, the Reward for Services Rendered Theory and the Reward by Monopoly Theory, see Oddi, A. Samuel; *Un-unified economic theories of patents, the not quite holy grail*, 71 Notre Dame L. Rev.267.

⁸⁹ Machlup, p. 21.

most efficient way to stimulate the industrial exploitation of technical knowledge, all for the benefit of economic progress.⁹⁰

It has been argued, as a consequence, that only those inventions induced by the patent system ought to deserve its protection. If the invention was not directly motivated by a future granting of a patent, a patent should not be rewarded with such.

This line of argument, also called “the Patent-Induced Theory”, would prohibit patent protection for inventions which sees the light of day due to for instance market demand, scientific curiosity or by chance. Two authors of the Patent induced theory are Edmund W. Kitch⁹¹ and Frederic M. Scherer⁹².

F.M. Scherer distinguishes between three types of inventions. Firstly inventions with high social benefit at a low entrepreneurial cost and therefore higher profits. Secondly, inventions with low social benefit, introduced at a high cost and lastly those inventions with an uncertain social benefit and an uncertain cost to the entrepreneur. According to Scherer only the latter two would deserve patent protection.

The first category of inventions will reach the consumer anyway because of the striving to stay ahead of competition. The investors will appropriate their investments due to lead-time, learning curve advantages and market recognition.⁹³

The second group of inventions is regarded as detail development in a highly competitive climate. Here the fierce market conditions eat up the first mover advantages before the cost of invention is recuperated. The patent protection is needed to stall copying by competitors and to induce the investment necessary for further innovation.⁹⁴

The last type of inventions identified by Scherer are revolutionary in kind. They cause thorough changes in consumption or production. They constitute a high-risk investment and are therefore considered to be dependent on the patent system if not seriously delayed or disregarded.⁹⁵

4.1.1.3 Prospect Theory

The Prospect Theory is an analogy to the US mineral claims system presented by Edmund W. Kitch. In his article from 1977⁹⁶ he argues that a patent right should be treated as any other property right. His aim with the analogy is to show that the patent system can be used to make technology

⁹⁰ Machlup p. 21.

⁹¹ Kitch, Edmund W. ; *Graham v. John Deere Co.: New standards for patents*, the Journal of the Patent Office Society.

⁹² Frederic M. Scherer; *Industrial market structure and economic performance*, 2nd Edition. 1980, pp 447-448.

⁹³ Ibidem p 447.

⁹⁴ Ibidem p 448.

⁹⁵ Ibidem p 448.

⁹⁶ Kitch, Edmund W.; *The Nature and Function of the Patent System*, The Journal of Law and Economics, Vol. XX (1), April 1977. Cited as Kitch (1977).

development more efficient. The analogy is made in a very specific context. Kitch compares the advantages with the patent system complementing trade secret protection over a system with trade secret protection only for technological information. To reduce the total cost of innovation, the Prospect Theory promotes broad patent claims and a generous novelty test. The advantages of the patent system complementing trade secret protection over a system with trade secret protection are thus primarily six.

With a broad patent grant the patentee can maintain control over the development of the invention. If the patentee can co-ordinate the search for improvements, duplicative investments will be avoided.⁹⁷

In a world with trade secret protection only, the incentive to invest in information is easily appropriated by competitors. Without the bundle of rights known as patents it is cheaper to bag a free ride on someone else's efforts to identify a market and educate potential consumers in a new technology.⁹⁸

Patents minimise transaction costs. If the information is protected though public it will not lose its value when displayed to prospective users. Patents facilitate know how and trade secret licensing and render development of inventions more efficient.⁹⁹

In a world where technology is kept secret in fear of competitive free riding, it is plausible that money is invested in finding something that someone else already has the answer to. If a patent is awarded, the technology is not only protected but also signalled to the world. Duplicative investments in inventing the wheel twice are reduced and¹⁰⁰ resources spent on secrecy are saved.¹⁰¹

Finally, a patent system is less discriminatory regarding for the type of invention protected. Processes can be kept from competitors without patent rights. Products displaying the inventive solution are harder to protect with trade secret protection only. With a patent system complementing trade secret protection the patents and processes are on a more equal footing when it comes to incentive and profitability.¹⁰²

⁹⁷ Kitch (1977) p. 276.

⁹⁸ Ibidem p. 276-277.

⁹⁹ Ibidem p. 277-288.

¹⁰⁰ Ibidem p. 278-279.

¹⁰¹ Ibidem p. 279.

¹⁰² Ibidem p. 279.

4.1.1.4 Race-to-Invent Theory

In an article from 1990 Robert P. Merges and Richard R. Nelson¹⁰³ argue that economic growth and society as a whole will benefit more from a rapid pace of invention and innovation than the avoidance of duplicative research and development.¹⁰⁴ They reject that development co-ordinated by a single firm is better than competitive development.¹⁰⁵ They also object to the one firm domination through broad patent grants suggested by the Prospect Theory.¹⁰⁶

Empirical studies have led them to the conclusion that different fields of technology do not develop at the same pace. After having presented four models¹⁰⁷ of technological invention they argue that broad patents would hamper development within these models.

In order to live up to the notion that “faster is better”,¹⁰⁸ they propose narrow patent grants or at least industry adjusted patent breadths. With their focus on the incentives for a fast development, Merges and Nelson wish to increase the bargaining power of the follow on inventor vis-à-vis the initial inventor.¹⁰⁹ If the patent scope doesn’t exceed the scope of the invention, inventors will not refrain from developing existing technology in fear of being sued for patent infringement.¹¹⁰

4.1.1.5 Rent Dissipation Theory

A highly theoretical for how the authorities could limit wasting resources in the hunt for patent protection was presented by Mark F. Grady and Jay I. Alexander in 1992¹¹¹. According to Jay and Alexander society benefits from innovation as long as the cost of an innovation is less than its total value to society. The difference between the macroeconomic benefit and the microeconomic cost of development is called “a rent”. The patent right, offered as a reward to the innovator, enables the innovator to reap the difference between the society surplus and his costs of development.

However, the barrier to imitation offered by the patent right might induce several players to take part in the race for the patent reward: a race with only one winning patentee. The accumulated investment by the multiple competitors may be greater than the value of the innovation to society. The

¹⁰³ Merges, Robert P., Nelson, Richard R.; *On the Complex Economics of Patent Scope*, 90 Colum. L. Rev. 839.

¹⁰⁴ Ibidem p. 878.

¹⁰⁵ Ibidem p. 872.

¹⁰⁶ Ibidem pp. 871-872.

¹⁰⁷ “Discrete invention”, “cumulative invention”, “chemical technologies” and “science-based technologies”, Ibidem pp. 880-885.

¹⁰⁸ Ibidem p. 878.

¹⁰⁹ Ibidem p. 876.

¹¹⁰ Ibidem p. 916.

¹¹¹ Grady, Mark F., Alexander, Jay F.; *Patent Law and Rent Dissipation*, 78 Va. L. Rev. 305.

rent is dissipated by redundant investment in the innovation and the price charged for the final product, shielded by the patent right, becomes a cost to society.¹¹²

Three potential sources of rent dissipation are identified by the authors. First is the search for a pioneering invention. The broader patents awarded, the more competition for the solution protected. Second, in the race for an improvement, if the original technology “signals” follow-on improvements it might cause redundant investment in the search for modifications. The third is the waste from keeping inventions secret instead of disseminating them through the patent system.¹¹³

The rent dissipation theory predicts that only inventions of comparatively small value, signalling a large potential for improvement, will receive patent protection.¹¹⁴ Inventions with little potential improvement will not receive any patent protection because it does not prevent any race for development and patents granted to socially highly valued innovation would cause redundant investment at the conception stage.

Nor would highly valuable inventions not signalling any improvement possibilities receive any patent protection. These would only increase the race for the original patent and there is no improvement to motivate the rent dissipation in the initial race.¹¹⁵

Also the courts are assumed to uphold patents so that the total cost of development, both for the fundamental technology and the second-generation solution, does not exceed their value to society.¹¹⁶

4.1.1.6 Economic Theory

Information can be characterised as a public good. A public good has two special features. First, it can be consumed by one person without leaving anything less for any other consumer. Second, private profit-motivated firms are reluctant to supply the goods because it costs too much to prevent non-paying consumers to benefit from it.¹¹⁷

When private investors won't finance potential information, the government, according to the theory of information economics, can intervene in three different ways in order to stimulate inventive activity;

- 1) the state itself, instead of private actors, produces the information,
- 2) the government subsidises private actors for the production of information, or

¹¹² Ibidem p. 308.

¹¹³ Ibidem pp. 308-309 and p. 342.

¹¹⁴ Ibidem p. 320.

¹¹⁵ Ibidem p. 321.

¹¹⁶ Ibidem p. 321.

¹¹⁷ Cooter, Robert, Ulen, Thomas; *Law and Economics*, 3rd ed., USA 2000, p. 42.

3) the state creates and protects property rights in information.¹¹⁸

Invention in itself is uninteresting for a private firm unless it generates a profit. Invention is only the first step in a sometimes very lengthy process towards creating a profit-generating product¹¹⁹. The process of turning a invention into a demanded product is called innovation.

Innovation, as proposed by Joseph A. Schumpeter, consists of five functions; invention, entrepreneurship, development, investment and diffusion. Invention corresponds to the layman's definition. It is when a new technology or solution to a problem is revealed through insight. Development is the very often demanding testing and modelling of the idea, which results in a marketable product or process. Entrepreneurship is the decision-making that pushes the project forward; the financial solutions, the co-ordination of the venture and the identification and working of the market all need to be decided upon.

All these steps are cost generating and an investor is needed to risk the funds to keep the project alive until the marketed product starts generating a profit. The same person or entity can do these activities, but not necessarily. The last step, the diffusion, is when the product is placed on the market and imitated by other producers who aim at taking as large share of the market for the particular innovation as possible.¹²⁰

The lapse between the first commercial introduction of the product by the first firm, and the first commercial transaction involving the imitated product is called the first firm's lead-time. A product can generate the most profit during the lead-time when it faces no competition. The product must generate at least as much profit to cover the costs of the former steps in order to be considered a success.

If the research and development is very expensive and will result in a product that is very easily imitated, the project will be halted. The risk that the product will not generate as much profit to cover the investment is too high. Copying must be curtailed if the invention isn't to be subsidised by public funds.

A patent is a governmentally sanctioned lead-time which allows the innovator to set a price above the marginal cost of production and earn the economic rent¹²¹ to recoup his costs of innovation.

The consumer is charged a price above the price of production. However, a new product has reached the consumer due to the decreased risk of expensive research and development.¹²²

Information being something of a public good, it is, without public subsidy or property protection, prone to overuse in a "tragedy of the commons".¹²³

¹¹⁸ Ibidem p. 126.

¹¹⁹ The reasoning also concerns processes.

¹²⁰ Schumpeter, Joseph A.; *The theory of economic development*, USA 2002, pp 57-94.

¹²¹ Dam p. 250.

¹²² Scherer, Frederic M., *Industrial Market Structure and economic performance*, p.624.

Too many have the privilege of using a resource and none has the right to exclude another. Harshly put, if information is free, it will not generate a profit. If it does not generate a profit, it will not be privately produced.¹²⁴

Privatisation of commonly held resources is, however, a double-edged sword. Just as property rights can prevent overuse of a resource, too many property rights lead to underuse in a “tragedy of the anticommons”¹²⁵. An “anticommons” is a resource covered by a large number of individual exclusionary rights and none of the proprietors has an effective privilege of use. The resource is never exploited because the unanimous consent that is necessary is never reached.¹²⁶

4.2 Summary

The only theory that stands out is the Reward Theory. It has a slightly different perspective than the others. It is based on natural law theory. But does not contradict the public policy based theories. The Reward Theory, just as the Race to Invent Theory, focuses on the inventor and the invention whereas the other theories focus on innovation. But the inventor is dependent on market penetration and commercial success if he is to receive any reward at all. So in a sense the Reward Theory presupposes what the economic theories emphasise. The time perspective is what really distinguishes the Reward Theory from the others. The Reward Theory is retrospective, the patent is a remuneration for a problem solved. The other theories presented here treat the patent as an incentive for invention, in other words they are forward looking.

Kitch, Scherer, Merges, Nelson, Jay and Alexander all try to optimise the patterns of innovation.

As for the Patent-induced Theory it tries to distinguish what ought to be protected. It is true that if only those inventions spurred by the patent system were protected by it, society would gain marginally by this. However, neither the cost nor the reason behind an invention is regarded in the patentability examination.

Moreover, just because the initial idea was cheap, it does not mean that the market introduction comes free of charge or that competitors will refrain from duplication.

¹²³ The expression first used in Hardin, Garrett; *The Tradgedy of the Commons*, Science, Vol. 162, 13 December 1968, p. 1243.

¹²⁴ However, one must bare in mind that public funds or patent protection are not the only spurs to development of new information. The competition for the favour of the consumer is another non-negligible source of new information, just as altruistic motives. It is more fair to say that without patents, private production of new information will be sub-optimal.

¹²⁵ Michael A. Heller, Rebecca S. Eisenberg, *Can patents deter innovation? The anticommons in biomedical research*, Science, Vol. 280, 1 May 1998, p. 698.

¹²⁶ Ibidem p.698.

Edmund W. Kitch has clearly dissociated himself from The Patent-Induced Theory with the proposal of the Prospect Theory¹²⁷.

The one theory that borrows most from pure economic reasoning is the Prospect Theory. This theory tries to show the advantages of having patent protection over a system with only trade secret protection for technological innovation. What distinguishes it from the other theories presented is that it deliberately gives the first right-holder a very strong position vis-à-vis subsequent inventors. Due to the liberal standard for novelty and the favouring of broad patents the original inventor is given control not only for present innovation, but also for future innovation in the same line of technology.

Merges/Nelson and Jay/Alexander also try to render technological development more efficient and their theories are very much a response to the Prospect Theory. Merges and Nelson argue that society would benefit more from a technological change that was time-efficient rather than cost-effective. Broad patent scope across industries, as proposed by Kitch, is therefore not preferable. The conclusion of the Rent Dissipation Theory is that the question of patent breadth should be decided so that the cost of rivalry for the sole right to the invention does not exceed the innovation's benefits to society.

The main purpose of the patent right according to economic theory and the lowest common denominator of the legal theories presented, is the hindering of competitive free riding. The exclusivity of the patent right is the stimulus necessary for optimal private investment in technological development. It is the force of this exclusivity which is debated among legal scholars

The right to exclude will therefore be treated as the main purpose of patent law.

¹²⁷ Kitch (1977) Section IV, pp. 280-284.

5 What is a Compulsory License?

The first definition of compulsory patent licensing laid down in an international convention can be found in Art. 31 of the TRIPS agreement. It speaks of “use of the subject matter of a patent without authorization of the right holder, including use by the government or third parties authorized by the government”. This is the broader meaning of compulsory licensing and it covers any use where statute or customary law imposes third party use upon the patentee. This would include royalty free licensing pursuant to competition authority decrees, royalty bearing, non-discriminatory licensing as a judicially imposed remedy for violations of competition laws, implied licenses and the denial of injunctive relief and the award of damages in infringement actions¹²⁸¹²⁹.

The usual and stricter meaning of compulsory licensing refers to the right of governments, established in the national patent law, “to compel the transfer, from the patent holder to a third party of some or all of the patent holder’s rights”¹³⁰ to the patented subject matter. There are therefore three parties to a compulsory license; a government agency, the patentee and the beneficiary of the compulsory license. To offer compulsory licenses is a state right which comes with an legislative obligation to compensate the patentee for involuntary use. Basically this means “altering the exclusive right to use the invention to a right to receive royalties for its use”¹³¹.

5.1 History

If one takes the early European patent privileges into consideration, it is fair to say that compulsory patent licensing is a relatively recent institution. It was created in opposition towards the sole sanction against patent suppression, revocation.

In the beginning patents were royal or state privileges granted to individuals in medieval Europe; privileges that gave the grantee the exclusive right to

¹²⁸ Something that would include U.S. doctrines of Reverse Equivalents (Merges, Robert; *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 Tenn. L. Rev. 75) and the doctrine of Patent Misuse (James B. Kobak, Jr., *The New Patent Misuse Law*, 71 J. PAT. & TRADEMARK OFF. SOC’Y 859, (1989)).

¹²⁹ Dratler Jr., Jay; *Licensing of Intellectual Property*, New York 2003, § 3.03, p. 3-22.

¹³⁰ Halewood, Michael; *Regulating Patent Holders: Local Working Requirements and Compulsory Licensing at International Law*, Osgoode Hall Law Journal, Vol 35, No. 2, p. 260.

¹³¹ Penrose Edith T.; *The economics of the International Patent System*, Baltimore, 1951 p. 162.

exercise a trade, sell a product or use a process. These exclusive privileges were granted to attract foreign craftsmen to practise their skills within a city-state or kingdom. The patent privileges were not only granted but also revoked at the will of the sovereign.

The first known patent legislation, the Venetian Patent Act of 1474, stipulated that the patent had to be used actively, if not, it would be cancelled by the Venetian State. Utility, novelty and production with the use of the patented solution was important in Venetian patent law and in subsequent German patent laws of the 16th century. In England the royal patents were not only a way of introducing new arts from abroad, but also a way for the regents to control industry in the growing empire. As a revolt against the despotic practices of Elizabeth I and James I, the power to issue patent was taken away from the royal prerogative and legislated upon in the Statute of Monopolies of 1623. The English statute as well as the first French patent law of 1791 adopted the royal obligation to exploit in the face of revocation.

Also the American patent law of 1790 used the patent system to support the import of foreign technology with a national novelty standard for “import patents”.¹³²

One of the main purposes of the patent systems up until the 17th century was the encouragement of national trade.¹³³ The sovereigns and states wished to take part in the development abroad. Patents with an obligation to exploit the privilege were a way to attract technicians, skilled labour and to develop the natural resources of the jurisdiction. The issue was never one of “right of inventors” but of industrial development.¹³⁴

With the industrial development of the 17th century grew the fear of patent suppression by foreign patent holders. The excess productivity increased the interest for export of nationally produced goods. The competition on the export market could be reduced through patenting and the demand satisfied through imports. No government wanted to see its own state turn into another state’s export market at the expense of its own domestic industry. On the other hand, it was not economically sound for any industry, no matter what nationality, to establish a production site in every jurisdiction. The opposition to compulsory working grew with industrial development. Cancelling of the patent was considered too harsh for non-working. Compulsory licensing was introduced as a middle course between the abolition of non-working and revocation of the patent grant for patent suppression.

The first statutory evidence of compulsory patent licensing is the South Carolina Patent Act of 1784 which provided for compulsory licensing in

¹³² Michael Halewood; *Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law*, Osgoode Hall Law Journal, Vol. 35 No. 2 (1997), p. 251.

¹³³ Penrose p. 6.

¹³⁴ Ibidem p. 138.

cases of suppression of inventions.¹³⁵ In 1790 The House of Representatives of the United States of America refused a Senate proposal of compulsory patent licensing amendment to the first federal patent law issued earlier that year.¹³⁶

The first international conference on patents was held in Vienna in 1873. It was unofficial but attended by representatives from 13 countries. The Conference, with the United States of America in the lead, declared its disapproval of compulsory working requirements¹³⁷ and in the first draft to the PC, the conference recommended compulsory licensing of patents “in cases in which the public interest should require it”.¹³⁸ The recommendation did not make it to the final draft which entered into force on July 7, 1884. Compulsory working was established at an international level and so was forfeiture as the only sanction for patent suppression; an order which was retained until 1925.¹³⁹

At a national level, compulsory licensing of patents was still rare but provided for more often. In 1910, four countries made provision for compulsory licensing instead of revocation of the patent for failure to work. Five other nations did the same thing for other reasons.¹⁴⁰

At the conference in The Hague the participants could finally agree on replacing revocation with compulsory licensing as the principal remedy against patent suppression. Non-working was, however, only three (3) votes away from being entirely abolished, but the persistence of Japan, Poland and Yugoslavia kept it alive.¹⁴¹ The United States of America, which had tried to erase the patent exploitation requirement ever since the first conference in 1873 and was against compulsory licensing saw, it as “a step in the required direction”.¹⁴²

Today the United States of America is one of the few industrialised countries which have not adopted a general compulsory licensing regime in its patent law.¹⁴³ Most other members of the Paris Convention have at least a rule modelled upon Article 5 A.

¹³⁵ Machlup p. 5 footnote 21.

¹³⁶ Penrose pp. 165-166.

¹³⁷ Penrose p. 167.

¹³⁸ Edith T. Penrose cites the following paragraph in, *The economics of the International Patent System*, Baltimore, 1951 at p. 47, footnote 11; “(f) It is advisable to establish legal rules, according to which the patentee may be induced, in cases in which the public interest should require it, to allow the use of his invention to all suitable applicants, for an adequate compensation.”

¹³⁹ Penrose p. 167.

¹⁴⁰ Ibidem p. 167.

¹⁴¹ Ibidem p. 84.

¹⁴² Ibidem p. 85.

¹⁴³ See also text accompanying footnotes 167-181.

5.2 International Co-Operation

Today there exist several international texts dealing with the right to patent. Although some of them have not resulted in a forcible treaty, the drafting efforts have not always been in vain. The negotiations have revealed both obstacles and paths of agreement previously unseen.

The two major present texts in force on the law of patents are the Paris Convention¹⁴⁴ (PC) and the TRIPS agreement¹⁴⁵. There are several other treaties in force, especially regarding the *ex ante* patent proceedings, but these are the only ones treating the compulsory licensing of patents in an international context.

Within the framework of the European Union the European Commission has proposed a Council Regulation for a Community Patent containing a compulsory patent licensing scheme.¹⁴⁶

The Directive 98/44/EC on the legal protection of biotechnological invention is also accounted for in this section. It is rather an act of supranational legislation than an international treaty but it concerns the subject matter of the dispute treated here. The same goes for the jurisprudence of the European Court of Justice mentioned below.

5.2.1 The Paris Convention

After nine years of preparation The Paris Convention for the protection of Industrial Property came into force in 1884. Since then it has been a subject for numerous revisions, the last one in Stockholm in 1967. The contracting states create a Union.

The topics treated in the articles of the PC are of four different kinds; the establishment of an administrative framework for the maintenance of the convention, the regulative rights and duties of the member states, provisions guaranteeing the principle of national treatment and substantive mandatory rules of law on various topics of intellectual property creating rights and duties for private parties.¹⁴⁷

Compulsory licensing of patents is regarded in two different ways. First it is a remedy against abuses of the exclusiveness of the patent right which the

¹⁴⁴ The Paris Convention for the protection of Industrial Property as revised in Stockholm in 1967. The convention in whole can be found at <http://www.wipo.int/clea/docs/en/wo/wo020en.htm> (last visited 2004-06-30).

¹⁴⁵ The Agreement on Trade Related Aspects of Intellectual Property Rights including Trade in Counterfeit Goods. The TRIPS agreement is Annex 1c to the GATT agreement currently administrated by the WTO. The complete TRIPS agreement can be found at http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm (last visited 2004-06-30).

¹⁴⁶ Proposal for a Council Regulation on the Community Patent, Brussels, 1.8.2000, COM (2000) 412 final, 2000/0177 (CNS).

¹⁴⁷ Bodenhausen; *Guide to the application of the Paris convention for the protection of industrial property. As revised in Stockholm in 1967.*, Geneva, 1968, pp 9-16.

member states may apply at their own choice¹⁴⁸. Second it is the sanction which must proceed forfeiture of a patent for a breach against a national obligation to exploit it¹⁴⁹. The former is a legislative right of a member state and the second is a mandatory rule stipulated in the interest of the patentee.

Sweden¹⁵⁰ is a member of the Paris Union and so are the rest of the members of the European Union and the United States of America¹⁵¹.

5.2.2 The Uruguay Round and the Trade Related Intellectual Property Rights Treaty

The Agreement on Trade Related Intellectual Property is Annex 1C of the WTO Agreement, 1992. It is not an autonomous treaty. It interrelates with other parts of the WTO treaty as such, the Paris and Berne Conventions and with the IPIC treaty¹⁵².

It was not evident that Intellectual property was to be one of the subjects treated within the GATT framework.¹⁵³

That it finally ended up there is a result of three events; the failed revision movement during the 1970's and early 1980's of the Paris Convention, the United States unilateral trade practices and the United States withdrawal from UNESCO¹⁵⁴. The revision movement and the United States national trade practices grew out of the fact that "piracy goods" started to emerge as a major issue in international trade. The main pattern was that "western" copyright, trademarked or patented goods were produced and sold in South America and in Asia without consent from the right holder. The American legislative apparatus received massive attention from local industry to put an end to this international theft¹⁵⁵.

The revision movement of the Paris Convention divided the signatories into two groups with two opposing objectives. The industrialised countries wished to introduce effective rules for intellectual property enforcement and formal international dispute mechanisms to the benefit of the right holder. The other group was mainly made up of developing countries that sought to increase technology transfer into their jurisdictions in order to promote economic development. They wanted to limit the right holders right to

¹⁴⁸ Article 5, Section A (2).

¹⁴⁹ PC Article 5, Section A except for paragraph A(2).

¹⁵⁰ Sweden has been a member of the Paris Union since 1885.

¹⁵¹ The U.S.A. has been a member of the Paris Union since 1887.

¹⁵² Gervais, Daniel; *The TRIPS Agreement. Drafting History and Analysis*, Cornwall 1998, p. 27.

¹⁵³ The General Agreement on Tariffs and Trade. The GATT has transformed into the World Trade Organisation (WTO).

¹⁵⁴ The United Nations Educational Scientific and Cultural Organisation which administers the Universal Copyright Convention (UCC). The United States did not leave the UCC. Terence P. Stewart. (ed.); *The Gatt Uruguay Round. A Negotiating History (1986-1992)*, Volume II, Deventer 1993, p. 2255.

¹⁵⁵ Bello, Judith H., Holmer, Alan F.; "*SPECIAL 301": Its Requirements, Implementation and Significance*", 13 Fordham Int'l L.J. 259 (1989-1990).

compensation in the case of compulsory licensing. The members of the Paris Union failed to find common ground for four successive revision conferences in Geneva (1980), Nairobi (1981) and Geneva (1982 & 1984).

In 1984 the United States withdrew from UNESCO. Not yet a member of the Berne Convention for the Protection of Literary and Artistic Works, the United States lost its influence on copyright protection at an international level.

In the same year the United States made intellectual property actionable under Section 301 of the Trade Act of 1974¹⁵⁶. This was an act of legislation which made it possible for the United States President to take action against, what they regarded as “unjustifiable or unreasonable” trade practises. The United States initiated bilateral negotiations with several countries¹⁵⁷ and made them strengthen their intellectual property laws under threat of import restrictions to the US market.

In 1986, during the preparatory work for the Uruguay Round of the GATT negotiations, the United States, in the search for a new forum to strengthen intellectual property at an international level, proposed that all intellectual property should be included in the forthcoming negotiations. The proposal made it to the final agenda, although it was heavily opposed by a number of developing countries.

Once the GATT negotiations were launched, the United States kept them alive and subject to their own negotiation strategy through the “Special 301” provision of the US Omnibus Trade and Competitiveness Act of 1988. The special 301 legislation required the United States Trade Representatives to identify those foreign countries that do not have “adequate and effective protection of intellectual property rights” and put them on a special watch list or a priority watch list. Once listed the country faced an investigation and possible trade retaliation, for example increased duties or import restrictions. Those on the priority watch list were given immediate attention. During the Uruguay round of negotiations, India, China, Thailand, Brazil, the European Community and Australia were put on the priority watch list and twenty-three other countries were under supervision.¹⁵⁸

The TRIPS negotiations inherited the participants’ fixed positions of the PC revision movement. The Northwest hemisphere plus Japan, wished to strengthen the intellectual property rights and protect them as any other property. The developing countries, however, saw intellectual property more as a public good and sought to weaken the position of the right holder vis-à-vis the local authority in order to promote technology transfer.¹⁵⁹

¹⁵⁶ Trade and Tariff Act of 1984, 98 Stat. 2948, 3005 (1984).

¹⁵⁷ South Korea (1985), Brazil (1985, 1987), Singapore (1984), Taiwan (1983), Stewart p. 2256.

¹⁵⁸ Argentina, Canada, Chile, Colombia, Cyprus, Egypt, Germany, Greece, Indonesia, Italy, Hungary, Japan, Korea, New Zealand, Pakistan, Philippines, Spain, Taiwan, Turkey, Saudi Arabia, United Arab Emirates, Venezuela and Yugoslavia. Ibidem p. 2258.

¹⁵⁹ Ibidem p. 2255.

In retrospect, it is clear that the developed countries gained the upper hand. The unilateral US trade legislation played not a negligible part in that outcome.¹⁶⁰

As for compulsory patent licensing, it was a central topic throughout the negotiations.¹⁶¹ Developing countries with Brazil in the fore were clearly in favour, whereas the developed countries with the US and the European Community in the lead, pleaded for restrictions.¹⁶²

The result is a compromise between the two standpoints laid down in Article 31 of the TRIPS agreement. Compulsory patent licensing is still available to the local legislators. Article 5 (A) if the PC is still in force.¹⁶³ In comparison with Article 5 (A) of the PC it is not limited regarding the grounds but the national legislative freedom has been tightened considerably in a sort of check-list of procedural requirements which have to be met before a compulsory license can be granted.

One of the objectives of the TRIPS agreement, laid down in article 7, is to promote “the transfer and dissemination of technology”, an objective which cannot reduce the requirements for local legislation. Article 31 is mandatory.¹⁶⁴ The objectives in Article 7 are more of a political nature.¹⁶⁵

Even if the members are allowed to take legislative measures “to protect public health and nutrition, and promote the public interest in sectors of vital importance to their socio-economic and technological development”¹⁶⁶, these grounds are not a way to evade Article 31. The second sentence of Article 8.1 stipulates that such measures must be consistent with the TRIPS agreement, including Article 31.

Measures against abuse of intellectual property and unreasonable restraints on trade, treated in the second paragraph of Article 8, are subject to the same requirement.

With the developments of the Uruguay negotiation round in mind, it is not hard to see that the final text of Article 31 is heavily influenced by the USA’s national experience on the subject, especially if one considers the more narrow interpretation of Article 27.¹⁶⁷

The so often quoted statement by the U.S. Supreme Court “[c]ompulsory licensing is a rarity in our patent system”¹⁶⁸ is a statement that needs

¹⁶⁰ Ibidem p. 2313.

¹⁶¹ Gervais p.15.

¹⁶² Stewart p. 2295.

¹⁶³ TRIPS, Article 3.1.

¹⁶⁴ “..., the following provision shall be respected”, Article 31 (A), first paragraph.

¹⁶⁵ “The protection and enforcement of intellectual property rights *should...*” (my emphasis).

¹⁶⁶ TRIPS Article 8.1.

¹⁶⁷ See text accompanying footnotes 282-283.

¹⁶⁸ Dawson Chemical Co. V. Rohm & Haas Co., 448 U.S. 176 (1980).

qualifying. It is true that the general U.S. patent law¹⁶⁹ does not contend any general rules on compulsory licensing.

There exist however two *lex specialis* with compulsory licensing rules, the Atomic Energy Act¹⁷⁰ and the Clean Air Act¹⁷¹ and a number of legal institutions with the same effect.

Compulsory licensing in the “public interest”, or as it is formulated in the TRIPS agreement “in the case of national emergency” or “public non-commercial use”¹⁷², have an American equivalent in 28 U.S.C § 1498.¹⁷³ TRIPS Article 31.c, first clause¹⁷⁴ and 31.g¹⁷⁵ can be traced back to the U.S. doctrine of misuse¹⁷⁶. The United States also has a legal doctrine with the same purpose as compulsory licensing of interdependent patents¹⁷⁷, the doctrine of reverse equivalents.¹⁷⁸

Even the international rules on the compensation to the right holder¹⁷⁹ have borrowed their vocabulary from the U.S. rules. In U.S. infringement cases the right holder is entitled to adequate damages¹⁸⁰, a standard not used in antitrust cases.¹⁸¹ The United States does not practise a local working requirement for the patent issued, but has achieved the same result, attracting foreign investors and technology transfer, through other policies, protective duties being one of them. Theoretically, this makes the United States the leading compulsory patent licensor in the world.

¹⁶⁹ 35 U.S.C.

¹⁷⁰ 42 U.S.C. §§ 2181-2187.

¹⁷¹ 42 U.S.C. § 7608.

¹⁷² TRIPS, Article 31. b.

¹⁷³ See also Richard J. McGrath and David M. Schlitz: *Patent infringement claims against the United States Government*, 9 FEDCBJ 351. And Richard J. McGrath; *The unauthorised use of patents by the United States Government or its contractors*, 18 AIPLAQJ 349.

¹⁷⁴ “the scope and duration of such use shall be limited to the purpose for which it was authorised”.

¹⁷⁵ “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 which led to it cease to exist and are likely to recur”.

¹⁷⁶ For the U.S. doctrine of patent misuse, see e.g. James B. Kobak, Jr., *The New Patent Misuse Law*, 71 J. Pat & Trademark Off. Soc'y 859, (1989).

¹⁷⁷ TRIPS, Article 31.l.

¹⁷⁸ Robert P. Merges; *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 Tenn. L. Rev. 75.

¹⁷⁹ TRIPS, Article 31.h and k.

¹⁸⁰ 35 U.S.C. § 284

¹⁸¹ F.M. Sherer; *The economic effects of compulsory patent licensing*, New York University Monograph Series in Finance and Economics, New York, New York University, 1977, pp. 48-50. The author wishes to extend his gratitude to Prof. F.M. Sherer for lending a rare copy of his 1977 monograph across the Atlantic Ocean. See also F.M. Sherer, Jayashree Watal; *Post TRIPS options for access to patented medicines in developing countries*, CMH working paper series, paper no. Wg4:1, June 2001, pp. 24-26. TRIPS, Article 31. k.

5.2.3 The Doha Round¹⁸²

The WTO, Doha Negotiation Round (the Doha Round) was launched in November 2001¹⁸³. One of the main objectives of the Doha Round, is to make the WTO Member States live up to the agreements arising from the Uruguay Round. The vast majority of the members having problems with implementing current WTO agreements are developing countries.

The General Council of the WTO has agreed on about 50 issues regarding implementation-related matters.¹⁸⁴ The implementation issue concerns twenty-one topics that are listed in the Ministerial Declaration.¹⁸⁵ One of these topics is Trade Related Aspects of Intellectual Rights.

Among other issues treated during the Ministerial Conference in November 2001 was the intersection between public health and the implementation/interpretation of the TRIPS Agreement. A separate declaration on the subject was produced, the “Declaration on the TRIPS Agreement and Public health”.¹⁸⁶ This latter declaration was a response to the concerns of developing countries about the TRIPS Agreement being a possible hindrance to access to existing medicines.

The declaration says that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”¹⁸⁷. It also recognizes the right of a member to use the flexibility of the TRIPS agreement to this end. Measures mentioned are the customary rules of interpretation of public international law, exhaustion of intellectual property rights and the grant of compulsory licenses.¹⁸⁸

However, it also acknowledges that “WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.”¹⁸⁹

The problem concerns the situation when a country wishes to grant a compulsory license for a patented solution to a national emergency. Every Member State is free to determine what constitutes a national or similar extreme emergency. Once a national emergency is declared, the government

¹⁸² The author is indebted to Frida Colste at the Swedish Ministry of Foreign Affairs for much of the material used in this section.

¹⁸³ Ministerial Declaration WT/MIN(01)/DEC/1 adopted on 14 November 2001, www.wto.org.

¹⁸⁴ See WTO document WT/MIN(01)/17, Ministerial Conference - Fourth Session - Doha, 9 - 14 November 2001 - Implementation-Related Issues and Concerns - Decision of 14 November 2001, www.wto.org.

¹⁸⁵ See WTO document WT/MIN(01)/DEC/1, Ministerial Conference - Fourth Session - Doha, 9 - 14 November 2001 - Ministerial Declaration - Adopted on 14 November 2001 www.wto.org.

¹⁸⁶ WTO document WT/MIN(01)/DEC/2, Ministerial Conference - Fourth Session - Doha, 9 - 14 November 2001 - Declaration on the TRIPS Agreement and Public Health - Adopted on 14 November 2001, www.wto.org.

¹⁸⁷Ibidem paragraph 4.

¹⁸⁸Ibidem paragraph 5.

¹⁸⁹Ibidem paragraph 6.

in question does not have to negotiate with the patentee for a voluntarily licence of the patent right which is required according to TRIPS Art 31.b. However, if the member in question does not have the capacity to produce the patented knowledge, the compulsory licence is not of much value. A compulsory licence does not have extra territorial effect, so one cannot force another Member to comply with a foreign compulsory license decree. One solution would be if the Member is short of both production capacity and internal demand to make a new production plant profitable, it could produce for export. It is just that the legality of such a solution is not obvious.¹⁹⁰

This catch 22 situation of having the legal right to issue a compulsory license but not the manufacturing capacity to make any use of it, is generally referred to as the paragraph 6 matter.

Being one of the issues that the members were far from finding a solution to in November 2001, the Ministers instructed the TRIPS council to treat this as a matter of priority and make a report to the Trade Negotiations Committee by the end of 2002.

5.2.3.1 August 2003 Decision

No consensus on the paragraph 6 matter was reached until the 30 August 2003 and only after a change in the EU and the US negotiation strategies.¹⁹¹ The decision of the General Council of 30 August 2003 (the August 2003 Decision) is a waiver from the geographical limitation of a compulsory licence¹⁹². It is also an exception from the adequate remuneration standard set out in Article 31.h of the TRIPS agreement. The decision can be seen as an instrument to globalize national, governmental authority just as the rights of the patentee have become both standardized and international. However, it was only established after the US had made sure that it could not be used by other governments to the detriment of its home industry.

The order created by the decision concerns pharmaceutical products defined as “any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration”¹⁹³. Active

¹⁹⁰ TRIPS, Article 31. f. Speaks of production predominantly for the supply of the domestic market. Since it does not say for the domestic market only, there seems to be a possibility for export for the beneficiary of the compulsory licence. Daniel Gervais proposes the interpretation that “[s]ome exports are permitted, but not if they constitute a main use of the compulsory license”, Gervais p. 166.

¹⁹¹ Duncan Matthews: “WTO decision on implementation of paragraph 6 of the Doha declaration on the TRIPS agreement and public health: a solution to the access to essential medicines problem?”, Journal of International Economic Law 7(1), 2004, p. 97-98.

¹⁹² See WTO document WT/GC/M/82, General Council - Minutes of Meeting - Held in the Centre William Rappard on 25, 26 and 30 August 2003, www.wto.org.

¹⁹³ WT/L/540, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health - Decision of 30 August 2003 Article 1, http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (last visited 2004-06-30). Article 1 of the Declaration on the TRIPS agreement and public health reads “We recognize the gravity of the public health problems afflicting many developing and least-

ingredients necessary for the manufacture and diagnostic kits needed for the use of the pharmaceutical product at issue are explicitly included.

The August 2003 Decision expands the ordinary notion of a compulsory license as to number of parties and geographical area. As explained above, the usual and stricter meaning of a compulsory license only involves three parties and one jurisdiction. With the August 2003 Decision, an order of possibly five parties and two jurisdiction is established. The possible parties are one “eligible importer”, one “exporting member”, “The Council for TRIPS”, one producer and an importer.

Any member of the WTO agreement can become an eligible importer. Least-developed members are considered as eligible importers as from the August 2003 Decision. Other members must notify the Council for TRIPS of their intention to use the system as an importer. A Member may notify at any time that it will use the whole system or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.¹⁹⁴

Sweden and the USA are two among a number of countries which have declared that they will not use the system as importing members.¹⁹⁵ Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and United Arab Emirates have announced that if they use the system, it will only be for national emergencies or extremely urgent situations.¹⁹⁶

The August 2003 Decision requires that the importing member first tries and fails to obtain a voluntary license from the patentee.¹⁹⁷ The country member must then assess and find its capacity to produce the pharmaceutical product insufficient in order to qualify as an importing member. The insufficient production capacity must be reported to the Council of the TRIPS.¹⁹⁸ Least-developed country members are deemed not to have necessary product capacity.¹⁹⁹

Any country member with the intention to use the use the August 2003 Decision system must report to the Council of the TRIPS its intention to issue a compulsory license for the product in question, the name of the

developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics”, WTO document WT/MIN(01)/DEC/2, Ministerial Conference - Fourth Session - Doha, 9 - 14 November 2001 - Declaration on the TRIPS Agreement and Public Health - Adopted on 14 November 2001, www.wto.org.

¹⁹⁴ WT/L/540 Article 1.b.

¹⁹⁵ The other member countries are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Switzerland, and United Kingdom, Ibidem Article 1.b, note 3.

¹⁹⁶ The General Council Chairperson’s statement, 30 August 2003, WTO press release 30 August 2003 Intellectual Property, see

http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm (last visited 2004-06-30).

¹⁹⁷ TRIPS Article 31.b.

¹⁹⁸ WT/L/540 Article 2.a (ii).

¹⁹⁹ Ibidem Annex.

product and the quantity needed.²⁰⁰ The importing member must then notify a potential importer who must seek a voluntary license from the right holder.²⁰¹ Failing that, the potential importer must seek a compulsory license from the importing government on a single country basis.

Procedurally, the government of the exporting member must seek a voluntary license of the right holder as well²⁰² and failing that, take the necessary steps to obtain a compulsory license to produce the pharmaceutical products at issue. As for the government of Sweden this means that it might appear as a representative of the importing government in Stockholm's District Court.²⁰³

The waiver of the geographical limitation concerns the exporting member. The compulsory license issued by the exporting member under the August 2003 decision must stipulate that only the amount needed by the importing member may be manufactured by the producer. Everything produced under the compulsory license must be exported to the importing country member.²⁰⁴ Also, the products produced under the compulsory license must be distinguishable through, for example, labelling, marking, packaging, colouring and/or shaping of the product. The distinct features of the products produced under the August 2003 decision may only have a marginal effect on the price of the product.²⁰⁵ The quantities, the destinations and the distinguishing features of the product produced under the compulsory license must be published on the internet.²⁰⁶ The address of the website, the information posted on it, other conditions of the compulsory licence and its duration must be notified to the Council of the TRIPS.²⁰⁷

The exception to the adequate remuneration standard is to the benefit of the eligible importing member. Its purpose is to avoid the situation where the importing member becomes liable for compensating the right holder for the involuntary use of his patent rights in two jurisdictions. If the importing member pays a royalty for the production of the pharmaceutical products, the importing member doesn't have to compensate the patentee additionally for the involuntary importation to its own jurisdiction.²⁰⁸

An importing member is obliged to prevent re-exportation of the pharmaceutical products produced and imported under the August 2003 decision system.²⁰⁹ All members of the WTO shall ensure the availability of

²⁰⁰ Ibidem Article 2.a (i) and (iii).

²⁰¹ TRIPS Article 31.b.

²⁰² Ibidem Article 31.b.

²⁰³ 65 § third point patentlagen (1967:837).

²⁰⁴ WT/L/540 Article 2.b (i).

²⁰⁵ Ibidem Article 2.b (ii).

²⁰⁶ Ibidem Article 2.b (iii).

²⁰⁷ Ibidem Article 2.c.

²⁰⁸ Ibidem Article 3.

²⁰⁹ Ibidem Article 4.

effective legal means to prevent that the August 2003 decision system is not abused.²¹⁰

5.2.4 European Harmonisation

5.2.4.1 European Patent Convention

The European Patent Convention²¹¹ (EPC) entered into force in 1977. It is a multilateral agreement initiated by, but not exclusive to, what is now the European Union.²¹² With the intention to harmonise and render the application procedure more cost effective, the convention has established a common procedure for the grant of patents in the contracting states. The patents issued by the convention are called European Patents and are granted by the European Patent Office (EPO), located in Munich, Germany.²¹³

It is only the *ex ante* procedure which is based there. However, the EPC does not exclude a national examination procedure nor a national patent. Once granted the European Patent is governed by the national patent regimes in the contacting states designated by the applicant. It shall have the effect of and be subject to the same conditions as a national patent granted by the designated state.²¹⁴

One important exception is that the grounds for revocation of a European Patent listed in Article 138 are exhaustive²¹⁵. This in combination with the common examination procedure harmonises the patentable subject matter in the contracting states.

²¹⁰ Ibidem Article 5.

²¹¹ The European Patent Convention in its entirety can be found at <http://www.european-patent-office.org/legal/epc/e/mal.html#CVN> (last visited 2004-06-30).

²¹² The members of the EPO are; Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Hellenic Republic, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia and Turkey.

²¹³ EPC Article 2.1. and Art. 6.2.

²¹⁴ EPC Article 2.2.

²¹⁵ According to Article 138 a European Patent can only be revoked if:
the subject-matter of the European patent is not patentable,
the European patent does not disclose the invention sufficiently clearly,
the subject-matter of the European patent extends beyond the content of the application as filed or, if the patent was granted on a divisional application or on a new application filed in accordance with Article 61, beyond the content of the earlier application as filed;
the protection conferred by the European patent has been extended;
the proprietor of the European patent is not entitled to the patent,
the grounds for revocation only affect the European patent in part, revocation shall be pronounced in the form of a corresponding limitation of the said patent. If the national law so allows, the limitation may be effected in the form of an amendment to the claims, the description or the drawings.

Altogether, it is more fair to speak of a European patent as a bundle of patents with a common application and examination procedure²¹⁶.

5.2.4.2 Directive 98/44/EC on the Legal Protection of Biotechnological Inventions²¹⁷

Directive 98/44/EC on the legal protection of biotechnological invention is exclusive to the European Union. The purpose of this much debated piece of supranational legislation²¹⁸ is to harmonise the patentability of biotechnological inventions in the national patent regimes. This harmonisation was established in order to encourage private investment in biotechnology and genetic engineering and boost the development and competitiveness of the European industry.²¹⁹

Both *ex ante* and *ex post* considerations are touched upon. As for patentability criteria, neither the TRIPS nor the European Patent Convention discriminates any area of technology as long as the invention is new, contains an inventive step and is industrially applicable.²²⁰ The Directives dictate that additional standards or hindrances for the patentability of biological material and microbiological processes are to be abolished in national patent law²²¹. The Directive has also been incorporated into the Implementing Regulations to the European Patent Convention by a Decision of the Administrative Council of the European Patent Convention of June 1999.²²² Directive 98/44/EC is thereby a supplementary means of

²¹⁶ Koktvedgaard, M., Levin, M.; *Lärobok i immaterialrätt*, 6:e uppl., s. 45, Stockholm, 2000.

²¹⁷ Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

²¹⁸ It's mere adoption took ten years, see Report from the Commission to the European Parliament and the Council, Brussels, 07.10.2002, COM (2002) 545 final, p. 7 and (Annex 3).

The Netherlands, supported by Italy and Norway, applied in October 1998 for an annulment at the European Court of Justice. The Court dismissed the application, Case C-377/98 Kingdom of the Netherlands v. European Parliament and Council of the European Union [2001] ECR I-7079.

For activity concerning the subject matter of Directive 98/44/EC since its adoption see COM(2002) 545 final (Annex 4).

By the first of October 2002, had only six member states implemented the directive in due order (Denmark, Finland, Ireland, the United Kingdom, Greece and Spain), COM(2002) 545 final (Annex 1).

²¹⁹ Directive 98/44/EC recital 1-3

²²⁰ Directive 98/44/EC Article 3 (1), TRIPS Article 27, EPC Article 52.

²²¹ Directive 98/44/EC recital 22 and Articles 1-3.

²²² JO EPO 7/1999, p. 437. See Rules 23 b *et seq.*, see http://www.european-patent-office.org/epo/pubs/oj99/7_99/7_4379.pdf (last visited 2004-06-30).

interpretation of the relevant parts of the EPC²²³ and is to be considered in the examination procedure²²⁴.

The Directive defines “biological material” as “any material containing genetic information and capable of reproducing itself or being reproduced in a biological system”. Microbiological processes are defined as “any process involving or performed upon or resulting in microbiological material”. “Crossing” or “selection” or other pure natural phenomena are also considered biological in the process for the production of plants.

Article 5.1 stipulates that elements “isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.”

A mere DNA sequence without any particular function is not considered a patentable invention.²²⁵ If one is applying for a patent covering a DNA sequence, in whole or partially, the industrial application must be indicated.²²⁶ The scope of protection is defined further in Articles 8, 9 and 10.

Exceptions to patentability are also laid down²²⁷ in the Directive and thus limiting the member nations to invoke TRIPS Article 27 for further limitation of the patentable subject matter.

There is a potential overlap between the plant variety protection offered by the Council Regulation on Community plant variety rights²²⁸ and a patent on a biological subject matter. This is a conflict motivating *ex post* regulations, a compulsory licensing scheme. Article 12 stipulates that the patentee of a biotechnological invention may be granted a compulsory license if he is prevented from exploiting his patent because of a breeders right. The compulsory license is to be non-exclusive and the proprietor of the plant variety right must be compensated with an “appropriate royalty”. If the applicant is granted a compulsory licence, the holder of the variety right is entitled to a cross license on reasonable terms. The patentee must also prove that he has tried to negotiate a voluntary licence and that his patented invention, in comparison with the protected plant variety, constitutes a “significant technical progress of considerable economic interest”.

Article 12 works both ways and a breeder has the same rights and obligations as a patentee.

²²³ Implementing Regulations to Part II of the Convention, Chapter VI, Rule 23 b, see <http://www.european-patent-office.org/legal/epc/e/ma2.html#REG> (last visited 2004-06-30).

²²⁴ Guidelines for Substantive Examination, Part C, p. 47, see http://www.european-patent-office.org/legal/gui_lines/pdf_2003/rlec75.pdf (last visited 2004-06-30).

²²⁵ Directive 98/44/EC recital 23.

²²⁶ Directive 98/44/EC Article 5.3.

²²⁷ Excluding provisions are Article 4 (plant and animal varieties), Article 5.1. (The human body as a whole) and Article 6 (inventions contrary to ordre public and morality), Directive 98/44/EC.

²²⁸ Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights.

Directive 98/44/EC does not treat the purpose of patent law explicitly. However, when arguing for the necessity to make human tissue patentable, the Commission states that patents on biotechnological inventions “will certainly be of fundamental importance for the Community’s industrial development”,²²⁹ and that genetic engineering is a field where “research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable”²³⁰. Apart from the internal-market line of argumentation for the harmonisation of the European patent law, the Commission also states that harmonised, European patent laws are “essential in order to maintain and encourage investment in the field of biotechnology”²³¹. Altogether, this represents a clear utilitarian view of patent protection.

The Directive on the Legal Protection of Biotechnological Inventions entered into force 1998.07.30.²³² It was to be implemented in national legislation no later than 2000.07.30.²³³

5.2.4.3 Proposal for a Council Regulation on the Community Patent²³⁴

In August 2000, the Commission presented a proposal for a Council Regulation on a Community patent.²³⁵ The purpose of the proposal is fourfold, (1) eliminate the distortion of competition which may result from the territorial protection of the Member States national patent rights, (2) ensuring the free movement of patent-protected goods, (3) minimise the meaning of the “nationality” of production and distribution sites and (4) to stimulate private investment and thus innovation of European research results.²³⁶

The proposed Regulation is limited to govern the Community patent ex post, once it has been granted. The ex ante procedures are proposed to be governed by the European Patent Convention and administered by the European Patent Office in Munich.²³⁷ It will become a Community patent first when the patent has been granted by the Office.

²²⁹ Directive 98/44/EC recital 1.

²³⁰ Ibidem recital 2.

²³¹ Ibidem recital 3.

²³² Directive 98/44/EC Article 17 and OJ L213 of 30.7.98.

²³³ Directive 98/44/EC Article 15.1 By the first of October 2002, had only six member states implemented the directive in due order (Denmark, Finland, Ireland, the United Kingdom, Greece and Spain), se COM (2002) 545 final (Annex 1).

²³⁴ Proposal for a Council Regulation on the Community patent, Brussels, 1.8.2000, COM (2000) 412 final, 2000/0177 (CNS).

²³⁵ Proposal for a Council Regulation on the Community patent, Brussels, 1.8.2000, COM (2000) 412 final, 2000/0177 (CNS).

²³⁶ COM (2000) 412 final, p. 6.

²³⁷ Ibidem pp. 7-8.

The proposed patent right is unitary in nature. It will have the same effect throughout the community. It will be granted, transferred, declared void or allowed to lapse in respect of the whole Community only.²³⁸ Furthermore, the Community patent is further proposed to only be subject to the provisions of the proposed Regulation and to the general principles of Community law, hence completely separated from the national systems of industrial property.²³⁹ It is, however, to be governed by the same principles of patent law as laid down in international law and implemented in national legislation.

The autonomy of the proposed Community patent is further accentuated by a separate judicial system also presented in the Commission proposal. The establishment of a centralised “Community Intellectual Property Court” is proposed with exclusive jurisdiction over questions relating to validity and infringement of a Community patent.²⁴⁰

The proposal also provides for administrative compulsory licensing of patents. It is not a court of justice which has to decide whether a compulsory licence ought to be granted or not, but the European Commission.²⁴¹

Before the Dutch presidency of the Council of the European Union, the Netherlands announced their priorities for their term of office.²⁴² Due to the lack of unanimity within the European Council during the preceding Irish presidency on the establishment of a Community patent, the topic is not one of the top priorities of the Dutch presidency. “The issue will only be placed on the Council’s agenda if the member states opposing the plan are willing to contribute in a constructive manner to breaking the impasse.”²⁴³

5.2.4.4 European Court of Justice Case-Law

In two judgements of 18 February 1992²⁴⁴, The European Court of Justice established that compulsory licensing of patents or plant variety rights on the grounds that the property right is exploited by imports from another member state and not through production on national territory is incompatible with the rules of free movement of goods.

The Court found that since the patent law of the Member States has not been unified at a Community level, the power to determine the conditions and rules regarding the protection conferred by patents is still vested in national legislature according to Article 295 of the Treaty.²⁴⁵ However, Article 295

²³⁸ Ibidem p. 9.

²³⁹ Ibidem p. 9.

²⁴⁰ Ibidem pp. 13-15.

²⁴¹ Ibidem pp. 46-47 and Article 21.

²⁴² NL 2004, The Dutch Presidency of the Council of the European Union: Priorities, p. 12.

²⁴³ Ibidem p. 12-13.

²⁴⁴ Case C-235/89 Commission v. Italian Republic [1992] ECR I-777, and Case C-30/90 Commission v. United Kingdom and Northern Ireland [1992] ECR I-829.

²⁴⁵ Case C-235/89 paragraph 12 and 13 and Case-39/90 paragraph 16 and 17.

does not mandate the Member States to adopt measures obstructing the principle of free movement of goods within the common market.

Restrictions on intra-community trade can be justified for the purpose of safeguarding the protection of the specific subject matter of industrial and commercial property rights unless they constitute a means of arbitrary discrimination or a disguised restriction on the trade between Member States.²⁴⁶

The specific subject-matter of patents consists of three actions by the patentee; the exclusive right to use an invention with a view to manufacturing industrial products, to put these inventions into circulation for the first time, either directly or by the grant of licenses to third parties and the right to oppose infringements.²⁴⁷ The Court found the subject-matter of new plant varieties to be essentially the same.²⁴⁸

The Court also found that the patentee, through the obligation to work the patent nationally, was encouraged to manufacture on the territory of the state where the patent had been granted rather than to import the patented product from the territory of other Member States.²⁴⁹ The legislation at issue was therefore a measure having the effect equivalent to a quantitative restriction in the meaning of Article 28.²⁵⁰

It was rather the encouragement of domestic production than the specific requirements of the property rights at hand that motivated such rules and they could therefore not be accepted in the light of Article 30.

That the Members States as members of the Paris Union are allowed to provide for Compulsory patent licensing in the case of non- or insufficient national patents according to Article 5 (A) of the Paris Convention does not relieve the members of the EU of their obligations according to the Treaty.²⁵¹

²⁴⁶ Article 30 of the Treaty read in the light of case 10/89 SA CNL-Sucal NV v. Hag GF AG [1990] ECR I-3711, paragraph 12. Case C-235/89 paragraph 16 and Case C-30/90 paragraph 20.

²⁴⁷ Case C-434/85 Allen and Hanbury's v. Generics [1988] ECR 1245, paragraph 11. Case C-235/89 paragraph 17 and Case C-30/90 21.

²⁴⁸ Case C-235/89 paragraph 17.

²⁴⁹ Case C-235/89 paragraph 20 and Case C-30/90 paragraph 24.

²⁵⁰ Case C-235/89 paragraph 21 and Case C-30/90 paragraph 25.

²⁵¹ Case C-235/89 paragraph 27 and Case C-30/90 paragraph 31..

6 Grounds for Compulsory Licensing

Both the Paris Convention and in the TRIPS agreement mention some possible grounds for involuntary licensing.

Article 5 (A) of the Paris Convention mandates the member states to rectify patent abuses through compulsory licenses. It is up to the Member States to define what constitutes an abuse of the patent right. Failure to work is given as an example. Article 30 of the TRIPS agreement expresses this more clearly. The grounds alluded to in the article are national emergency and other circumstances of extreme urgency²⁵², anti-competitive practices²⁵³, public non-commercial use²⁵⁴ and dependent patents²⁵⁵. Non-working is not mentioned in Article 31 of the TRIPS agreement.

6.1 National or Extreme Urgency

Article 30 A (b) mentions national or extreme urgency as possible grounds for compulsory licensing. It is stipulated that the pre-negotiation requirement is waived in these two circumstances. National or extreme urgency seems to imply when a nation is threatened from an exterior or interior force. It is evident that such a situation gives the patent holder an unacceptable leverage in licence negotiations. In a critical situation, a Government does not want its power nor the welfare of a people to be dependent on a profit-seeking patent owner. Patent law is usually also complemented with a governmental expropriation legislation for these situations.

The strong patent rights of the medical industry and the threat of national stability being partly health-related, this is a source of strong conflicts of interest. The two major events, after the TRIPS agreement had entered into force and where compulsory licensing was heavily debated were health related. One time was the USA the defending party and the other time the plaintiff.

The former situation concerned the AIDS²⁵⁶ crisis in Africa.²⁵⁷ In 1994, one-eighth of the population suffered from AIDS. Although medication

²⁵² TRIPS Article 31. b.

²⁵³ TRIPS Article 31. c and k.

²⁵⁴ TRIPS Article 31. c.

²⁵⁵ TRIPS Article 31. l.

²⁵⁶ Auto Immune Deficiency Syndrome.

²⁵⁷ The facts of the dispute are taken from Sara M. Ford; *Compulsory licensing provisions under the TRIPS agreement: balancing pills and patents*, 15 AM. U. Int'l. L. Rev 941 (2000).

retarding the symptoms of the disease was available on the South African market, very few could afford the medication. The medicines were protected by patents, for the most part owned by American companies. In 1997 the South African Parliament proposed a new law allowing the Ministry of Health to grant compulsory licensing of the patented medicines, rendering them affordable to the needy. The United States Government, acting on behalf of the American industry, strongly opposed the proposition. The issue was settled outside the WTO dispute settlement system.

The latter situation concerned the anthrax terror attack in the USA effectuated through the public mail system in the autumn of 2002. The leading medication against anthrax is the antibiotic ciprofloxacin, a substance patented by the German Bayer Corporation and sold under the trademark Cipro.

At the time, the U.S Government estimated that it would need medication for 10 million people in order to handle the effects of a large-scale anthrax terrorist attack. This would correspond to 1.2 billion pills, 120 pills being the recommended course of treatment for ciprofloxacin. It would take Bayer 600 days to supply such an amount of Cipro at a price of \$1.77 per tablet.²⁵⁸ The US Government has the right to use patents without a license under 28 US 1498²⁵⁹ and approved the quality of ciprofloxacin of five domestic generic companies that could start manufacturing the drug instantly.

The parties finally agreed that the US Department of Health and Human Services would buy 100 million tablets for a price of 95 cents per tablet from the Bayer Corporation. The agreement provided for an option of a second order of 100 million tablets at 85 cents and a third order at 75 cents per tablet.²⁶⁰

6.2 Anti-Competitive Practices

Patent law and competition law have throughout the decades swirled around each other like the double helix of the DNA. Their inter-relationship has changed because the two institutions have, over the years, been redefined independently.

The theoretical development of the two blocks of law is a discourse of American dominance.

As accounted for earlier²⁶¹ patent theory has gone from regarding patents as a reward for creative effort to a incentive to invest. The theories concerning

²⁵⁸ Talking points on Cipro patent dispute by James Love found at www.cptech.org/ip/health/cl/cipro/talkingpoints/html (last visited 2004-06-30).

²⁵⁹ United States Code Annotated Title 28. Judiciary and Judicial Procedure Part IV—Jurisdiction and Venue Chapter 91—United States Court of Federal Claims. § 1498. Patent and copyright cases.

²⁶⁰ U.S. Department of Health and Human Services Press Release, October 24, 2001 found at www.cptech.org/ip/health/cl/cipro/dhhs10242001.htm (last visited 2004-06-30).

²⁶¹ See Chapter 4 above.

competition, or antitrust, have gone through several phases. The first theoretical tools that were not just based on assumptions emerged after the Second World War with the so-called “*Harvard School*”.²⁶²

The Harvard School was more occupied with how a market was structured than the behaviour of the market players. Market shares were seen as strong indicators of foul play. As a reaction toward the Harvard School of analysis emerged another line of theory in the early seventies, “*The Chicago School*”²⁶³.

The Chicago School argued that many of the Harvard School assumptions were wrong. Market dominance was many times not a structural problem but the effect of competitive behaviour among the market players.

Both these schools of theory have implications for the strength of patent rights. As for the Harvard era, patents being nation wide, it is not hard to draw the conclusion that it is the patent right which creates the dominant position. It might also be that a large market player has built up an equally large patent portfolio. The position of the patent holder is weakened even more if the Reward Theory of the time is interpreted so that the right holder might be considered to have been rewarded too much.

Most of the compulsory patent licensing under Antitrust judgements in the USA were given when the Harvard School of Antitrust and the Reward Theory dominated the analytical scene.²⁶⁴

Chicago economists might have done wonders for competition law but their theories were not all magic for patent theorists. The main tool of analysis of the Chicago School is microeconomic price theory. It presupposes a constant level of technology²⁶⁵ and is hostile towards pricing above the marginal cost of production which is seen as a monopoly profit²⁶⁶.

In the real world, the level of technology is not constant. Firms compete with new applications every day. What the Chicagoan economist calls monopoly profit Joseph Schumpeter calls necessary economic rent for future investment. By redefining patent rights as not being monopolies rewarded to inventors but as incentives to invest in new competitive technologies²⁶⁷ and introducing a more dynamic analysis of market power, patent law and competition law have become more compatible than ever.

²⁶² Faull & Nikpay (eds.); *The EC Law of Competition*, New York 1999, p. 5.

²⁶³ Ibidem p. 6.

²⁶⁴ During the years 1941-1957 300 defendants and somewhere between 40,000-50,000 patents were affected by compulsory patent licensing under antitrust judgements. Marcus A. Hollabaugh, *Compulsory Patent Licensing under Antitrust Judgements*, Staff Report of the Subcommittee on Patents, Trademarks and Copyrights of the Committee on the Judiciary United States Senate, 86th Congress, 2nd Session, pursuant to S. Res. 240, p. 5. The conclusion of the report is well reflected in the following statement taken from the seventh of the seven final recommendations of the report “...where...an industry has been monopolized by business practices...the monopoly should be attacked as such. It is not sufficient...to substitute compulsory licensing relief for relief which would dissolve the monopoly.” Ibidem p. 54.

²⁶⁵ Faull & Nikpay p. 9.

²⁶⁶ Faull & Nikpay p. 22.

²⁶⁷ See Chapter 4 above.

However, patent law is not to be considered a carte blanche from investigations of competition law authorities.

6.2.1 European Competition Law and Compulsory Licensing of Patents

Compulsory licensing of intellectual property is only relevant when it comes to unilateral abuse of a dominant position, sanctioned in Article 82 of the Treaty of Rome. In order for Article 82 to apply the three criteria, dominance, abuse and effect on intra community trade must be fulfilled.

Consequently, the mere possession of a patent does not confer abuse of a dominant position.²⁶⁸ It is how the patent protection is used which may attract the attention of competition authorities.²⁶⁹ If a patent is exercised within the specific subject matter of the patent the action is presumed to stand clear of Community law. The specific subject matter of a patent right was defined in the *Centrafarm*- case;

“In relation to patents, the specific object of industrial property is the guarantee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements.”²⁷⁰

There are judgements stating that the exercise of the specific subject matter of an intellectual property could still be considered a breach against Article 82.²⁷¹ Since these cases concern intellectual property other than patents, it is not evident how relevant they are for patent rights. Administrative practise indicates that they can only be distinguished to some extent.²⁷²

²⁶⁸ Case C-24/67 *Parke, Davis & Company v. Probel and others*, 29 February 1968 [1968] ECR 55, page 72 at paragraph 3.

²⁶⁹ Case C-24/67 *Parke, Davis & Company v. Probel and others*, 29 February 1968 [1968] ECR 55, page 72 at paragraph 5.

²⁷⁰ Case C-15/74 *Centrafarm BV v Sterling Drug Inc* [1974] ECR 1147 at paragraph 9. It is noteworthy that from a theoretical perspective, the European Court of Justice sees the patent institution as a reward and not an incentive. Furthermore, according to this definition the exclusive use of a patent is not unconditional but dependent on the intention to manufacture or to put the patented subject matter on to the market.

²⁷¹ See Case C-238/87 *Volvo AB v Erik Veng* [1988] ECR 6211 at paragraph 9 stating that “arbitrary refusal to supply spare parts to independent repairers” and a “decision no longer to produce spare parts for a particular model even though many are of that model is still in circulation” may be prohibited by Article 82. The case concerned protected designs and models.

See also Joined Cases C-241/91 P and C-242/91 P *RTE v Commission* (Magill) [1995] ECR I-797 stating that unilateral refusal to license a copyright, for which there exists no actual or potential substitute, to a competitor to produce a new product in a different market with an untapped consumer demand can be a breach against Article 82. Paragraphs 52-56.

²⁷² Hans Henrik Lidgard, *Licensavtal i EU*, Stockholm 1997, p. 321.

A question related to the obligation to license is the royalty demanded by the right holder. The patentee has the right to a royalty. However, he cannot charge whatever royalty he pleases since an excessive license fee can be just as effective as a refusal. The level of the licence fee lies outside the specific subject matter of a patent.²⁷³ Case law treating excessive royalties is scarce when it comes to patents.

The European Court of Justice has delivered two judgements on copyright licensing fees. In the *SACEM*- case the ECJ stated that the amount of the royalty charge may be such that article 82 applies.²⁷⁴ In the *Tournier*- case the ECJ stated that “[w]hen an undertaking holding a dominant position imposes scales of fees for its services which are appreciably higher than those charged in other Member States and where a comparison of the fee levels has been made on a consistent basis, that difference must be regarded as indicative of an abuse of a dominant position.”²⁷⁵ It is then up to the right holder to motivate the suspiciously high licence fee.²⁷⁶

6.3 Failure to Work

One of the thoughts to bear in mind regarding patent law is that the patents granted within a jurisdiction are to contribute to the national industrial development and not just constitute blocking rights preventing competitors from entering a country, or controlling the import to a specific state.²⁷⁷

The failure to use or “work” a patented invention is one example given on abuse of patent exclusivity in Article 5, Section A (2). The same Article gives the countries in the Paris Union the right to issue compulsory licenses in order to hinder patent abuse and therefore failure to work a patent.

The members of the Union are free to define what constitutes failure to work a patent.²⁷⁸ Normally, working of a patent means industrial execution of the invention either through manufacture of the protected product or industrial application of a patented process within the patent-granting country. Consequently, neither import nor sale of a patented product or an article manufactured by a patented process is regarded as working.

²⁷³ Case C-24/67 *Parke, Davis & Company v. Probel and others*, 29 February 1968 [1968] ECR 55, page 72 at paragraph 6, “...the sale price of the protected product may be regarded as a factor to be taken into account in determining the possible existence of an abuse...”.

²⁷⁴ Case C-402/85 *Basset v Société des auteurs, compositeurs et éditeurs de musique (SACEM)* [1987] ECR 1747 at paragraph 19.

²⁷⁵ Case C-395/87 *Ministère public v Jean-Louis Tournier* [1989] ECR 2521 at paragraph 38.

²⁷⁶ Ibidem paragraph 38.

²⁷⁷ Bodenhausen p. 70, note (o).

²⁷⁸ Bodenhausen p. 71, note (h).

The geographical area in which the working must take place is usually one state jurisdiction but is subject to the will of the members of the Union and can comprise more than one country.²⁷⁹

An application for a compulsory patent on the grounds of insufficient working must be refused if the right holder can justify his inaction by giving legitimate reasons.²⁸⁰ It is for the competent authorities of the Member States to decide what constitutes a legitimate reason.²⁸¹

Non-working is not mentioned in the TRIPS agreement as grounds for compulsory licensing. TRIPS Article 27.1 states that “patents shall be...enjoyable without discrimination as to ...whether products are imported or locally produced”. A section which can be interpreted in two ways.

On the one hand it could mean that importation to a jurisdiction is to be regarded as placed on equal footing with the production within it.²⁸² This is the more rigid reading of the Article and a widening of the definition of working. On the other hand it could also be understood as an enlargement of the geographical area to be considered when determining whether the patent is worked or not. If the patented subject matter is produced or applied in one Member State it is to be regarded as worked in all of the Member States.²⁸³ This is the more extensive interpretation of the article and an abolition of non-working as grounds for compulsory patent licensing among the members to the TRIPS agreement.

If a right holder chooses not to produce, apply or import the patented subject matter in one jurisdiction, the State subjected to the blockade would be able to grant a compulsory license according to the first interpretation but not according to the second.

6.4 Interdependent Patents

If a combination of two patented technologies, infringing upon one another, owned by two right holders, and would seem to be a profitable product or process, the parties have two choices apart from an invalidity process. One can buy or license the patented technology from the other or they can join their efforts and launch a combination of the two together.

As for the last option the joint venture negotiations might fail. In theory, the risk of bargaining breakdown is especially high when an agreement is most

²⁷⁹ Bodenhausen p. 71, note (h).

²⁸⁰ PC Article 5 Section A.4.

²⁸¹ Examples given on such legitimate reasons are if the patented subject matter is illegal, unrealisable or a losing transaction. Bodenhausen, p. 73, note (o).

²⁸² Carlos M. Correa: *The GATT agreement on trade-related aspects of intellectual property rights: new standards for patent protection*, [1994] 8 EIPR 331.

²⁸³ Daniel Gervais: *The TRIPS agreement: drafting history and analysis*, London 1998, p. 148.

desirable from a social perspective. That is when a radical improvement has been made and patented from an existing patented solution. The difference between a radical improvement and an ordinary one is measured in economic terms. The market value of radical improvement is much higher than that of an ordinary improvement or of the first invention.²⁸⁴

The bargaining failure is thought to be due to three main reasons. First, the difficulty in validating the separate contributions of the first inventor on the one hand and the improver on the other. Second, the difficulty in estimating how the technology will develop and how profitable it will be.²⁸⁵ Third, the bargaining breakdown is most acute if the agreement to be reached is a one-time transaction. If the parties frequently need to exchange rights it is likely that the parties will invest in administrative structures or institutions in order to render the transactions more efficient and governmental intervention is unnecessary.²⁸⁶

The purpose of Article 31.1 is to prevent the situation where the parties cannot reach an agreement when it is socially valuable. It stipulates that a compulsory license can be granted in order to break the first inventors hold up position when the second patent involves an “important technical advance of considerable economic significance in relation to the invention claimed in the first patent”²⁸⁷. But the above is only valid if the pioneer inventor is given a cross license to the second patent.²⁸⁸ The improvers’ compulsory license in the first inventors’ technology shall then only be assignable together with the second patent.²⁸⁹

6.5 Analysis

Technological transfer, according to the TRIPS agreement, shall in the first place be realised through voluntary, free market transactions.²⁹⁰ The rules on involuntary licensing of patents laid down in the TRIPS agreement formed after the theories of market failure; public goods, monopoly power and severe informational asymmetries.²⁹¹

The Public Goods Theory holds that private profit maximising companies will not provide goods or services where the risk of free riders is high and where it is very expensive to distinguish non-paying from paying

²⁸⁴ Robert P. Merges; *Intellectual property rights and bargaining breakdown: the case of blocking patents*, 62 Tenn. L. Rev. 75 (1994), p. 79.

²⁸⁵ Ibidem p. 75.

²⁸⁶ Ibidem pp. 83-84. See also Robert P. Merges; *Contraction into liability rules: Intellectual property rights and collective rights organizations*, 84 Calif. L. Rev. 1293 (1996).

²⁸⁷ TRIPS Article 31.1 (i).

²⁸⁸ TRIPS Article 31.1 (ii).

²⁸⁹ TRIPS Article 31.1 (iii).

²⁹⁰ TRIPS Article 31.b first paragraph.

²⁹¹ Robert Cooter, Thomas Ulen; *Law and Economics*, third edition, USA 2000, pp. 40-43.

beneficiaries. National defence is the textbook example. The national emergency ground²⁹² is motivated by the Public Goods Theory.

Technology transfer agreements can be used to shield anti-competitive behaviour. The intersection between patent law and competition law is far from obvious and technology transfers are in no way exempted from the rules of competition.²⁹³

The interdependent patent provisions in the TRIPS agreement²⁹⁴ are drafted under the influence of the theory of severe informational asymmetries. This source of market failure is due to an imbalance of information between the parties to an exchange. The imbalance is so severe that the exchange will not take place. The government can then intervene through a compulsory licensing in order to realise a socially desirable exchange.

Common for all three grounds motivated by economic theory is that they should be interpreted objectively and from a macro economic perspective. Compulsory licensing is not a way to circumvent the market forces. Competition law is to protect competition and not competitors, the hold up scenario is only a problem when the market is deprived of a socially valuable solution and an issue is only public when it meets the criteria of “public goods”.

So far, compulsory licenses are motivated by economic efficiency. What is legally admissible is something else. International law holds only two restrictions on the national legislator regarding the grounds for compulsory patent licensing. One is clear; compulsory licensing of semi-conductor technology can only be for public non-commercial use or to remedy anti-competitive behaviour.²⁹⁵ None the less, public non-commercial use is a fairly broad exception.

The other limitation is rather ambiguous.²⁹⁶ Article 27 of the TRIPS agreement could be understood as a widening of the definition of “working”. But it is equally possible that it precludes the right to offer compulsory licenses for failure to work among the members to the TRIPS agreement. Either interpretation is a change in well-established practise.

What the AIDS crisis in Africa and the Anthrax attack in the United States of America show is that there is a political dimension to compulsory patent licensing which is not negligible. This is something which cannot be considered by a judge in court but very well by the national legislative authority when shaping its compulsory patent regime.

²⁹² TRIPS Article 31.b second paragraph.

²⁹³ See also Commission Regulation (EC) No 772/2004 of April 2004 on the application of Article 81 (3) of the Treaty to categories of technology transfer agreements.

²⁹⁴ TRIPS Article 31.l.

²⁹⁵ TRIPS Article 31.c.

²⁹⁶ See text accompanying footnotes 282-283.

7 General Procedural Requirements For Compulsory Licensing

7.1 Individual Merits

Every use without the authorisation of the patentee, by the government or a third party, can only be granted on a case-by-case basis²⁹⁷.

Regimes where a particular field of technology or particular patentees are automatically made eligible for a compulsory license seem to violate this principle.²⁹⁸

7.1.1 Market Exploration Time

If local legislation obligates the patentee to exploit his patent industrially within the jurisdiction, the patentee has a right to a period of grace in order to organise his means of production before he can be sanctioned with a compulsory license for non- or insufficient working of his patented knowledge. This period of market introduction is that which expires the last between “four years from the date of the filing of the patent application or three years from the date of the grant of the patent”²⁹⁹. With the vague Article 27.1 in mind, this formal requirement to be considered is when dealing with patentees outside the TRIPS jurisdiction.

7.1.2 Prior Negotiations

The claimant licensee must have made reasonable efforts to obtain a voluntary license for a reasonable period of time. This is not a mandatory requirement when the compulsory license is permitted in order to remedy a anti-competitive practice³⁰⁰.

7.1.3 Public Use Exceptions

The requirement for prior negotiations with the patentee is waived in the cases of national emergency, circumstances of extreme urgency and public

²⁹⁷ TRIPS Article 31.a. and COM(2000) 412 final, Article 21.5., 1st sentence.

²⁹⁸ Gervais p. 165.

²⁹⁹ PC Article 5 A.4. and COM (2000) 412 final, Article 21.1, 6 chapter 45§ patentlagen (1967:837).

³⁰⁰TRIPS Article 31.k.

non-commercial use³⁰¹. Nor is it a mandatory requirement when the compulsory license is permitted to remedy an anti-competitive practice³⁰². The right holder shall, however, be informed about it when practically possible. On the other hand, the unauthorised patent user is under no obligation to investigate whether the information used is patented or not.³⁰³

7.1.4 Scope of Compulsory License

The scope and duration of a compulsory license must be limited “to the purpose for which it was granted”³⁰⁴. Geographically the scope is limited to a supply predominantly for “the domestic market of the Member authorising such use”³⁰⁵. The authorised use is to be non-exclusive³⁰⁶ and non-assignable “except with that part of the enterprise or goodwill which enjoys such use”³⁰⁷. The non-assignability requisite also applies to a cross license in a “first patent” except “with the assignment of the second patent”³⁰⁸. The geographical limitation is however subject to an antitrust sanction³⁰⁹.

The geographical scope is negotiated in the Doha round.

7.1.5 Termination of Licenses

The compulsory license should be “liable to be” revoked as soon as the purposes for which it was granted no longer justify the license, taking into consideration the interests of the persons to whom the license was granted. The situation that motivated the license should then be unlikely to recur.³¹⁰

7.1.6 Judicial or Similar Review

Paragraph (g), (i) and (j) of Article 31, provides for judicial review by an authority with the power to overturn a decision to grant, continue, or renew a compulsory license. Decisions concerning the level of reasonable compensation must also be subject to scrutiny by a higher authority. As to the procedural standards, Part III of the TRIPS agreement is fully applicable.

³⁰¹ TRIPS Article 31.b and COM (2000) 412 final, Article 21.5, second sentence.

³⁰² TRIPS Article 31.k and COM (2000) 412 final, Article 21.5, second sentence.

³⁰³ TRIPS Article 31.b.

³⁰⁴ TRIPS Article 31.c and COM (2000) 412 final, Article 22.1a and 6 chapter 50§ first sentence patentlagen (1967:837).

³⁰⁵ TRIPS Article 31.f and COM (2000) 412 final, Article 22.1d.

³⁰⁶ PC Article A.4 and TRIPS, Art. 31.d and COM (2000) 412 final, Article 22.1b and 6 chapter 49 § second passage patentlagen (1967:837).

³⁰⁷ PC Article 5, Section A4, *in fine* and TRIPS, Article 31.e and COM (2000) 412 final, Article 22.1c and Article 22.1b, 6 chapter 49§ third passage patentlagen (1967:837).

³⁰⁸ TRIPS Article 31.1 (iii), COM (2000) 412 final, Article 22.1g.

³⁰⁹ TRIPS Article 31.k.

³¹⁰ TRIPS Article 31.g, COM (2000) 412 final, Article 22.1e and 6 chapter 50 § second sentence patentlagen (1967:837).

7.1.7 Adequate Remuneration

The royalty of an voluntary license is decided between a voluntary patentee and the licensee. A beneficiary of an compulsory license must also pay a fee to the right holder. It can be negotiated between the compulsory licensor and the licensee or it can be determined by the authority granting the license. In the last case there is nothing voluntary about the technology transfer at all.

When decided upon by the relevant authority, the royalty shall be “adequate in the circumstances of each case, taking into account the economic value of the authorization”³¹¹.

The first statement has a double meaning. First, it precludes a national order with a fixed royalty rate. Each royalty must be decided upon the merits of the individual case.³¹² Second, when deciding the royalty the economic strength of the licensee shall be taken into consideration.³¹³ The second part indicates that the authority at hand shall also take into account the normal price of the license, if available from the right holder.

Consequently, the royalty does not necessarily have to equal the price of a license at arms-length, even if it must be taken into consideration.³¹⁴ This would contradict the natural meaning of the prerequisite “adequate”.³¹⁵

7.1.7.1 Two Former Compulsory Licensing Regimes

The United Kingdom made provision for compulsory licensing for patents on food, medicine and surgical devices between 1949 and 1992³¹⁶. The British way of deciding the fee to be paid by the licensee was first to decide the right holders cost of innovation. To the sum of worldwide research costs, national cost of clinical trials and sales promotion was added a 22.5% profit element. The product of this calculation was then applied on the right holder’s average price of his product. In two cases this led to a royalty

³¹¹ TRIPS Article 31.h.

³¹² A country that used to exercise a fix royalty rate for compulsory licenses was Canada. Between 1970 and 1992, the rate was set at 4% of the licensee’s price-in-store. F.M. Sherer, Jayashree Watal; Post TRIPS options for access to patented medicines in developing countries, CMH working paper series, paper no. Wg4:1, June 2001, http://www.cmhealth.org/docs/wg4_paper1.pdf (last visited 2004-06-30).

³¹³ Gervais, p 166. Mr. Carlos M. Correa has proposed some other factors to be considered when fixing the royalty rate such as the patentee’s cost of development, subsidies or other contributions that lowered the right holder’s cost of development and the degree to which development cost have been amortised. Correa, p. 333.

³¹⁴ The market price may also conclude more than just the right to exploit the patent. Normally the patentee also pays for the know-how that makes the patent exploitable . The need to remedy an anti-competitive practice may justify an inferior compensation. TRIPS Article 31.k.

³¹⁵ Correa p. 333.

³¹⁶ The United Kingdom had to change their Section 41 of the Patents Act of 1949 when ratifying the TRIPS agreement since the product specific scheme was a violation of TRIPS, Art. 31. A. Sherer/ Watal, p. 18-19.

corresponding to 18% of the patentees average price of the patented product. In another to a 22% royalty rate.³¹⁷

Canada introduced a compulsory licensing scheme in 1923 but it was eliminated in 1992 as part of the NAFTA agreement negotiations. Only patents on drugs and food were eligible.³¹⁸ From 1970 the rate was set at 4% of the beneficiary licensee's price-in-store, no matter what the circumstances of the case.³¹⁹

7.2 Comment³²⁰

The procedural requirements for national compulsory licensing regimes are few and generous. The TRIPS agreement requires negotiations for "a reasonable period of time" before a commercial, non-voluntary license is granted. However, the national legislator is free to define what constitutes a reasonable effort. It is also free to waive this requirement in order to solve a major public health crisis.

A government can use any patent and authorise any use for a government purpose as long as the right holder is adequately compensated.³²¹

The process of the granting and review of its terms can be entirely administrative. Considering the grounds for compulsory licensing it might even be preferable that it is partially so. An administrative agency might be better equipped to evaluate the overall usefulness of a compulsory license than a judge, educated and limited by the pleas of the parties involved in the case.

As for the so often debated level of remuneration to the right holder for the involuntary use, it is only stated that it shall be decided upon *in casu*. For increased transparency, each jurisdiction could establish guidelines for the determination of the mandatory royalty.

In the case of a product or a process often made out by several patents which can be owned by several different right holders, international law admits an order where the beneficiary of compulsory patent pays the remuneration to a fund. The different right holders can negotiate their share of the fund at their own expense. Furthermore, the national legislator is free to place the burden of proof for the adequacy of the remuneration on either the applicant or the right holder.

³¹⁷ Sherer (1977) p.45 and Sherer/ Watal, p. 26.

³¹⁸ Sherer/ Watal pp. 19-21.

³¹⁹ Sherer (1977) pp. 45-46 and Sherer/ Watal pp. 27-28.

³²⁰ This section draws heavily on the work of Mr. James Love. See his two articles "Check list for fast track compulsory licensing (v. 1.0)"

<http://www.cptech.org/ip/health/cl/fasttrack.html> (last visited 2004-06-30) and
"Compulsory Licensing: Models for state practice in developing countries, Access to medicine and compliance with the WTO TRIPS accord."

<http://www.cptech.org/ip/health/cl/recommendedstatepractice.html> (last visited 2004-06-30).

³²¹ TRIPS Article 44.2. offering the possibility to deny injunctions against governmental use without the consent of the right holder.

8 Swedish patent law

The present Swedish patent law³²² entered into force 1st January 1968.³²³ The purpose of patents or the Swedish patent law is not mentioned except for in one place, a brief commentary by the head of the Justice Department, Hans Rune Persson, when commenting on the Patent Committee's work on compulsory licensing due to a public interest of particular importance. He says that the very purpose of the patent regulation is to give inventors and enterprises a time-limited sole right to use the patented invention. Through this one aims to stimulate technical development and innovation as well as the publication of inventions and free use of the inventions after the patent duration³²⁴

The Swedish patent law has been updated to include Sweden's international commitments numerous times. The last revision was initiated by the Swedish Justice Department in 2001³²⁵ and was completed 1 May 2004 with Law (2004:159)³²⁶. The main purpose of this latter revision was to incorporate Directive 98/44/ EC on the legal protection of biotechnological inventions and to update the Swedish patent law vis-à-vis the TRIPS agreement. As for the rules of compulsory licensing this meant some changes in the actual material in addition to careful editing, which will be accounted for below.

Compulsory licenses are granted through judicial procedure.³²⁷ Stockholm's Tingsrätt³²⁸ is the exclusive forum.³²⁹ An applicant must also inform the Swedish Patent and Registration office of his application.³³⁰ A compulsory license can only be granted to someone with both the technical skill and the financial means to honour the license.³³¹ The applicant must also show that he has sought a voluntary license on reasonable terms without success.³³² An exclusive license can never be awarded, the patentee cannot be hindered

³²² Patentlagen (1967:837).

³²³ It succeeded the Ordinance of 16 May 1884 (No. 25) Regarding Patents (Förordningen den 16 maj 1884 (nr. 25) angående patent) which provided for compulsory license in two situations; patent suppression (15 §) and a prior user right (16 §).

³²⁴ Prop. 1966:40 p. 180-179.

³²⁵ Memorandum 2001:49, Legal protection for biotechnological inventions – incorporation of Directive 98/44/EG. (DS 2001:49, Rättsligt skydd för biotekniska uppfinningar – genomförande av direktiv 98/44/EG).

³²⁶ Law (2004:161) amendment of the patent law (1967:837) (Lag (2004:159) om ändring i patentlagen (1967:837)).

³²⁷ 6 chapter 50 § patentlagen (1967:837).

³²⁸ Stockholm's district court.

³²⁹ 9 chapter 65 § patentlagen (1967:837).b

³³⁰ 9 chapter 64 § patentlagen (1967:837).

³³¹ 6 chapter 49 § first passage patentlagen (1967:837).

³³² 6 chapter 49 § first passage patentlagen (1967:837). This is an incorporation of Article 31.b of the TRIPS agreement effectuated with Law (2004:161) amendment of the patent law (1967:837) (Lag (2004:159) om ändring i patentlagen (1967:837)).

from using the invention himself nor from licensing it to others.³³³ The imposed use is non-assignable except as a part of an enterprise which is actually, or about to, exercise it.³³⁴

The Court decides which of the patentee's rights should be transferred to the claimant. It also decides the terms of the license and the compensation to the right holder. If required by essentially changed circumstances, the court may cancel the license or change its terms.³³⁵ Even if it is not mentioned in the wording of the law, the preparatory work of the law declares that the compulsory license should be proportionate to the situation it is to rectify.³³⁶

The Swedish patent law contains four grounds for the granting of a compulsory license; failure to work³³⁷, interdependent patents³³⁸, public interest of particular importance³³⁹ and a prior user right^{340,341}.

8.1.1 Failure to Work

Since 1 May 2004 does 45 § patentlagen (1967:837) reflect three different corps of law, with three different jurisdictions.

First, the Law as it stood before 1 May 2004 is still valid when it comes to patents outside the EEC/WTO. To this extent is 45 § patentlagen (1967:837) modelled upon Article 5 A.4 of the Paris Convention.

The patentee is obliged to practise the subject matter of the patent to a reasonable extent, within the country of origin, that is in Sweden. If the patentee cannot present an acceptable reason for his omission, the Court can grant a compulsory license to the applicant, provided that three years have passed from the date when the patent was issued or four years from when the application was filed, whichever period expires the last.³⁴²

The practise has to consist of the manufacture of the patented product or application of the patented process.³⁴³ This is an obligation which can be

³³³ 6 chapter 49 § second passage patentlagen (1967:837).

³³⁴ 6 chapter 49 § third passage patentlagen (1967:837).

³³⁵ 6 chapter 50 § patentlagen (1967:837).

³³⁶ NU 1963:3 s. 307 and Prop 1966:40 p. 184.

³³⁷ 6 chapter 45 § patentlagen (1967:837).

³³⁸ 6 chapter 46 § patentlagen (1967:837).

³³⁹ 6 chapter 47 § patentlagen (1967:837).

³⁴⁰ 6 chapter 48 § patentlagen (1967:837).

³⁴¹ It succeeded the Ordinance of 16 May 1884 (No. 25) Regarding Patents (Förordningen den 16 maj 1884 (nr. 25) angående patent) which provided for compulsory license in two situations; patent suppression (15 §) and a prior user right (16 §).

³⁴² 45 § first passage patentlagen (1967:837).

³⁴³ NU p. 298 and Prop 1966:40 p. 166.

fulfilled through voluntary licensing,³⁴⁴ but it cannot be circumvented by importation.³⁴⁵

Legislative history presents a few acceptable reasons for the non-working of a patent; legal impediments, lack of raw materials and if the patentee uses an alternative invention. Insufficient financial means, an insufficient market or inability to find potential licensees are not regarded as legitimate reasons for non-use of the patented subject matter.³⁴⁶ The Court is, however, free to judge the circumstances in the particular case.³⁴⁷

Second, the obligation to practice the subject matter of the patent can be fulfilled through importation from another Member of the EEC.³⁴⁸ This is a mere codification of the ECJ rulings C-235/89³⁴⁹ and C-30/90³⁵⁰.

Lastly, importation from a member of the WTO is to be on a par with working in Sweden.³⁵¹ Clearly, the Swedish legislator chose the more extensive reading of Article 27 in its incorporation of the TRIPS agreement.³⁵²

Of some interest is the fact that the government, bearing in mind the situation of foreign screening due to patents, is of the opinion that if the terms of the importation are so unreasonable so that the screening in practice does not come about or only comes about to a limited extent, the patented invention cannot be considered as used to a reasonable extent according to § 45 patentlagen (1967:837).³⁵³ As the final law turned out, this opinion can only be considered when dealing with patents originating outside the EU/ WTO.

³⁴⁴ NU p. 299.

³⁴⁵ NU p. 298 and Prop 1966:40 pp. 165-166.

³⁴⁶ NU p. 299 and Prop 1966:40 p. 165.

³⁴⁷ NU p. 299.

³⁴⁸ 45 § second passage patentlagen (1967:837).

³⁴⁹ C-235/89 Commission v. Italian Republic [1992] ECR I-777. See also chapter 5.2.4.4 above.

³⁵⁰ C-30/90 Commission v. United Kingdom and Northern Ireland [1992] ECR I-829. See also chapter 5.2.4.4 above.

³⁵¹ 45 § second passage patentlagen (1967:837).

³⁵² See text accompanying footnotes 282-283 above. Interestingly the Justice Department seemed somewhat ambivalent in its interpretation of Article 27 of the TRIPS agreement. Initially the Justice Department proposed the more rigid interpretation of Article 27.

However, in the proposition to the Riksdag (the legislative assembly of Sweden) the Justice Department argues for the more extensive reading of Article 27. Finally it was the initial position of the Department which was adopted by the Riksdag. See Memorandum 2001:49, Legal protection for biotechnological inventions – incorporation of Directive 98/44/EG. (DS 2001:49, Rättsligt skydd för biotekniska uppfinningar – genomförande av direktiv 98/44/EG), pp. 22, 81, 91, 45 and Prop. 2003/04:55 Limits on gene patents etc. – incorporation of the EC Directive on legal protection for biotechnological inventions (Prop. 2003/04:55 Gränser för genpatent m.m. - genomförande av EG-direktivet om rättsligt skydd för biotekniska uppfinningar) pp. 17, 114-116, 150.

³⁵³ Prop 2004/04:5 p.115.

8.1.2 Interdependent Patents

The amendment of Law (2004:159)³⁵⁴ meant only minor changes in the right to a compulsory license due to overlapping and blocking patent rights.³⁵⁵

Today, 46 § patentlagen (1967:837) has the exact same meaning as Article 31.1 of the TRIPS agreement. If a patentee cannot exploit his patented invention without infringing another, previously issued patent, the patentee of the later patent may be granted a compulsory license for the earlier patent. The patentee of the later invention must, however, show that his invention represents an important technical advance of considerable economic significance.³⁵⁶

The new reading of 46 § patentlagen (1967:837) also gives the earlier patentee the right to a cross-license on reasonable terms in the later patent.³⁵⁷

Before the amendment, the later patentee had to show that a compulsory license of the earlier patent was reasonable due to the importance of the later patent or if any other particular reason was at hand.³⁵⁸ The proprietor of the previously issued patent could also be granted a compulsory license to use the later patent, unless particular reasons speak against it.³⁵⁹

As for 46 § patentlagen (1967:837), the amendment involved two improvements. First, the grounds to be considered are presented in the provision itself. The former reading was rather vague in this point although the preliminary work provided some guidance.³⁶⁰ Second, the compulsory license or a cross-license has become more transparent since the discretion of the Court has been curtailed. The Court can no longer refer to particular reasons when issuing an compulsory license or when denying a cross-license.

³⁵⁴ Law (2004:161) amendment of the patent law (1967:837) (Lag (2004:159) om ändring i patentlagen (1967:837)).

³⁵⁵ Memorandum 2001:49, Legal protection for biotechnological inventions – incorporation of Directive 98/44/EG. (DS 2001:49, Rättsligt skydd för biotekniska uppfinningar – genomförande av direktiv 98/44/EG). Bodenhausen p. 70. 46 § patentlagen (1967:837).

³⁵⁶ 46 § first passage patentlagen (1967:837).

³⁵⁷ 46 § second passage patentlagen (1967:837).

³⁵⁸ 46 § first passage patentlagen (1967:837) prior to Law (2004:161) amendment of the patent law (1967:837) (Lag (2004:159) om ändring i patentlagen (1967:837)).

³⁵⁹ 46 § second passage patentlagen (1967:837) prior to Law (2004:161) amendment of the patent law (1967:837) (Lag (2004:159) om ändring i patentlagen (1967:837)).

³⁶⁰ It was not required that the second patent should be of importance to the industry as a whole but there had to be a substantial interest in launching the improvement on to the market (NU p. 300). The improvement had to represent a considerable technical advance (Prop 1966:40 p. 171). A less noteworthy improvement could be issued a compulsory license if the applicant's market didn't intrude the first patentee's (NU p. 301). If the improvement was of particular importance for society, the improver could still be issued a compulsory licence even if he was a competitor to the first right holder (Prop 1966:40 p. 171). Disproportion between the importance of the inventions or the businesses of the parties could reverse the presumption of a cross license stipulated in the second section of the paragraph (NU p. 301).

The latest revision also created an entirely new paragraph, 46 a § patentlagen (1967:837) which reflects the increased interplay between breeders' right and patent law. Breeders and patentees have an equal right to a compulsory license to each other's rights when they hinder the exercise of each other's inventions. These compulsory licenses are to be granted on the same grounds as interdependent patent licenses, this being an incorporation of Article 12 of Directive 98/44/EC.

8.1.3 Public Interest of Particular Importance

Another general limitation of the patent right, not to be confused with expropriation, is compulsory licensing in consideration of a public interest of particular importance.³⁶¹ The preliminary work provides some guidance to the interpretation of this generally stipulated section of the law.

The Patent Committee and the head of the Justice Department pointed out that it was grounds for compulsory licensing to be used with considerable caution. It can only be considered when it comes to basic functions of society. The examples given are national security, the people's supply of medical products and provisions, the power supply, the system of communication and military preparedness^{362 363}.

Society also has an interest in sound competition in the market place. An abuse of a dominant position created by a patent right should in the first place be solved by competition law. Only if the measures of competition law are insufficient should 47 § patentlagen (1967:837) come into question.³⁶⁴

It is also stated with emphasis that the interest considered should be public in an objective sense. The conditions of the applicant are irrelevant and governmental enterprises do not occupy a place apart.³⁶⁵

The Patent Committee anticipated that the Court might find, all facts considered, that a deviation from the lost profit principle is motivated in

³⁶¹ 47 § patentlagen (1967:837). Compulsory acquisition is stipulated in 78 § patentlagen (1967:837), a paragraph not treated here.

³⁶² As for military inventions one has to consider Law (1971:1078) about defence inventions (Lag (1971:1078) om försvarsuppföringar). If a military invention, originating in Sweden or elsewhere, is essential for Swedish military forces, the Swedish government can use it without consent or declare that the patent shall benefit the Swedish government regardless of whether the holder of the Swedish patent is Swedish or foreign (13 and 18 §§). The patentee may seek adequate remuneration for governmental use or take over at Stockholms District Court, StockholmsTingsrätt (4 §).

³⁶³ NU p. 301 and Prop 1966:40 p. 179.

³⁶⁴ NU pp. 301-302 and Prop 1966:40 p. 179. When reading the statements concerning the interaction between patent law and competition law, one should bear in mind that the competition law of the time (Lagen (1953:603) om motverkande i vissa fall av konkurrensbegränsning inom näringslivet) rested on slightly different principles than the present one (Konkurrenslagen (1993:20)).

³⁶⁵ NU p. 301 and Prop 1966:40 p. 179.

cases of compulsory license in consideration of a public interest of particular importance.³⁶⁶

8.1.4 Prior User Right

The remaining grounds for granting a compulsory license is the prior user right in paragraph 48. This prior use right, together with 4 §³⁶⁷ patentlagen (1967:837), can be traced to a Natural Rights Theory line of thinking and the inventors natural right to his invention. The patent law is, however, formed after mainly utilitarian considerations. It is, for example, the first to file and not the first to invent who has a right to a patent.³⁶⁸

One may be granted a compulsory license if one has exercised someone else's patented invention before the patent application was made public. One must however establish a particular reason for this right to be issued. The applicant must furthermore show that he had no knowledge of the patent application and that he reasonably could not have been informed of it³⁶⁹.

He who has not put into use the patented invention yet but has made substantial preparations for professional use thereof, has the same burden of proof.

The compulsory license can only cover the existing use or the use that has been prepared for, not future expansion or development.³⁷⁰

This paragraph has not been interpreted by any court. The Committee has declared that this is a special provision to be used when important considerations are adduced, something made clear when the particular reasons mentioned above are referred to, such as when substantial values are at stake, both for the applicant individually and for the national economy.³⁷¹

8.1.5 Compensation

According to § 50 patentlagen (1967:837), the patentee has a right to compensation for the imposed use of his invention. There are no principles for the determination of the compensation laid down in the law. The preliminary work of the patent law and commentators assert that the patentee shall, as a general rule, be fully compensated for the involuntary

³⁶⁶ NU p. 308 and Prop 1966:40 p. 184.

³⁶⁷ The essence of 4 § Patentlagen is that if someone uses an invention professionally before some else files a patent application for the invention the former may continue to use the invention regardless of the patent. The use may not be obviously contrary to the interests of the patent applicant. The prior user right is only assignable with the enterprise where the prior right emerged or should have taken place.

³⁶⁸ 1 § Patentlagen (1967:837).

³⁶⁹ So called "qualified good faith".

³⁷⁰ 48 § patentlagen (1967:837).

³⁷¹ NU p. 303 and Prop 1966:40 p. 181.

use of his patented solution.³⁷² Where there exist comparable licenses negotiated at arms length, the rate of royalty may provide appropriate guidance for the compensation.³⁷³

However, voluntarily negotiated royalties are usually also payment for valuable know-how and include other arrangements than the right to use the subject matter. A compulsory license does not include know-how.³⁷⁴

Deviation from the lost profit standard is proposed in three cases. First, if the patentee has abused his patent right to such a degree that a compulsory license in the public interest³⁷⁵ is under consideration. Second, if the patentee has not fulfilled the local working obligation in § 45 Patentlagen. Then the remuneration must be set so that it does not precludes the licensee's competition with the licensor. The licensor's compensation will be determined by a two-step hypothetical lost-profit calculation. First one must estimate what the profits of the patentee would be if he had satisfied the domestic demand with local production. The compensation is then supposed to correspond to what the patentee would lose from the estimated, hypothetical profit in the competition with the beneficiary of the compulsory license.³⁷⁶

The last case is when the patentee has violated the competition laws.³⁷⁷ In the case of anti-competitive behaviour the patentee is to be compensated for his research costs and the social importance of the invention but the licensee must be able to maintain a competitive price.³⁷⁸

As mentioned above³⁷⁹, the Patent Committee anticipated that the Court might find, all facts considered, that a deviation from the lost profit principle is motivated in cases of compulsory license in consideration of a public interest of particular importance.³⁸⁰

8.1.6 Summary

Sweden has had a compulsory license regime since the nineteenth century. Swedish patent law contains four grounds for compulsory licensing. One provision regarding patent suppression is modelled upon Article 5 A of the Paris Convention. The legislative freedom vis-à-vis international commitments has been used on three occasions. The legislator has provided for a prior user right and the authority to grant a compulsory license in the case of a public interest of particular importance and to remedy the deadlock situation of overlapping patent rights. The latter two grounds have

³⁷² What is generally conceived as “lost profit” compensation. NU, p. 308. Jacobsson m.fl. p. 298.

³⁷³ Jacobsson m.fl., p. 299.

³⁷⁴ Ibidem p. 285 and p. 299.

³⁷⁵ 47 § patentlagen (1967:837).

³⁷⁶ NU p. 308. Jacobsson m.fl., p. 299.

³⁷⁷ Ibidem p.299.

³⁷⁸ Ibidem p.299.

³⁷⁹ See text accompanying footnote 366.

³⁸⁰ NU p. 308 and Prop 1966:40 p. 184.

eventually found corresponding elements at an international level in Article 31.b and 31.l of the TRIPS agreement. The TRIPS agreement has in its turn motivated a revision of the Swedish rules.

No compulsory license has been granted since the present Patent Law of 1967 entered into force. Interpretative sources are scarce.

The amendment of 2004³⁸¹ made the Swedish Patent Law congruent with Sweden's international commitments. The revision brought with it no surprises except when it comes to compulsory licensing due to insufficient working, 46 § patentlagen (1967:837). ECJ case law³⁸² abolished the obligation for the patentee to work his patent within the EEC. The Swedish Riksdag chose³⁸³ to abolish this obligation within the geographical area of the WTO members. A partial but substantial breach of the jurisprudence of Article 5.A of the Paris Convention stating that importation of a patented product is not considered to be sufficient working of a patent.³⁸⁴ The members of the EEC/ WTO constitutes such an important market that most inventions of any importance should be patented within their jurisdiction.

³⁸¹ Law (2004:161) amendment of the patent law (1967:837) (Lag (2004:159) om ändring i patentlagen (1967:837)).

³⁸² Case C-235/89 Commission v. Italian Republic [1992] ECR I-777, and Case C-30/90 Commission v. United Kingdom and Northern Ireland [1992] ECR I-829.

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³⁸⁴ Bodenhausen p. 69, NU p. 298 and Prop 1966:40 pp. 165-166.

9 Analysis

Myriad Genetics has a valid patent. It has a right to hinder others from using its patented knowledge. There are many others with patent rights in BRCA1 and BRCA2 technology. The situation at hand is, however, not to be considered a tragedy of the Anti-Commons. It is not the right holders who prevent each other from using the technology as a whole, it is one right holder, Myriad Genetics, which may charge a third party, Prof. Olsson, for the use of one patent. If Lund University Hospital does not pay the agreed royalty, Myriad Genetics may prevent the Department of Oncology from using the patented screening method.

9.1 Compulsory License, On What Grounds?

Is a compulsory license a way to free the use of the Myriad Genetics patent number EP0705903 for Dr. Olsson? Compulsory licensing of patents is a well-established but highly controversial institution. It has been so at the international level ever since the first international patent conference in 1873 up to today's WTO negotiations.

It is true that compulsory licensing strikes at the very core of the patent right, in other words the sole right of the patentee to use his invention.

Regarding the legal framework only, it is hard to understand why it is so disputed. On the one hand, national legislators have considerable freedom to shape their own patent laws and compulsory licensing regimes. On the other hand, existing rules on compulsory licensing of patents do not pose much of a threat to right holders; at least not the Swedish rules.

The debate is more understandable if one considers the political dimension of the topic. There exists a clear north – south tension. Whereby the northern hemisphere is for compulsory licensing of patents when it is carried out in its own territory. But against it when it is enforced in the southern hemisphere, even when it is correctly done by international standards. Whereas the countries of the southern hemisphere want the same right of self-determination as the countries of the northern hemisphere. The August 2003 Decision marks a détente between the two positions since the northern countries, with the U.S. in the fore, forced intellectual property protection into the WTO agreement. How this truce will work in practice is yet to be seen.

In the case at hand, a compulsory license must be applied for in Stockholm's District Court, Stockholms Tingsrätt. The EPC does not contain any rules on compulsory licensing and once a European Patent is issued it shall be regarded as a national patent. The European rules of free movement of goods does not stand in the way of issuing a compulsory license. Myriad Genetics is not an enterprise with a European location.

There are many potential patentees for a compulsory license. If an application is made by Prof. Olsson for a compulsory license it is possible that it will attract other rent-seeking patentees also claiming the right to compensation. International conventions or Swedish patent law does not hinder a solution where the Court orders a common remuneration to all of the patentees to be divided among the right holders at their own expense.

Prof. Olsson and his colleagues do not need additional know-how to assimilate patent number EP0705903.

9.1.1 Prior User Right

The main question is on what grounds Prof. Olsson deserves a compulsory license for the Myriad Genetics Patent. Prof. Olsson does not claim that he used the patented process of diagnosing breast and ovarian cancer before Myriad Genetics patent application became public. Unless he can prove that he did, he does not merit a prior user right³⁸⁵.

9.1.2 Overlapping Patent Rights.

The transaction between Dr. Olsson and Myriad Genetics seems to have the character of a one-time event. But since Dr. Olsson does not have a patent that overlaps the Myriad Genetics patent, a compulsory license due to interdependence³⁸⁶ cannot come into question.

9.1.3 Local Working

Prof. Olsson will also have difficulty in claiming that Myriad Genetics has not fulfilled its obligation to work its patent within Swedish jurisdiction³⁸⁷. Myriad Genetics is the proprietor of a European patent right. Its administrative headquarters are in the USA. The USA is a member of the WTO and therefore, according to the new wording of 45 § patentlagen (1967:837), Myriad Genetics' activity in the USA will be taken into consideration when assessing its activity in Sweden.

Myriad Genetics has offered Dr. Olsson and his colleagues at the University Hospital of Lund to perform the diagnoses for them. The screening made by Myriad Genetics in the USA is to be placed on equal footing with local working in Sweden. Insufficient use of patent number EP0705903 is not relevant grounds in this particular case.

³⁸⁵ 48 § patentlagen (1967:837).

³⁸⁶ 46 § patentlagen (1967:837).

³⁸⁷ 45 § patentlagen (1967:837).

9.1.4 Public Interest

Is Dr. Olsson's access to Myriad Genetics' patent a public interest of particular importance according to 47 § patentlagen (1967:837)?

From a theoretical perspective, 47 § patentlagen (1967:837) is to correct the market failure of public goods.³⁸⁸

The Myriad Genetics patent does not contain a solution to, nor a treatment for, women's breast and ovarian cancer. The patented technology is only a way of diagnosing it. Its advantage is that the patient can be diagnosed at a very early stage.

In explaining what constitutes a public interest, the preparatory work mentions state security, power supply, general communications and the public's access to nutrition and medication. One cannot disregard the fact that the statement was written at a time when the above-mentioned activities were provided for by the public sector to a far greater extent than today. Purely private interests can never be satisfied through such a license on these grounds. The public sector status of Prof. Olsson's activity at Lund University Hospital is not relevant.

Breast and ovarian cancer is a tragedy for the stricken individual. However, hereditary breast or ovarian cancer is not infectious, it is not a pandemic. The disease does not pose a threat to public health nor society as a whole. Any woman can consult a Swedish doctor and get a letter of referral to an oncologist. The diagnosis of one patient does not hinder the next woman from getting a diagnose as well. The diagnosis of breast and ovarian cancer does not pose a public good dilemma. Therefore, hereditary breast and ovarian cancer does not activate the economic theory which justifies the rule.

According to the preliminary work, the situation at hand can still be a public interest of particular importance for reasons other than the market failure of public goods.

Swedish healthcare and the treatment of cancer are included in general welfare. It is financed by the taxpayers and liable to a fee payable by the patient.

One of the public interests of particular importance mentioned in the preparatory works, is the public's access to medication. The wording implies that it was medical products the legislator had in mind, not medical processes. Medical process patents were not common in the 1960's when the present patent law came into force.

If one would treat the process patent at hand in analogy with a product patent, does Myriad Genetics, through its patent, hinder Prof. Olsson from diagnosing his patients?

Myriad Genetics does not deny Prof. Olsson and his colleges the patented technology. The company has offered to conduct the screening for a fee.

In order to define this cost one has to distinguish between full sequence analysis of BRCA1 and BRCA2 and testing for a previously specified

³⁸⁸ See chapter 6.5 above.

known mutation. Myriad Genetics also makes a distinction between on the one hand health care and screening performed on commercial terms and on the other non-commercial research.

Prof. Olsson's medical profession and academic research are one entity. But his activity seems to correspond to a very high degree to the circumstances Myriad Genetics accounts for when evaluating whether the licensee's activity is to be considered as non-commercial. There is nothing in the draft agreement which obliges Myriad Genetics to classify the activity of the licensee as one thing or the other.

If Myriad Genetics considers the activity of Lund University Hospital to be of a commercial nature, the Department of Oncology has to pay the full price for the full sequence analysis of BRCA1 and BRCA2 performed by Myriad Genetics and the testing for a previously specified known mutation performed by Prof. Olsson and his colleagues. If Myriad Genetics considers the activity of Lund University Hospital to be non-commercial research, the Department of Oncology has to pay the full price for the full sequence analysis of BRCA1 and BRCA2 performed by Myriad Genetics but the testing for a previously specified known mutation performed by Prof. Olsson and his colleagues is offered free of charge.

The demanded down payment apart, the actual royalty fee corresponds to the Department of Oncology's internal cost of conducting the screening. When demanded, the royalty raises the cost of each screening by 100%. Together with the down payment, the royalty may constitute an extraordinary budgetary burden for the department which in turn could prevent Prof. Olsson from diagnosing his patients at the early stage made possible by the patented technology.

Does this signify grounds for a compulsory license according to 47 § patentlagen (1967:837)? No, it does not. There exists an explicit political will for patenting of industrial applications of a sequence or a partial sequence of human gene. One effect of the latest revision is that Prof. Olsson and his colleagues at Lund University Hospital are potential patentees and are placed on equal footing with Myriad Genetics. In future, Lund University Hospital might hold the same status.

Human genes are made patentable in order to stimulate private investment in this area. If Prof. Olsson was awarded a compulsory license on patent number EP0705903, the relation between him and Myriad Genetics would be asymmetrical in a way not motivated by patent law. Prof. Olsson would bag a free ride on Myriad Genetics costs of development and still be able to charge Myriad Genetics and others for the use of his patented solutions.

Furthermore, the conclusion is made by analogy with medical products from a statement in the preliminary works written at a time where the public sector was far greater than today. Patented pharmaceutical products are subsidised by the taxpayers through the general welfare system. Even if this expense stretches the budget of the country, no compulsory licenses are issued for this reason.

Also, compulsory licensing is simply not the solution to limited financial means. The patentee has a right to adequate compensation for the

involuntary use of the beneficiary of the compulsory license. Apart from the down payment, Myriad Genetics' fee for performing the screenings corresponds to the Department of Oncology's own cost of performing them itself. It is true that Myriad Genetics with its industrialized screening program enjoys the advantages of large scale production but the corresponding level of Dr. Olsson's screening cost and Myriad Genetics' royalty fee indicates that the latter's down payment is motivated by the patentee's just claim to an economic rent on his investment.

If Myriad Genetics' royalty claims should hinder Lund University Hospital from diagnosing its patients, the hospital should request a greater public appropriation or raise the patient's fee. Nothing holds that health care must be arranged by the government only. If the government cannot afford it, over time, private health providers will offer cancer diagnoses outside the general welfare system. This is an activity to be regulated by the appropriate authorities.

9.2 The Heart of the Matter

The heart of the matter seems to be that Prof. Olsson is reluctant to take the risk of pre-publication exposure of his research to a third party and competitor in the race for academic esteem and patent rights.

Is Prof. Olsson's research a public interest of particular importance?

The Swedish government think that Dr. Olsson's research is important enough to merit public funding, even if private entities have started to produce knowledge in the field of hereditary breast and ovarian cancer. Dr. Olsson's research might contribute to a greater understanding of breast and ovarian cancer and this is important. It does not change the fact that the diagnosing of Swedish cancer patients is not solely dependent on the research of Dr. Olsson and his colleges. Prof. Olsson's research is not a public interest of particular importance in the meaning of 47 § patentlagen (1967:837), especially not if one sees the members of the Department of Oncology not only as publicly funded researchers but as potential private patentees and entrepreneurs.

The fact that Myriad Genetics, apart from the down payment, does not charge more for the screenings than the cost of performing them³⁸⁹ could indicate that the commercial value of its patented process lies elsewhere than in the collection of royalties.

Furthermore, Myriad Genetics is only interested in full sequence analysis, meaning blood from a patient that has not yet been diagnosed with cancer. Once the patient through a full sequence analysis has been diagnosed, the department may perform further BRCA1 and BRCA2 screenings independently subject to the license fee. It is true that Myriad Genetics

³⁸⁹ See text accompanying footnotes 32-37.

removes the demand for payment if the screenings are made for research purposes, but then it is only screenings of known mutations that are free of charge. Screenings of samples of blood where a mutation is unidentified is still to be conducted by Myriad Genetics and is liable to a fee even if the specimen is part of pro bono research.

In order to get the permission to conduct screenings free of charge, the licensee must indicate what research is being carried out. Thus, if a licensee has been given permission to conduct free screenings for research purposes it is not difficult for Myriad to put two and two together and come to the conclusion that research is made on the blood that the licensee is not allowed to screen. Even if an academic entity does not try to obtain the permission to perform the research screenings free of charge, Myriad Genetics might still be able to sort out what their partners are doing.

In this way Myriad Genetic gains access to high-risk blood without ever being in contact with the patients. Blood, which is the main tool in the research for further understanding of breast and ovarian cancer. The blood samples are also a necessity in the development of eventual, profitable cures for these diseases.

The particularity of the Myriad process patent and the grant back clause of the draft agreement, gives Myriad Genetics not only a strong position on today's market for screening for mutations in the BRCA1 and BRCA2 genes, but also free access to and perhaps even control over future developments in the field.

Whether this position is motivated from a patent law perspective depends on which patent theory one adheres to. The Reward Theory stipulates that the patentee shall be compensated through monopoly-like pricing and license fees in proportion to his contribution to society. It is retrospective and does not recognize the right holder as having any claim to future developments of the technology in question.

The strong position of Myriad Genetics is, on the other hand justified by modern economic theory³⁹⁰ and the writings by Edmund Kitch. Mark Skolnick and his colleagues brought the patented method to the market driven by a potential profit, and the patent, however broad, is motivated from an efficiency perspective. As a strong right holder, Myriad Genetics can control and co-ordinate further development so that duplicative investments are avoided

Prof. Olsson's research and Myriad Genetics' patent are two different solutions to the same public goods problem, the sub-optimal production of new information by private entities. In order to stimulate the development of new knowledge, governments act both directly and indirectly; directly through governmentally funded research and indirectly through the

³⁹⁰ The notable exception is the Race To Invent Theory presented by Robert P. Merges and Richard R. Nelson. The Race To Invent Theory seems closer to development through an open research society as described by Robert K. Merton than development through patent rights as they are shaped today. See chapters 3.1 and 4.1.1.4 above.

establishment of patent rights. The former is a direct public cost and the latter is introduced at the macroeconomic cost of monopoly-like pricing. The government has to finance basic research since it does not generate short-term profits. Private investors will invest in research and development when they see a potential profit with an acceptable risk. Patent rights help private investors to estimate when they can shoulder this public responsibility. Hence, in principle, Prof. Olsson produces new public knowledge and Myriad Genetics produces new products and services to a paying public.

In reality the two parties are more equal than what the theory holds. Directive 98/44/EC and Law (2004:161) amendment of the patent law (1967:837)³⁹¹ made Prof. Olsson a potential patentee³⁹² and entrepreneur just as much as is Myriad Genetics. Also, the Swedish Minister of Education is currently investigating the possibility of dividing the ownership of the patents filed by university employees between the university researcher and the university.³⁹³ This makes public universities possible entrepreneurs just as much as private companies.

Hence, the issue to be decided on is a matter of principle between two equals. Is Myriad Genetics only entitled according to the value of its contribution or should the company be able to stretch patent law to its limit in order to extract as much profit as the market can bear?

There is nothing in this case which motivates a deviation from the utilitarian perspective of patent law advocated by the Swedish Minister of Justice to the advantage of the Natural Rights oriented view of the European Court of Justice. The latter view would circumscribe the patentees' normal liberty of action. Prof. Olsson's is an equal to Myriad Genetics in a patent law perspective. The diagnosing of cancer is not a public good. Poor public financing is not relevant in this case. Patients are not solely dependent on Dr. Olsson's research and Myriad Genetics is free to stop others from using its patented process.

If one thinks that the patent issued to Myriad Genetics is too broad, Swedish authorities cannot invalidate it nor redefine it in order to make it narrower.³⁹⁴ However, if the Swedish legislator is of the opinion that economic efficiency is of secondary importance in the search for greater understanding of breast and ovarian cancer and emphasises the pace towards new knowledge, a more competitive research climate can be created through the same legislative technique as used with military inventions.³⁹⁵

³⁹¹ Law (2004:161) amendment of the patent law (1967:837) (Lag (2004:159) om ändring i patentlagen (1967:837)).

³⁹² See chapter 8 above.

³⁹³ Thomas Östros; *Forskare ska inte längre äga sina resultat*, Dagens Nyheter, 2004-02-05.

³⁹⁴ See text accompanying footnote 215.

³⁹⁵ See footnote 362.

The government may authorize any use of a patented product to a third party as long as the right holder is adequately remunerated.³⁹⁶

It is therefore permissible to establish a rule which gives publicly funded researchers the right to use patented biological research tools where the right holder demands the right to perform the patented process himself for a fee. Such a rule does not have to be confined to biological research tools.

If the Swedish government sees itself as a potential exporter in accordance with the August 2003 decision, it might be practical to avoid legal proceedings when failing to obtain a voluntary license. The rule can be widened to embrace such a negotiation breakdown.

In order to forestall other future eventualities, there is also the possibility to establish a carte blanche for governmental use of any patented invention on the pattern of the US Act 28 U.S.C § 1498.

In any case, the right holder must be adequately remunerated for the involuntary use. The remuneration is to be subjected to administrative or judicial review. The decision-making body can be the government itself or a governmental agency which also can decide the level of the remuneration. The remuneration can be appealed against at Stockholm's Crown Court, Stockholms Tingsrätt.

If the rule is established outside the patent law, it will not usurp patent law principles nor the compulsory licensing institution.

³⁹⁶ See text accompanying footnote 321.

10 Conclusion

The answer to the opening question is no. A compulsory license is not a way to free use for Prof. Olsson and the Department of Oncology at Lund University Hospital of Myriad Genetics Patent number EP0705903. The answer is negative for two reasons. First, even if Prof. Olsson's department would merit a compulsory license of Myriad Genetics patented process, it would still have to pay for the use of the technology. Myriad Genetics would have a right to adequate compensation for the involuntary use by Prof. Olsson and his colleagues.

Second, a compulsory license is not a way for Prof. Olsson to obtain freedom of action over the patented technology; simply because neither the activity of Lund University Hospital nor the behaviour of Myriad Genetics meets the prerequisites for a compulsory license to be issued for the benefit of Prof. Olsson.

In order to obtain a compulsory patent license the applicant must have made an honest effort to obtain a voluntary license from the patentee and failed. It is hard to make a genuine analysis of the situation at hand since Prof. Olsson and his department have not answered Myriad Genetics' proposal and the parties have not entered into any negotiations.

From the facts of the case, it is easy to conclude that the Department of Oncology cannot claim to have a prior user right,³⁹⁷ nor does it merit a compulsory licence because of overlapping or dependent patent rights.³⁹⁸ Myriad Genetics is to be considered a national producer,³⁹⁹ and patent number EP0705903 does not conflict with any absolute public interest.⁴⁰⁰

It is true that the patent might have some effects on the research conducted at the Department of Oncology, but this activity is not a public interest of particular importance. The activity protected by the compulsory license regime is the care of the patients and it is not disturbed by the Myriad Genetics patent.

There are legislative techniques, sanctioned by international law and used by the Swedish legislator, to preserve the academic freedom of Prof. Olsson and his colleagues but they do not preclude that Myriad Genetics has the right to pecuniary compensation for its contribution to society.

³⁹⁷ 48 § patentlagen (1967:837).

³⁹⁸ 46 § patentlagen (1967:837).

³⁹⁹ 45 § patentlagen (1967:837).

⁴⁰⁰ 47 § patentlagen (1967:837).

Supplement A

Patents valid in Sweden mentioning “BRCA1” and “BRCA2” in their abstract. The search was conducted in The European Patent Office online database, www.espacenet.com, on 2003-04-16. Patents typed in italics mention both the BRCA1 and 2 gene and are therefore on both lists.

BRCA1

1. WO0236819 (The Academy of Applied Science)
2. EP1006181 (Affymetrix Inc.)
3. *WO9902715 (Allegheny Health, Education and Research Foundation)*
4. EP0918788 (The Board of Regents, the University of Texas System, based on application WO9801460)
5. WO9812327 (Board of Regents, the University of Texas System)
6. WO02100897 (Centre National de la Recherch Scientifique and Université Claude Bernard Lyon 1)
7. *WO9808394 (Cornell Research Foundation Inc.)*
8. EP1036199 (Gene Logic, based on application WO9929903)
9. EP1126034 (Gene Logic Acquisition Corp.)
10. WO0118254 (The Government of the United States)
11. WO9818966 (Lescallet, Jennifer)
12. EP0705903 (Myriad Genetics Inc., Centre de Recherch du Chul, Cancer Institute Tokyo)
13. EP0699754 (Myriad Genetics Inc., The University of Utah Research Foundation, The Government of the United States of America) **Revoked 18 May 2004**
14. EP0705902 (Myriad Genetics Inc., The University of Utah Research Foundation, The Government of United States of America)
15. WO9927075 (Myriad Genetics)
16. WO0066767 (North Shore Long Island Jewish Health Systems)
17. WO9805677 (Oncormed Inc.)
18. EP0820526 (Oncormed Inc., based on application WO9729213)
19. *WO9915704 (Oncormed Inc.)*
20. EP0929668 (Onyx Pharmaceuticals Inc., based on application WO9810066)
21. WO9633271 (The Regents of the University of California)
22. WO9855650 (Rijksuniveriteit te Leiden)
23. WO02103320 (Rosetta Inpharmatics Inc.)
24. WO9811256 (The Trustees of Columbia University in the City of New York)
25. WO9950280 (Trustees of the University of Pennsylvania)
26. WO9823779 (The University of Utah Research Foundation)
27. *WO 9730108 (Vanderbilt University)*
28. WO9519369 (Vanderbilt University)
29. WO9743441 (Visible Genetics Inc.)

30. WO0208254 (The Wistar Institute of Anatomy and Biology)
31. EP0950189 (The Wistar Institute of Anatomy and Biology, based on application 29. WO9805968)

BRCA2

1. *WO9902715 (Allegheny Health, Education and Research Foundation)*
2. EP0858467 (Cancer Research Campaign Technology Limited, based on application WO9719110)
3. EP0977847 (Cancer Research Campaign Technology Limited, based on application WO9848013)
4. *WO9808394 (Cornell Research Foundation Inc.)*
5. EP1036197 (GeneLogic, based on application WO9928506)
6. WO0118254 (The Government of United States of America)
7. WO9855616 (Incyte Pharmaceuticals Inc.)
8. WO0053630 (Lexicon Genetics Inc.)
9. EP1025203 (Lexicon Genetics Inc., based on application WO9910479)
10. WO9820030 (Lexicon Genetics Inc.)
11. EP0785216 (Myriad Genetics Inc., Endo Recherche Inc., The Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership)
12. EP1260520 (Myriad Genetics Inc., Endo Recherche Inc., The Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership)
13. EP0994946 (Oncormed Inc., based on application WO9909164)
14. *WO9915704 (Oncormed Inc.)*
15. WO9915701 (Oncormed Inc.)
16. *WO9730108 (Vanderbilt University)*
17. WO0238795 (The Wistar Institute of Anatomy and Biology)

Applicants

1. The Academy of applied Science (1 BRCA1)
2. Affymetrix (1 BRCA1)
3. Allegheny (1 BRCA1/2)
4. Board of regents, the University of Texas System (2 BRCA1)
5. Cancer Institute Tokyo (1 BRCA1, co-applicant with Myriad Genetics)
6. Cancer Research Campaign Technology Limited (2 BRCA2)
7. Centre de Recherch de Chul (1 BRCA1, co-applicant with Myriad Genetics)
8. Centre national (1 BRCA1, co-applicant with Université Claude Bernard Lyon 1)
9. Cornell (1 BRCA1/2)
10. Endo Recherche Inc. (2 BRCA2, co-applicant with Myriad Genetics)
11. GeneLogic (2 BRCA1, 1 BRCA2)
12. HSC Research and Development Limited Partnership (2 BRCA2, co-applicant with Myriad Genetics)

13. The Government of the United States (3 BRCA1 of which two as an co-applicant with Myriad Genetics, 1 BRCA2)
14. Incyte Pharmaceuticals (1 BRCA2)
15. Lescallet, Jennifer (1 BRCA1)
16. Lexicon Genetics (3 BRCA2)
17. Myriad Genetics (4 BRCA1, 2 BRCA2)
18. North Shore Long Island Jewish Health Systems (1 BRCA1)
19. Oncormed (1 BRCA1/2, 2 BRCA1, 2 BRCA2)
20. Onyx Pharmaceuticals (1 BRCA1)
21. The Regents of the University of California (1 BRCA1)
22. Rijksuniveriteit te Leiden (1 BRCA1)
23. Rosetta Inpharmatics (1 BRCA1)
24. The Trustees of Columbia University, New York (1 BRCA1)
25. The Trustees of the University of Pennsylvania (1 BRCA1)
26. The University of Utah Research Foundation (1 BRCA1)
27. Université Claude Bernard Lyon 1 (1 BRCA1, co-applicant with Centre National de la Recherche Scientifique)
28. The Vanderbilt University (1 BRCA1, 1 BRCA1/2)
29. Visible Genetics Inc. (1 BRCA1)
30. The Wistar Institute of Anatomy and Biology (2 BRCA1, 1 BRCA2)

Supplement B⁴⁰¹

The principal rule stipulates that the human being has 46 chromosomes divided upon 23 pairs. 23 from the mother and 23 from the father. We thus have two of each chromosome.

Each chromosome is packed with genes. The genes are placed in a certain order as wild strawberries on a straw. The genes in every pair of chromosomes are also mirroring. For every gene in one chromosome, there is one corresponding gene in the other chromosome, in the chromosome pair. The genes code proteins, meaning that the genes tell the proteins what to do in the human body. There are also non coding genes.⁴⁰²

At times there is something wrong, a mutation, with the genes in the chromosomes.

Sometimes there is a mutation in both the gene inherited from the mother and the one from the father. The offspring then has a pair of genes where both are defect. This is called a recessive heritage⁴⁰³ which, dependent on what pair of genes are defect, might, but not necessarily, cause a disease.

There might also be an anomaly in just one gene in a pair of corresponding genes. The mutated gene can come from either the mother or the father. The other gene in the gene pair, inherited from the other parent, can be totally normal but matched with a “bad” twin. This is called autosomal dominant trait⁴⁰⁴.

Hereditary breast or ovarian cancer could be caused by autosomal dominant trait, a mutation in the BRCA1 or/and the BRCA2 gene. The former is placed in the 17th chromosome pair and the second in the 13th chromosome pair. Both are inherited by the mother only and causes a higher susceptibility for developing breast and ovarian cancer. About 90% of women with a mutant BRCA1 gene will develop breast cancer. Such a mutation will also increase the risk of cancer in the ovary. A mutation in a second gene, BRCA2, is also inherited as an autosomal dominant predisposition to breast cancer but not in the ovary. Mutations in BRCA1 and BRCA2 are responsible for about two-thirds of all familial breast cancer.⁴⁰⁵

⁴⁰¹ I would like to thank Prof. Håkan Olsson (Interview 2002-10-03) and Niklas Loman (interview 2002-12-20) for helping me explain the facts of this chapter. Any faults in the text above are of course mine. For a more detailed account of the medical effects of BRCA1 and/or BRCA2 mutations see Antoniou, A. et al.; Average Risks of Breast and Ovarian Cancer Associated with BRCA1 or BRCA2 Mutations Detected in Case Series Unselected for Family History: A Combined Analysis of 22 Studies, Am. J. Hum. Genet. 72:1117-1130, 2003.

⁴⁰² Klung, William S., Cummings, Michael R.; Concepts of Genetics, sixth edition, USA 2000, P. 6.

⁴⁰³ Ibidem p. 48.

⁴⁰⁴ Ibidem p.458.

⁴⁰⁵ Ibidem p. 642 and p. 652.

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Ylva! Thank you for everything...