LUND UNIVERSITY

Are European patents obstacles to Swedish cancer research?

Lidgard, Hans Henrik

Published in:
Gene technology and economy

2002

Document Version:
Publisher's PDF, also known as Version of record

Link to publication

Citation for published version (APA):
Lidgard, H. H. (2002). Are European patents obstacles to Swedish cancer research? In S. Lundin, & L. Åkesson (Eds.), *Gene technology and economy* (pp. 52-71). Nordic Academic Press.

Total number of authors:
1

Creative Commons License:
Unspecified

General rights
Unless other specific re-use rights are stated the following general rights apply:
Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.
• Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
• You may not further distribute the material or use it for any profit-making activity or commercial gain
• You may freely distribute the URL identifying the publication in the public portal

Read more about Creative commons licenses: https://creativecommons.org/licenses/

Take down policy
If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

LUND UNIVERSITY

PO Box 117
221 00 Lund
+46 46-222 00 00

LUND UNIVERSITY

Juridiska fakulteten

LUP

Lunds Universitets Publikationer
Institutionellt Arkiv vid Lunds Universitet
Adress: http://www.lu.se/forskning/avhandlingar-och-publikationer

Detta är en digitaliserad version av ett kapitel i en bok publicerad av Nordic Academic Press. Förlaget har gett sitt tillstånd till publicering i LUP.

Referens för den publicerade versionen:
Lidgard, Hans-Henrik.
Are European patens obstacles to Swedish cancer research?
I: S. Lund (red.),
Gene tecknology and economy.
Nordic Academic Press, 2002, s. 52-71.

Digitaliseringen har skett inom projektet Retrodigitalisering av nutida svårtillgänglig svenskpublicerad HumSam-forskning, finansierat av Kungliga biblioteket.

Are European Patents an Obstacle to Swedish Cancer Research?[1]

Hans Henrik Lidgard

Introduction

In a pithy article first published in the Swedish medical journal *Läkartidningen* in 1999 and now translated in this volume, Håkan Olsson, Professor and Head of the Department of Oncology at Lund University Hospital, addresses the problems caused by patenting in the field of biotechnology. The article was triggered by patent protection granted to a U.S. company, which restricts cancer research and impedes open health care.[2]

A series of complex issues come to light when work in gene technology leaves the stage of basic research and approaches the commercial phase. Håkan Olsson has studied whether a hereditary genetic trait in chromosomes 13 and 17 gives a susceptibility to breast cancer and possibly also ovarian cancer. He and his research team have analysed the genetic make-up of a number of Swedish families. They have found associations and are obviously looking for further indications which can affect prediction, diagnosis, and treatment. Their research builds on the work done by Marie-Claire King's research group ten years ago, which led to the identification and patenting of two responsible genes by research groups other than the ones doing the basic research. As a result of various circumstances, the right to both patents was acquired by the American company Myriad Genetics, which thus controls development in the field.

According to Håkan Olsson, Myriad requires that analyses of blood to trace the occurrence of these genes should be carried out in the company's American laboratories, at a significant cost for each analysis. Sordid profit is infringing on the freedom of academic research, and Håkan Olsson therefore asks:

- Is it reasonable to patent 'inventions' in gene technology?
- Can patent protection be allowed to impede urgent, serious and non-commercial research?
- Can patent protection be circumvented by coercive measures?
- Should patentees be able to monopolize analytical work in medical care?

He sums up:

> It is my firm opinion that we must protect our biological heritage against outside exploitation by maintaining a protectionist stance in Sweden. We should invest huge efforts in our own research to characterize genes involved in various diseases and avoid sending data, blood samples, or DNA abroad, with the possible result that companies in other countries could acquire a monopoly on genetic diagnoses and therapy for diseases that are important in our own country.

In this article I examine the system from a legal perspective.[3] Are there solutions to the problems encountered by a researching physician, or must the rules be changed?[4]

Patenting in the Field of Biotechnology

Patent protection is granted in accordance with section 1 of the Swedish Patents Act for an 'invention', if it can be put to industrial use (see Llewelyn 1994). Apart from the requirement of industrial application, the act stipulates two additional requirements:

According to section 2 of the Act, the invention must be 'new' – absolutely new; it must not be known or described in any context before the date of application. Even the inventor's own measures of presenting or describing the idea may restrict the novelty of the invention.

In his article, Håkan Olsson touches on the difference between the European and the American view of novelty. In the USA, the inventor has a grace period of 12 months and can thus present his research findings at symposia and in scientific journals without creating obstacles to subsequent patenting. American researchers do not need to be cautious with information up to the point when the patent application is submitted. This is an old stumbling block in European patent law. In the USA the crucial thing is who first made the invention, and this can be proved in various ways. In Europe, the determining point is the date of filing, and prior disclosure is not allowed.

In addition, the invention must 'differ significantly from what is previously known'. It may not be a solution that immediately suggests itself to an expert; it must have an element of surprise.

Swedish law essentially agrees with that in other countries. Patent law, like other law on intellectual property, has been subject to international coordination for more than a century.[5] At the European level, cooperation has advanced as a result of the European Patent Convention,[6] but internal cooperation in the EU has been more difficult to achieve. The draft convention for a single market patent has not been implemented,[7] but it now seems as if the Community is taking a new path which could lead to uniform European patent protection.[8]

Is it Reasonable to Patent Genes?

Håkan Olsson asks, 'Is it reasonable that it should be possible to patent human genes which evolution has furnished all human beings with?' The question is fundamental and has both an ethical and a technical dimension. In itself, the identification of a gene can scarcely be said to meet the requirements for an invention. It is rather a discovery of something that already exists, and therefore genes, like other substances and organisms in the body, should be outside the scope of patent protection.

The Patent Act states that discoveries cannot be patented.[9] Nor can surgical procedures, diagnoses, or therapies for humans or animals be patented.

Swedish law also states that patenting may not conflict with public

order.[10] The critics think that it is unethical to manipulate biomedical mechanisms – perhaps especially those which affect our genes – and, therefore, it should not be possible to obtain sole rights.[11] The ethical arguments have made a great impact on the technical patent discussion, as was particularly clear in connection with the compilation of the Directive on the Legal Protection of Biotechnological Inventions.[12]

It may seem that gene technology should automatically fall outside the protection of the law. Patents have never been viewed as a suitable instrument for biological products or processes,[13] and Håkan Olsson's problems should therefore be solved. However, section 1 of the Act ends with the additional statement: 'patents may nevertheless be granted for microbiological processes and the products of such processes.' This amendment is a later adjustment to the European Patent Convention, and it adds a completely new perspective on the matter. The wording gives the impression that it is possible to patent the body's own substances provided they are sufficiently small: microbiological processes or the products of such processes. In reality the size should not be of crucial significance.[14]

In the USA, the discussion has primarily concerned patent technicalities and biotechnological inventions are not dealt with in a different way from other inventions. If the formal patent requirements are satisfied, patent protection is granted. Whether the protected idea may be exercised is another matter, considered by the competent pharmaceutical authority. This was also the starting point for the 1988 proposal for a directive on biotechnology.[15]

In Europe the ethical discussion since 1988 has had a more prominent place, and there has been greater hesitation than in the USA. The decisive battle was held in the European Parliament in the mid-1990s. First the Parliament rejected a rather technical proposal in 1988, but a few years later it passed a law which did not differ much, but which focused more on ethics.[16]

The Directive was supposed to have been implemented in national law by 1 July 2000. The implementation in Sweden, at least, has been delayed, and by November 2000 there was still no concrete proposal.[17] By all appearances, however, the Swedish Patent Office

is already following the directive, and the coming amendments to the law will be little more than a codification of existing practice.

The Directive declares that 'Member States shall protect biotechnological inventions under national patent law.'[18] Article 5 states:

1 The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2 An element 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.
3 The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

The provision makes it clear – after a hesitant introduction – that patents can be granted for isolated body parts, including a gene or a sequence of genes, if the industrial use is specified.[19] This is what happens today.

Biotechnological research – besides being easy to copy – is simply far too complicated and costly not to be protected. Without protection, Western European companies could not dare to make the huge investments already made by protected American and Japanese competitors. Trying to change this development would be neither realistic nor desirable. Håkan Olsson's objective is of course not a ban on working with gene technology; instead, he wants to ensure that patent protection does not impede independent and non-commercial research.[20]

Who Should Be Rewarded with Patent Protection?

In his article, Håkan Olsson puts forward two objections to the granting of patent protection.

The first is that it is not the research team which makes the fundamental, pioneering discovery that gets its name on the patent of the gene. Instead, the protection is granted to the one who sees

the application potential. This truth also concerns other areas. It is one matter to demonstrate deeper connections and another matter to define the invention and specify its concrete use. Patent legislation has always protected inventors, not researchers.

The second objection is that the system makes researchers hold their cards close to their chests, with the resultant loss of openness in contacts with other researchers. The motto in the research world is now: 'apply for a patent first and talk later'. This is a major change of attitude, but is it the patent legislation that has caused the problem; or are there other reasons? Those of us who witnessed the more heated discussions at the end of the 1960s remember the debate about academic freedom versus industrial and commercial interests. Expressed in terms of patents, the view then was that the universities should devote themselves to basic research and publish their findings to prevent the knowledge from being monopolized by patenting. Industry would have to manage its applied activities according to its own ability. The bulkheads between industry and the academy were watertight.

Today, universities have a third duty alongside teaching and research, namely, to make the results of their work available to society. Lund has been highly successful: one need only look at the science park of Ideon, with more than 100 biotechnology companies. According to the clause in the Act on the Right to Employee's Inventions which excepts teachers,[21] our Swedish researchers are permitted to take the results of tax-financed research with them when they leave the university to build up their own private operations, with no obligations to the academy.

A new element of personal gain has thereby affected research, which may perhaps explain some of the changes in the research environment. Whether or not this is good for the national economy may be discussed.[22] Denmark has recently revised its system so that the universities own the results of the work carried on there. This has long been the situation at privately financed American universities.[23]

Patenting in Biotechnology: Conclusions

The conclusion is that it is politically established that biotechnological inventions may be patented – with reservations and with caution. It seems unlikely that this development can be reversed. In Sweden, the dividing line between basic research and industrial application is becoming blurred, which may have a negative effect on an open dialogue, but it is an incentive for researchers to seek new achievements. The essence of Håkan Olsson's statement is not opposed to these phenomena.

Limits to Patent Protection

The crucial objection is rather that patent protection prevents serious, urgent, and non-commercial research, either by prohibiting it outright or through prohibitively expensive royalties.

Myriad Genetics' patent, as I interpret it, means that the company has sole right to use identified genes (BRCA1 and BRCA2) for diagnosis and the production of medicines against breast cancer and ovarian cancer.[24] Research teams at Lund University cannot therefore screen blood samples to determine whether there are cancer mutations which can be associated with these genes. They are obliged to send blood samples to the USA for analysis. Research is blocked by Myriad's exclusive right as defined in the patent, and Myriad can, if the company so wishes, prevent any infringement by legal action. This is the core of the patent protection and the basis for Håkan Olsson's critique.

The patent protection is not without legal exceptions, however.

Section 3 of the Patents Act states that exclusive right does not apply to the following:

- non-commercial use
- products marketed in the Community
- experiments relating to the subject-matter of the invention
- pharmacy preparations

These exceptions were added in 1978 when the Patents Act was revised in harmony with the European Patent Convention (EPC)

and the Patent Cooperation Treaty (PCT). Yet the amendment was primarily occasioned by the Community Patent Convention.[25] It is in the first instance the exceptions in points (a) and (c) that are relevant in this context.

Exceptions for Non-Commercial Use

The patent gives an exclusive right which can be exercised to prevent others from using the invention for commercial purposes. Section 3 of the Patents Act exempts private use. Usage within state or municipal administration is regarded as commercial, and this also applies to activities for charitable or non-profit purposes.[26] The activities do not need to be of an economic kind to be regarded as commercial.

Private use without commercial intention is not covered.[27] If Håkan Olsson wishes to screen himself and his family out of pure curiosity, it would not be an infringement of the American company's patent protection.

Yet the question of the exception goes further. Håkan Olsson seems to want to make a distinction between the work he does in his capacity as a non-commercial researcher and the work he does as a senior physician in the health service. Because of the ethics committees' requirement for patients' informed consent and the right of patients to be informed of test results, Håkan Olsson suggests that activity switches from research to medical care. Pure research is exempted according to this view.

I have heard the same suggestion by other medical scientists, and it seems to be generally accepted amongst Swedish researchers. However, it is difficult to find any proof of a 'research exemption' in the act or its legislative history (see Cornish 1999:735). Doctrine has only treated the matter superficially.[28]

My interpretation is that the work carried on at Lund University is captured regardless of whether Håkan Olsson defines it as research or medical care. As far as I can see, it is irrelevant to refer to the patient's consent.

Exceptions for Experimental Work

I disregard exception in point (b), which ensures that if the holder of the right has himself sold the product in the European Community, he cannot prevent the product from being moved from one country to another. This rather intricate exhaustion issue has nothing to do with the problems discussed here.[29]

In contrast, it seems possible that the third exception in section 3 could be invoked, with its reference to use 'for experiments relating to the subject-matter of the invention'.[30]

The exception is fundamental. The holder of a right is granted exclusive rights, in exchange for which he discloses his invention in a way that is so clear and unambiguous that anyone who so wishes can apply it and build on the knowledge. This means that one may experiment with the invention to improve it and even apply for a patent for the improvement.[31] During the lifetime of the base patent, any such new invention will probably be dependent on the main patent, requiring an agreement between the parties before the patent right is exercised.[32] It is also likely that clinical trials can be carried out to ascertain the true effects and any side effects of a product, without this being regarded as an infringement of the patent (see Cornish 1999:746 ff.).

Yet this exception, which was added to Swedish law in 1978, must, like other exceptions, be interpreted restrictively.[33a] It does not allow an exception for research of the type that Håkan Olsson calls for. It is only when research work in gene technology aims to improve the patented product that the activity escapes being an infringement. It is conceivable that the protected gene could be linked or fragmented in a certain way (if this is possible at all) to give an improved product, which perhaps could even be protected by a (dependent) patent. On the other hand, the researchers in Lund may not consume the invention. If it had been possible to perform the mutation analyses without payment, Myriad's patent would of course lack the value it has today.

I believe that Håkan Olsson is calling for a real exception for research to be enjoyed by those doing non-commercial research, and which would preferably be extended to include important state-financed medical care. However, there is no such exception

in Sweden, nor elsewhere in Western Europe as far as I have found.[33b]

In the USA, there is talk of a 'research exception' which is said to have developed in case law[34] as a cautious variant of the Swedish exception for private use. More recent cases show a strict application of the law. In 1987[35], Scripps had official patent protection for the process of refining and producing Factor VIII:C from blood plasma. The patent also covered the final product but the production method was costly. Genentech developed an alternative process with the aid of recombinant DNA technology, but was forced to use the patented technology in its development work.

Scripps won its suit for patent infringement. Genentech did not have the right to use the patented technology to produce a more appropriate product, which seems to suggest that American law does not permit experiments to improve a product in the way that Swedish legislation does. It may be added that attempts[36] to establish legislative exceptions for research work have been rejected.[37]

Limits to Patent Protection: Conclusions

There is a widespread notion in Sweden that research which is not commercial should be exempt from the straight-jacket of patent law. In Europe, there is a certain amount of support for carrying out experiments with the patented product in order to develop and improve it. On the other hand, neither in Sweden nor abroad is there any support for the idea that research is a free zone when it uses the invention in the way stated in the patent. It does not matter whether the work is characterized as research or care.

Do the Rules on Compulsory Licensing Offer a Solution?

European legislation, but not American, offers compulsory licensing as a possibility to prevent the abuse of patent protection. A compulsory licence does not mean that the patent protection is declared invalid. If anything, it confirms the validity of the patent, but it forces the holder to transfer a right to the applicant in exchange

for a payment. For the patent holder, a compulsory licence means that he loses control over how the patent is exercised, but only in the country where the licence is granted. If a compulsory licence to the Myriad patents were granted to Lund University, it would not be possible for the university to offer screening services to Denmark within the patented field.

It should also be pointed out that compulsory licensing is an exception to the patent protection and a licence is granted only exceptionally. Koktvedgaard and Levin speak of situations 'where the existence of society or people's life and death are at stake'.[38] This is perhaps too extreme, but the limits in the law are clear. There are three situations in which compulsory licensing may be relevant:

- If the invention is not 'exercised' within the country 'on a reasonable scale' within three years unless there is an 'acceptable reason' for failure to do so (section 45);
- in consideration of 'public interest of particular importance' (section 47);
- to protect anyone who has previously used the invention in Sweden (section 48).

Compulsory licenses and the conditions for them are issued by an ordinary court, but only if the licensee can be expected to use the invention in an acceptable way. The license is non-exclusive and know-how is not included.

Exercise of the Invention within the Country

The original purpose of compulsory licensing was to safeguard production in Sweden and prevent foreign patents from blocking work in this country. The law therefore presumes that the invention will be 'exercised' in the country after a brief transition period, and the import of a finished commodity is not such exercise. Swedish membership of the EU, however, has changed the situation in that exercise in the member states is equated with exercise in Sweden. Production here in Sweden must also take place 'on a sufficient scale'. If only part of the national need is satisfied by production in the

country, ordinary courts of law must determine whether it is sufficient.[39] Nor can the patent holder avoid a compulsory licence by starting production after a claim has been made.[40]

If the holder of the right can show 'acceptable reason' for the insufficient exercise, no compulsory licence is granted. An acceptable reason may be a lack of raw materials or parallel patents for the same invention. If the holder of the rights chooses to exercise only one of several of his patents, it does not mean that a compulsory licence can be requested for the other.[41] On the other hand, if one patent concerns manufacture and the other use, it is not sufficient to exercise the latter in Sweden.[42]

Screening for BRCA is not production in the traditional sense, but analytical work. The services are offered in the USA, not in Sweden. The reason for the failure to exercise the invention in Sweden is probably that it would not be rational. If this is the only reason, it is most likely not enough. If a Swedish laboratory is willing to do the analyses at a lower cost, including a reasonable royalty to the American company, the likelihood that a compulsory license will be granted increases. The lack of guiding case law, however, is troublesome.

Consideration for Public Interest

The other possibility of obtaining a compulsory licence is if 'consideration for public interest of particular importance' so requires. The legislative history states that the rule is to be applied with 'considerable caution'.[43]

What is to be understood as public interest of particular importance must be judged from case to case – but a general need is not sufficient. Could the circumstances described by Håkan Olsson be such interest? Probably, yes. It appears likely that a compulsory licence can be enforced out of consideration for cancer research and the needs of medical care. To this could be added that information from gene banks is not sent out of the country or transferred to private companies.[44] As regards this provision as well, it must be underlined that there is a lack of case law.

Furthermore, companies are also reluctant to use compulsory licensing. The non-exclusive right and lack of access to know-how

reduces the interest. Yet another reason is that it takes several years to have a compulsory licence granted.

Compulsory Licensing: Conclusion

Case law gives scant guidance as to how the rules for compulsory licensing should be interpreted[45] – but they would appear to be applicable if Myriad Genetics' attitude should prove to be some kind of abuse, either to force the utilization of the company's services in the USA or to make prohibitive demands for the granting of a licence. In addition, we must protect sensitive genetic information and the treatment of serious diseases, important factors of strong public concern which require special attention.

It is doubtful, however, whether a compulsory licence would really lead to a solution of the problems facing researchers in Lund. The price paid for a licence would probably be high, and above all it takes a long time to obtain one. On the other hand, this might be an interesting test case for the University of Lund.

Summing Up

The perhaps unsatisfactory answer to Håkan Olsson is that patent legislation gives a patent holder a protected position that is difficult to challenge. The law awards exclusive rights, and it is only in exceptional cases that patent protection is restricted or a compulsory licence is granted.

Håkan Olsson nevertheless presents powerful reasons for questioning individual aspects of the system.

First of all, there might be ways to facilitate an open scientific discussion prior to the filing of a patent application. Publication should, however, be done in a way that allows exact documentation of time and content, and moreover, the actual patent application must follow quickly. There is a risk that there would be so many reservations that the present rule might seem attractive after all.

Furthermore, it would not be unreasonable to have some form of 'research exception' for important research, but once again the difficulty is where to draw the dividing lines. Perhaps the division that the research world already seems to make between commercial

and non-commercial research activities may serve as a starting point. Problems easily arise, however, when the non-commercial activities lead to commercial inventions. Patent-granting authorities must tighten the demands for what can be considered to be a patentable invention in the field of biotechnology. It should not be possible, for example, to monopolize analyses and diagnoses just because it has been determined how something in the human body functions. The linkage to use is not particularly remarkable, and exactly the same sequence always has the same use.[46] The requirement for what constitutes an invention should not be set so low that important analyses in medical care are impeded in an unacceptable way.

If the institution of the compulsory licence is to work, the procedural forms must be simplified, especially in sectors where technology is constantly being developed and changed.

Finally, in Sweden we must decide on a policy for how genetic information from individuals[47] and selected population groups[48] may be handled. The registration of personal data is one thing, but here it concerns our own core, and what could be more important than that this information is carefully supervised?[49]

Yet, these are all matters for future legislation. The present rules mean that Myriad Genetics, with its patents and patent applications, can acquire a firm grip on research and treatment efforts that are undertaken within the scope of the patent protection. It is not through the use of exceptions in the law that we will put any problems right. Existing patent law allows for a careful scrutiny of the protection granted. In a field as dynamic as biotechnology, there may often be 'prior art' which undermines the novelty value. Likewise, it is relevant to ask if the patent identifies the right inventor and if it contains factual errors in view of later developments.

Apart from the fact that any commercial company has reason to avoid coming into conflict with opinion leaders of Håkan Olsson's calibre, they have every reason to fear a frontal assault on their patent protection. Scrutiny may reveal lacunae or forgotten parameters. Commercial companies understand such language, and it usually leads to suitable negotiated solutions.

Notes

1 Associate Professor, Faculty of Law, Lund University. This article was completed in November 2000.

2 Håkan Olsson is not alone in the views expressed in his article. The US National Institute of Health (NIH) in the USA is also trying to prevent intellectual property law from unduly impeding important research. See Report of the NIH Working Group on Research Tools, 4 June 1998, http://www.nih.gov/news/researchtools/index.htm, and NIH Proposed Guidelines for Recipients of NIH Research Grants, 64 Fed. Reg., No. 100, May 25, 1999, pp. 28205–28209.

3 Many answers to the questions posed in the article can be found in Bengt Domeij's excellent dissertation on the patenting of medicines (1998). It could be cited frequently in this essay, and it has been especially useful for the section on exceptions to patenting.

4 I have not tried to evaluate Myriad's patent and the protection it gives. Many teams of researchers have been involved, and all have contributed small pieces to the puzzle, which sometimes means that there are various reasons for questioning the patents on purely technical grounds. The information may already have been so well known that the application for a patent should have been rejected, and further development may have undermined the claims on which the protection was based. I assume that the patent cannot be challenged in a court of law. The other assumption from which I proceed is that the patent protection for which Myriad has applied really comprises the analysis of blood samples to discover the occurrence of the genes in question. Håkan Olsson's data give grounds for such an assumption and claims have evidently been made by Myriad.

5 The Paris Convention for the Protection of Industrial Property of 20 March 1983, as subsequently modified, serves as the basis. Yet there is a significant number of international conventions which specify different parts of patent law. Of particular importance is the harmonization of international application procedures which has taken place as a result of the Patent Cooperation Treaty (PCT), Washington, 19 June 1970, amended on 28 September 1979 and modified on 3 February 1984.

6 European Patent Convention (EPC) of 5 October 1973, text as amended by the act revising Article 63 EPC of 17 December 1991 and by decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, and 5 December 1996.

7 Convention for the European Patent for the Common Market 76/76/EEC: Council Resolution of 15 December 1975 on the Convention for the European Patent for the Common Market, OJ 1976 L 17/43.

8 The European Commission's proposal of 1 August 2000 for the Council's Ordinance on Community Patent, COM (2000) 412 Final.

9 Sena 1999:739.

10 The concept of 'accepted principles and public order' gives the impression of being a catch-all exception. This is not the case, however; it concerns fundamental values in the legal system which can be expressed in the constitution or in penal legislation. In practice, the patenting of genes has not been deemed to fall under this concept; patents have been granted by the Swedish Patent and Registration Office (PRV) and the European Patent Office (EPO). See, e.g., Decision of the Opposition Division of EPO, 8 December 1994, *Relaxin,* 27 IIC (1996) 704, after objections had been put forward by Fraktion der Grünen in European Parliament.

11 Swedish law says nothing about the patenting of germ lines/germ plasma. Patenting occurs only for body cells according to PRV's response to the OECD Questionnaire on Intellectual Property Practices in the field of Biotechnology (25 June 1997). This attitude conforms to fundamental principles to ensure human dignity and integrity. See premiss 16 in the preamble to the Biotechnology Directive, note 13 below.

12 See, e.g., Bruun 1992:209 and Greenpeace's arguments in *Transgenic Plant – Novartis II*, decision G 1/98 of the EPO Enlarged Boards of Appeal of 20 December 1999.

13 Koktvedgaard 1994:435.

14 The 1998 Biotechnology Directive (note 13), article 2.1.b) states that the term microbiological process refers to 'any process involving or performed upon or resulting in microbiological material'. Biological material is defined as containing genetic information which can reproduce itself or can be reproduced in a biological system. It is not clear from the definitions whether microbiological material differs in any crucial way. See Koktvedgaard 1989:119, 120: 'the distinction between *macro- and microbiology* – nowadays seems artificial and untenable.' See also Heitto 1999:655, 661 ff.

15 Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions, COM(88)496 final. For a commentary, see Koktvedgaard 1989.

16 Article 6 of the Directive clarifies that the procedure for cloning human beings and changing genetic identity in human gametes cannot be patented. Nor can the use of human embryos be patented, or processes leading to unnecessary cruelty to animals.

17 The matter is not the subject of a government inquiry, but is being prepared by the Ministry of Justice. A memo on the matter is expected in spring 2001. Heitto 1999:658 seems to be of the opinion that the legislation does not need to be harmonized if the desired practical results are achieved. I suspect, however, that there are greater requirements of the implementation measures. Cf. the Court of Justice of the European Communities, Case 143/83, *Commission v Denmark*, 30 January 1985, [1985] ECR 427 p. 13. The directive on equal pay was to be implemented in an unambiguous way in the national legal system. Vague statements in legislative history were not sufficient.

18 The first sentence in article 1 of the Biotechnology Directive (note 13).

19 Oser (1999:7) says: 'If the teaching is restricted to the mere reproduction of genetic information, it is merely an enrichment of the state of knowledge, *i.e.,* a pure discovery, irrespective of the technical means used to decode this genetic information. On the other hand, if, as a result of the indication of the function, a claimed DNA sequence causally contributes to a technically exploitable result, it is an invention.' The US Patent and Trademark Office is preparing tighter guidelines which will include, among other things, requirements for 'substantial utility'. See Grisham 2000:921.

20 On the other hand, it is of major concern to society that the protection should be confined to the real invention and not serve as an obstacle to broader research. It is not the gene that should be protected, not even when it has been isolated; only when the applicant can demonstrate inventiveness and a specific application can protection be granted. As knowledge of this inaccessible area increases, the patentability and scope of protection are narrowed.

21 Act (1949:345) on the Right to Employee's Inventions, section 1, paragraph 2: 'In this capacity, teachers at universities, colleges or other institutions belonging to the educational system shall not be considered as employees according to this Act...'

22 The Swedish minister of education is interested in the Danish system after an inquiry conducted by the Stockholm School of Economics. See *Dagens Industri*, 20 October 2000: 'Universities will be allowed to earn money from inventions.'

23 Before 1980, American universities could not patent research that was financed by federal funding. The environment then was of course even more open. See Flores 1999:819.

24 The crucial patent seems to be United States Patent 5,693,473, Shattuck-Eidens, *et al.* 2 December 1997, Linked breast and ovarian cancer susceptibility gene. Abstract: 'The present invention relates generally to the field of human genetics. Specifically, the present invention relates to methods and materials used to isolate and detect a human breast and ovarian cancer predisposing gene (BRCA1), ... to germline mutations in the BRCA1 gene and their use in the diagnosis of predisposition to breast and ovarian cancer. ... The invention also relates to the therapy of human cancers which have a mutation in the BRCA1 gene, including gene therapy, protein replacement therapy and protein mimetics.'

25 Community Patent Convention (note 5). Article 31 of the original convention, changed in 1989 to article 27.

26 Nordisk Utredningsserie 1963:6, p. 145; cf. Holmqvist 1976:56.

27 Ibid., p. 200.

28 Koktvedgaard and Levin 1997:249 compare with section 12 of the Copyright Act (production of copies for personal use), but say that the patent rule does not have the same practical significance. In the authors' assessment, very few inventions have reason to be used outside commercial activity, but they add that 'The rule covers not just purely private circumstances but also other forms of non-commercial use, e.g. in scientific research and in connection with teaching.' No further support is given for this view.

29 Interested readers are referred to Lidgard 1998:31.

30 Domeij 1998: 457 ff. deals in more detail with the experiment exception.

31 There is no real definition of what an experiment may be considered to be. In all likelihood, it concerns an investigation of something unknown in order to achieve clarity or verify hypotheses. Unlike the case of trials, the knowledge leads further. See van der Merwe 2000:380–389, 385.

32 Bernitz *et al.* (1998:131) say that it is 'permitted to pursue experiments *with* a patented invention, but not *with the aid of* an invention'. Patent law presupposes that the patent holder's competitors should be able to build on the protected invention. Cf. Koktvedgaard & Levin 1997:249.

33a Proposition 1977/78:1, p. 201

33b Germany may be an exception to the rule. See German Supreme court (BGH), Klinische Versuche, 18 May 1995.

34 *Whittemore v. Cutter* 29 F.Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) and *Sawin v. Guild* 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,931).

35 *Scripps Clinic and Research Foundation v. Genentech,* 666 F. Supp 1379 (N.D. Cal. 1987) and 707 F. Supp 1547.

36 Proposed Patent Competitiveness and Technological Innovation Act of 1990, H.R. 5598 (1990). Proposed amendments to section 271 of title 35, U.S.C.: 'It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary purpose of research or experimentation. If the patented invention has a primary purpose of research or experimentation, it shall not be an act of infringement to manufacture or use such invention to study, evaluate, or characterize such invention or to create a product outside the scope of the patent covering such invention.'

37 A partly similar question concerns the possibility of carrying out tests with generic substances during the term of the patent in order to demonstrate bioequivalence to the protected substance and perhaps also submitting the parallel substance for registration with the national medical products agency. In Europe the patent holder is not considered able to prevent such work even during the time when the substance is protected by a prolonged patent. See Council Regulation 1768/92/EEC of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ 1992 L 182/1, now incorporated in Swedish law through chapter 13 of the Patents Act; see van der Merwe 2000:380. On this point, the European attitude is harder than the American one. See Drug Price Competition and Patent Term Restoration Act of 1984, which was incorporated through 35 U.S.C. (e)(i) and which includes exceptions for clinical trials before the application for registration. For a detailed exposition of the European attitude, see Domeij 1998:461 ff.

38 Koktvedgaard and Levin 1997:31.

39 In UfR 1966, p. 566, Ciba Geigy's production in Denmark did not cover all the required Danish need, and there were grounds for issuing a compulsory licence.

40 NJA 1937, p. 90 – *Steward David & Equipment Corp. v. AGA* – rules that when a compulsory licence is granted, no regard is paid to exercise which has taken place after the suit was filed.

41 See Nordisk Utredningsserie 1963:6, p. 299.

42 NJA 1945, p. 110 – *Farbenindustrie AG v. AB Ewos* – concerned a compulsory licence for a patented method when only the parallel patent on use was exercised in Sweden.

43 Proposition 1966:40, p. 178.

44 Koktvedgaard 1989:126.

45 It is not just in Swedish legal usage that cases of compulsory licensing are rare. This also seems to be true of most countries in continental Europe. In contrast, the institution has been used more frequently in the UK and Canada, while US patent law has no rules at all for compulsory licensing. Instead, principles concerning 'patent misuse' and 'essential facility' have been developed in competition law.

46 Walles 1994:466.

47 Work in Sweden is currently geared to protecting personal integrity. See the report on genetic integrity, Socialutskottets betänkande 1999/2000:SoU5. Today there are certain rules in the Ordinance on Personal Data (1998:1191), which in section 9 requires preliminary inspection of computerized personal data on hereditary susceptibility discovered by a genetic investigation. The government is preparing to summon a parliamentary committee with representatives of all the parties in parliament, with the task of putting forward a concerted proposal as to how it will be possible to guarantee in all spheres of society that no discrimination takes place on account of a person's genetic constitution.

48 There do not appear to be any Swedish initiatives dealing with the need to protect de-identified information, which could nevertheless be of general significance to society in the way that Håkan Olsson discusses in his article. Motion 1999/2000 Ub479 by Ulla-Britt Hagström (Christian Democrat) deals with the issue, particularly the biobanks that exist in the Nordic countries. It is possible that the matter will be handled by the parliamentary committee mentioned in the previous note, although the work there focuses on personal integrity.

49 The report from the National Board of Health and Welfare, *Biobanker i hälso- och sjukvården m.m.*, 3 May 2000, contains proposals for a special law on biobanks in health care. The proposal is a first step to control information and prevent inappropriate dissemination. The rules are proposed to apply to newly established banks but will also embrace existing registers in medical care and industry. All material must be coded, and only coded material may be sent abroad. The report does not consider the risk that even coded material on population groups can be sensitive. See also the guidelines on research ethics issued by the Medical Research Council, under the heading 'International Collaboration'.

References

Bernitz, U., G. Karnell, L. Pehrson & C. Sangren. 1998. *Immaterialrätt.* 6th ed. Stockholm: Jure.

Bruun, N. 1992. Genteknik och etik. *Nordiskt Immateriellt Rättsskydd* 1992, p. 209.

Cornish, W. 1999. Experimental Use of Patented Inventions in European Community States. *International Review of Industrial Property and Copyright* 1999, p. 735.

Domeij, B. 1998. *Läkemedelspatent.* Stockholm: Jure 1998.

Flores, M. A. 1999. Taking the Profit out of Biomedical Research Tools: Rational Limits on Genomic Patents. *Nature Biotechnology* 1999, p. 819.

Grisham, J. 2000. New Rules for Gene Patents: Rational Limits on Genomic Patents. *Nature Biotechnology* 2000, p. 921.

Heitto, J. V. T. 1999. The Biotech Directive from a Finnish point of view. *Nordiskt Immateriellt Rättsskydd* 1999, p. 655.

Holmqvist, L. 1976. *Patenträtt.* Stockholm: AWE/Geber.

Koktvedgaard, M. 1989. Retsbeskyttelse af genteknologisk udvikling af planter og dyr. *Nordiskt Immateriellt Rättsskydd* 1989, p. 119.

Koktvedgaard, M. 1994. Genteknik og patentret i nordisk og europeisk perspektiv. *Nordiskt Immateriellt Rättsskydd* 1994, p. 435.

Koktvedgaard, M., and M. Levin. 1997. *Lärobok i immaterialrätt.* 5th ed. Stockholm: Norstedts.

Lidgard, H. H., 1998. Regional konsumtion i EU hindrar parallellimport från lågprisländer. *Europarättslig Tidskrift* 1998, p. 31.

Llewelyn, M. 1994. Industrial Applicability/Utility and Genetic Engineering: Current Practices in Europe and the United States. *European Intellectual Property Review* 473.

Nott, R. 1998. 'You Did It!' The European Technology Directive at Last. *European Intellectual Property Review* 347.

Nyberg, A. 1999. Legal Protection of Biotechnological Inventions – Directive 98/44/EC on the Legal Protection of Biotechnological Inventions. *Nordiskt Immateriellt Rättsskydd* 1999 p. 645.

Olsson, H. 1999. Kommersialiseringen av gener – patent på bröstcancergener pilotfall: Sverige får inte stå vid sidan av utvecklingen. *Läkartidningen* 96:37, pp. 3920–3923.

Oser, A. 1999. Patenting (Partial) Gene Sequences Taking Particular Account of the EST Issue. *International Review of Industrial Property and Copyright* 1999, p. 1.

Sena, G. 1999. Directive on Biotechnological Inventions: Patentability of Discoveries. *International Review of Industrial Property and Copyright* 731.

van der Merwe, A. 2000. Experimental Use and Submissions of Data for Regulatory Approval. *International Review of Industrial Property and Copyright* 2000, p. 380.

Walles, R. 1994. Genteknik och patenträtt i svenskt och europeiskt perspektiv. *Nordiskt Immateriellt Rättsskydd* 1994, p. 466.