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Biotech Patents and the Future of Scientific Research

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Introduction

Biotechnology is a promising technology. But is also a very capital intensive one. That means that it is necessary for those who provide the financial resources that they can obtain some guarantee that the investment can be earned back. In a competitive market such is not easy, as competitors can free-ride on the efforts made by others, who have invested in the R&D. The competitor, in a perfectly competitive market, can simply copy the technology, without R&D costs, and bring the resulting products or processes on the market, at a price which will in most cases be lower than the price charged by the innovator, who is obligated to charge higher prices, in order to obtain at least some return on investment. Such a position is not an attractive one for the innovator.

It is therefore that a patent system, which provides a monopolistic protection for the innovator/patent holder, has the distinct advantage that it spurs innovation. The patent holder, having a monopolistic right, is capable of charging a monopoly price, which will be higher than the market price, which in turn provides better prospects to obtain a return on investment.

That the patent system has positive effects on innovation is not the subject of much debate. The debate in the context of the patent system is predominantly held in the context of the scope of the rights conferred. Indeed, due to the monopolistic nature of the patent, one must scrutinise very carefully as to whether the patent holder is not over-rewarded. When the protection offered by the patent granted is not commensurate with what the innovator was prepared to provide to the public at large or the man skilled in the art, it can be said that the patent system has not functioned well. One of the basic principles underlying the patent system is that the patent holder can only obtain the protection he is entitled to in conformity with what he has provided to society. If the innovator has only given a small invention to society, it would be unfair to grant broad protection to the patent holder for

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this modest contribution to the state of the art. On the other hand, if the innovator has given an important and far-reaching invention to society, no reasonable person would see a problem in granting a commensurately broad patent to this inventor. It is then also said that the patent system provides the *quid pro quo*, a kind of deal that the inventor is entitled to obtain the scope of protection, which corresponds to the scope of the invention he has made.

These fundamental underlying principles of the patent system are of crucial importance. They help in better understanding some of the current discussions relating to the patentability of biotechnological inventions. These inventions, and even more their patentability, have become quite controversial in some circles. It has also been claimed that they could have a negative effect on scientific research. Whether this is true or not, is not easy to tell, but it must be emphasised that some of the arguments professed are not always based on a proper knowledge of the patent system, and of what the patent system it is capable of protecting and what not. In this contribution, some of the issues relating to this debate will be highlighted.

Anything to worry about?

New developments in biotech patenting cause concern with research institutions. One of the most recent examples are the patents granted for the BRCA1 and BRCA2 breast cancer genes.[1] Simplifying the intricacies of the patents, it can be said that they cover predictive genetic screening test methods. Aim of the test is to establish whether the patient has a mutation in a gene which might be the cause of breast cancer.

Some of these concerns might or might not be justified. But what is clear, however, is that another large part of these concerns are also fed by misconceptions of the patent system and the way it functions. As has already been made clear earlier, the patent system is based on a sort of trade-off, *i.e.*, the inventor is granted a exclusionary right for a limited period (20 years from the date of filing of the application in Europe), in return for a disclosure of his invention in sufficient detail to the public in general and the man skilled in the art in particular. A number of requirements must be fulfilled before a patent can be granted. The invention must be novel*, i.e.,* it may not be part of the state of the art. The invention must also be inventive, *i.e.,* it may not be obvious to the man skilled in the art to come to that invention based on what is known in the prior art. Thirdly, the invention must have an

[1] EP 699754, granted 10 January 2001, and EP 705903, granted 23 May 2001.

industrial application, *i.e.,* it must be capable of being applied in any type of industry, including agriculture. A final, but crucial requirement is that the invention must be sufficiently disclosed so that the man skilled in the art can carry out the invention without undue burden or inventive skill. When these hurdles can be passed, a patent is granted. Some of the cases which made it in the press, such as the aforementioned BRCA patents, or the 'junk DNA' patents, might turn out to be unpatentable in the end.[2]

Part of this concern is thus based on a less than complete picture of the patent system. Some of the alleged problems can be tackled with a proper application of patent law criteria, *e.g.,* patenting research tools, reach-through claims, diagnostic patents or the research exemption. We will come back to some of these issues later in this contribution.

Some concerns need to be taken seriously, however, such as blocking effects of patents, patent thickets and the raising costs of scientific research as a consequence of patenting research tools.

Scope of protection

Scope of protection is an important feature in the study of patent law. In biotechnology, the issue obtains even more attention, in view of the potential consequences of a broad scope for scientific research and technological development.

An economic approach vis-à-vis scope of protection gives us more insight into the basic mechanisms underlying the patent system and its effects on third party behaviour. As a general rule it can be said that scope of protection must be broad enough to recompense the cost of invention. It must not be too broad, because of the restricting effects of patent protection, which can reduce incentives to make improvements.

Narrow scope, on the one hand, leads to more competition. This is socially costly, however, in economic terms, as more competition leads to more 'wasted investments'. More competition also implies less profit for the innovator. This will in turn lead to a reduced incentive to innovate, or tendency to keep innovations secret. Broad scope, on the other hand, provides more protection against (trivial) improvements and second-generation innovators. It allows the patent holder to collect most of the social

[2] The BRCA patents are now being opposed at the European Patent Office, amongst others on the grounds that they would not fulfil the patentability requirements in the form they are claimed currently.

value. As a consequence, such an innovator will be less inclined to keep invention secret. This in turn should be capable of promoting dissemination of information.

It must be said, however, that broad scope makes it more difficult for newcomers or subsequent innovators to enter the market. This might lead to a tendency to disinvest. This in turn can have a stifling effect on technological development.[3]

Enablement or disclosure requirement

When discussing scope of protection, it is inevitable to talk about the disclosure requirement. Said requirement is important in determining scope of the patent. The disclosure requirement is based on the *quid pro* quo of the patent system, *i.e.*, the inventor is prepared to disclose the details of his invention in return for a temporary exclusionary right. In order to fulfil this *quid pro quo*, there must be sufficient disclosure in the patent application so as to allow the man skilled in the art to carry out the invention without having to exercise inventive skill or undue burden.

In the case law of the European Patent Office (EPO), the standard which has been developed after a long process of case law is that the disclosure must cover the whole area of the subject matter claimed. Earlier case law had held that the standard was that one way of carrying out the invention was sufficient. But such a standard could have as a consequence that when a broad variety of embodiments are claimed, the description of only one of them could be sufficient to obtain a broad patent. Under certain circumstances, this might be justified, if it can be readily assumed that the other embodiments are based on the same principle. But this will not always be the case, and even less so in the case of complex inventions, such as biotechnological inventions. In such an event, the patent holder would obtain more than he is entitled to, based on the disclosure he has made to the public. The new standard developed by the EPO in its case responds better to this concern. In the United Kingdom, the House of Lords has held in the famous Biogen case that a distinction must be made between two types of inventions, *i.e.,* the invention as a general principle, in which case a general disclosure

[3] See also, Bostyn, S.J.R., A European Perspective on the Ideal Scope of Protection and the Disclosure Requirement for Biotechnological Inventions in a Harmonized Patent System; The Quest for the Holy Grail?, 5 Journal of World Intellectual Property, 2002, 1013 et seq.

suffices, and on the other hand the invention as a discrete method or product, in which case each of them must be disclosed.[4]

In the US, it has been held in case law that in unpredictable arts, *e.g.*, biotech, more detailed disclosure is required, which will imply that the description of only one example or embodiment for an invention claiming many more embodiments will not be considered to be sufficient.[5]

Grace period

For research institutions, and their academics, it is of crucial importance to publish the findings of their research as soon as possible. This is not only based on the mission of public research institutions, who, as publicly funded bodies, have a responsibility vis-à-vis society, which consists of, amongst others, professional colleagues with which they have to share the results of their research as soon as they have them, so that society can benefit from them, *e.g.* in the process of finding cures against hereditary diseases. But it is not only this mission which urges publicly funded research institutions to publish their findings rapidly. There is also a more mundane explanation for this rush. Scientists are evaluated in their careers on the basis of their peer review publications. The sooner they can publish their findings, the more important the scoop, and the more beneficial such is for their careers.

The patent system stands at odds with this system. Under the patent system, the invention must be kept secret until a patent application has been filed, at least in Europe. As soon as an invention has been described in a publication, it can no longer be patented, since it is not novel anymore vis-à-vis the state of the art. There can thus be circumstances under which a researcher wishes to publish his innovative findings, but that can be detrimental for a patent application which should also be filed in relation to this innovation. Therefore, scientists face more and more situations in which they have to postpone publication until a patent application has been filed.

In some countries, amongst others in the US, there is a remedy to this problem, namely the so-called grace period. The system of a grace period

[4] *Biogen Inc. v. Medeva plc,* House of Lords, 31 October 1996, RPC [1997] 1.

[5] For a detailed analysis of the disclosure requirement in Europe and the Unites States, see Bostyn, S.J.R., Enabling Biotechnological Inventions in Europe and the United States. A study of the patentability of proteins and DNA sequences with special emphasis on the disclosure requirement, *Eposcript Series*, nr. 4, EPO (European Patent Office), Munich, 2001(hereinafter Bostyn, EPO, 2001).

implies that a researcher can publish his scientific findings relating to an innovation he has made, without this publication being novelty destructive for a later filed patent application relating to that same innovation, at least if the publication is not made longer than 12 months before the filing of the patent application.[6] The system thus allows research institutions to reap twice the fruits of their labour. On the one hand, there is a scientific publication, which has a positive effect on the reputation of the researcher in question and the institution he is employed at, and on the other hand, the research institution is also capable of benefiting from patent protection for a specific invention, which can be an additional source of income in terms of royalty fees or a lump sum in case of transfer of the patent.

Hitherto, there is no grace period system in most of the European countries. It has been debated repeatedly whether such a system ought to be introduced in the European patent system. Publicly funded research institutions in Europe have in large majority been in favour of the introduction of a grace period in patent law.[7] Arguments in favour of the introduction of a grace period can be summarized as follows:

- It allows the research community to publish without such publication being novelty destructive vis-à-vis a later filed patent application;
- This is also true for governmental bodies, and publicly funded research institutions;
- A grace period provides a solution for the inherent conflict between high level scientific research and necessary funding, often requiring patent protection as return on investment;
- It protects against inadvertent making available of details concerning the invention. Researchers who have made an invention, and who are not knowledgeable about the intricacies of the patent system, may disclose details of the invention inadvertently;
- It protects against disclosing details concerning an invention in the framework of trials or technical assistance, and prevents a flood of secrecy agreements.

Arguments contra the introduction of a grace period can be summarized as follows:

[6] See 35 USC 102(b), US Patent Act.

[7] For an excellent analysis of the arguments in favour and against the introduction of a grace period, see, Straus, J., Expert Opinion on the Introduction of a Grace Period in the European Patent Law. Submitted upon request of the European Patent Organisation, 2000.

- It is said that the introduction of a grace period would create legal uncertainty, as it is not always easy to determine the relationship between the publication and the claimed invention in the patent application;
- A grace period would create difficulties in determining whether a patent application or subsequent publication is based on the original publication, or whether it is based on further research, which would imply that it could be an invention in its own right;
- A grace period would also create difficulties in determining what the exact scope of the invention is which is laid down in the publication. This plays a particular role of importance in the case of improvements;
- It might give a false idea of being free to communicate without taking into account potential competitors;
- A competitor may learn from the early publication, work on the subject and make a further patentable invention using the published information. The original inventor might then be blocked if he also tries to get his invention patented.

In its report evaluating the patentability of human gene related inventions, the Royal Netherlands Academy of Arts and Sciences (KNAW) considers introduction of a grace period to be a positive development. It is felt that it can stimulate scientific research while maintaining interest to publish. The KNAW considers that a relatively short grace period is preferable, since too long a period could have negative effects on legal certainty. A grace period of six months has been suggested to be acceptable.[8]

DNA and diagnostic testing patents

One of the possible applications of DNA technology is predictive diagnostic testing. Such tests aim at determining whether a patient has a specific mutation in a specific gene, which might be the cause of a future hereditary disease, even though such tests rarely determine beyond all doubt that a particular patient will develop a specific disease. This is a very important technology indeed, as it allows people to be better informed about their future health situation, to be more alert, and in some cases a precautionary

[8] 'De gevolgen van het octrooieren van humane genen voor het wetenschappelijk onderzoek in Nederland: Advies van de Commissie Genoctrooien', Amsterdam, KNAW, 2003, 38 (hereinafter KNAW 2003).

therapy with drugs can be prescribed. Evidently, there are also patent rights vested in these testing methods.

Under European patent law, diagnostic methods performed on the human body are excluded from patentability.[9] The products used in such diagnosis, such as diagnostic kits, are patentable. In other words, it is thus merely the method of performing diagnosis which is excluded. Currently, there is a question before the highest administrative judicial instance of the EPO, the Enlarged Board of Appeal, to determine the exact meaning and scope of this exclusionary provision. Important question to solve is whether only those methods performed on the human body which give an immediate result as to the treatment are excluded, thus not including intermediate steps, or whether also intermediate steps performed on the human body which are of value to diagnosis are excluded from patentability.[10] The latter interpretation could *e.g.* exclude from patentability taking of samples, or other intermediate steps in the process of arriving at a final diagnosis. It is expected that it will take more than one year before a decision is taken in this matter.

Diagnostic methods performed outside the human body, *i.e., ex vivo*, are not excluded from patentability. Most predictive DNA diagnostic testing methods are *ex vivo* methods, and as such they fall outside the exclusionary provision of Art. 52(4) EPC. That makes their patenting not less controversial. The BRCA patents in particular shook the scientific community. In these patents, a plethora of tests were claimed, all to determine whether a patient had a specific mutation in a gene, which might cause breast cancer in the future. Besides the fact that the patents are very broad, there was also another reason why these patents caused the turmoil. The patent holder, Myriad Genetics, had decided to pursue a rather aggressive licensing strategy relating to their patents. They granted only exclusive licenses, implying that only a very limited number of licensees over the world are allowed to use the technology in the patent and to perform these tests. Such an exclusive licensing system has another perverse effect, namely an upward effect on price, making it rather expensive for research institutions to carry out these tests, or paying to the licensee the fee to carry out these tests. This type of screening tests is in particular used in research stages in the context of clinical trials, and it was then also feared that it would have a hampering effect on scientific research. On top of this all, Myriad Genetics does not allow local screening, but requires the samples to be sent to the US.

[9] Art. 52(4) EPC.
[10] The case is pending under G 01/94.

Currently, the BRCA1 patents are in Europe in Opposition before the EPO. It is to be seen what comes out of these proceedings. Arguments relate predominantly to the inventive step issue and insufficient disclosure. Even though it is too early to say anything about the outcome at this very moment,[11] it can be expected that the patents will be narrowed as an outcome of these proceedings.

In connection with these patents, it has been suggested to exclude also *ex vivo* diagnostic methods from patentability. It is submitted that this is not a realistic alternative, in view of the importance of the diagnostic industry in health care. It can be expected that in the absence of patent protection, this industry could come to a practical standstill.

Would broadening the research exemption to include clinical use be a solution to tackle some of the objections mentioned above? We will discuss this later in this contribution.

Another argument which has been uttered in relation to this patent is that it would be contrary to *ordre public* or morality. When the application of an invention is contrary to *ordre public* or morality, it is, at least under European patent law, excluded from patentability.[12] In the view of this author, this type of patents is not contrary to *ordre public* or morality. It is difficult to see why such an invention would violate fundamental rules of *ordre public* or morality. One can evidently ask questions about the ethical standards of the company exercising such commercial strategies, but that is not a question of patent law.

Compulsory licensing[13] will in most cases not be an option either, as under many statutes the grant of such a license will require exceptional circumstances or substantial public health risks.

Price regulation instead of patent system amendments seems to be a better solution to tackle cost effects.[14]

[11] May 1, 2004
[12] Art. 53(a) EPC.
[13] We will discuss compulsory licensing further in this contribution.
[14] For an analysis of these cases, see Bostyn, S.J.R., A Test too Far? A Critical Analysis of the (Non)-Patentability of Diagnostic Methods and Consequences for BRCA1 Gene Type Patents in Europe, 5 *Bio-Science Law Review*, [2001/2002] 4, 111-121.

Purpose-bound patent protection

It will be clear now that a considerable number of objections against the patentability of DNA related inventions are actually more inspired by the scope of such patents than they are against the patent system as such. We have already emphasised that there are means within the patent system to tackle some of the concerns relating to patent scope. Part of the problem is also that media reports in connection with biotech patents tend to forget about these checks and balances, and limit themselves to report on granted biotech patents, which in some cases are granted in a country where the patent system is not subject to any examination of the patent application. That does not improve the situation.

One of the concerns which have been expressed is that full product protection for DNA related inventions is undesirable. One of the basic features of full product protection is that the patent protects the product produced by any method. This provides a potentially broad protection, even though the consequences have to be mitigated. A product patent still makes it possible for others to patent new uses of the patent, and even new methods for producing the products can be patented separately, if it can be shown that the patent holder of the product patent could not have foreseen the new process or method. It is also possible to obtain separate protection for new medical uses of the protected product. A patent for a product does thus not provide the patent holder with a claim on the future.

But irrespective of the possibilities left to others after a patent for the product has been granted, it has been said that in the field of biotechnology full product protection provides too broad a protection. It is argued in this context that this is due to the specific nature of DNA, which is unique. If one wishes to work on a cure against a hereditary disease, such will require the use of the relevant gene(s), which might already be patented.

One of the alternatives suggested is to limit protection to the specific purpose which one has disclosed in one's invention. At first glance, this seems to be an interesting alternative, as by definition the scope of the patent will be narrower. No product patent can be granted, and consequently no monopoly can be vested anymore in the gene itself, which would allow one to control further use. It gives the impression of providing a fair solution, as protection will be limited to the specific application or purpose described in the patent application, and would therefore do justice to the public. But this is only part of the picture. Purpose-bound patent protection can also have disadvantages. It leads to a plethora of narrow patents, and therefore adds to

the patent thicket problem, which we will discuss later. It could also give a rather unrealistic idea of certainty. It is illusionary to think that it is possible to draw precise borderlines between various purposes, especially if the claimed purpose or application is of a more general nature.[15]

Patenting research tools

The research community has also been rather hostile vis-à-vis patents granted for so-called research tools. Patents have indeed been granted for research tools. From a patent law point of view, this is not a surprising event, since they are not excluded per se from patentability.

To define a research tool, is easier said than done. One can think of various definitions. Following the definition used in the NIH Working Group on Research Tools Report (1998), it could be said that "we use the term 'research tool' in its broadest sense to embrace the full range of resources that scientists use in the laboratory, while recognizing that from other perspectives the same resources may be viewed as 'end products'."[16]

The concern which has been expressed in the research community relates to the effects of such patents for scientific research. Research tool patents are by definition upstream patents. And upstream patents have the nature of causing dependency and potentially blocking effects, especially when such upstream patents are granted broadly. The checks and balances in the patent system can avoid many of these concerns. If the patentability criteria of novelty, inventive step, industrial application and sufficient disclosure are being fulfilled, there is no reason to refuse patent protection. Potential negative effects such as dependency and blocking effects can be mitigated by a correct application of the said requirements. There will be lack of industrial application if no function is disclosed. And in some cases, the enabling disclosure requirement will present an obstacle.

In the view of the KNAW, there is no need to discourage patentability of such tools with specific measures. The checks and balances in the patent system will mitigate the negative effects.[17]

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[15] For more details, see Bostyn, S.J.R., Patenting DNA Sequences (Polynucleotides) and Scope of Protection in the European Union: An Evaluation. *Background Study for the European Commission* Within the Framework of the Expert Group on Biotechnological Inventions, European Commission, 2004, forthcoming.

[16] See also Nuffield Council of Bioethics, *The Ethics of Patenting DNA*, 2002, 47.

[17] KNAW 2003, 44.

Research exemption

The research exemption remains an important, be it difficult, concept under patent law. Almost all European countries have express statutory provisions allowing experimental use with or on the invention without a required consent of the patent holder. Such activities will not constitute patent infringement.

Problem remains, and even more in the area of biotech, to distinguish pure research and more commercial applications, in particular in case of clinical trials. Clinical trials are crucial in the development of cures against diseases. Some phases of the clinical trials are carried out by research institutions. It is thus important to know whether the activities they carry out in this context will constitute a patent infringement or not.

We do have case law in Europe relating to clinical trials relating to the marketing of generic drugs. It is clear from that case law that there is no uniform interpretation in Europe. Some countries consider clinical trials with a view to registration of a generic medicament to fall outside the scope of the research exemption, since such activities aim at the commercialisation of the product and can thus not be considered to be research *(e.g.,* The Netherlands). Other countries consider these trials to fall within the research exemption, as the aim of the serials is to accumulate knowledge as to side effects, efficacy etc. (*e.g.,* Germany).[18]

Some researchers have claimed a broadening of the research exemption. Such a claim must be carefully evaluated, so as to avoid that the patent holder is unduly limited in the exercise of his patent rights. Broadening the research exemption might also have negative effects for technological development, while it does not necessarily lead to a better position for researchers. Broadening the exemption can very well lead to even more legal uncertainty.[19] In addition to the uncertainties surrounding the research exemption comes that there is no harmonization in Europe.

In the US, there is no statutory research exemption, but there is a case law based exemption. It must be said, however, that the US interpretation is very narrow. In Madey v Duke (CAFC 2002), the Court of Appeals for the

[18] For more details, see Bostyn, S.J.R., The Prodigal Son: The Relationship Between Patent Law and Health Care, 11 *Medical Law Review*, 2003, (67) 110-111.

[19] For more details, see Bostyn, S.J.R., Patenting DNA Sequences (Polynucleotides) and Scope of Protection in the European Union: An Evaluation. *Background Study for the European Commission Within the Framework of the Expert Group on Biotechnological Inventions*, European Commission, 2004.

Federal Circuit held that: "regardless of whether a particular institution or entity is engaged in an endeavour for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defence. Moreover, the profit or non-profit status of the user is not determinative."[20] Under US law, there is thus very little room for research being exempted from patent infringement. Despite this, US research is not hampered. This is also an issue which deserves some further study, and a lesson for our European researchers.

Compulsory licensing

Broadening the application of the compulsory licensing scheme has also been suggested as a possible solution to tackle unwanted patents, such as *e.g*. the BRCA patents. It must be clear from the outset that the compulsory licensing scheme has been designed to be applied in exceptional circumstances only. It is therefore a burdensome procedure.

In principle it is only possible to grant a compulsory license if a voluntary license under 'reasonable terms' is refused. It is difficult to evaluate what the wording 'reasonable terms' means. The system can only be activated when a period of time has lapsed, in most cases a period of three years of non-working of the patent by the patent holder.

Exceptions to the procedural scheme exist in case of emergency or crisis, public interest etc. It has been argued that compulsory licensing should be possible in the case of *e.g*. the BRCA1 gene patents. It is difficult to see how the conditions could be fulfilled, however. It can hardly be accepted that there is a public health threat which necessitates the application of a compulsory licensing scheme in the case of the mentioned patents. This is even more so because the said patents are predictive screening methods, and it is difficult to see how this could be interpreted as a health care threat.

Lowering the threshold to *e.g.* health care related issues in general can have serious negative effects, since it would open the door to a broader application of the system, thereby depriving the patent holder of the exclusionary rights he is entitled to under the patent. This could have

[20] *John M.J. Madey v Duke University*, 307 F.3d 1351, 64 USPQ 2d 1737 (CAFC 3 October 2002).

negative effects on technological development. One has also to be wary of the domino effect it might have on other industries.

In general, it can be submitted that it is not a good strategy to use compulsory licensing as a price regulating mechanism. Pricing is in some cases the main reason why the scheme is brought to help.[21]

Blocking effect of patents

There is a tendency in present day patent strategy to start filing for patents at a very early stage of technological development of a specific product or process. This is what is called patenting upstream inventions. From an economic point of view, there are a number of side effects which have to be analysed in this context. Patenting at an early stage might cause more dependency. More dependency will in turn lead to patent and royalty stacking. And patent and royalty stacking might have a blocking effect on competitors or subsequent innovators.

In this context, it has also been said that we can see an evolution towards patent thickets, a plethora of patents through which an innovator has to find his way in order to avoid patent infringement.[22] If we discuss patent thickets, there are basically two phenomena which are to be addressed, *i.e*. the complements problem and the hold up problem. The complements problem can be summarized as the phenomenon that the accumulated costs of resources owned by different monopolists is higher than if they were in one hand. The hold up problem can be summarized as the phenomenon that each patent requires a licensing fee, and the cumulative effect can be substantial, holding up subsequent innovators.[23]

It has been claimed that patent thickets are capable of having substantial stifling effects on technological development. Whether this is the case or not is too early to tell, as there is yet insufficient evidence.

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[21] For more details, see Bostyn, S.J.R., Patenting DNA Sequences (Polynucleotides) and Scope of Protection in the European Union: An Evaluation. *Background Study for the European Commission Within the Framework of the Expert Group on Biotechnological Inventions*, European Commission, 2004.

[22] Shapiro, C., Navigating the Patent Thicket, Innovation Policy and the Economy, 2, available at http://haas.berkeley.edu/~shapiro/thicket.pdf.

[23] For more details, see Bostyn, S.J.R., Patenting DNA Sequences (Polynucleotides) and Scope of Protection in the European Union: An Evaluation. *Background Study for the European Commission Within the Framework of the Expert Group on Biotechnological Inventions*, European Commission, 2004.

Morality in patent law

Public ordre and morality exceptions can be found in European patent law. Again, these are instruments to be applied only in exceptional circumstances. Problem in Europe is that we have no uniform interpretation. This is quite normal, as concepts such as ordre public and morality are concepts which are related to national customs and traditions.

In Directive 98/44/EC relating to the legal protection of biotechnological inventions, a non-exhaustive catalogue of subject matter which has been excluded form patentability can be found in Art. 6.: "the following, in particular, shall be considered unpatentable:
(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes."

The insertion of such a catalogue is not per se a positive development. Positive is that it forms an ethical barrier to stimulation of undesirable activities. But it can be seen as negative in view of the fact that an express catalogue is a random indication of a state of minds/affairs at a specific time. It does not take into account evolution in the mindset, and is therefore not sufficiently flexible to adapt to changing circumstances.

A good illustration is the issue of stem cells and use of human embryos. Even though we might consider some practices with embryonic stem cells to be undesirable today, this can change completely within a few years.

In this context, it is worth observing that the European Group on Ethics in Science and New Technologies (EGE) is not against patenting stem cells under all conditions. In their view, non-modified stem cells should not be patentable. In vitro modified stem cell lines could be patentable. And processes involving human stem cells are also considered patentable. Such an interpretation can be welcomed and has at least an eye glancing to the future. The decision of the Opposition Division (OD) of the EPO in the Edinburgh case (EP 0695351),[24] however, witnesses a more conservative view. The OD in the said case has given a broad interpretation to the exclusion under Rule 23d(c), which is the equivalent of Art. 6 Dir. 98/44/EC. In the view of the OD, use of human embryos is not confined to use of

[24] Claim 1: " a method of isolating and/or enriching and/or selectively propagating animal stem cells, [...] the source of cells includes stem cells containing a selectable marker [...] "

human embryos as such, but includes also human embryonic stem cells by destruction of human embryos. And such is against morality. From a legal point of view, it is surprising to read that a broad interpretation is to be given to the exclusion laid down in the said Rule. According to a well accepted principle in law, exceptions are to be interpreted narrowly. The OD has exactly done the opposite in this case. The case is currently under review at the Technical Board of Appeal, and it is to be seen whether the Board will follow the line of reasoning of the OD.

It must also be clear to legislators, even if we are afraid that it is not always clear to them, that the exclusion of patentability does not prohibit the activity as such. Efficiency of patentability exceptions for undesirable scientific projects is very limited. The mere fact that a particular technology cannot be patented, *e.g.,* human reproductive cloning, does not necessarily imply that carrying out such research is also prohibited. Human reproductive cloning was excluded from patentability much earlier than carrying out such techniques or research was being prohibited. An exclusion from patentability for certain practices, the carrying out of which are not prohibited by law, will not have any effect on the practices as such. This is an important lesson for legislators. Undesirable projects should be prohibited by statute. Once such practices are prohibited by law, their patentability will by definition be excluded, since such inventions will be contrary to ordre public or morality. In the absence of statutory provisions prohibiting the carrying out of such techniques, an invention applying these techniques can never be excluded from patentability on the basis of being contrary to ordre public or morality. If the law allows these techniques, there is no reason to assume that applying these techniques would be contrary to *ordre public* or morality. It is the responsibility of legislators to choose the appropriate forum to regulate undesirable projects or techniques.

Technology transfer

Europe has no similar system as the US Bayh-Dole Act[25] to stimulate commercialisation of research done at publicly funded institutions. Under the Bayh-Dole Act, publicly funded research institutions are strongly encouraged to seek intellectual property (IP) protection for the results of their research.

[25] *The Bayh-Dole Act*, December 12, 1980, P.L. 96-517, and amendments included in P.L. 98-620, passed in 1984, incorporated into 35 USC 200-212, US Patent Act.

Stimulating publicly funded research institutions to seek IP protection can have various beneficial effects. It is first of all capable of generating additional financial resources to pursue further research. Such additional financial means are welcome, as they could finance a sequel research project, and provide the means to create new research positions for promising scientists. Secondly, such a policy can also stimulate innovation in publicly funded research institutions, as there is a reward made for the effort. Possible drawbacks must also be recognised. In Europe, such a policy might have as an effect that publication of research findings could be postponed, until a patent application has been filed. The extent of such a drawback is rather relative, and the force with which it is emphasised is fed by fear for the unknown rather than the severity of the consequences. Second drawback is that it makes publicly funded research institutions function more like private corporations, where accountability and efficiency are constantly guarded. This might be true to some extent, but it can be questioned whether accountability and efficiency should remain dirty words in the operation of institutions who finance their activities with taxpayers' money.

In Europe, we still have a long way to go when it comes to awareness of IP protection of publicly funded research institutions. No uniform policy exists within a country, let alone in Europe. Many institutions do not have an up to date IP policy which reconciles the interests of the institution and incentives for the researcher. This stands at odds with the growing pressure on publicly funded research institutions to seek IP protection for the results of their research.

In the view of the KNAW, there is a strong need for professional technology transfer offices at universities.[26] Such offices at universities or other publicly funded research institutions have as their mission to seek IP protectable innovations in said institutions, and seek interest on the market for these innovations. An efficient technology transfer office and a well developed policy offers incentives to researchers to seek IP protectable innovations, and the offices have the appropriate network to be able to bring this innovation on the market, be it by licensing the technology or by transferring the innovation after it has been patented.

Investing in professional technology transfer offices at publicly funded research institutions could have many beneficial effects. It would first of all provide possibilities for universities to generate extra research funds. It would secondly also have positive effects for the researchers themselves,

[26] KNAW 2003, 39

who would be freed from evaluating patent issues, for which they have not been trained.

Professional technology transfer offices can only be created at a cost. In view of their competence and networks, such professional technology offices must be staffed with real professionals, and these will not be cheap. Experience in the US, *e.g.* MIT, Stanford and others, has proved that the investment made in this know-how is more than worth the investment, as these offices are capable of generating considerable amounts of money in return. In the light of these initial costs, the KNAW has proposed that for smaller countries, one could think of a centralized office. Separate technology offices in such countries cannot operate on such a scale that they can be staffed with professional but expensive consultants. A centralized, or to some extent a regional office can solve this problem of scale. But that requires that universities and publicly funded research institutions put aside the rivalries, for which they are known since ages.

Conclusion

The biotech era has brought many changes in our lives. This has many beneficial effects, if we think only at the new cures against previously debilitating diseases. In view of the huge investments required to finance these new products and processes, it was not difficult to predict that patent law would also have a role to play in this new era. This role has not always been a positive one, at least, that is the perception of some people. Many of the negative reactions, also from the scientific community, are based upon a rather one-dimensional view of the patent system as the system which helps private enterprise to accumulate wealth at the expense of the public and public research. We have demonstrated above that the picture is somewhat more complicated and especially more balanced. Without doubt, there are some side effects which are not entirely desirable, but that is not the exclusive privilege of the patent system. In this contribution we have tried to provide a more balanced view of the patent system, and also of the checks and balances present within the system to tackle some of the reproaches made. Some concerns are indeed worth further scrutiny, such as the blocking effects of patents and the phenomenon of patent thickets. Other drastic solutions such as broadening the application of the compulsory licensing system, or extending the diagnostic method exception also to *ex vivo* methods can have more negative effects than benefits.

Introduction of a grace period seems an issue that would be capable of accommodating both the needs of researchers to publish the results of their research, while at the same time maintaining opportunities to obtain patent protection for the results of that research.

Professionalizing technology transfer at publicly funded institutions can also be seen as an important priority to be put in practice. And the research community would also be much helped with a clear scope of the research exemption, but it is to be feared that reaching such clarity will take more time than we would welcome.