

Biotech Patents

Grant Requirements & Scope of Protection

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This article is more of a summary of certain aspects analysed in my dissertation “Biotech Patents – Equivalency and Exclusions under European and U.S. Patent Law” and hopefully this paper will present to you the sentiment of the its conveyed message.¹ I will not go deeply into the legal/technical analysis, which was necessary to arrive at the conclusions outlined here and which are mainly deduced from the EPC and the U.S. case law. The issues I will focus on are those I believe to be of central concern for the balance between patent holders and third parties, *viz* the material requirements for the grant of a patent and a granted patent’s scope of protection.

I will start out with a brief background of the tension presently governing biotechnological inventions. Within this overview I will also explain the reason why in my mind particularly disclosure and infringement doctrines present the critical thrust for future reflection and doctrinal emphasis by granting authorities and courts.

Next I will sum up the deductions made in the book from the more thorough analysis of the European disclosure requirement, followed by the U.S. corresponding condition for patent-grant.

Because infringement determinations take place in national courts there is no uniform European approach to compare to the U.S. practice and hence I have chosen practices of United Kingdom and Germany for the purpose of my comparative analysis of a patent’s scope of protection. Because of their complex substance though, the different infringement doctrines cannot be described in this paper and thus I will have to refer to the book for a deeper overview. Yet as a final point and in order to achieve “balance” I will point to important aspects for an analytical framework for considering the scope of protection.

¹ Due to the voluminous basic book, in this article I will not for every statement substantiate it with a footnote. If you would want to read further about these issues I refer you to the book, *Biotech Patents – Equivalency and Exclusions under European Patent Law*, Jure, Stockholm 2001.

Biotech Innovations

Genetic research promises not a few, but many, changes in many different fields of law. To a large extent the field of genetics is built upon the technical application of new discoveries, or new implementations of earlier ones. The possibilities of making changes at molecular/genetic level have confronted man with a reality where we are being forced to view life in new perspectives. The distinction between what is technical and what is “life” has provoked tension in society, and that tension is still with us.

The patent system has come into focus as never before, and its opponents often rest their case on “feelings” that patenting biological material in different respects is not at all proper. Evidently many of those opponents do not really comprehend though what a patent right means, for instance that it is not a right to exploit but a right to prevent others from doing so if exploitation is permitted by society.

There are many issues concerning biotechnology that have to be considered, but rather than by opposing patents, those purposes can perhaps be better achieved by adopting specific laws that regulate the different matters. For instance by prohibiting human cloning, regulating the use of research animals so as to spare them suffering, making provision for environmental considerations, etc.²

The patent law is complex in itself. Not only does it comprise different fields in addition it relies upon a variety of mechanisms. The law on genetic research and development ranges from ethics governing research and use of biotechnological matter to governmental regulatory rules, professional rules etc., all of which to some extent reflect changes of social policy in the light of scientific developments.

This policy change is also reflected by the application of patent law in recent years, which has allowed patentability to most of these types of inventions.³ In addition, these concerns are mirrored by endeavours at international level. The patent system has itself been challenged with respect to biotechnological inventions because of obstacles to free research.

Proponents of the system as appropriate for protecting such inventions emphasise the necessity of exclusivity in order to ensure the vast investments in this field of research, much of which could be of societal benefit in terms of new medicaments or improved grains etc.

As the analysis showed, the policy issue should rather be for the scope of the protection conferred by a patent right so as to reflect the contribution made by the inventor. This given the eligibility issue concerning biological matter has been firmly settled and the different practices have made protection available, for instance, to gene sequences.

² Article 53(a) EPC is being thoroughly analysed in an upcoming work by the author.

³ In Europe article 53 (b) EPC explicitly excludes from patentability plant and animal varieties, and essentially biological processes.

“Unduly” Broad Protection

Unduly broad protection, however, would undermine the patent system itself, since the arguments that it is an impediment and “unfair” would then have substance. This makes it essential that the protection conferred to a granted patent should rest upon what the inventor has also claimed and disclosed. Notification purposes and the *quid pro quo* for the dissemination of knowledge are the policy considerations behind these legal bases.⁴

All in all, the real issue of balance should turn on the scope of protection. Therefore its determination and its basis were comprehensively focused upon. For biotechnological inventions particularly, the actual disclosure was of the greatest interest from the more technological perspective, in order to provide a fair and practical basis of protection. Because of its legal complexity, with its different components, the different approaches to deciding on infringement were addressed with more emphasis on those differences and their consequences for the breadth of protection in comparison.

As the patent system in itself has been so much questioned for biotechnological inventions because not everyone considers it proper to provide exclusivity to biological material or processes, it is all the more essential to keep this right within judicious limits. This balance between the right holder and third parties is fundamental to the achievement of societal benefit. The eligibility issue must be seen in the context of the whole patent system. Therefore it must be emphasised that, although in principle eligible for protection, the claimed subject matter must in the specific case meet the basic patentability criteria, which ensure its attainment of a certain “level” of innovation.

In addition there are two important aspects of patent law, which in reality limit the scope of exclusivity and thereby decide the central policy issue concerning a patent’s actual blocking effect. The condition of sufficient disclosure for the grant of a patent and its conferred scope of protection are critical for the balance. As legal instruments they are practical to control the effect of a patent and depending on the requirements and method used for their legal application the legitimacy of the system in terms of balance if necessary can be retained. This paper will keep in focus as a central issue the “proper” balance of the system as a whole when analysing the effect of a patent right in terms of the content of the exclusivity granted.

The questioning of patents in biological products and processes and the issue of “broad claims” are interrelated⁵ Given that in principle patents to biotechnological inventions are available, in order to maintain a well-balanced system the broad claims conferred to such patents is the real problem to focus upon. The present policy issue under patent laws for biotechnological inventions

⁴ Other issues like inventive step are also important in order to avoid giving exclusivity to minor progress from prior art, although it is not included in the scope of the study. Even if under the German practice inventive step is substantially related to equivalence, inventiveness is not so in neither British practice nor U.S. one.

⁵ An example is the Onco-mouse patent, which is claimed broadly and not supported by the description. The claims are directed to all non-human mammalian onco animals, yet the specification of the patent contains only an explanation of a method for the production of mice carrying an activated onco-gene sequence.

would thus be their protective scope. This because the requirements of supporting the claims and the protection are central to ensuring that the exclusive right does not go beyond the contribution made to the art by the inventor, since otherwise it would act as an impediment to the system.

A strong patent right should not be confused with easy acquisition, which is all the more important for those biotechnological inventions that serve as building blocks for further development in this field. Therefore I will more thoroughly discuss the requirement of disclosure, under which particularly the criterion to enable what is claimed becomes a concern for biotechnological inventions.

Disclosure – Europe

Under the EPC it is only a qualified truth that, in order to be disclosed an application is required to contain sufficient information to enable a person skilled in the art⁶ to use his common knowledge and carry out the invention within the whole area claimed.⁷ Since if one way is shown to work invokes a rule of presumption, this means that not all the claimed subject matter must actually be enabled.⁸ Likewise the enabling of a process shown to work with only exemplified subject matter essential for its correct performance might be presumed to work, for instance, on a whole genus.

Although some particular variants being unavailable or some unspecified variants of a functionally defined component feature being inoperative a patented invention might anyhow be sufficiently disclosed.⁹ Provided suitable variants are known either through the disclosure or from common knowledge, and which are working the same way, the requirement is met. Regarding functionally defined claims the disclosure need not include guidance on how to obtain all the possible component variants.

Provided the process as such is reproducible, generally applicable biological processes are not insufficiently described solely because some starting materials or genetic precursors, for instance a particular DNA or plasmid, are not readily available to obtain each variant of its expected result.¹⁰ No requirement can be taken under Art. 83 EPC to mean that a specifically described example of a process must be identically repeatable. So long as the process reliably leads to the

⁶ A skilled person in the field of genetic engineering (in 1978) was not to be seen as a Nobel Prize laureate but rather as a graduate scientist, or a team of scientists of that skill, working in laboratories which developed from molecular genetics to genetic engineering techniques. (Cf. TBA EPO, August 31 (1990), 23 IIC 678, 682 (1992) – Fusion Proteins/Harvard. The person is oriented towards practicalities, and the development of the art normally expected by him does not include solving technical problems by performing research in areas not yet explored. (October 21, 1990, (1995) EPOR 69, 76 – *Alpha-Interferons II/Biogen*.)

⁷ See Straus, Joseph, *Patenting Human Genes in Europe – Past Developments and Prospects for the Future*, IIC, Vol. 26, 1995, p 936. T 409/91, which specifically address the complicated relationship between EPC articles 83 and 84 (clarity of claims). See also Brandi-Dohrn, M., *Unduly Broad Claims*, 25 IIC, 1994 for further references in marginal note 71.

⁸ T 409/91.

⁹ T 292/85.

¹⁰ *Ibid.* Official headnotes.

desired result, variations in the constitutions of an agent, such as within a class of genetic precursors,¹¹ used in a process are insignificant for disclosure.¹²

Generic classes can be claimed by a combination of structural limitations and functional tests. Although without knowing in advance which member would be made readily available, the skilled person could obtain embodiments of the claim, thus variations within the class are insignificant for disclosure.¹³ The basic rule, however, is that an invention must be disclosed to work within the whole scope of the claims, and its assessment is rather the point of dispute from the perspective of fair balance. The EPO practice has been challenged in national courts, and one British court judgement is particularly interesting by comparison.

The British Approach

In *Biogen v. Medeva*¹⁴ disclosure was at issue and, based upon overly broad product claims, the court rejected a patent allowed under the EPO practice. Academically the interest in this context foremost refers to policy differences between European countries, yet it also illustrates important points to resolve on the aspect of fair balance. For the purpose of this short paper it will thus give you a more concrete example of the intricate policy issues governing disclosure and specifically of its enablement-criterion.

The case concerned a claim to a class of products. The patent¹⁵ claimed the expression of both HbCaG and HbCaG antigens in relation to both bacterial and nonbacterial hosts. These could be used for the production of vaccine against Hepatitis B.¹⁶ An example was given of how to make one of these only, which in reality means the patent disclosed only one embodiment of the invention. Because it disclosed no principle enabling the other claimed products but the example, this product claim was found overly broad and was therefore rejected. In the court's view the claim covered more than one invention, and claim to all recombinant DNA molecules coding for Hepatitis B antigens was too broad,¹⁷ because for different inventions every single one must be fully disclosed. The basis for the rejection was that no principle or broad technology for achieving the same results had been established.¹⁸

The reasoning rested upon T 292/85, in which it was noted that broad claims allowed for other ways to achieve the invention that could not have been

¹¹ Such as recombinant DNA molecules.

¹² T 281/86.

¹³ T 301/87.

¹⁴ *The House of Lords Biogen v. Medeva*, HL, 31-10-1996.

¹⁵ Claim 1.

¹⁶ Biogen has a European patent EP182442 filed on 21 December 1979. This patent is of note because the European patent office upheld the patent when an opposition was filed, but the UK patent office ruled that the patent was obvious.

¹⁷ Expression of the antigen could also be achieved without the use of the teaching that the patent contained. Medeva was therefore free to go ahead with its plans to sell its Hepatitis B vaccine in the UK.

¹⁸ The court also ruled that there was no inventive step, as the work that Biogen undertook in 1978 was obvious.

envisaged without it.¹⁹ The dissimilarities of technical facts distinguished however the present situation from it. Interestingly, the technical contribution in the present case was perceived only as the making of the plasmid pBR322 with fragments of Dane particle DNA in order to transform *E. Coli*, which in turn caused the expression of the genes of HBcAG and HbsAg. In addition, the recombinant DNA molecule was made from the standard pBR322 plasmid and from large fragments of Dane particle DNA. This clearly shows the significance of establishing the contribution made by the invention to the state of the art, in order to distinguish the invention from prior art and thereby not allow the inventor to claim subject matter not invented by him.

Under the EPC practice, on the other hand, the opposition filed when the patent was granted was dismissed and Biogen's patent was found valid. As breadth of patent claims granted could not be challenged for lack of description-support under Art. 84 EPC, the breadth of claims was not a ground for opposition.²⁰

Granted claims can, however, be based upon lack of disclosure, more specifically the requirement of enablement. Regarding the claim of consideration in the *Biogen v. Medeva*, the same outcome could have been reached under the EPC, on the basis of serious doubts of workability within the whole range claimed. Even though one example was given, since no principle or a broad technology enabling the whole range of products was shown, the finding of insufficient disclosure could be justified.

For the outcome the decisive practice is the application of the reversal of proof for finding insufficiency in these situations, as one way of workability presumes to work on the whole claim. The burden of proof to refuting this presumption is set at a relatively high level and perhaps the required evidence for rebuttal is the relevant concern under the EPC case law and not whether "broadness" of claims can be opposed.

Practical Use

Another interesting feature of the disclosure since it concerns practical use is "industrial applicability". This requirement does *not* under European law *require the showing of practical use*, perhaps with the exception of gene sequences.²¹ This application of it can be justified by the argument that inventors are before their time and therefore it might be difficult to realise an invention's possible uses.

Practical use in this sense must be distinguished from the showing of a function, which is required for biological material to qualify as inventions rather than non-patentable discoveries. Considering that what the patent ensures is the exclusive commercial use makes a requirement of practical use logic for protectability. The reason I bring it up being that this question is very much an issue of policy, the solution to which has consequences for the balance of exclusivity between a patent's incentive for innovation and blocking effects.

¹⁹ T 296/93, on the subject of disclosing a priority document, was thus distinguished.

²⁰ The breadth of claims is considered when the patent application is examined. For amendments article 84 EPC applies, *see* in T 923/92.

²¹ Article 5.3 of the Directive 98/44/EC.

Practical reality for the most part is competitive, and the work going on within the biotechnological field is not random research by a lone research genius, but rather methodically oriented. The typical picture of several research teams working towards the same objective and considering the overall concerns raised about patentability of biological material make a condition of practical use rational. If no practical use can be shown, there is less reason to allow exclusivity that blocks further research. The utility requirement as it is assessed under U.S. patent law might provide the means of restoring a proper balance, even though a strict assessment of it can present difficulties and yet not remedy overly broad claims. Overly broad means here claims that are either not commensurate with the contribution made to the art, or have not reached the level worth protecting. Those patents, if enforced, would therefore shift the balance from “fair” towards advantageous for patent holders and not necessarily beneficial to society.

The requirement of utility is more demanding than industrial applicability, in that it clearly relates the exclusive right to practical use, excluding from the possibility of patenting subject matter which is merely discovered to have a function. Although isolated for making it useful, it requires further research beyond wishful thinking.

To maintain a balance between patentees and third parties a fair basis is required for exclusivity, which accurately reflects the invention’s contribution to the art. What is more, for notification purposes the content claimed should also be clear from the patent as filed. Considering the exclusivity assured by the patent system, it is not too demanding to require a patentee to particularly point out and distinctly claim the subject matter for which protection is asked and to ensure its workability. This brings into focus the question of what is the invention-identity exactly.

Invention-identity

To base the protection – that is to determine the scope of protection – on the invention as identified under the disclosure requirement would reflect those concerns expressed in the foregoing and help to uphold the proper balance. This approach would ensure symmetry so that the disclosed invention was consistent with the subject matter decisive for the actual protection conferred.

The legal effect of making the invention, as properly identified by the disclosure, the basis on which to decide the extent of the patent right is that infringement decisions based upon Art. 69 EPC would depend upon the requirements under Art. 83 EPC. From an overall systematic perspective, this assessment is logical and contributes to coherency. No purpose behind the patent system justifies the granting of a claim whose broadness allows protection to cover, for instance, products later obtainable by other ways of achieving them, even though those other ways are not envisaged without the invention. That situation is better dealt with if proper through the application of equivalents in deciding the scope of the patent. The call for a distinct basis for identity-purposes from which to decide on the patent content stresses the worth of strict disclosure requirements.

Even if the invention itself envisages technical development in a certain direction and thereby in fact contributes to a later solution to the problem, this is

not accomplished at the time of grant. Therefore, unsupported claims, such as those non-workable or not obtainable without undue burden within the whole area of the claim, must be considered overly broad.

Note here that this is not to say that each and every embodiment of the claim must be reduced to actual practice. Yet their enabling must be shown, for instance by example/s reduced to practice and with no serious doubt of the invention's workability. If undue experimentation is needed for performing the invention, the claim merely indicates a possible line of research and is basically prematurely filed. Other research teams may well come up with the actual solution, in which case they would be the ones with the possibility of patenting. Broad claims to inventions requiring inventiveness or further experimentation beyond the point of undue burden are therefore not justified.

The question of enablement and that of reproducibility are related, yet not identical. The enabling of the invention, where the rule of presumption may be invoked, refers to the possibility of reducing the claimed invention to practice. Reproducibility, on the other hand, refers to its repeatable achievement. This means that the presumption of enablement because one way is shown to work although interrelated is distinct from the question of reproducibility. For examining disclosure thus the correct perspective to establish identity is from the disclosed features as properly identified with respect to the invention's effect.

Since to be patentable the invention must be reproducible without undue burden, the requirement applied in a strict manner should in another manner exclude the enforcement of overly broad claims – those would not meet the disclosure requirement – for instance those including embodiments not obtainable but rather envisaged by the invention. From a balanced perspective, an interpretation of the *British Biogen v. Medeva* decision that all members of a claimed class have to display the principle might be unduly strict for the inventor. If failure to enable one single compound in such a claim would lead to rejection the disclosure requirement would entail unreasonable practical experimenting before filing. The claim should not for that reason be invalidated for lack of sufficient disclosure.²²

Quid pro quo

In the EPC the reflection of the so-called *quid pro quo* for patents is found in Art. 83. In terms of maintaining a fair balance, Art. 84 EPC may not necessarily have to apply per se, since basing the identity upon the actual disclosure allows for considerations of support. The failure to disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art constitutes the grounds for opposition²³ and for revocation.²⁴

This concept suggests that the fair content of patents be based upon the subject matter identified from the requirements of disclosure. If the disclosed teaching is

²² The decision concerns the interpretation of the traditional British concept of the “lack of fair basis” regarding classes of chemical compounds.

²³ Article 100(b) EPC.

²⁴ Article 138 (1)(b) EPC.

by the skilled person²⁵ perceived to constitute a complete invention the subject matter is patentable. Speculative or unfinished inventions, in need of further development in order to reach the point of actual contribution in the patent sense are not.²⁶ The language addressing the expert who considers the disclosure may appear more demanding than for inventive activity.²⁷ However, it has to be borne in mind that the technical situation differs, in that for the purpose of evaluating sufficiency of disclosure (and hence support) he has knowledge of the prior art and of the invention, while in evaluating inventive-step he has knowledge of the prior art only.²⁸

The material application of the disclosure requirement has been directed to the essence of the genetic information at molecular level, i.e. the informational elements essential for obtaining the effect of the invention. Furthermore the manner in which the existing information is transformed, or in which new information in existing entities is incorporated, decides the inventions identity. By subsuming non-available variants under a feature of a claim seen as generic, all the variants may be claimed on the basis of reliable performance of the genetic information. This suffices even though not every one of the features reliably leads to the next step or to the end product.

The same reasoning governs the consideration of starting materials, based on natural material with the inherent allelic variation. Thanks to the concept that the genetic information as such could be reliably derived, without corresponding connection between information and the natural basic material, this variation is not seen as detrimental to the reproducibility of the invention because its effect is nonetheless achieved.

The approach affects the consideration of reproducibility because the achievement of a causal perceivable result is, in this manner, restricted to the guidance about the transformation steps of the genetic information. For notification purposes it is important, though, that the breadth of claims, upon which ultimately the scope of protection depends, also corresponds to the technical contribution to the art as the disclosure reflects it.

Not least this is important because a patents blocking effects concerns not only competitors but also scientists in the area of basic research. People for whom use in the sense of patent law is commercial are affected, even though their use would be directed primarily towards private purposes or low-scale commercial use that would not diminish the exclusive right in terms of economics. Thus again we have

²⁵ Another important implication is to define the so-called average expert. The average expert whose skills are decisive to answer the question whether the invention could be carried out according to the disclosure.

²⁶ According to the case law of the German Federal Supreme court only a “complete invention” constitutes a patentable invention, otherwise, a “speculative”, “unfinished” invention is at stake, See Straus, marginal note 70.

²⁷ TBA EPO, June 20, 1994, 1995 OJ EPO – *Expression in Yeast/Genentech*, under No. 5.1.3.3: “A skilled person working in one area of genetic engineering (e.g., expression in yeast) would regard a means found possible in a neighbouring area of genetic engineering (e.g., the bacterial art) as being usable in his own area, if the transfer of technical knowledge appears to be easy and to involve no obvious risks”. Therefore, there was a sufficient incentive for an expert at least to try to transform knowledge from the bacterial art to yeast, No. 5.1.3.4 of the reasons.

²⁸ T 694/92, point 7 of the reasons.

support for an argument that if an inventor chooses to define a claim broadly, he should also be required to show his capability of reducing it to practice and to clearly define the area for which he seeks protection. This in order to achieve the economic benefits of an extensive exclusive right.

Remarks

The considerations under the disclosure requirement may be divided into three main sub-requirements, each of importance for the post-determination of the scope of protection.

- The assessment of the industrial applicability/utility requirement.
- The assessment of the reproducibility requirement and undue breadth of claims.
- The assessment of the rule of interpretation as applied with respect of the invention-identity, including the proof required for evidencing non-workability, i.e. enablement.

The interpretation of these sub-requirements provides a means of refuting overly broad claims and thus avoiding the validity of claims contrary to the purpose of the patent system. A stricter assessment would keep, or restore, the balance of the system by conferring fair protection on the patentee with a reasonable degree of certainty for third parties that extends no further than to the contribution made by the inventor to the art.

In the foregoing the policy considerations behind the disclosure requirement of fair balance and their solution under European patent laws have been analysed. Under U.S. patent practice the same policy issues are present, but differently solved. Therefore the next section, yet with reference to the European law, will focus on the condition under U.S. patent law to disclose inventions as a requirement for patent-grant. While analysing that issue we will compare the solutions thereunder to assessment under the EPC in order to identify the differences and their possible consequences for the breadth of claims.

U.S. Practice

In comparison to the European law under the U.S. practice it is more of a distinction between undue breadth of claims in the strict sense and undue breadth because of inoperative embodiments. In *re Fisher*,²⁹ *In re Vaeck*³⁰ and *In re Wright*³¹ all concern the breadth of the claims in the strict sense, i.e. that the scope of the claims must be commensurate with their enabling. Case law does not explicitly argue in terms of the invention argument and the principle that the

²⁹ *In re Fisher*, 427 F.2d 833 (CCPA 1970).

³⁰ *In re Vaeck*, 947 F.2d 488 (Fed.Cir.1991).

³¹ *In re Wright*, 999F.2d 1557 (Fed.Cir.1993).

identifying disclosure affects the scope of the invention. However, since in theory the same correlation between them applies under U.S. law, the identification position of the enablement criterion becomes evident.

The recognition of the claimed invention is decisive for its evaluation for enablement, which although not explicitly recognised in case law in rationale should form the basis for the scope of the patent. In case law the invention is recognised by a generalisation of the scope of the claims and that this generalisation is limited to what is reasonable in view of the examples provided. In the case of generic claims or claims that rest on broadly stated parameters, there must be established a scientifically reliable relationship between the disclosed features and parameters in the given examples as of the claims.

The point at which disclosure is satisfactory depends in turn on the technology in question. In *re Fisher*³² concerned a generally stated technology in which the claims were found unduly broad because they were not proportionally disclosed. The finding indicates as relevant factors to consider the amount of features and parameters mentioned in the examples, which in this case did not suffice to show their satisfactory relationship.

On this understanding, claimed processes which works on a smaller group of living embodiments shown by examples for disclosing a broader claimed group could meet with problems. To avoid the finding of undue breadth under the reading of *In re Wright*,³³ the broader claimed group must be obtainable without undue experimentation. That is to say that the teaching thought to achieve them must provide for success. Therefore sufficient guidance about the process, its different steps of and its adaptability must be disclosed to lead the skilled person to success without experimentation beyond what is reasonable.

Biotechnological products – genes for instance – exemplified for a restricted number of species but claimed to work in an entire genus or class pose problems of enablement. In *re Vaeck*³⁴ is an example where claims based on the taxonomic system of the genus were rejected as unduly broad. To make it possible to predict whether they will work within the entire genus and not leave one to unreasonable experimentation, satisfactory guidance on the biological elements used in the process must be submitted for such claims.

Even though biotechnology as a relatively new science is still seen as unpredictable, as it has developed certain aspects of it those have become predictable. Since if the DNA sequence is known the protein it encodes can be specifically elucidated, the patenting of DNA sequences that code for specific protein poses no problem of disclosure. The reverse, however, is not certain. Even though a protein sequence is known, there may be several different DNA sequences that could encode that very protein³⁵ and therefore more guidance to ensure enablement might be required.³⁶

³² *In re Fisher*, 427 F.2d 833 (CCPA 1970).

³³ *In re Wright*, 999F.2d 1557 (Fed.Cir.1993).

³⁴ *In re Vaeck*, 947 F.2d 488 (Fed.Cir.1991).

³⁵ The DNA code comprises the four nucleic acid bases adenine, guanine, cytosine and thymidine. These bases are grouped in sets of three known as triplets or codons, and each codon codes for an amino acid in the protein. Therefore, a DNA sequence of 90 bases will encode a peptide with 30 amino acids. The four bases give a total of 64 possible codons but there are only 24

In relation to considerations of breadth, the presence of inoperative embodiments in a claim poses a problem. Case law does not explain, nor could clear guidance be discerned from it, to what extent in-operatives of some embodiments of a generic claim are significant for undue breadth. With respect to microbiological claims in some circumstances such claims might be accepted,³⁷ for instance those where the majority of the class are operative, a reasonable number of the class tested to find the inoperative members unimportant and those inoperative species are recognised. In *Amgen v. Chugai* the Federal Circuit indicates that embodiments within generic claims to biotechnological inventions are to be considered similarly inoperative, although the problem is not explicitly addressed within that context.³⁸

Compared to the EPO assessment thus, case law indicates a stricter requirement to show enablement within the whole scope of the claim. In U.S. practice one can discern a demand for several examples rather than one to ensure workability. The notion of reduction to practice if claiming biotechnological products also seems to be more strictly applied under U.S. law, so as to mean actual reduction to practice and possession of the invention.

Then again, under U.S. practice later development can be used to show enablement for the invention as filed. In reality this means that even if at the time of filing the disclosure did not enable the skilled person without undue burden to achieve the invention as claimed, technology developed later, i.e. between filing and the grant or final court decision, may ensure the enabling in the first place.

A first-to-invent system could justify such an assessment, since, regardless of the actual filing, it could be argued that the first inventor gets the patent. It could perhaps also be explained as consistent with the approach taken for the doctrine of equivalents, which may include technology developed later. On the other hand it seems contradictory to the notion of reduction to practice decided at the time of filing. If only later development enables the invention, by definition it could not have been reduced to practice at the time of filing. For the sake of balance, and in order to have inventors file earlier under a first-to-invent system, this assessment could, however, serve the purpose of rewarding the actual inventor.

naturally occurring amino acids, giving redundancy in the code – some amino acids are encoded by up to six different codons while others are coded by a single unique codon.

³⁶ In the case of the proteins insulin-like growth factors I and II, the U.S. courts overturned arguing that the structure of the naturally occurring genes could not have been predicted from knowledge of the protein sequence. Although a gene that would code for the growth factors could be designed, there were over 1,000 possible genes that could encode the proteins and therefore the DNA sequence of the naturally occurring gene would not be obvious.

³⁷ Hunter, *Legal Protection of Biotechnology*, p. 50; Cooper, I.P., *Biotechnology and the Law*, C. Boardman Co., New York 1982, § 4.02(12) p. 4-88.

³⁸ *Amgen Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200 (Fed.Cir.1991). The court did, however, endorse a strict application of enablement by requiring the disclosure of particular analogues covered by the claim, as the examples given did not suffice to show achievement of the full scope of the claim.

Strict Interpretation

Needless to say, if broad claims are allowed they are broad but justified since the conditions for protection by patent are thereby fulfilled. As the claims would then be enabled in their specific case, by definition those could not be labelled as overly broad. There is a danger for weak patents if the practice slid to accept claims that are not justifiably enabled, so therefore the claimed range of matter does not reliably work.

Case law indicates a substantive interpretation of the enablement requirement, and this standard refers to the acceptable amount of experimentation to achieve the invention. As a standard it is founded on the requirement to enable the making and use of an invention within the whole area claimed. This means that the scope of the claims must be commensurate with the scope of enablement,³⁹ or else the claims – whether narrow or broad – are overly broad. Claims, whether narrow or broad, should therefore not meet the requirement of disclosure if no enablement is shown.

The strict standard discerned from *In re Wright*⁴⁰ is in agreement with the spirit of the law of promoting technical innovation for the benefit of society. What the decision did was to more precisely clarify the level to which enablement had to be shown and *In re Fisher*⁴¹ sets this standard for the invention's reduction to practice. This strictness is in accord with the policy consideration that the scope of the claims shall be commensurate with the scope of enablement. Certainly, then, the actual enabling requirement⁴² works to maintain the balance of the system by only rewarding the promotion of the useful arts and is therefore legally well founded under the law.

Lenient View – Consequences

The practical situation commonly resembles that in tPA development, where often different teams are working towards the same objective and the first one to reach it as the “inventor” gets the patent. This differs from the situation in Europe, where exclusivity is awarded to the first filer. In both systems, this competitive environment points to the importance of a strict assessment of enablement, since otherwise the “actual” contributor might not be the one getting the patent.

Lenient view risks awarding the patent to someone still in the initial phase of attaining the objective pursued, even though he has merely foreseen the solution to the specific problem. Incontestably the inventor should be the one credited with the exclusive right, rather than someone who without actually succeeding is just trying to find a solution. This to avoid a system that is counterproductive, as the blocking effect of a patent might stop others perhaps more successful from finding a good solution.

³⁹ Legally this requirement is based on section 112 of the Patent Act and has been further defined by case law.

⁴⁰ *In re Wright*, 999 F.2d 1557 (Fed.Cir.1993).

⁴¹ *In re Fisher*, 427 F.2d 833 (CCPA 1970).

⁴² See further Canady, K.S. *The Wright Enabling Disclosure for Biotechnology Patents*, 69 *Washington Law Review*, 1994, p. 455 ff.

The illustrative example of the importance of a strict standard is situations where new technical development becomes known. The first to put the science into practice in reality may have made a relatively small contribution to the art, which is still unknown and has unforeseeable technical possibilities. To grant a broad patent in such a field could very effectively block further development. Perhaps the patentee might succeed in making progress in the field, but freer research possibilities here would be of greater value from a societal perspective. To apply a more lenient enablement standard is risky, yet if an inventor by his new exploration within the field comes up with a great contribution to the art this should be recognised and rewarded. Even so, it is vital to require adequate showing of actual contribution rather than lines of research.

Policy Remarks

Patents are often applied for at the earliest in order to guarantee the inventor the results from further research on, for instance, a gene. In this way the patent-holder may secure the developments of and patents to subsequent inventions, in which the gene plays either a crucial part or is derived from it. In the long run, though, and to ensure strong patents no one should benefit from another assessment than a strict enablement requirement. For the sake of argument, the practical consequence of a patent granted to an invention based on the discovery of the double helix structure could have blocked a whole science. This begs the question relevant in this respect, namely how could that possibly be known at that early stage of the development?

The development since taken place regarding this one example could not possibly have been foreseen at that time. In a similar situation, granting authorities could not possibly have any idea of the magnitude of the contribution made by the invention for which a patent is sought. From this scenario the obvious question is how this risk could be taken into account when deciding on the permissible breadth of claims. Given the impossibility of evaluating the invention in relation to the field it starts to explore as a small or large contribution, strict application of the enablement requirement is justified. The blocking effect is also obscure and regardless of whether a small or large contribution to the art is involved, this aspect matters. Otherwise the patent system will frustrate its own purpose, as an incentive for innovation for the benefit of society on the whole.

The other example underscoring the significance of a strict enablement standard is inventions consisting of a successful practical application of generally known principles. This situation also highlights the importance to not grant patents broader than what is enabled. In literature different practical situations have been put forward as reasons for not granting broad claims and situations are instanced in which broad claims would be unacceptable.⁴³

Given the relevancy of the application as first filed in *Regents of California*,⁴⁴ involving a chemical genus, no description was given of the chemical species in

⁴³ Merges, R.P. and Nelson, R.R., *On the Complex Economics of Patent Scope*, Columbia Law Journal 1990, p. 839 (884).

⁴⁴ *Regents of University of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed.Cir.1997).

terms of precise definition, such as by structure formula. Nor was the chemical name of the claimed subject matter disclosed sufficiently to distinguish it from other materials. The description requirement necessitates a description of the invention and not merely an indication of the result that might be achieved if the invention is made.⁴⁵ In this situation the free research possibility could possibly contribute to more valuable solutions. As the claims were not shown to work, i.e. to be made and used within their scope, they were overly broad and in line with the policy aspects behind the system should therefore be rejected.

Observations on Disclosure

Recent advances in genetic engineering have considerably improved the possibility of disclosing in sufficient detail the methods employed to achieve the biotechnological inventions applied for. Those kinds of inventions have been challenged for disclosure, and two especially serve as cases in point to show that previous judgement can be overturned. The litigation over erythropoietin between Amgen and Chugai/Genetics Institute and tissue plasminogen activator in Genentech's litigation elucidated important issues surrounding biotechnological patents. Above all, these cases have stressed the fact that different countries may well arrive at opposite conclusions when looking at the same or similar patent claims.

As the enforceability of some of the broad biotechnological claims has been questioned, and often those patents contain several claims to products, intermediates and processes that involve DNAs and proteins, from the basis of this analysis of disclosure we will further analyse its implications for the scope of the patent. We have now seen the approach in the European and the U.S. practices, both of which have dealt with and resolved those patents in a traditional fashion, by principles derived from the chemical approach yet with some adjustments to the unique characteristics of the science.

The study⁴⁶ made clear, though, that the intrinsic characteristics of biotechnological inventions pose problems for the application of those traditionally developed principles, above all perhaps because for the effect it is often particular information rather than exactly identical embodiments that is relevant. Apart from this complexity, the evident difficulty of disclosing the invention clearly and exactly may have resulted in a more lenient enablement requirement, questionable for reasons discussed in the foregoing.

From a balanced perspective, however, one cannot impose on the inventor an excessively demanding obligation that in reality would make the patenting of his contribution to the art impossible. The over-riding difficulty for the inventor is the presumption for the legal consideration of biotechnology as still being unpredictable, because even though chemistry is also unpredictable, biotechnology adds to it living biological activities and heredity characteristics.

⁴⁵ *Ibid.* at 1560, 11 and 12.

⁴⁶ Westerlund, Li, *Biotech Patents – Equivalency and Exclusions under European and U.S. Patent Law*.

Similar chemical compounds do not necessarily have similar activities, and similar chemical processes cannot be guaranteed to produce the desired result without experimentation. In like manner, a small structural change in a protein can have profound effects on its activity. The case of human insulin is an example of this. The reversal of two amino acids in one chain of the insulin molecule resulted in a short acting insulin. The fact is that a biotechnology process that produces one protein cannot be assumed viable for the production of other proteins, which of course has consequences for its disclosure and possible claiming.

The legal consequences of this unpredictability can be seen from several decisions examined in the study, which have tended to hold the inventors to a high disclosure standard. The scope of disclosure of biotechnology-related claims has been limited to what was actually accomplished by the inventor, an assessment in accord with the purpose of the system. To avoid a shift of balance to the benefit of the inventor at the expense of third parties, this assessment should also continue. This because such a shift would risk retarding technological development within the field and thereby ultimately at the expense of society at large.

The incentive to invent should remain regardless of the level of contribution required manifested. This standard, set at the point where the invention can actually be accomplished, thus not allowing protection to what might be accomplished in the near future, should serve all parties, the industry included. The industry's demand for protection of the investments that it has made in research is a frequently posed argument for strong patents. Strong patents, however, must not be confused with easy acquisition of the exclusive right, a situation that in the long run would benefit no one.

No legal basis can be found for giving exclusivity to someone only for the discovery of a line of scientific research, which could just as well have been discovered by others and pursued at about the same point of time with equally justification for opportunities of exclusivity. If others have not pursued research in that direction, strict requirements should not pose any problem. Instead of the need to file a patent application as early as possible – when additional research must be conducted to actually obtain its desired objective – strict requirements would contribute towards fairer reward of actual contributions, and this reasoning should be applicable from both scenario perspectives.

The vital point is clarity of the necessary conditions for patents, regarding both the criteria for grant and its limits. Demanding requirements affect equally the parties concerned and also serves beneficial for making clear to the true inventor the scope of exclusivity. "True inventor" means the one who has made a contribution in terms of actual work and not merely, for instance, systematically screened biological material and so found a large number of different EST-sequences, genes or the like. The other aspect is that the biological subject matter patented⁴⁷ should receive fair protection in relation to its contribution to the art. For instance, a small contribution to the art, i.e. a small invention, should be conferred with corresponding scope of protection.

⁴⁷ Considered as inventions within the meaning of patent law and meeting the basic patentability criteria.

Early Filing

As emphasised in the foregoing, it is far from uncommon for more than one research team/company to be working along similar research lines. Biotechnological products may be the subjects of patents from more than one company and sometimes the actual identity of the product is unclear. In the case of erythropoietin, it was some time before the entities of Genetics Institute's (epoietin beta) and Amgen's (epoietin alfa) versions of the drug were differentiated. Patents containing broad process claims can be relevant to many products and potential products. However, the validity of some of these broad claims may be called into question in the light of recent court decisions that have tended to narrow the scope of very broad biotechnological patents.

Often patent rights are applied for when a novel chemical compound has been shown to have some pharmacological or other activity. As with genes, patent rights are often applied for as soon as some kind of function has been found, and once they are granted the patentee can stop its commercial use. The gene is "owned" in the sense of the patentee being able to stop others from using it in research for commercial ends, which would cover practically all research due to the strict interpretation of the research exemption. A product claim claims the active chemical ingredient of a pharmaceutical as a new chemical substance, often referred to as a new "composition of matter" and is regarded as the best type of claim.⁴⁸

In the U.S. no research exception exists but instead a considerable amount of work may be carried out on a patented drug, provided the research is aimed at providing data that the FDA requires for marketing authorisation. In Europe, however, such research is forbidden and considered an infringement of the patent. The blocking effect on further research and technology development because of this tendency of early filing is obvious. At such an early stage in the development of products, the compound identified may well not be the one ultimately progressed to factual use.⁴⁹ This kind of claim must therefore be framed so as to be broad enough to cover any potential compounds from the research project, which is the reason for the practice of generic claims to chemical compounds.

The reason for a claim to a gene as such could be twofold. One is to secure its lawful access in further research on the gene. A patent to a gene also gives the patentee the actual opportunity to control the research conducted on it, since he can prevent others from using it. Another reason is to guarantee the exclusive rights to the potential products derived from the gene at a later stage of progress. Typically, biotechnological patents claim isolated and purified DNA sequences that code for certain proteins, vectors to transform cells so that they produce a certain protein, the transformed cells, processes to manufacture the product and sometimes the isolated and purified recombinant protein itself. Moreover, patents

⁴⁸ Before 1968, in the major international markets, pharmaceutical products could be patented in the U.S., the UK and France only. The date of introduction of pharmaceutical product patent protection in Sweden was 1 June 1978, in Denmark 1 December 1983 and in Finland 1 January 1995.

⁴⁹ It is estimated that only one compound for every 10,000 compounds synthesised actually reach the market. Pharmaceutical Report, London 1998.

may claim living matter like micro-organisms, cell lines and transgenic plants and animals.

Some of the early biotechnology patents may in the light of more recent cases and practices not uphold on challenge. The mere fact that a claim is broad is not the real issue, the basis for challenge is rather that a claim, be it broad or narrow, is not sufficiently disclosed to justify a broad protection. The proper balance must be decisive and is principally brought into focus with regard to the obvious need of early filing and the permitting of broad claims. To maintain that balance, the width and the character of the claimed invention must affect the disclosure required.⁵⁰

Required Use

In order to be patentable, inventions must have a use. Our analysis of the disclosure requirements has revealed a distinction between the European and the U.S. practices regarding use. In Europe, inventions must be capable of industrial application, whereas in the U.S. they must satisfy the utility requirement, and in theory some biotechnological inventions fall down on this practical utility condition.

The strict application of the U.S. utility requirement, for instance it requires clinical data to prove a drug's utility, differs fundamentally from that of industrial applicability. This was particularly the case with anticancer therapies, for which pre-clinical tests have been poor predictors of clinical activity. At the present time this is not a real problem, as the USPTO does accept pre-clinical data as indicating the utility of biotechnological products.⁵¹ Other products that have come up against utility problems have been human genes for which the encoded protein has not been elucidated, even though practical utility is often present in these inventions and they may be patented in principle.

The European industrial applicability requirement is interpreted more leniently, as practical utility is not required. To meet this requirement it is sufficient for an invention to be produced in an industry if it is only to be used for research purposes. Stricter application of use might, however, be an effective remedy for overly broad claims.

If an invention does not work then by definition it lacks utility and also it is incapable of industrial application. The legal distinction between the two notions is that since the invention under the former must have practical use it requires more than the mere workability, whereas the latter requires only the invention to be capable of production in some kind of industry. A strict interpretation of utility is particularly relevant to the chemical, pharmaceutical and biotechnological fields. Broad claims for these inventions may include compounds or techniques that are of no practical use and therefore do not have the stated utility. This condition for patentability can and has been used to restrict claims to examples that actually work.

⁵⁰ As been held in the *British Court of Appeal in Biogen Inc. v. Medeva Plc.*

⁵¹ *Pharmaceutical report*, London 1998, p 5.

The connection between the function and its industrial application is unavoidable. As the indication of the function or effect of, for instance, a gene sequence can be used to derive the useful application, the connection shows in that the function must be disclosed.⁵² Evidence of the teaching does not solely depend on an indication of a biological function,⁵³ which would not have been logical from the “technical” patent-law spirit. Given biological material with an established biological function is an invention, then logically, biological material with a technical function must be an invention.

The present understanding of the industrial applicability requirement⁵⁴ should not comply with the EC Directive, at least for gene sequences.⁵⁵ To interpret the notion based upon the condition of actual use that as a minimum refers to commercial sale for research purposes would bring the assessment closer to U.S. practice. This approach would restrict broad claims to covering what is actually usable, which for biological matter might be desirable as a principle for policy considerations of free use of such material where it does not constitute actual contributions.

Claim Drafting

Practical *consequences of claim drafting* for the actual protection can be seen for a novel drug substance that, for instance, may be claimed by name or by structure, or a combination of both. Usually a broad group of related chemicals are claimed in a partial chemical structure under the U.S. practice known as a Markush structure, where a core structure is given and several different optional chemical groups may be attached to it.⁵⁶ This type of claim may cover thousands of chemicals and is known as a generic claim, and for biotechnological claims a generic claim may cover a whole genus. Dependent claims further restrict the scope of the broad generic claim until finally specific compounds or substances are claimed. Where a generic claim is very broad, it may be restricted by the examples given.

As small changes to a chemical structure or to a gene sequence can have huge effects on its activity, it is unlikely that all of the compounds or substances potentially covered in a generic claim will possess the desired pharmacological activity. Therefore many of the compounds claimed will ultimately lack utility if interpreted strictly and therefore be non-patentable or at least not upheld by challenge in the U.S. To restrict the scope of broad claims by reference to the

⁵² Recital 24 of the EC Directive lay down as a criterion for the industrial applicability that a gene sequence used to manufacture a protein presupposes that the function of the protein is specified.

⁵³ Recital 16b of the text of the EC Directive adopted at first reading.

⁵⁴ That it suffices for an invention merely to be produced and used in an industry.

⁵⁵ If the mere production/manufacturing in industry sufficed, there would have been no need for article 5(3) of the EC Directive stating that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

⁵⁶ *Pharmaceutical report*, London 1998, p. 25.

actual examples made and tested, i.e. shown to have some utility, is a feature of patent practice in Japan.⁵⁷

Both in Europe and the U.S.⁵⁸, detailed examples of how to make a claimed invention must be provided, otherwise it may be refused or challenged on grounds of insufficient disclosure. In addition, there must be some indication of biological activity, such as pharmacological result, or the patent may under U.S. patent law be refused or challenged for lacking utility. Under the European assessment such biological activity, or function, seems to be required for the biological product to be included within the concept of an invention. The utility requirement under U.S. law for a product claim can be met later on, when technical development has made possible what was not possible at the time of the grant.

No legally founded argument justifies patents granted for unobtainable products, since the patent would then risk “rewarding” the wrong person. This consideration has to do with the question of enablement. The invention must be sufficiently disclosed and the protection should cover the inventor’s actual contribution to the art, i.e. what he has actually made available. Product patents are “strong” patents, and those products which would only be obtainable as a result of later development, contributed by an as yet unknown inventor and not necessarily the patent-holder, are not easily justified for coverage by the exclusivity.

A high utility standard is from an objective patent law perspective justifiable as a means of promoting technological development and innovation. To apply as a principle the level of practical use for commercial purposes reduces the risk of blocking effects on useful development. Pure research activities or research tools are less likely to impede further development. Then again, those methods and products used purely for research activities can well be kept secret under trade secret protection and/or licensed only to selected researchers/companies anyhow. The balance is delicate, as to leave those kinds of inventions without patent protection does not necessarily mean that they will be free of use, and the knowledge might not become publicly available.

The patent right, however, confers stronger exclusivity and in keeping with its content the inventions for which an actual use can be shown are those which should also be patentable. Nothing about the inventive activity taking place in the U.S. indicates a reduction compared to what is going on in Europe, so the argument that a stricter assessment would endanger inventiveness does not stand up to challenge. Taking into account the blocking effects and other societal concerns about biotechnological inventions in this context, that aspect should be of negligible importance for the benefit of society.

Comparative Aspects

Comparative aspects have been discerned and the major differences will here be briefly mentioned. The basic policy consideration is the same; in return for

⁵⁷ *Ibid.* p. 25.

⁵⁸ In Europe this is demanded under the sufficiency of disclosure requirement and in the U.S. under the enablement requirement.

exclusivity the invention must be clearly disclosed. The European patent systems use the concept of sufficient disclosure (Article 83 EPC), whereas U.S. patent law employs the concept of enablement (Section 112). In Europe a distinction is made between essential and non-essential claim features – a distinction not recognised in U.S. practice. In Europe “class of compounds” is applied as the fair basis for determining the necessary disclosure, whereas this concept is not applied in its strict sense in the U.S.

The European and the U.S. practices both apply the condition for disclosure to generic claims like a genus, that workability is presumed for the entire genus failing indications to the contrary. Yet there may be dissimilarities regarding the level of doubts that overturns this presumption; serious doubts under the EPC and in U.S. practice reasonable doubts. Moreover, in Europe under the presumptive rule it relates the enablement test to the features contributing to the effect, whereas in the U.S. enablement must be shown for each embodiment as claimed.

When put into practice, however, the two systems apply similar methods. The European notions would be the defining and the disclosed feature, the identification and reproducibility. The U.S. practice rests mainly on the notions of undue experimentation and undue breadth of claims in general, and of undue breadth because of in-operatives. Thus, despite differences in the concepts on which the practices are based, the comparison of the two approaches revealed not an identical but a similar procedural practice.

The European consideration of “defining feature” clearly shows similarities to the U.S. manner of assessing “undue breadth in general”. The European notion of “disclosed feature” and the U.S. “undue breadth because of in-operatives” are also comparable. While similarities of procedural practice show in a specific case their result need not necessarily be identical. The reason seems to be the differences mentioned above concerning essential/non essential claim features and generic claims, which affect the breadth of claims.

Scope of Claims

For the sake of clarity, the scope of enablement should be reflected in the granted patent. Mainly for notification reasons and for the patent-holder as well, since otherwise he runs the risk of suing for infringement without the patent being upheld, thereby incurring unnecessary expense. Restricting the scope of disclosure, in the sense of establishing identity as a basis for the enforceable protection, would more accurately reflect the contribution made by the inventor. If that identity is based upon the embodiments as claimed, and adequately enabled, the patent right will also reflect a condition for the inventor to claim exactly what he wants protected. This is not irrational, given the competitive reality of biotechnological science. Keeping non-working embodiments from the scope of claims has mainly two consequences for third parties engaging in research close to a patent.⁵⁹

⁵⁹ It would also benefit a patentee in his capacity of third party, if he wanted to apply for an invention closely related to a patent that still possesses inventiveness.

To begin with, it should prevent exclusivity being given to subject matter merely on route to later developed inventions. Thereby it would ensure fairness to competitors, making it possible for them as well to develop those inventions. From a societal perspective this should be positive, since then creations might both be quicker than and possibly superior to those developed at a later stage by the patentee. It is not necessarily the patent-holder, who has not been able to fully develop the whole scope of his claim, which would provide the “best” solutions to those as yet unaccomplished creations.

As for embodiments of product claims, if a process other than the one disclosed in the patent develops the product, then exclusivity ought rather to be conferred on those reducing the embodiments to workable practice. This argument is based upon the policy aspect that if a patent covers those products becoming later obtainable, the reward will exceed the contribution made and thereby exceed the value contributed to society. Also, to keep non-working embodiments from protection has the positive affect upon the freely usable state of the art. Deciding the invention’s identity from the aspect of workability would keep outside the protection subject matter for further development by anyone, a constructive approach for research possibilities.

The requirement to show the utility of the invention as the U.S. practice applies it makes the issue of use relevant to the patent’s scope. To conclude, a strict application of disclosure may render the effective protection more limited than implied by the breadth of the claims. This in turn would cast doubt on the extent of the enforceable protection of granted patents with broad biotechnological claims.

Decisive for the European identity are the essential features plus the application of the class of compounds as the fair basis, which allows for generic claims shown by one or few examples. This approach affects the breadth of claims under Art. 83 EPC for claims to non-essential features in that an undisclosed non-essential feature achieving the same effect as explicitly disclosed ones is allowed, yet it is within the scope of the claim. Moreover, an undisclosed essential feature with the same effect as the disclosed one which falls within the class of compounds, or the generic claim, is allowed provided the identical effect is based on recognisable structural similarity or has the same end-products. The consequence is that those features although not explicitly disclosed they are anyhow within the scope of disclosure and therefore literally covered by the patent.

Essential and Non-essential Features

U.S. patent law makes no distinction between essential and non-essential claims features⁶⁰, whereas all features are considered essential.⁶¹ The enablement requirement does, however, firmly include the examination of undue broadness of claims and a claim so considered is a reason for rejection. Undue breadth because of non-operability is examined under the enablement requirement. A claim may

⁶⁰ Section 35 U.S.C. section 112 (1).

⁶¹ Nor is such distinction made within the practice to accept amendments on the claims, which implies that all features are treated in the same way.

be unduly broad because in-operatives of claimed features in a teaching are not sufficiently exemplified regarding all the claimed features, if the result is uncertainty about a sufficient amount of the claimed features operating as claimed.

Undue breadth in the strict sense, that the scope of the claims must be commensurate with the enablement, applies in cases where experiments within a small taxon formed the basis for claims directed to the same activity within a larger taxon.⁶² The state of the particular field affects the required proof of enablement. Predictable field and/or predictable steps or biologically connections demand less factual proof of enablement than unpredictable phenomena. That is, the more unpredictable the field, the more proof is required of enablement.

The pertinent question concerns the actual effect of the distinction between the two systems and their different methods for the scope of disclosure. As this is decisive for the allowance of claims within a granted patent, the main point of interest is the required level of disclosure. By not allowing broad unsubstantiated claims, a high standard serves to restrict claims more to what is actually contributed by the inventor, which approach thereby helps to maintain the balance of the system. Overly broad claims may be rejected at an early stage in the patent procedure, thus making clear that only patents with claims actually enforceable in a post-grant situation of an infringement suit are allowed. Such an assessment contributes to clarity for all parties concerned and thus to coherence within the system.

It is primarily the European practice to assess the disclosure requirement regarding the identity that forms the basis for broad claims. The class of compound concept used⁶³ to determine the identity of generic claims on which the enablement examination focuses opens up for broad unsubstantiated claims. Accepted as a consequence are claims based on structure and properties that cover whole classes or genus which do not necessarily possess the same characteristics or which are used in a process and provide the same end-result.

Under similar circumstances the U.S. assessment appears more hesitant to accept those kinds of claims, by requiring more examples to ensure enablement within the claimed scope. Given the complexity and uncertainty of the field in question, generic claims to analogues were rejected due to the paucity of examples.⁶⁴ On the other hand it was accepted for the skilled person to delete or replace a residue of a protein to discern whether it was within the claims.⁶⁵

As for undue breadth in the strict sense, the European assessment rests on the defining features and the outcome depends on the knowledge and reliability of the underlying process as a whole.⁶⁶ The approach differs from the U.S. practice that focused on the reliability of the steps in the process to attain the claimed generic

⁶² The separate U.S. requirement that the best mode to enable the skilled person to carry out the invention must be disclosed does not alter the conclusion. Since the best mode example is the same for enablement in general it does not result in a higher standard of disclosure.

⁶³ See for example T 292/85 and T 310/87.

⁶⁴ *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed.Cir.1991).

⁶⁵ Ex part Mark, PTO BPAI, 24-06-1989, 12 USPQ2d 1904.

⁶⁶ See T 292/85 and T 19/90.

embodiments on the basis of examples.⁶⁷ The European approach thereby opens the way to unsupported claims considered in the strict sense. Then again, since unlike the European approach the examination of enablement is not directed specifically at the invention's effect with respect to biotechnological inventions, in effect the U.S. approach risks the refusal of claimed genus even though the disclosed examples may show the relevant characteristics for attaining the effect.⁶⁸

The European reproducibility requirement⁶⁹ seems in the main to be less demanding than U.S. practice under the undue experimentation requirement.⁷⁰ Primarily this difference rests on the level of doubts of workability required for overturning the presumption of enablement, serious doubts substantiated by evidence to the contrary under the European approach, whereas under the U.S. approach reasonable doubts are sufficient. Moreover, under the European practice the one way of workability is clear as a presumption for workability of the rest, but not explicitly so under U.S. law.

Scope of Protection

The breadth of claims as analysed under the disclosure requirement refers to what has been disclosed in a patent application and thereby to what extent the inventor enabled the invention to the skilled person. The factual breadth of claims, however, is the subject matter protected against, i.e. what is actually enforceable in an infringement suit. The actual breadth of granted claims is in fact not decided until the situation of an alleged infringement.

Both for patent-holders and for third parties it is therefore vital to know as exactly as possible the extent of the exclusive right for which an invention is granted a patent. Because of the prospect of new phenomena not at present known or even foreseen, the determination of the patent scope must rest on a strict theory if to avoid broad non-substantiated claims that risk blocking or delaying further development.

Because under U.S. practice more features have to be disclosed, a broader protection is indicated for inventions that have met the requirement and been granted patents, if this is determined on the basis of the disclosed invention. However, because of the different components of the national infringement practices this supposition may not be entirely correct. The European practices include equivalent means within the patent-scope, but to differing extents,

⁶⁷ In *Fisher*, 427 F.2d 833 (CCPA 1970); In *re Vaeck*, 947 F.2d 488 (Fed.Cir.1991); and In *re Wright*, 999 F.2d 1557 (Fed.Cir.1993).

⁶⁸ In *re Vaeck*, 947 F.2d 488 (Fed.Cir.1991).

⁶⁹ See T 281/86; T 283/86; T 347/87; T 299/86; T 181/87 and T 923/92.

⁷⁰ See *Hormone Research v. Genentech. Amgen v. Chugai*, 927 F.2d 1200 (Fed.Cir.1991) seems to be an exception to this. The allelic variants and degeneration variants occurring were not deterrent to the claim of DNA sequences. The same applied in the case of natural variants in starting material to the claim of the plasmid, and in the case of the expression of human t-PA where the disclosure of its nucleotide and amino acid sequence sufficed, irrespective of the non-exact repeatability of the example to E.coli cells.

depending on national practice, but those equivalent means should in turn include non-essential features. With the requirement of use not taken into account this condition coupled with the basic disclosure requirements leaves the European practice corresponding to that of the U.S.

What has been said does not mean that no difference exists between the two systems. The answer is due to the concrete evaluation of the scope of the patent in an infringement situation. Its determination includes the different tests of literal and substantial infringements, and the outcome depends upon the manner in which infringement is decided under the respective doctrine. What the analysis point to is that the answer of factual protection cannot be derived from the disclosure requirement alone. Rather the answer depends on the prerequisites for grant and the resulting patents analysed against the different systems infringement doctrines.

The complex picture behind the patent system relevant to maintaining the balance and thereby to achieving the fundamental purpose behind it could be described as follows. The picture serves to illustrate the perspective from which to analyse different consequences of certain interpretations and to elaborate a theory that takes into account the overall balance of the patent system, to form a fair basis for all parties concerned.

Analytical Framework

Constructing an analytical framework which decides on infringement from those legal guidelines for interpreting *the scope of protection* in precise manner and which is operable in actual circumstances is a difficult task. There are opposing interests to consider, and a balance to be struck between the opposite poles of the patentee and third parties in view the system's purpose of promoting development. It may even appear that a more elaborate test for infringement could threaten in reality to compound the difficulties of evaluation and, consequently, those of prediction, but on the other hand it might reflect the "fair" protection of a patent right more accurately.

The analysis pointed to it being imperative to introduce the necessary components for the infringement determination and to have as its basis the claims read from what is disclosed to work to identify the invention. In order to avoid imprecision, the relevant features have to be clarified, since the patent protection should not be a hollow right, nor should it counteract its purpose of promoting science and technology for society's benefit. Limiting the aspects of comparison, for instance, particularly in combination with a division into essential and inessential elements of the claim, results in broader protection compared with approaches focusing on the distinctive elements of the particular technology.

The *aspect of unfairness* to third parties is, for instance, illustrated by the legal actions between Amgen and Genetics Institute concerning erythropoietin. If the patentability requirement had been assessed less demandingly, the entire market would have been conferred on only one of the two companies, probably Amgen since they were the first to reduce the gene to practice. In Europe, as it seems, the two companies must acquiesce in sharing the market for erythropoietin.

Considering how much both companies have invested in research, this can hardly be termed “unfair”.

Defined Right

The argument that a more well-defined, and therefore in some circumstances narrower, exclusive right would result in a diminution of research is not justified. Different research teams are manifestly willing to hazard enormous capital expenditure on researching the same technical problem, while fully aware of the fact that several competitors are trying to pip them at the post and “snatch” the patent right, leaving them with no possibility of recouping their investments.

With regard to the biotechnological field, the argument that research teams would try to keep the results secret would not stand up to challenge either, save possibly for research tools. It has to be borne in mind that more clearly defined patent rights in conformity with the actual contribution made would not necessarily result in narrow protection. This would mean the patentee being given the protection to which commensurate with his contribution, and adequate disclosure is central in this respect.

We can again take the scenario of several teams working on the same line of research. In Europe the one applying for and obtaining a patent would deprive the other teams of the commercial use of the subject matter claimed. That fact would of course provide a perfect incentive for everyone to patent their achievements at the point where they had actually achieved something. For the U.S. it is the first to conceive, and if he applies for a patent within one year from public knowledge, he should get one. Keeping those inventions a secret would jeopardise the possibilities of exclusively benefiting from them, and therefore they would certainly apply for patents and thereby disclose their invention to the public.

As has been made clear it is important that patent practice should avoid a future situation where patents are granted on loose grounds and seemingly cover more than has been reduced to practice. For instance, patents for ESTs must not cover the full target genes if that have not been obtained by the application date. Due to uncertainty regarding the actual extent of protection, as competitors would not risk potential infringement those patent-holders would impede technological development.

Disclosed subject matter founded more on prediction or merely indicating further research, results in an uncertainty which ultimately holds back development in the particular field of research and would generally undermine the patent system. With a properly balanced protection on the other hand the exclusions from patentability regarding specific inventions within the biotechnological field,⁷¹ as is the law in Europe, could be questioned.

⁷¹ Art. 53 (b) EPC, and its exclusion from patentability for plant and animal varieties and essentially biological processes.

Predictable Basis

The necessity of establishing a predictable basis for protection regarding any kind of biotechnological invention is evident from this study, and to both patentee and competitors, in order to make possible well-founded decisions for further research. Account must be taken of the relevant aspects, which should be the distinguishable factors reflecting the distinction between the invention and further contribution to the art. One cannot elaborate a test for infringement that would not account for those aspects for the reason that they may be difficult to apply. This is not to say that prediction cannot be obtained, but simply that even if the relevant aspects are not easy to apply, they must be included under the legal framework.

Things will be made more predictable by a change of policy direction requiring the patentee to recognise that the right covers the concrete contribution to the art, which the inventor at heart should be relatively clear about the content of. The patent right is not a “market-right”, but rather protects a specific invention made. Strict requirements for disclosure and well-defined criteria for the post-determination of the scope of the patent are both necessities to keep the protection related to the technical contribution. The patent would in some circumstances become narrower than seemingly at present, yet again the assessments under the different patent laws already indicate such an approach.

There are no persuasive arguments for a practice enabling the first inventor to attain the “level” of patentability to gain exclusivity in the entire research field that follows from the invention, rendering other people’s research within that field futile. Such a situation would frustrate the fundament of the patent system and thereby undermine it. To allow several players in the same biotechnological market could not logically be considered unfair, since this is the case in every other technological market. Rather this is the nature of free competition, which, obviously, in reality is restricted by the exclusive rights.

Two prominent aspects of broadness may be distinguished which both relate to the disclosure requirement. The first aspect is whether third parties can accurately perceive the limits of the patented invention. For *notification purposes*, therefore the patent should be disclosed in a clear manner that straightforwardly demonstrates the technical teaching which is protected. The other is the obligation of support for the claims for which patent right is granted, since the claims should not merely serve to define the scope of protection but should also reflect the technical features of the invention.⁷²

The analysis of the disclosure requirement shows that full proof of the workability of every single feature of the claim cannot be required, which is the reason why approximates or functional definitions and open-ended definitions are approved of, provided they are not speculative. Regarding such claims, the disclosure becomes vital to the post-determination of the patent’s scope, given the terms of the claims and the extent of protection must be commensurate. The actual protection cannot cover areas of activity not yet having been explored by the inventor and would therefore arise out of speculation of questionable workability. In those situations the disclosed identity should be reviewed *de novo*, if necessary

⁷² As also stipulated in Rule 29 EPC.

for taking fully into account the “fairness” to all parties concerned so as to mirror faithfully the invention as the claims defines it.

This is not to say that the evaluation for grant would be superfluous. Since the granting authorities have thoroughly examined the invention relative to the requirements, the patent must be presumed enabled. Nevertheless, where reasonable doubts of the workability of a feature have arisen, the court should review the disclosure in order to find out the invention’s “real” identity, from which to proceed the claim construction to determine infringement. Another question is how far the “failure” of the invention within ranges of broad claims can be accepted. For clarity of claims, one question is how obscurities would play out for the inventor’s actual protection.

To define an invention solely by the result achieved would in general be improper, since it would not then be a fair generalisation of the specific means employed. Nor, in that case, would it clearly indicate how the invention solved the problem. Practical reality provides yet another persuasive argument for a *de novo* determination of the claims in an infringement suit, namely that equivalents, by definition, cannot be applied to inoperative features. This in itself points to the importance of construing the claims from the disclosed identity. Although, this must be assessed with caution and based on the presumption of validity so as to avoid “automatic” appeals from losing parties at the opposition/trial level.

Rules of Interpretation

The analysis revealed as the decisive factor for disclosure being the predictability of the claimed teaching. Due to practical reality, protection must be permitted to extend beyond the exact claim language and the specific examples set out in the claims. Otherwise an excessive burden would be imposed on the patentee and competitors would be free to take advantage of the teaching described in the patent without them putting too much effort into research and development. To maintain balance claims must not, however, be allowed to form the basis for protection of subject matter not described by them or which has not been reduced to practice. This is also the basis derived from the study.

A medium requirement in return for the exclusivity should be for the inventor to correctly draw claims reflecting the invention to the extent he wants it protected. He would then have to define its limits and show its workability. Certain rules of presumption should be applied to ease the burden of proof concerning what is claimed, while still permitting third parties to contest the workability of features by evidence to the contrary.

Later understanding may indicate, or show, the non-workability of claimed features, and there is no persuasive reason to award protection for them. Likewise, equivalents cannot be applied to prior art or, arguably, to what was obvious to the skilled person at the application date, since those subject matters could not thereby have been granted a patent in the first place. The analysis made plain that the policy considerations under the different practices are pretty much the same; it is the preferred solutions which differ and which could also lead to different outcomes with respect to the scope of a patent right.

Different Solutions

For European law a doctrine of equivalents can be derived from Art. 69 EPC, as it has also been interpreted in the British and German practices respectively. The principles behind the doctrine are that of fairly protecting the patentee but not allowing this to detract from legal certainty for third parties. Leaving aside the problem of defining it, the “proper” balance is hard to accomplish in reality. The greatest difficulty in the way of harmonisation probably stems from different understandings of “proper,” for which there are historical explanations.

The protection against equivalents in itself is not much disputed, although its concept and application may vary. Pointed out is how the range of equivalents is closely bound up with the claim drafting. As the study established the application of equivalents results in protection beyond the strict literal meaning of the words used in claims, yet the claims remain central as a basis and thus for the boundaries of the patent right. This understanding is also the foundation of U.S. patent law.

In this short paper I cannot more specifically go into the different approaches or outline what could create more precision to measuring the range of equivalents within the legal framework of a doctrine. I will point to certain points specifically relevant for biotechnological inventions, one of which is the aspects used for the comparison between a patent as it is claimed and an allegedly infringing product or process. Having said this I will point to the tripartite test of U.S. practice, i.e. the comparison between the function, way and result, which works relatively well for biotechnological inventions in that it takes into account equivalent means closely related to the patented invention. In contrast to German practice, where perhaps the way in which the invention works should be emphasised.

Besides this aspect being relevant with respect to biotechnological inventions for distinguishing purposes, this conclusion is also endorsed by the wording of the EC Directive. We can take as a hypothetical example the successful expression of human insulin. The first expression system makes the A and B chains of insulin separately. After purification, these two chains are combined to make human insulin. Later a second bacteria expression system to make human insulin is invented. Disregarding the issue of product patent here, the question then becomes whether this upgraded bacteria expression system, even if it would produce identical result, would infringe the first one. By only focusing on result, or effect, of the process and deciding from a broad application of equivalents based on obviousness the latter might infringe.

Distinguishable Aspects

Some distinctively *new technological realities* come into play with respect to biotechnological inventions compared with inanimate inventions. For the issue of infringement the relevant question should be what are the distinguishing aspects between inventions? Apart from the more obvious differences regarding function and result for these inventions it is often the way in which it works that distinguishes one from another. In this respect one also finds that the “way” aspect is highly dependent upon the definition of the function. This fact again emphasises the importance of deciding the invention’s identity, so as to reflect its

reduction to practice and thus avoid extensive broadening beyond what is contributed by it.

Relevant for the outcome in a specific case is the basis relative to which the distinguishable aspects are evaluated. An element-by-element basis of comparison should in most cases result in narrower protection compared to the invention as a whole, with the exception of cumulative effects. If instead the invention-as-a-whole approach is chosen, the outcome may differ depending on the definition of the invention, i.e. the essence or fundamental character or else. In contrast to inanimate matter, biotechnological inventions are not generally assembled from simple elements and thereafter put together to structures of greater complexity.

Instead, with few exceptions, biotechnological inventions involve the modification of a pre-existing system of living matter already characterised by a high degree of complexity. The starting material for biotechnological inventions is usually highly integrated before the innovation takes place. Therefore the disclosure and the description of the claimed invention must ultimately focus on a modification of existing complexity in terms of precisely definable constituent elements, rather than a creation of something new.⁷³

Biotechnological science today has advanced in ability to implement and redirect the biological information incorporated in living matter. The possibility of defining most of those in terms of structure in a relatively precise manner had consequences, for instance, for the assessment of the disclosure. The move from functional towards structural definition reflects the requirements of description and basis for the patent right analogous to inanimate inventions.

However, biotechnological inventions are founded on the basic organisational principles of living matter. This should necessitate descriptions that include approximations of some organisational principles which it is not yet possible to describe in terms of structure. Although the science has now progressed so as to allow a shift of balance towards structural terms. In one sense structural definitions serve better to clearly define the boundary lines of the patent and thereby result in a more predictable determination of the scope of protection in an infringement situation.

What current infringement doctrines neglect though is the additional aspect of biotechnological products in their informational value. Structure alone is not the sole invention: even if the full structure is not used, its informational value may be used and still not amount to an infringement. This is precisely the predicament. Also the knowledge of finding an original gene, which may require searching through the ten thousand to hundred thousands of base pairs in a mammalian gene for those few segments which code for a desired one, let's say pit hGH, goes beyond its use for hGH.

We can take as a hypothetical that in order to patent met hGH under the requirement of reducing the invention to practice this knowledge has to be disclosed. An hGH clone derived from this naturally occurring hGH, in itself already known and therefore not patentable, could be used by cross-species hybridisation, to pull GHs (growth hormones) from other species such as bovine

⁷³ Stephen A Bent, Richard L Schwaab, David G Conlin, Donald D Jeffery, *Intellectual Property Rights In Biotechnology Worldwide*, 1987, ISBN 0-333-39288-4, p. 7.

etc. Therefore disclosing this information might be detrimental to other ongoing/future innovative activities.

A genetically and molecularly descriptive mode provides more predictability than morphologically or physiologically descriptions, such as those biological qualities plant breeder's rights relates to. For the characteristics relevant for plant breeder's rights those often rely on process-oriented and functional phraseology. For the purpose of patenting, therefore, the disclosure of obscure organisational principles of living would be necessary in order to characterise the invention. Such descriptions would be more imprecise and less predictive of the protective scope.

Compared with chemical inventions, biotechnological inventions by nature should be more likely to be described at multiple levels. For this reason analogy between the two fields of inventions must be viewed with caution and, as can also be seen from the analysis of case law, the differences between the two fields have provoked differences in the assessment of the doctrine of equivalents.

From U.S. case law the central aspects that serves to distinguish biotechnological inventions from one another, and thus delimits the scope of protection for patented ones, can be seen with respect to the aspect of function, the way variations work compared with the patented embodiment and the result. These three aspects of comparison seem suitable to confine the protection to what the inventor has accomplished in the biotechnological field. Therefore, they should be equally central for assessing infringement that considers biotechnological inventions.

Range of Equivalents

The different distinguishing "levels" applied is a problem for predictability. By level is meant the *necessary distinction* between the patented invention and the allegedly infringing subject matter, to put the latter either inside or outside the scope of protection. The comparison between the function, way and result must be evaluated and forms the basis to decide whether equivalency should be applied or not. A statement of the obvious is that objectivity is desirable for the sake of predictability.

As previously explained there are compelling reasons for considering modifications from the perspective that the inventor is obliged to claim the subject matter he wants protection for. Inability to claim the whole invention must be distinguished from the inherent impossibility of claiming later development. Whether protection should cover equivalent later development is another matter and relates to the appropriate date from which to measure equivalents.

Whichever is chosen, this should be the basic notion in the present competitive environment. That is not to say that the very strict rule of "what is not claimed is disclaimed" should apply, but rather that the protection should closely follow the claims, although not necessarily under a strictly formalistic claim reading. Considering the broadening aspect of equivalency protection, it would not seem unreasonably "unfair" for the patentee to have to live with the consequences of his failure to claim and disclose his invention.

The median approach is to include within the scope of protection the application of equivalents to subject matter immediately derivable from the invention. The application of equivalents to obvious subject matter, within the meaning of inventive step, would include those derived from the patent without inventive effort although but with a reasonable amount of experimentation. With this approach, the doctrine of equivalents would stop where a new invention takes off, as under the German practice⁷⁴ although it may be questioned whether that is best in line with the pursuit of balance.

Then again, experimentation necessary to find out the differences should indicate differences outside the range of equivalents. The biotechnological field requires a certain amount of experimentation to bring about inventions – patentable or not, infringing or not. The field is typically a complex and time-consuming one in order to reach the final results. An allegedly infringing invention within this field developed without much experimentation and coming close to the patented invention should indicate insubstantial differences.

Measuring Date

Measuring the range of equivalents from the infringement date as is the law under the U.S. practice and as indicated by the revised article 69 EPC, provokes different considerations. The freely usable state of the art should not only come into play with respect to obvious prior art, but should also have some significance for normal development taking place during the patent term. Arguably it would be wrong to prevent someone from doing something which is merely an obvious extension of what he has been doing or what has been known in the art before the priority date. The same argument applied to the infringement date would be that it is wrong to prevent a man from doing something which is obviously merely a normal advance in science due to the ordinary development of technology.

The reason for protection not including later development that normally takes place is third-party considerations based on equity. The question of whether to extend the protection to development directly due to the invention is a much more complicated one. Third-party considerations are involved, but it also emphasises fairness to the patentee, and considering of the actual contribution made to the art. Should the European countries switch to *the infringement date* and still apply equivalents in the same manner as previously and on an invention-as-a-whole basis, this would *broaden the protection*. All in all, the compelling argument is that only evident equivalents should then fall within the patent's scope. The patent would then cover the varied embodiment if immediately derivable from the claims when reading the specification.

Proper Basis

German law divides claim elements into essential and inessential from the problem/solution perspective. The British approach is to purposively construe the

⁷⁴ Although not relevant under the U.K. or U.S. practices.

claims, relying on, as it would seem, construing them in terms of function. U.S. practice considers all elements as material but compare the invention from the aspects of function, way and result seemingly equally relevant and under the standard of insubstantial differences. To avoid injustice in certain circumstances case law opens for viewing the differences elucidated from the tripartite test with regard to the fundamental character of the invention as a safeguard.

The subject matter identified from an analysis of the problem/solution, may, as in Germany differ in identity from the same subject matter analysed on another basis. Under the purposive construction in accordance with British practice, the subject matter is identified from an analysis of the “purpose” of the invention, which in *Kastner*⁷⁵ was defined in functional terms and not on the problem/solution basis, and from which the material effect was determined.

The analysis revealed how with respect to biotechnological inventions, and the approach of comparing the function, way and result aspects, it is important to relate the definition of function directly to what is disclosed and reduced to practice, since too broad a definition of the function affects the “way” comparison. The “essence” of the invention must be determined strictly with regard to the invention as disclosed to avoid broadening the protection beyond the contribution made to the art.

As was pointed out earlier regarding “identity”, non-workable features of the claim by definition cannot be applied with a range of equivalents, which is one reason why the proper claim construction is imperative for deciding the scope of protection. Equivalents on the basis of the result of an achievement, or a function, or a manner of performance not disclosed in the patent specification, fail on the grounds that the skilled person cannot discover such an equivalent substitute.

The “failure” in this respect stems from the requirement that the considerations must be based on the invention described in the claims as disclosed in the patent specification. Unworkable embodiments of the claim could not, by definition, have been essential to the invention. Equivalents to non-working parts of a patent as granted, i.e. which accordingly were not in fact reduced to practice, fail on the grounds that the skilled person is by definition incapable of recognising equivalent substitutes for such a feature.⁷⁶

Therefore a *de novo* consideration might be desirable where there are indications that the disclosed patent as such, or in part, was not sufficiently disclosed to its reduction to practice, which would not necessarily render the patent invalid but would restrict the doctrine of equivalents. The patent would not have to be revoked because of the non-workability of certain elements of the claim; it might still be enabled, although the parts of the claims not disclosed as to working would be allowed a range of equivalents.

This approach would provide for the contingency of other techniques that may exist or come into existence achieving workability later on. This assessment would, for instance, avoid the situation of open-ended EST patents, where the full-target gene has not been reduced to practice, coming within the scope of protection. Since those sequences are not reduced to practice, they do not come

⁷⁵ *Kastner v. Rizla Ltc.*, (1995) RPD & T.M. 585, (CA).

⁷⁶ This is not an evident conclusion from U.S. practice, owing to the different time for measuring equivalents, viz the infringement date.

within the identity as properly disclosed. Therefore no application of equivalents would extend their protection.

End Remarks

Equally significant is the construction of claims in accordance with their incorporated limitations. Suppose, for instance, that the patent claims a cDNA and the specification shows one sequence that has been obtained without introns and describes with respect to that particular cDNA sequence methods by which it is obtained. “A”, being an indefinite term, should then linguistically be read as “any,” which has no basis in the specification. Therefore the identity of the invention, decided from what is disclosed, should be that “the” particular sequence and no other sequences, in spite of the wording “a” in the claim.

The granting authorities should have noticed this and perhaps even rejected the claim for lack of enablement, unless amended to “the”, but this may not always be the case. There is no persuasive argument that would justify “error” by the granting authorities resulting in protection against any sequences. Rather than to invalidate the claim under the proper claim construction the court may overcome this deficiency and proceed to the next step.

The patent concerned that particular cDNA as shown in the specification, which means that the proper claim construction precludes protection for sequences containing the cDNA, which besides the exons also includes the introns, the reason being that the exclusion of introns was in fact the invention made. The isolation of the coding section, i.e. the exons, was the identity of the invention. Thus, by definition, protection by equivalents cannot be extended to sequences containing both exons and introns. Claim limitations such as, for example, those where for patentability reasons the claim is directed at a specific sequence (structure) must be taken into account. As a result, different structures, even though no differences would occur with respect to function, way or result, might not be included within the range of equivalents and thus it would not infringe.

As for potential blocking effects, which, as unexplored lines of research, should be all the more significant for pioneer inventions, the distinction between equivalent means and later developments is central.

Take a claim to a DNA encoding human protein X. A certain DNA sequence developed later and encoding an allelic mutant of human protein X, which has several different codons from specific sequences described in prior art, should be common practice to obtain. If equivalents are measured from the infringement date, such a sequence could infringe even if not all codons were described at the application date. The inclusion within the patent scope of the allelic mutant, which has these subsequently described codons, would technically be a “later developed element.”

Unless the specific DNA obtained has an effect that is either qualitatively different from the technical state at the infringement date, or qualitatively homogenous but quantitatively superior, it should infringe. For the sake of balance it is desirable to avoid an assessment that would extend the range of equivalents beyond the inventor’s achievement. Given measuring equivalency from the infringement date is more rational under a practice that requires the

inventor to define the subject matter he wants protected, the focus on claim limitations and clear boundaries of the claimed invention then becomes central.

The legal framework for deciding infringement cannot be other than complex and will have to consider different aspects in order to arrive at fair protection for the patentee with a reasonable degree of certainty for third parties. The different practices analysed have approached the same policy problem in different ways. Although the approaches differ, seen in the context of inventors also being aware of the peculiarities of a specific approach and thus being able to draft claims accordingly, the end result in terms of the scope of protection may not substantially differ. Clearer criteria and more predictable application of them to the technology are desirable if we are ever to achieve an exclusive right with predictable limits.