Litigating biotech patents in Europe

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Litigation around Europe relating to biotechnology patents is likely to increase significantly over the coming years as biologics form an increasing number of newly approved medicines. Two high-profile biotech cases have just been heard by the UK patents court: *Monsanto v Cargill* [2007] EWHC 2257 and *Eli Lilly v HGS* (judgment awaited). Many of the challenges for biotech patentees and, eventually, biosimilar manufacturers will be the same as those faced in the pharmaceutical industry by "innovators" and "generics". This article looks at the legislative framework under which these patents will be considered, the scope of protection that might be given to biotechnology inventions and, briefly, the procedural issues that are common to all areas of patent litigation around Europe.

Legal framework

Two recent developments will affect the regime under which biotech patents are to be litigated around Europe:

- Changes to the European Patent Convention (EPC) have been introduced in the EPC 2000, which came into force on 13th December 2007. A number of changes have been made, the most relevant to litigation being a new protocol for the interpretation of claims.
- Directive 2004/48/EC on the Enforcement of Intellectual Property Rights (the "Enforcement Directive") was implemented by member states on 29th April 2006. It aims further to harmonise the litigation of patents around Europe, particularly with regard to the remedies available.

More fundamental changes are being suggested for the future, though, with proposals put forward for a Community Patent (ie, a unitary patent right throughout Europe) and the European Patent Litigation Agreement (EPLA). Progress towards a Community Patent has stalled and negotiations relating to the EPLA are contentious and seem to have faltered for the time being. However, the EU French presidency in late 2008 is hopeful of reactivating this proposal and the EU Portuguese presidency recently proposed an integrated patent litigation system.

If either of these proposals is adopted and a common jurisdiction introduced, it may be necessary to litigate existing European patents under the unified system in a new court with untested procedures. Given the amount of money frequently at stake during patent litigation and the value of companies' combined patent portfolios, it is easy to see why companies might be nervous at this prospect. As a result of the uncertainty over the future of patent protection in Europe, companies are amending their patent filing strategies. Some large companies are increasing their usage of the national route which offers both security and familiarity.

Scope of protection

In addition to procedural differences between the patent litigation systems in member states (see below), there exist differences in the legal interpretation of patent claims. All EPC contracting states must interpret patents in accordance with Article 69 of the EPC and so decisions in different countries are ultimately based on the same law. However, the reality is somewhat different. In *Pozzoli v BDMO* [2007] EWCA Civ 588, both the UK and French courts revoked a patent that had been upheld in Germany and differed in their construction of the claims of the patent in suit. There is a recognition of the need for consistent decisions throughout Europe, but guidance in a recent judgment (*Unilin v Berry* [2007] EWCA Civ 364, at paragraph 36) suggests that judgments in the courts of different member states can differ if either the judge is convinced that the earlier decision was erroneous or the case

turns on different evidence. Given the divergent opinions of judges and different legal representation in different jurisdictions, both scenarios are likely to be common.

The protocol to the interpretation of Article 69 was amended by EPC 2000. Article 2 of this protocol requires account to be taken of any element equivalent to those specified in the claims. This requirement brings to mind the "doctrine of equivalents" in the US, under which an act can infringe if, while not literal infringement, it is functionally or technically equivalent to what is claimed in the patent. This contrasts with the purposive approach adopted in the UK, in which the question asked is, "What would a person skilled in the art have understood the patentee to have used the language of the claim to mean?" In *Amgen v TKT* [2004] UKHL 46, a leading biotech patent case relating to erythropoietin, Lord Hoffmann took the opportunity to explain that the new protocol does not introduce a doctrine of equivalents, but there is "no reason why it cannot be an important part of the background of facts known to the skilled man which would affect what he understood the claims to mean". The approach to construction in the UK is therefore unlikely to be affected by the advent of EPC 2000. The effect on other jurisdictions remains to be seen.

The Biotech Directive

Also important in determining the scope of protection of biotech patents is Directive 98/44/EC on the Legal Protection of Biotechnological Inventions (the "Biotech Directive"). The Biotech Directive was passed on 30th July 1998 and was due to be implemented by member states by 30th July 2000. In fact, the Netherlands challenged the legality of the Biotech Directive before the European Court of Justice and very few member states had implemented it before the implementation date. The challenge was unsuccessful and all member states have now, at least in part, implemented the Biotech Directive.

The implementation appears not to be consistent across all jurisdictions. The first issue is the patents to which the Directive applies. In the UK and Germany, it applies only to patents that were filed after 28th July 2000 and 30th July 2000, respectively; whereas in the Netherlands, the new legislation implementing the Biotech Directive has completely replaced the original legislation and so would appear to apply to all patents, whenever the applications were made. Similarly, in France, the parts of the Biotech Directive that have been implemented have retrospective effect.

Moreover, the way in which some aspects of the Biotech Directive have been implemented in some member states is not consistent with the apparent intentions of the EU. Article 3(2) reads: "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature."

This is subject to the caveat in Article 5(3) that the industrial application of the gene sequence must be disclosed in the patent application but effectively allows *per se* protection for a gene sequence that has been isolated from its natural environment. However, there is the further caveat in Article 9: "The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function."

So, in effect, there are two caveats to *per se* protection for DNA sequences contained within the Biotech Directive. The first is that an industrial application must be disclosed in the application and the second is that protection extends only to a product that contains the gene and in which the gene is functional. Given that the value of a gene sequence is the properties that it confers on an organism and that in order to confer these properties it must be functional, this restriction appears non-controversial. Where it might have an effect is in respect of downstream products in which the genes are no longer active.

The wording of the Biotech Directive has been preserved in the UK and so, one assumes, could allow *per se* protection for genes in certain circumstances in the UK. However, prior to the Biotech Directive, case law in the UK offered purpose-bound protection for DNA sequences. In *Amgen v TKT*, protection was given only to the method of producing the polypeptide using the disclosed gene sequence in the manner described and not to any use of the sequence to produce erythropoietin. Similarly, protection was not given to the DNA sequence *per se* in the recent case of *Monsanto v Cargill*. In that case, Cargill imported soymeal from genetically modified soya beans into the UK and Monsanto sued Cargill for infringement of its patent to the gene sequence that conferred resistance to the herbicide glyphosate (Roundup) on the soya plants. The Judge found as a fact that the gene sequence was present in the imported soymeal, but held that the patent was not

infringed. The Biotech Directive did not apply to either of these cases so we are yet to see whether the court's interpretation of claims to DNA sequences might change following the implementation of the Directive. Indeed, had the Biotech Directive applied in *Monsanto v Cargill*, the question as to whether the DNA sequence was functional within the highly processed soymeal would have been determinative – clearly it was not functional.

Judgment is reserved in the trial between Eli Lilly and Human Genome Services which finished in January 2008. Lilly applied to revoke HGS's patent which claims a DNA sequence encoding neutrokine alpha. The patent is not subject to the Biotech Directive but the judgment, when handed down, should offer further evidence as to the approach to gene patents in the UK.

In France, it is stated in statute that the sequence or partial sequence of a gene is not patentable *per se*. Instead, only the technical application of the gene sequence, which must be fully disclosed in the patent application, is protected. This purpose-bound protection for gene sequences isolated from the human body would appear to be at odds with the wording of the Biotech Directive.

Similarly, in Germany, the industrial application of a full or partial gene sequence must be fully described in the patent application. However, the German provisions go further and in the case of sequences or partial sequences of human genes, the function must be included in the claim. Again, this produces purpose-bound protection.

By way of contrast, the EPO has also implemented the Biotech Directive, although it is not a member of the EU and was not bound to do so. Rule 26 provides that: "(1) For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this Chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation."

Rule 29 sets out the wording of Article 5 of the Biotech Directive in an attempt to stop speculative patents covering poorly characterised genes being granted by the EPO because the application as filed must provide a credible utility for the gene. However, claims to gene sequences *per se* are still allowed if a utility is provided elsewhere in the patent. Article 9 has not been implemented beyond the broad statement of Rule 26.

For any given biotechnology patent, it might be critical to both the validity and the infringement of the patent whether or not the Biotech Directive applies and, if it does, what interpretation is given to it in a particular country. Selection of the appropriate jurisdiction may not just be a procedural issue; the legal basis by which the patent will be judged may be different and have a fundamental effect on the outcome of the case.

Procedural differences in national court systems

European patents effectively are national patents and the rights conferred by them must be enforced and challenged nationally. Each jurisdiction around Europe has its own procedures and it may benefit a patentee, or a challenger, to select a jurisdiction that is most beneficial to its needs. Not only does the correct selection of forum increase the prospects of a successful outcome, but also the information and judgment gained from the first proceedings in Europe can serve as useful 'ammunition' in subsequent proceedings in other member states. In particular, judgments from the Netherlands, Germany and the United Kingdom have a degree of precedent value, as these countries boast specialist patent courts that are supported by sophisticated patent litigation systems. Some of the key differences are outlined below.

Interim injunctions:

- A patentee can apply for an interim injunction to stop an alleged infringing act or remove an alleged infringing product from the market before the matter is heard at trial.
- Procedures to obtain such an injunction vary between member states.

Disclosure:

- In the UK, there is an obligation to disclose all documents relevant to the litigation irrespective of whether they advance or are detrimental to the party's case.
- Subject to confidentiality agreements and court rules, this disclosure can be used in other jurisdictions.
- Disclosure is not automatically available in other member states.

Expert evidence, cross-examination and experiments:

- Court-appointed experts are used in most jurisdictions, for example Germany and the Netherlands, and there is no oral cross-examination of the expert.
- In the UK, the parties choose an expert who is then orally cross-examined in court by the other side.

Time to trial:

- In Germany, the Netherlands and the UK, a first-instance trial can normally be heard within a year. Time to hearings can be significantly longer in other member states.

Costs of litigation and recovery:

- Costs of litigation can also vary markedly across Europe.
- A "loser pays" policy has always operated in the UK, albeit that an issue-based approach is often taken in patent actions, such that a party will typically recover 60% to 70% of the costs spent on issues that it has won on. This compensates for the fact that litigation in the UK is comparatively expensive.
- The Enforcement Directive has brought a degree of harmonisation, in that the general rule now is that the unsuccessful party is liable to the successful party for reasonable legal costs.

Conclusion

As well as the usual challenges to patent enforcement around Europe, differences in the interpretation of biotech patents mean that the choice of jurisdiction is key to the success of an action brought under a biotechnology patent. Few cases have been decided under the various regimes that implement the Biotech Directive anywhere in Europe. Patent lawyers and biotech companies will be waiting with interest for the biotech patent decisions that come out of the courts in Europe to assess whether a real divergence becomes apparent or whether there is a degree of harmony. Biotechnology patentees will want to consider all these issues before deciding on which jurisdiction to start an action.

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