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OPINION

UK Patent Law Crosses the Channel¹

Remco de Ranitz² and Otto Swens³

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Introduction

Over the last half year, various reputed courts in the United Kingdom have handed down judgments that move UK patent law closer to the European Patent Office (EPO)/continental approach than it ever has been. This is a significant development not only for UK patent law, but for European patent law and in general, and an important step towards a more uniform, if not harmonised, “European” patent law.

“European” patent law?

As there is a European system for granting patents and a European Patent Convention (EPC), generally, it is assumed that there is a harmonised European patent law. However, this is not true. Under the EPC one can apply for “European” patents, which after grant by the EPO fall apart into a bundle of identical national patents. To put it differently: after grant of a European patent, one gets in Munich a bunch of identical flowers, whereat each flower represents a national patent. This sounds well harmonised and so one would think that such identical national patents would have a similar status as to validity and protection in each of the EPC Member States. However, this is far from the truth: it does not mesh. In a formal legal sense, patent law has not been harmonised, which is partly due to the text and status of the EPC, but also because other important legal matters not included in the EPC (procedural law, jurisdiction, etc) have not been laid down on a European level. Repeatedly—we mention *GAT v LuK*,⁴ *Roche v Primus*⁵ and *Merck/Merck Genericos*⁶—the European Court of Justice (ECJ) has declared that patent law has not (yet) been harmonised, but is a purely national matter.

This is a shame, because the ECJ could also have interpreted the Community/European (patent) laws in a more “harmonised” way.⁷ Had it done so, it would have contributed to a decrease of the chances of conflicting decisions in the different Member States.⁸ After all, proceedings on the basis of one and the same European patent often take place simultaneously in several Member States between the same parties on the same cause of action. A good example of what non-harmonised European patent law leads to in such situations is the ECB-DSS case. Within a year, the French and UK courts held the DSS patent invalid, whilst the German and Dutch courts upheld the patent.⁹ In all courts, basically the same invalidity argument was pleaded, namely added matter. The last court to render judgment in this matter, the UK Appeal Court, held in its judgment of March 19, 2008:

“In sporting terms, the score is currently 2–2 to the ECB at first instance level. All this is deeply regrettable. It illustrates yet again the need for a one-stop patent shop for those who have Europe-wide businesses.”¹⁰

Reputed patent judges and patent lawyers have long published statements against this lack of harmonisation¹¹ and have since made efforts at creating a workable alternative to the Community Patent—for negotiations are still dragging on without basically anybody still seriously believing that this could lead to anything—such as the so-called “European Patent Litigation Agreement”.¹² This initiative received wide acclaim, but all sorts of legal problems have arisen. For example, the European Commission does not support the EPLA as it is a Treaty that embarks on territory that “belongs”

1 Courtesy to IER (*Intellectuele Eigendom en Reclamerecht*, Benelux IP magazine). The authors represent Angiotech Pharmaceuticals Inc in patent proceedings in the Netherlands.

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4 Case C-4/03 [2006] E.C.R. I-6509.

5 Case C-593/03 [2006] E.C.R. I-6535.

6 Case C-431/05 unreported.

7 See, e.g. O.P. Swens and T.A.F. Engels, “Community law, patent law and TRIPS: a complicated Cocktail to mix”,

Pharmaceutical Law Insight, March 2008.

8 For instance, according to AIPPI Resolutions 137 and 165.

9 UK Patents Court (Kitchin J.), March 26, 2007; German Federal Patent Court (*Bundespatentgericht*), March 27, 2007; French *Tribunal de Grande Instance de Paris*, January 9, 2008; and Dutch District Court, The Hague, March 12, 2008.

10 Supreme Court of Judicature Court of Appeal (Civil Division dated March 19, 2008, *European Central Bank v Document Security Systems Inc* [2008] EWCA Civ 192).

11 See, e.g. AIPPI Resolution Q137 “The Future of the Patent System in Europe”, EXCO Sorrento 2000, April 14, 2000; and AIPPI Resolution Q165, “Optional Protocol to the EPC with regard to Litigation concerning European Patents”, Congress Melbourne, March 30, 2001.

12 Information on the latest developments regarding the Community Patent Treaty and the EPLA can be found at <<http://www.epo.org/patents/law/legislative-initiatives/community-patent.html>> [Accessed July 29, 2008] and <<http://www.epo.org/patents/law/legislative-initiatives/epla.html>> [Accessed July 29, 2008].

to European Community law. Efforts to overcome these and other issues have so far not been successful.

So what is left? In the end, it seems that at least for the time being it is up to the national courts to create some form of harmonisation in patent law in Europe. While equality of case law in all Member States is desirable, at the moment this appears the only way in which a maximum level of harmonisation can be achieved. As mentioned above, the EPC, "improved" by the recent EPC2000, and the EPO through its Guidelines for Examination,¹³ have done much to align the legal principles for assessing the validity of European patents and determining its scope of protection. Also, the EPO case law has given much guidance on the interpretation of the principles for assessing validity.¹⁴ Most of the European national courts, including the Netherlands, tend to regard the EPO Guidelines practically as "national law" and tend to follow the case law by the Board of Appeal, such as the Netherlands,¹⁵ which means that, at least, most European countries apply the same legal principles and follow the same interpretation thereof. We say "most", because not all EU Member States give such weight to the guidelines and case law of the EPO. In particular, the UK courts have up until now been fairly reluctant to appreciate the guidance of the EPO and have favoured applying their own, different legal principles.

UK law versus European/EPO patent law

By way of illustration, we discuss two important differences between the UK and EPO approach: inventive step and sufficiency. A patent can only be valid if it is novel, inventive (non-obvious) and sufficiently disclosed (the patent specification must make it sufficiently clear to the reader how to make the invention).

In most cases, the validity debate focuses on inventive step, and it is precisely inventive step which the UK courts approach differently from the "continental" courts that follow the EPO approach. The "continental" courts, including the Dutch courts, follow the EPO and apply the so-called "problem solution" method.¹⁶ This is a three-step method. First, the court defines which prior art is closest to the invention; next it phrases the difference between this prior art and the invention (= the problem solved by the invention); and, finally, it examines whether this solution is "obvious". The UK court does not use the "problem solution" method, but instead applies a four-step test, which starts by identifying the person skilled in the art and the general common knowledge of that person, with the result that irrelevant documents can often be combined with the "common general knowledge".¹⁷ Consequently, an invention readily becomes obvious. Another aspect occurs with chemical and pharmaceutical inventions. In such patents the "invention" often concerns a solution found through the use of—existing or non-existing—research methods. According to the "European" norm, such a solution will only be considered obvious when it is obvious for the average skilled person to solve the problem by conducting this research. According to the European norm, this is only at issue if the skilled person had a "reasonable expectation" in advance that the research would lead him or her to that particular solution of the problem. In the United Kingdom, however, such an invention¹⁸ is "obvious" already if a person versed in the art would assess the likelihood of success sufficient to warrant a trial ("obvious to try").¹⁹ This is a lower threshold for accepting lack of inventive step, in particular as the court may also be lowering the threshold further depending on the contribution to the art.²⁰ An "obvious to try" attack will, thus, generally, be successful unless there is "simply no²¹ likelihood of success".²²

Furthermore, at the EPO a product claim is sufficiently disclosed if the patentee describes at least one way to make the product. It is irrelevant if there are other ways to make the product which are not described in the patent. The product is monopolised and if the patentee is confronted with another party, that party infringes if he or she markets the product without the consent of the patentee, even if this party has manufactured the product in a different way. This also applies, according to settled EPO case law,²³ if the patent relates to a product of which the properties were

13 Guidelines for Examination in the European Patent Office, Published by the EPO, Munich, latest version: December 2007.

14 See, e.g. *Case Law of the Boards of Appeal of the European Patent Office*, 5th edn (2006); and Singer and Stauder, *The European Patent Convention*, 3rd edn (Heymans: Thomson, Sweet & Maxwell, 2003) Vols 1 and 2.

15 Prel. Rel. Judge, The Hague, December 30, 2004; *Mayne/Teva* (IER 2005/41), DC, The Hague, October 2, 2002; *Stork Titan/Koppens* (BIE 2003/39), Supreme Court, April 21, 1995; and *Kirin-Angem/Boehringer* (BIE 1995/103).

16 This principle has been laid down by the Hague District Court *inter alia* in *Geotechnics v Meuwissen* (BIE 2004/2), April 16, 2003.

17 This is called the *Windsurfing/Pozzoli*-approach, as stated by Jacob L.J. in *Pozzoli v BDMO* [2007] EWCA Civ 588.

18 More precisely: an invention where a skilled worker in a particular field could be expected to know of a use of material to achieve a certain result in that field, and the invention is concerned with the use of that material to achieve the same result in a part of that field which had not been previously disclosed.

19 This concerns the "fourth Windsurfing" step. It was first introduced in the judgment by Diplock L.J., *Johns Manville Corp's Patent* [1967] R.P.C. 479 at [493]. See also: *Terrell on the Law of Patents*, 16th edn (Thomson, Sweet & Maxwell, 2006), ch.7.4, pp.46–90.

20 High Court, *Conor v Angiotech* [2006] EWHC 260 (Pat).

21 Emphasis added by the authors.

22 Court of Appeal, *Saint-Gobain Pam v Fusion Provida* [2005] EWCA Civ 177 at [28].

23 See, *inter alia*, *Kawasaki Steel Corp* (T-595/90) [2004] O.J. E.P.O. 695; *El Du Pont* (T-233/93), October 28, 2006; *Alcan Int. Ltd* (T-1195/00), May 24, 2004; and *Novartis* (T-8/03), September 9, 2003.

already known and the desire to make it also existed already (but nobody was yet able to make it). In fact, in such a situation, the “real” invention, therefore, not so much lies in the product itself, but rather in the fact that the patentee has found a way to make the product. In particular in the latter situation, the UK courts are stricter. The UK courts take as a leading principle that if the “real” invention lies in the fact that (or: how) the patentee has found a way to make the product, then his or her monopoly should be restricted to that, and he or she should not be receiving a broader protection through a product claim. Such claim is then likely to be invalidated for lack of sufficiency, as happened in the first instance decision in *Lundbeck/Generics*.²⁴ The basis of this approach is generally the famous House of Lords decision in *Biogen/Medeva*.²⁵

Reading the above, it will not surprise the reader that the UK courts invalidate patents more often than the other European courts. The UK is for quite some time considered to be one of the most patentee-unfriendly jurisdictions in Europe, quite clearly applying principles out of step with the rest of Europe/the EPO. However, there are now clear signs that this is changing. In the last half year, there have been at least three judgments by UK judges held in high esteem, which show a move towards the “continental”/EPO legal principles. These judgments, which we will now discuss, are *Lundbeck v Generics*,²⁶ *Merck v Actavis*²⁷ and, finally, the landmark decision by the House of Lords decision in *Conor v Angiotech*.²⁸

UK Court of Appeal, *Lundbeck v Generics (UK)*, April 10, 2008

In the appeal of the *Lundbeck* case, the United Kingdom now seems to have abandoned the earlier decision abhorred by EPC followers (*Biogen v Medeva*) or at least the broad application of the teachings in this decision.

The matter concerns the validity of a patent in the name of Lundbeck relating to escitalopram (a SSRI anti-depressant). As mentioned above, the first instance judge²⁹ applied the “standard” UK approach when assessing inventive step and sufficiency. In respect of sufficiency, the judge considered that Lundbeck claimed a product, while the invention was not so much the product but rather that Lundbeck found two methods for making the product (which until then had not been made and in that sense did not yet exist). By claiming the product, Lundbeck got more than it deserved. The product could have been made in a different way than according to the two methods in the patent. The patent was thus revoked for insufficiency.

The Appeal Court did not concur. Lord Hoffmann considered first of all that the *Biogen/Medeva* decision does not yield as broad a principle as the first instance judge proclaimed. He explained that *Biogen/Medeva* concerned a patent in which a class of products—i.e. several products—was claimed and the patent failed to disclose how all of these products could be made. Lord Hoffman argued that this was different from the situation at hand, where only a single product was claimed. In such a case, the claim is valid at the moment that the patent discloses (at least) one way of making the product—and one way is sufficient. It could be argued that the patentee gets more than that which he or she contributed to the art, but that is not only the case in these cases and there is no basic principle in patent law that a patentee’s monopoly should always be restricted to that which he or she contributed to the art. In this respect, Lord Hoffmann refers to several EPO cases, which—he explicitly declared—“we have always regarded as carrying great weight”.³⁰ (Lack of) “sufficiency” must not be used to “correct” (read: unjustly restrict) patents in which a product is claimed, but where the “actual” invention is the fact that the patentee has found a way to make the product and what such way involves.

It is also interesting that it appears that the Appeal Court moved the UK test for inventive step slightly closer to the European approach. Lord Hoffmann considered that a patent does not lack inventive step if the solution is something that is obvious to try to the skilled person. Lord Robin Jacob agrees:

“It is not enough that an experiment revealing an invention would have been short and simple. There has to be a reason why the skilled man would have carried it out. Normally that would require at least an expectation

24 Kitchin J., first instance judgment in *Generics UK v Lundbeck* [2007] EWHC 1040 (Pat).

25 House of Lords, *Biogen v Medeva* [1997] R.P.C. 1.

26 UK Court of Appeal, *Lundbeck A/S v Generics (UK) Ltd* [2008] EWCA Civ 311 (<<http://www.ipkat.com>> [Accessed July 29, 2008], communication of April 10, 2008, “More than the patentee deserves? No problem . . .”).

27 UK Court of Appeal, *Actavis UK Ltd v Merck & Co Inc* [2008] EWCA Civ 444; [2008] W.L.R. (D) 168.

28 House of Lords, *Conor v Angiotech* [2008] UKHL 49.

29 Kitchin J., first instance judgment in *Generics UK v Lundbeck*, cited above fn.25.

30 See also: Howrey Client Alert, “‘Biogen insufficiency’—The End of the Road”, April 10, 2008, Howrey UK (London).

that something might come out of it. Otherwise, short and simple though it would have been, doing the experiment would have been pointless.”

This appears a higher threshold than “assess the likelihood of success sufficient to warrant a trial”, although the difference, we agree, is fairly subtle.

UK Court of Appeal, *Merck v Actavis*, May 28, 2008

A more dramatic move from the UK courts to acceptance of the continental/EPO principles came about a month later with the *Merck v Actavis* judgment, which dealt with patentability.

This case concerned a second patent by Merck regarding a second medical use of a specific dosage of finasteride for the treatment of androgenic alopecia (“aa”), a special type of baldness occurring in men. The main claim was drafted in the Swiss type format. The first instance judge, Warren J., held that the patent was invalid on the grounds that it was not novel pursuant to the provisions of the EPC, Art. 54 and was unpatentable for being a method of administration, pursuant to EPC, Art. 54(5).

On appeal, the discussion focused on the question of whether a new, non-obvious dosage for the treatment of a known medical condition can be novel with regard to the prior art, when it is claimed in the Swiss type format. Highly important in this case was the earlier UK decision of the Court of Appeal in *Bristol-Myers Squibb v Baker Norton* and the extent of bounding of the court to that decision.³¹ In the *BMS* decision, authority was held for the proposition that novelty could not consist of specifying a particular dosage regime in a Swiss form claim. This UK authority appeared contrary to the EPO’s Board of Appeal decision in *Genentech*,³² in which it was decided that a novel dosage regime could indeed be claimed in a Swiss type format.³³ Lord Jacob referred to these EPO decisions and considered that not only at the EPO, but also in Germany and even in New Zealand, Swiss type claims, in which novelty depends on a new treatment by a different dosage regime or method of administration, are accepted as novel and not considered as claims to a method of administration. Lord Jacob continued, saying:

“Our courts would normally follow such settled jurisprudence. That would be in accordance with what Lord Hoffmann said in *Merrel Dow Pharmaceuticals v Norton* [1996] RPC 76 at 82.”

This means: disregarding the “binding effect” of the *BMS* decision: “Here for reasons given and subject to the binding effect, if any, of *BMS*, we would follow the EPO . . .”. Furthermore, with regard to how binding the EPO case law is for the lower UK courts, Lord Jacob considers:

“In saying our courts would and should normally follow the settled jurisprudence of the EPO, it should be understood, of course, that they are not bound to do so. In the unlikely event that the commodore is steering the convoy towards the rocks we can steer our ship away.”

Note that Lord Jacob represents the EPO as the “commodore” and the United Kingdom merely as a “ship” in the commodore’s “convoy”!

Therefore, the Court of Appeal believes the decision in *Genentech* should prevail, but only if the the *BMS* decision has no binding effect. Thus, the subsequent question is: did the Court of Appeal believe that the *BMS* decision had binding effect? Well, it did not—first, because the *BMS* decision contains no ratio, or no ratio of sufficient clarity, to preclude patentability in the matter at hand. In the absence of such ratio, the Appeal Court held that it could disregard the *BMS* decision and adopt the *Genentech* approach.³⁴ Even more interestingly, however, is that the Appeal Court also held that even if there had been a clear ratio, it would still have been acceptable not to follow the *BMS* decision. If the EPO has adopted a settled view on principles of patent law (for example, through the EPO Board of Appeal case law), these principles should be followed. In such a situation, the settled EPO view overrules the binding effect of the earlier *BMS* decision.³⁵

³¹ Court of Appeal, *Bristol Myers Squibb v Baker Norton* [2001] R.P.C. 1.

³² EPO Board of Appeal, *Genentech/Method of administration of IFG-1* (T-1020/03) [2006] E.P.O.R. 9; and, in reference, EPO Enlarged Board of Appeal, *Eisai* (G-5/83) [1985] O.J. E.P.O. 64.

³³ EPO Enlarged Board, *Eisai* (G5/83) [1985] O.J. E.P.O. 64.

³⁴ *Great Western Railway v Owners of SS Mostyn* [1928] A.C. 57; and *Midland Silicones v Scruttons* [1962] A.C. 446.

³⁵ This is consistent with *Young v Bristol Aeroplane Co* [1944] K.B. 718, which must be interpreted narrowly, the Court of Appeal considered.

It is our belief that after the *Merck v Actavis* decision, the UK courts will take the EPO principles and case law will be taken much more seriously than before. It is clear that the Court of Appeal proclaims that the EPO principles and case law are not only guiding for these courts, but that they are, where it concerns matters of principle, even binding in the UK courts.

House of Lords, *Conor v Angiotech*, July 9, 2008

The third case to bring the United Kingdom closer to the continent was the House of Lords decision in *Conor v Angiotech*. The case was anxiously awaited and, immediately after it was handed down, numerous comments were published on the internet. What made this case so interesting? First of all, it concerned a European patent that was attacked by Conor for lack of inventive step in both the Netherlands and the United Kingdom. In both countries, Conor relied on the same pieces of prior art. In the Netherlands, the patent was held (partially) valid, but it was held invalid in the United Kingdom.³⁶ The Dutch first instance decision and the English appeal decision were issued on consecutive days. This timing highlighted the difference between the Dutch and UK approach even more. Secondly, the House of Lords only hear such cases that they consider to be important to the general development of law. Therefore, it was clear that the decision would be “fundamental”. The fact that the principle under review concerned inventive step, the most commonly used ground in invalidity cases, made the case even more interesting.

One of the most important considerations came immediately at the start of the judgment, where Lord Hoffmann considered that as a point of departure the view must be taken that in European patent law uniformity should exist in the legal principles applied when examining the validity of patents. Lord Hoffman phrases this as follows:

“3. There is still no European Patent Court. A European patent takes effect as a bundle of national patents over which the national courts have jurisdiction. It is therefore inevitable that they will occasionally give inconsistent decisions about the same patent. Sometimes this is because the evidence is different. In most continental jurisdictions, including the European Patent Office (‘EPO’), cross-examination is limited or unknown. Sometimes one is dealing with questions of degree over which judges may legitimately differ. Obviousness is often in this category. But when the question is one of principle, it is desirable that so far as possible there should be uniformity in the way the national courts and the EPO interpret the European Patent Convention (‘EPC’). In this case, as Pumfrey J. made clear in his judgment, there is a question of principle at stake. It is about how you identify the concept embodied in the invention which may constitute the ‘inventive step’ . . .”

In the decision, the House of Lords first dealt with the question of whether, upon examining inventive step, the level to which the specification to the patent shows that the invention works, or how it works, can be of importance. Lord Hoffmann considers that it cannot. The invention is the product specified in a claim and the patentee is entitled to have the question of obviousness determined by reference to his or her claim and not to some “vague paraphrase based upon the extent of his disclosure in the description”. There is no requirement in the EPC or the statute that the specification must demonstrate by experiment that the invention will work or explain why it will work. Referring to, amongst others, the EPO *Agrevo* decision,³⁷ Lord Hoffmann acknowledges that no monopoly can be given of a patent that concerns a purely speculative idea not supported by anything in the description. An invention should be “plausible”. However, Lord Hoffmann considered that these cases were far from the facts in this case. The description, after all, did claim that a taxol-coated stent would prevent restenosis and Conor did not suggest that this claim was not plausible.

As to the “obvious to try” test, Lord Hoffmann considered that this is still the appropriate test, if applied correctly. Lord Hoffmann noted in this respect that Diplock L.J. considered that the “obvious to try” test could be effective only in cases where there is a “fair expectation of success”. What level of “expectation” is required to accept that there is a “fair” expectation is subject to the facts and circumstances of the case. Lord Walker, however,

36 The Hague District Court, January 17, 2007, *Conor Medsystems v Angiotech—Boston Scientific* (BIE 2007/101); and UK Court of Appeal, January 16, 2007, *Conor v Angiotech* [2007] EWCA Civ 5.

37 *TBoA* (T-939/92).

was more critical of the “obvious to try test”. He appeared to argue that this test is no longer appropriate, particularly not where inventions are at issue that lie in the fields of pharmaceuticals and biotechnology. Lord Walker considered that during the last 40 years, the volume of high-tech research has increased enormously, especially in the fields of pharmaceuticals and biotechnology. The resources committed to research are enormous, because the potential rewards in worldwide markets are so great and the competition is fierce. In this climate, “obvious to try”, Lord Walker stated, has tended to take on a life of its own as an important weapon in the armoury of those challenging the validity of a patent. In this respect, Lord Walker quoted Sir Hugh Laddie³⁸:

“The problems can be approached by considering first the concept of ‘obvious to try’. . . . On its face, this produces an unworkable or irrational test. If the reward for finding a solution to a problem and securing a monopoly for that solution is very high, then it may well be worthwhile for large players to examine all potential avenues to see if one gives the right result, even though the prospects of any one of them succeeding are much less than 50/50. What makes something worth trying is the outcome of a simple risk to reward calculation. Yet, if the reward is very large, the avenues worth trying will be expanded accordingly. So, the more commercially attractive the solution and the more pressing the public clamour for it, the harder it will be to avoid an obviousness attack. In those circumstances a solution which is quite low down a list of alternatives, all of which are more or less worth trying, will fail for obviousness . . . as technology advances rapidly, this is a serious and growing problem.”

Lord Walker, however, did not draw a distinct conclusion from these considerations, and the other Lords did not discuss the “obvious to try” test further either. There was no discussion of the European approach to inventive step, the “problem solution” approach, let alone an indication that the Lords believed this to be a more appropriate approach. The Lords did not discuss the (fourth step in the) *Windsurfing/Pozzoli* test either. It appears that the Lords did not want to endorse or formulate a particular approach, but instead wanted to stress the importance of the facts and circumstances in each case. Nevertheless, the strong emphasis they placed on the “expectation of success” and their criticism of the “obvious to try” test does seem to represent a more liberal approach to inventive step than previously taken by the UK courts. It seems safe to say that in future the UK courts will be more willing to consider the motivation of the skilled person and the problem he or she was trying to solve in assessing inventive step. This certainly moves UK patent law closer again to the EPO/continental approach to inventive step and will probably lead to patents less readily invalidated for lack of inventive step, particularly pharmaceutical patents.

38 From “Patents—what’s invention got to with it?” in *Intellectual Property in the New Millennium*, ch.6, p.93.