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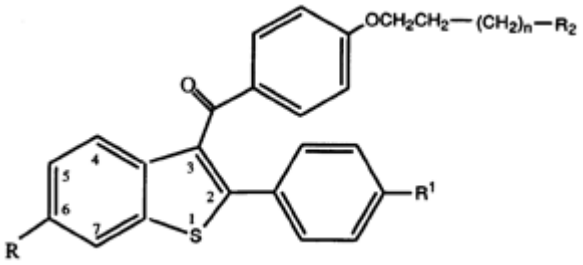
Grounds of invalidity of a drug patent

Pierre Véron (Véron & Associés) · Wednesday, June 20th, 2012

On 20 March 2012, the *Tribunal de Grande Instance* of Paris rendered its decision in the case relating to raloxifene, a molecule useful for treating or preventing osteoporosis in post-menopausal women, opposing Teva to Eli Lilly.

This decision raises many questions, first concerning drug patents in particular (patentability of second medical use, patentability of the resolution of a bioavailability problem or of a dosage?) but also concerning the liberties which the Court takes with the grounds of invalidity of European patents and European patents French designations.

The American company Eli Lilly is the holder of two European patents, EP 0 584 952 and EP 1 438 957, relating to the use of the raloxifene molecule for preventing osteoporosis.



The application for patent EP 952 was filed on 26 July 1993, claiming U.S. priority of 28 July 1992. This patent entitled "*Improvements in or relating to benzothiophenes*" relates to the use of a compound family, including raloxifene, in the preparation of a drug for use in the treatment or prevention of osteoporosis in post-menopausal women. This first patent was granted on 2 May 1997.

The application for patent EP 957 was filed as a divisional application derived from the previous patent application, also on 26 July 1996, claiming the same U.S. priority. This second patent, entitled "*Raloxifene in the treatment of postmenopausal osteoporosis*", was granted on 11 April 2007.

Raloxifene is marketed in France under the proprietary drug denomination Optruma® by Eli Lilly and under the proprietary drug denomination Evista® by Daiichi Sankyo.

Teva Santé and Teva Pharmaceutical Industries Ltd (hereinafter referred to as "Teva"), wishing to launch in France a generic drug of the raloxifene product, filed an opposition against patent EP 957

before the Opposition Division of the EPO and, by way of a summons dated 30 July 2009, initiated an action for invalidity of the French designations of the two European patents before the *Tribunal de Grande Instance* of Paris.

On 22 December 2009, the Opposition Division of the EPO revoked patent EP 957 for lack of inventive step. An appeal was lodged against this decision and is pending before the Technical Board of Appeal.

As Teva's generic drug had been marketed in France as of 15 March 2011, Eli Lilly lodged a counterclaim for infringement of its patents by Teva before the *Tribunal de Grande Instance* of Paris, which was already ruling on Teva's patent invalidity action. Daiichi Sankyo Europe GmbH, Daiichi Sankyo France and Pierre Fabre Médicaments voluntary intervened in the action in order to claim compensation for the damage they themselves suffered due to the alleged acts of infringement committed by Teva.

In its 20 March 2012 decision, the *Tribunal de Grande Instance* of Paris finally held that the French designations of the two European patents at issue were invalid. It decided in particular that while patent EP 952 is not invalid for lack of novelty as it concerns a second medical use, it is however invalid for lack of inventive step. On this occasion, the Court held that the resolution of a bioavailability problem is routine work implying no inventive step and also takes this opportunity to recall that it considers that a dosage is not a patentable subject-matter but a therapeutic method. The Court finally took into consideration grounds of patent invalidity which are not mentioned as such in Article 138 EPC, which is quite disturbing.

Lack of novelty and second medical use

Teva argued that claim 1 of patent EP 952, which is drafted in the form of a Swiss-type claim and constitutes a new therapeutic application of a known substance, probably lacked novelty pursuant to Article 54 EPC 1973 applicable to the patents at issue due to their filing dates.

Eli Lilly replied that the Swiss-type claims had been held valid by the Enlarged Board of Appeal precisely in order to allow the second medical use to be patentable and that the patentability of the second medical use has been clearly admitted since EPC 2000.

This issue was tricky because, as regards the invalidity of a patent, *i.e.* the retroactive sanction of a defect existing since the origin of the patent, it seemed logical to appreciate it according to the law in force at the date of origin of the patent (the filing of applications in 1993 as far as the European patents at issue are concerned). However, at that time, although Article 54 EPC 1973 prohibited the patentability of the second medical use, the Enlarged Board of Appeal had come, *contra legem*, to the opposite solution (EPO, 5 December 1984, Pharmuka, G 6/83), *i.e.* the possibility of a patent for a second medical use. Afterwards, Article 54 was amended in EPC 2000 to remove this obstacle to the patentability of a second therapeutic application.

In this difficult context, the Court gave its interpretation of a part of French case law prior to EPC 2000, which may seem quite difficult to follow from a logical point of view: while this case law refused the patentability of a new therapeutic application on the grounds that since the molecule was known, the second application was necessarily known as well, it did not prohibit the patenting of a second medical use if it could be established that this application was new or inventive and not already contained in the prior art. On this basis, the Court rejected Teva's ground of invalidity.

Lack of inventive step and resolution of a bioavailability problem; non patentability of a dosage

Nevertheless, the Court decided that patent EP 952 was invalid for lack of inventive step.

The most relevant prior art document for the skilled person who is a biochemist was the Jordan document which explicitly prompts one to verify the effect of anti-estrogens on osteoporosis. And although bioavailability remained a problem, it did not constitute real prejudice to overcome but rather a dosage problem requiring routine work, which may be long and expensive but implies no inventive step. On this point, the Court clearly followed the reasoning adopted by the Canadian Court of Ottawa which held the patent invalid for lack of inventive step, contrary to that of the U.S. Court which held the patent valid as it considered that there was an inventive step having regard to the issue of raloxifene bioavailability.

The Court also held invalid, for different reasons, all the other claims of patent EP 952. Having regard to claims 9 to 12 in particular, which relate to specific dosages for the administration of raloxifene, the Court held that the dosage was not patentable because it depends on the assessment and responsibility of each doctor and is part of the therapeutic method. It thus relies on the conclusion of a previous decision rendered by the same Court, presided by the same judge (TGI Paris, 3rd ch., 1st sect., 28 September 2010), which is contrary to the solution adopted on that point by the EPO case law and by some judges in neighbouring countries.

Double patenting?

Teva asserted that the subject-matters of patents EP 952 and EP 957 were identical, which violates the rule prohibiting double patenting.

Surprisingly, the Court agreed with Teva's assertion. It sought to demonstrate that there was finally no difference between claim 1 of patent EP 952 and that of patent EP 957. The only difference, which was the specification of oral administration (tablet or capsule) appearing in patent EP 957, was finally not a real difference because this specification provided no new or inventive teaching. According to the Court, this was a new ground of invalidity of patent EP 952.

The Court considers double patenting, *i.e.* the existence of two patents covering one and the same invention, as a ground of invalidity of one of these two patents. However, there cannot be grounds of invalidity of a European patent or of the national designation of a European patent other than those expressly mentioned in the EPC. Article 138 EPC very clearly states that the patent invalidity grounds are exhaustively listed: "*a European patent may be revoked with effect for a Contracting State* ***only on the grounds*** *that: (…)*". Double patenting does not appear in the listed grounds of invalidity. One could perhaps imagine that in this case, even if the applications were filed on the same day (26 July 1993), the first application filed would have deprived the second one of novelty, as, in the EPC (as in French law), the applications filed but not yet published are part of the prior art (see Art. 54(3) EPC, precisely in order to prevent double patenting). However, the lack of novelty is not the ground of invalidity held by the Court but rather double patenting. Moreover, in this case, one can wonder whether adding this last ground of invalidity was really useful when the Court had already sufficiently grounded the invalidity of the two patents at issue (mainly for lack of inventive step over the prior art). Finally, one may have doubts whether double patenting causes real damage when the holder of the two patents is one and the same person (Eli Lilly in this case). For the third parties, if these two patents are valid, it is immaterial whether they have to respect

either one of these two patents. For the holder, the conflict of exclusive rights that could potentially arise from the existence of two exclusive rights on one and the same invention is resolved by the mere fact that it is the sole holder of the two competing rights. And if one of these two patents is threatened by a ground of invalidity, so is the other patent.

In addition, the reference made by the Court to Article L. 612-4 of the French Intellectual Property Code, relating to divisional applications, as well as to the EPC and the case law of the EPO, again relating to divisional applications, could give reasonable cause for concern as this may create confusion between two completely distinct issues. The principle of divisional applications is not to prohibit double patenting but rather to affirm that a patent application should only cover a single invention (or a single general inventive concept) and not several inventions (Art. L. 612-4 § 1). If several inventions are actually covered by a single application, the latter must be divided (Art. L. 612-4 § 2). Such is the meaning of a divisional application in this context: recognising of a plurality of inventions in one initial application and isolating one of these inventions in a divisional application, in order to respect the principle of one invention per application. The prohibition of double patenting relates to a very different situation: the case where a single invention (not a group of inventions) is the subject-matter of several patent applications (and not of one patent application only).

Lack of clarity?

Teva asserted that the description of patent EP 952 only considered the case of **older** post-menopausal women so that amended claim 1, covering only the use of raloxifene for treatment or prevention in post-menopausal women, extended beyond the content of the application and was not clear. The Court dismissed these two arguments as it merely noted that the description did not relate to older post-menopausal women only but also related to women aged 45 to 60 and women whose menstruation ceased following a surgical intervention.

It is unsatisfactory that the Court handed down such a decision with regard to the lack of clarity of claim 1, as if it were a possible ground of invalidity. Article 83 EPC certainly provides that "*the European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art*" but Article 138 EPC then exhaustively defines the possible grounds of invalidity of the European patent or of the national designations of a European patent. Yet Article 138 EPC does not recognises the lack of clarity of a claim as a ground of invalidity. This lack of clarity may only constitute a ground for patent invalidity through the concept of insufficient disclosure (Art. 138(1)b EPC: the European patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art).

Original French decision.
English translation .

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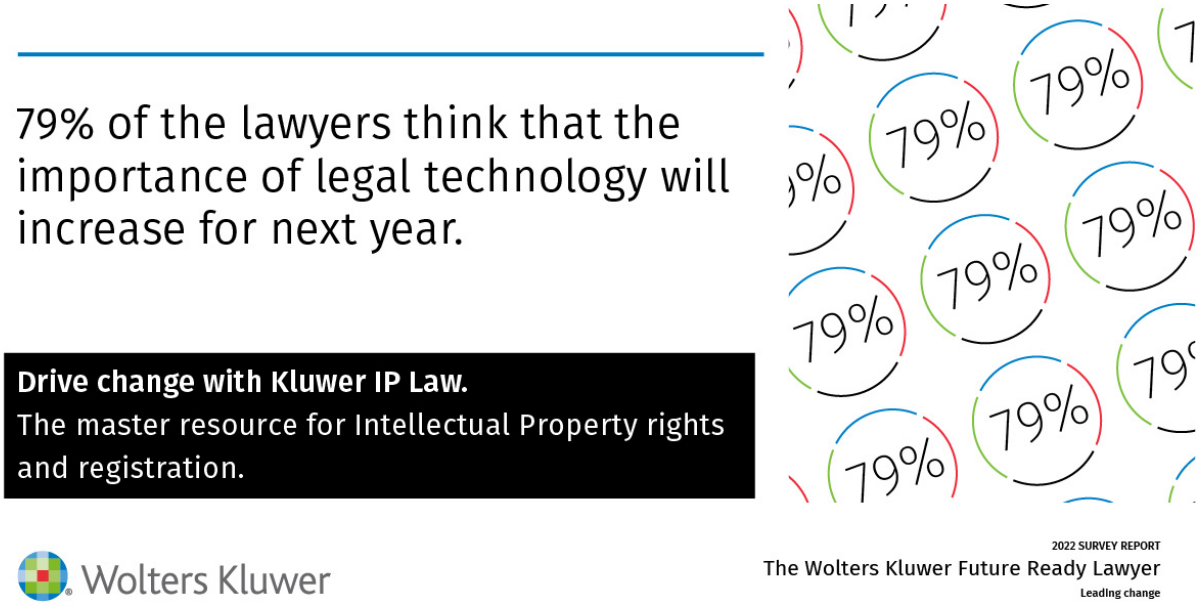

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