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The French defence: clarifying the scope of experimental use exemptions

The Paris High Court has accepted an experimental use exemption for biosimilars and for marketing authorisations outside the European Union

The question of which safe harbours exist in France against patent infringement for companies that wish to carry out experimental tests on patented compounds has led to legal uncertainties in the past.

France has a long history of allowing experimental use defences in the context of testing generics of patented pharmaceuticals. The courts have previously accepted that bioequivalence tests for the purpose of obtaining marketing authorisation do not constitute industrial or commercial acts and thus do not constitute patent infringement.

Case law already predominantly construed all experiments performed for the purpose of obtaining marketing authorisation as covered by the general experimental use exemption. However, once the marketing authorisation was obtained, any further production was unlikely to constitute research and would thus constitute infringement.

When the EU Directive on Medicinal Products for Humans (2001/83/EC, as amended by Directive 2004/27/EC) was implemented into the French IP Code, a specific exemption was added to the law dealing expressly with marketing authorisations.

The law thus provided that the following did not constitute patent infringement: "the studies and trials which are necessary in order to obtain a marketing authorization for a medicinal product, as well as any acts which are necessary to carry out such studies and trials and to obtain the authorization."

However, the law failed to define the marketing authorisations to which it referred and did not refer to the Community code relating to human medicinal products, or even to the notion of generics. As a result, uncertainty remained in several key areas, such as whether the marketing authorisation had to concern a generic of a patented pharmaceutical and whether the marketing authorisation had to be a European or French authorisation.

Paris High Court decisions

Two recent decisions of the Paris High Court in *Sanofi-Aventis Deutschland v Lilly France* (High Court of Paris, October 7 2014 and December 15 2014) have clarified the scope of the experimental use exemption for trials performed for the purpose of obtaining marketing authorisation.

The cases involved a biosimilar of insulin glargine Lantus. The patentee, Sanofi, suspected that Eli Lilly might be manufacturing a biosimilar of that insulin and launched seizure proceedings to obtain evidence of the infringement.

The two cases involved the control of the seizure proceedings and the application for a preliminary injunction that ensued.

In the course of these cases, Eli Lilly defended the claim on the basis of its right to perform any acts necessary to obtain marketing authorisation.

In the cases, it became apparent that large quantities of insulin had been manufactured for the purpose of testing large-scale processability and product stability.

The Paris High Court held as follows:

- The safe harbour is also available for marketing authorisations in respect of biosimilars — thus, the exemption is not limited to abridged generic marketing authorisations;
- The safe harbour covers all acts required to obtain a marketing authorisation, including large-scale manufacturing;
- The safe harbour covers all acts required to obtain a marketing authorisation, including those required by regulatory bodies after grant of marketing authorisation; and
- The safe harbour covers all acts required to obtain marketing authorisation, including for marketing authorisation sought outside of the European Union.

Of specific interest to the pharmaceutical industry is the recognition that even large-scale manufacturing after the grant of marketing authorisation can still be protected under the safe harbour if stability tests or other regulatory investigations require the production and maintenance of large stocks.

In addition, the ruling makes clear that it is possible to perform tests in France for the purpose of obtaining marketing authorisation, even if that marketing authorisation is not French or even European. Thus, it is possible to carry out research in France under the safe harbour, even if obtaining marketing authorisation is not immediately contemplated in France.

Grey areas

Issues that remain unanswered include the status of products that are manufactured for the purpose of obtaining marketing authorisation before the patent's expiry, but that could be marketed after it expires.

This issue was implicitly tried, as the patentee sought to impose surveillance on the subsequent use of the large stocks of products discovered. However, the judge considered that this question should be addressed in the proceedings on the merits. Thus, this issue may be answered in forthcoming decisions.

While the court's findings are food for thought, the decisions may well be subject to appeal.

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