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Generic plant protection products

What actions may be taken in the framework of a request for market authorization relating to a generic plant protection product before the expiration of the industrial property title (patent, supplementary protection certificate ("SPPC")) owned by the manufacturer of the reference product?

According to Article L. 613-3 of the French Intellectual Property Code ("FIPC"), if the holder of the relevant patent does not express his consent, the manufacture, offer, use, sale, possession or import of a protected medicinal or plant protection product is in principle prohibited. However, the French Intellectual Property Code provides for a certain number of exceptions to the patentee's exclusive right to exploit the patent.

Pursuant to Article L.613-5 of the FIPC:

"The rights afforded by the patent shall not extend to:

1. *Acts done privately and for non-commercial purposes;*
2. *Acts done for experimental purposes relating to the subject-matter of the patented invention;*
3. *The extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared.*
4. *Studies and experiments required to obtain the authorization to market a medicine as well as to the acts required for the performance of these studies and experiments and for the issuance of the market authorization."*

Regarding the exception set forth in Article L.613-5 d) of the FIPC

The provision set forth in Article L.613-5 d) of the FIPC was introduced by the Law n°2007-248 of February 26, 2007 transposing Directive 2004/27/EC of the European Parliament and of the Council of March 31, 2004, amending Directive 2001/83/CE on the Community code relating to the medicinal products for human use.

The reform aimed at facilitating and accelerating the performance of tests and the conduct of trials performed in view to obtaining a market authorization for generic medicinal products and avoiding that a vast majority of such tests and trials be performed outside the European Community (please see the introduction set forth of the parliamentary works).

This provision specifically concerns medicinal products and, we believe, may not apply by analogy to plant protection products.

In addition, our national set of legislations does not include any similar provisions for plant protection products.

This is indeed quite surprising as plant protection products, just like pharmaceutical products, are subject to a market authorization procedure requiring performance by the generic product manufacturer of bioequivalence trials.

We are again forced to note that the regulation governing plant protection products is always behind that governing pharmaceutical products and we have no other choice but to wait for a similar reform to be implemented for plant protection products.

Regarding the "experimental purposes" exception set forth in Article L.613-5 d) of the FIPC

Aside the recent exception set forth in Article L.613-5 d) of the FIPC reserved to pharmaceutical products, the main issue at stake is to determine whether the experimental purposes exception set forth in **paragraph b)** of said Article can apply to trials conducted in the framework of a request for a market authorization when the period of protection of reference plant protection product has not yet expired.

The answer depends on how the law is interpreted. As such the issue can only be settled through court decisions.

French courts have issued decisions concerning pharmaceutical products which are transposable to plant protection products since paragraph b) is drafted with general terms and therefore apply to any patented inventions, as defined in Article L.611-1 of the FCIP.

French courts consider in general that the experimental purposes exception must be strictly interpreted (Paris Court of appeals, 4th Chamber. July 3, 2002: PIDB 2003, 756.III.93).

Specifically, French courts make a distinction between so-called administrative acts (request for market authorization, issuance of a market authorization) and so-called factual acts (trials) for experimental purposes. The first type of acts do not infringe the exclusive right granted to the patentee whereas the second type of acts does infringe this exclusive right when such acts are made in the framework of a market authorization procedure relating to a patented product.

Regarding the possibility to conduct trials in France in view to

obtaining a market authorization for a generic product

The difficulty lies in the interpretation of the notion of "experimental purposes" because in the industrial sector research activities are always conducted with a commercial perspective. For the purpose of this article, the immediate objective of the trials and experiments is not the sale of a product but the preparation of a request for market authorization.

To the best of our knowledge, the *Cour de Cassation* (French Supreme Court) has never rendered a decision on this issue and the decisions issued by lower courts are not uniform:

- Some courts have held that acts of manufacturing and using the patented invention made in the framework of a request for market authorization of a generic product are justified under Article L.613-5 b) of the FIPC (Paris Court of first Instance, 3rd chamber, February 20, 2001: PIBD 2001, n°729.III.530 – October 12, 2001: PIBD 2002, 739.III.155 – January 25, 2002: PIBD 2002, 747, III, 342 ; see also Chr. Le Stanc, Juriscl. Pénal des Affaires Fasc. 30, n°55, February 2004) ;
- Other courts have held that trials conducted exclusively in view to obtaining a market authorization are to be considered as acts of infringement if they are made during the patent or CCP protection period; according to these courts the trials and experiments should only concern "the experiments made in view to contributing to the verification of the technical interest of the invention or to its development in order to extend knowledge" (Paris Court of Appeals, Paris, 4th Chamber., July 3, 2002: PIBD 2003, 756.III.93 – October 7, 2005: PIBD 2005, 819.III.685 ; Paris Court of Appeals, 14th Chamber., A, January 27, 1999 : RG 1998/51745 ; Lyon Court of Appeals, March 5, 1992: PIBD 1992, 525.III.363; see also P. Véron, RD propr. Intell. 1999 n°104, p.15 and n°107 p.17 ; RDPI 2000, n°107, p.31; M. Cousté and F. Jonquères : Propr. Industr., Sept. 2002, chron. 7).

In any event, since the *Cour de Cassation* has never rendered a decision in a case involving bioequivalence trials, a legal uncertainty remains on this point.

In practice, because of this legal uncertainty, laboratories have decided to **conduct trials abroad**, either in countries where the reference product is not protected or in countries where the legislation is less stringent (such as Canada for example), it being specified however that in the vast majority of EU Member States the applicable case law considers that bioequivalence trials conducted by generic product manufacturing laboratories in view to obtaining a market authorization whereas the period of protection of the reference product has not expired must be considered as acts of infringement.

Regarding the possibility to file a request for market authorization and obtain the issuance of a market authorization for a generic

product in France

It is now admitted that the purely administrative preparatory acts exclusively aimed at preparing a file, such as the preparation and the filing of a request for market authorization and the issuance of the same by administrative authorities, are not considered as factual acts (such as the manufacture, use, possession or import of products) likely to infringe industrial property rights.

It is also admitted that a market authorization does not in itself constitute a sale offer.

Manufacturing or sale activities subsequently to the issuance of a market authorization shall however be considered as infringing acts if the protection period has not expired.

Administrative acts involving the remittance of paper documents, subject however that they do not result in the communication of samples but merely of documents, and the publication of the market authorization are not considered as acts of infringement (Cour de Cassation. com., March 24, 1998, Allen and Hanburys c. Promedica et autre: Bull. civ., IV, n°110, p. 88; Paris first Instance court, January 30, 2008: PIBD 1998, 653.III.245). If samples are remitted, acts of infringement are established (CJCE, July 9, 1997, case. C-316/96 : JOCE C 271, September 6, 1997 ; PIBD 1997, 639.III.486).

This case law has been confirmed by legal authors and is not challenged in practice.

This is also the position adopted by a majority of countries.

The fact that the French Parliament decided in 2007 to codify this position for pharmaceutical products seems to confirm the case law applicable to plant protection products.

This is the reason why we believe – subject however to a reversal of the applicable case law – that the manufacturers of a generic plant protection is entitled to prepare a “hard” file in view to obtaining a market authorization for a generic product in France, even if the protection period of the reference product under a patent or supplementary protection certificate has not yet expired.

However, considering the lack of express legal or regulatory provisions and inconsistent case law, such manufacturers should not perform laboratory trials in France in the framework of the preparation of a request for market authorization concerning a plant protection products protected under an industrial property title.

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