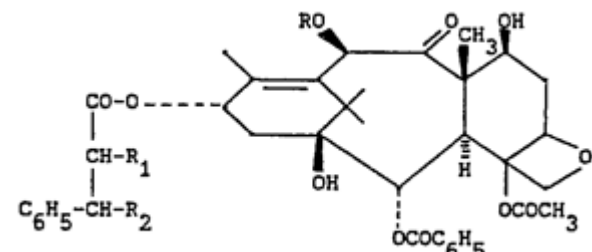


# Submission of a tender: imminent infringement?

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Aventis Pharma is the holder of supplementary protection certificate (SPC) No. 960006 related to European patent EP 253 738 granted on 31 January 1990, concerning the anti-cancer proprietary medicine Taxotere, known by its international common designation Docetaxel. The rights conferred by this certificate expire on 27 November 2010.

However, Aventis Pharma noticed that each of the three following competitors - the Dutch company Teva Pharma B.V. (represented in France by Teva Santé France), the French company Hospira France and the Indian company Intas Pharmaceuticals Ltd - had been granted, respectively on 26 January, 19 May and 31 May 2010, a market authorisation (MA), valid throughout the European Union or only in France, for the pharmaceutical product Docetaxel, a generic of Taxotere.

On 30 June 2010, Sanofi-Aventis sent a letter to each of these companies drawing their attention to the existence of its intellectual property rights and to the provisions of Article L. 613-3 of the French Intellectual Property Code which defines the acts relating to the subject-matter of the patent which are prohibited without the consent of the patent holder.

Because several tendering procedures related to public contracts for the supply of medicines, including Docetaxel, for the year 2011 and even 2012, are pending with a deadline for filing the tenders prior to 28 November 2010 (16 August or 19 August 2010), Aventis-Pharma and Sanofi-Aventis requested, in a letter dated 13 July 2010, that each of the three competitors confirm that it would not submit a tender for Docetaxel before 27 November 2010, the expiry date of Aventis Pharma's rights. Since their answers were not satisfactory, Aventis Pharma and Sanofi-Aventis then summoned them to appear before the Judge in preliminary proceedings at the *Tribunal de Grande Instance* of Paris, on the basis of Article L. 615-3 of the French Intellectual Property Code.

According to Article L. 615-3, such as modified by the 29 October 2007 Act, implementing Article 9 of Directive (EC) No. 2004/48, any person with authority to bring an action for infringement may request that the Judge in preliminary proceedings order any measure aimed at preventing an imminent infringement of its rights or aimed at putting a stop on allegedly infringing acts. Previously, such a preliminary injunction could only be requested to fight against an infringement which had already been committed. In this particular case, the claimants precisely wanted to prevent an imminent infringement of Aventis Pharma's rights and, on the basis of Article L. 615-3, the three competitors to be enjoined from:

- offering any proprietary medicines containing Docetaxel, by submitting a tender in response to invitations to tender during the period of validity of Aventis Pharma's rights,

- manufacturing, importing, holding, using and providing specimens of proprietary medicines and selling any proprietary medicines containing Docetaxel during the validity period of the SPC.

In three orders issued on 19 August 2010, the Judge in preliminary proceedings at the *Tribunal de Grande Instance* of Paris dismissed the requests of Aventis Pharma and Sanofi-Aventis.

Sanofi-Aventis' request was dismissed because it was neither the holder nor the licensee of the intellectual property right in issue and therefore did not have authority to bring an action for infringement.

However, the request made by Aventis Pharma, the SPC holder, was dismissed on the ground that an imminent infringement of this intellectual property right was not sufficiently established. The judge considered that none of the facts alleged by the claimants was sufficient to deduce a will of the defendants to respond to the invitations to tender with a deadline for filing the tenders prior to 28 November 2010 and to characterise the likelihood of an imminent infringement of Aventis Pharma's rights.

Aventis Pharma had first of all mentioned a MA granted to the defendants. According to the Judge, the MA requested by and granted to the defendants for their generic product did not necessarily mean that they intended to commercialise their generic product before the expiry of Aventis Pharma's rights.

And, more generally, the Judge considered that the French legislator had with due consideration ensured that the generic companies could carry out all the formalities to put their products on the market, such as the request for the MA or the request for prices to the *Comité Economique des Produits de Santé*, before the expiry of the intellectual property rights over the originator product.

Therefore, the Judge in preliminary proceedings follows French case law which has consistently held that the MA request does not constitute in itself an act of infringement (*TGI Paris*, 30 Jan. 1998, PIBD 1998, No. 653, III, 244; *TGI Paris*, 3rd ch., 12 Oct. 2001, PIBD 2000, No. 739, III, 155; *TGI Paris*, 3rd ch., 2nd sect., 25 Jan. 2002, PIBD 2002, No. 747, III; *TGI Paris*, preliminary ord., 11 Dec. 2002, PIBD 2003, No. 767, III, 338) and that the acts necessary to achieve studies and trials required to obtain this administrative authorisation benefit from the experimental use exception and do not constitute an infringement (*TGI Paris*, 3rd ch., 20 Feb. 2001, PIBD 2001, No. 729, III, 530; *TGI Paris*, 3rd ch., 12 Oct. 2001, PIBD 2002, No. 739, III, 155; *TGI Paris*, 3rd ch., 2nd sect., 25 Jan. 2002, PIBD 2002, No. 747, III, 342; this solution was expressly transcribed by the Act No. 2007-248 of 26 February 2007 in Article L. 613-5 d) and is in line with the solution already adopted by the *Tribunal de Grande Instance* of Lyon on 21 July 2008 (*TGI Lyon, preliminary ord., 21 July 2008, Docket No. 2008/01373*) and by many other European courts for which the administrative formalities such as the grant of the MA or the price determination of the generic medicine, which the generic companies generally want to complete at the earliest and before the expiry of the originator title (patent or SPC), do not constitute per se, in the absence of any other circumstances, evidence of an imminent infringement of this title.

Aventis Pharma had also mentioned the absence of an explicit reply to its 30 June and 13 July 2010 letters. However, the Judge neither found in this element anything likely to establish the imminence of an infringement.

As for the letter dated 30 June 2010, intended to draw the defendants' attention to the existence of intellectual property rights, the Judge remarks that it did not call for a reply.

As for the letter dated 13 July 2010 in which Aventis Pharma requested that the defendants confirm that they would not submit a tender for Docetaxel, the Judge remarks that all the defendants had replied to confirm their intention to respect the intellectual property rights or to invite the claimant to enter negotiations through an attorney-at-law (invitation that Aventis Pharma itself decided not to accept).

Secondly, the Judge points out that Aventis Pharma cannot force the defendants to make statements of intention. Indeed, it is likely that what Aventis Pharma wanted from the defendants through its letter dated 13 July 2010 was what practice in the field of business refers to as "statements of intention". These declarations of intention have various applications such as a "letter of intention" a "memorandum of agreement", a "letter of comfort" or a "gentleman's agreement" which all have in common to express an intention or a statement of principle while proclaiming the will not to be legally committed. It was in fact a moral commitment of this kind, not a legal commitment, that Aventis Pharma wished to obtain from the defendants: the moral commitment not to respond to the invitations to tender with a deadline for filing the tenders prior to 28 November 2010. And the Judge could only find that Aventis Pharma could not compel the defendants to enter into such a moral obligation if they did not want to.

And, as for the defendants' silence as to their will to submit a tender in response to the invitations to tender at issue, even after the service of the summons, the Judge considers that it is legitimate. The tendering procedures for public contracts, in order to remain fully effective, rely on a principle of confidentiality of applications and of tenders, pursuant to Article 32 §2 of the French new Public Procurement Contracts Code (this principle was the legal obstacle to the defendants' only being able to enter into a moral and not into a legal obligation not to respond to the invitations to tenders). The defendants could legitimately be opposed to legal proceedings intended to oblige it to reveal its commercial strategy. And of course this silence legally justified and kept was not sufficient by itself to characterise the defendants' effective will to submit a tender.

Finally, the Judge concluded that there was no evidence of the defendants' will to submit a tender in response to the invitations to tender with a deadline expiring before 28 November 2010. Consequently, in the absence of an imminent infringement being sufficiently established, one of the legal requirements for the action of the Judge in preliminary proceedings, set out in Article L. 615-3 of the French Intellectual Property Code, was thus lacking and the Judge could only decide that there was no ground for initiating preliminary proceedings.

It is interesting to note that, in an *contrario* approach, the Judge's decision means that if there had been evidence of the defendants' will to submit a tender in response to the invitations to tender with a deadline expiring before 28 November 2010, the Judge would obviously had admitted an imminent infringement of the rights conferred by the SPC. The Judge implicitly considered that the submission of a tender in response to the invitations to tender during the period of validity of the SPC is an infringement of this title although the supply of the products at issue would have taken place after the expiry of the SPC.

Such a solution seems logical since the rights conferred by the SPC, pursuant to Article 5 of Regulation (EC) No. 469/2009, are the same as those conferred by the basic patent. And Article L. 613-3 a) of the French Intellectual Property Code prohibits, save consent by the owner of the patent/SPC, the "offer" of the product subject-matter of the patent/SPC. In a similar way, in a 30 January 2001 decision, the commercial chamber of the French *Cour de Cassation* underlined that pursuant to Article L. 613-3 of the French Intellectual Property Code, the offer constitutes an act of infringement when the product offer is made in France although the sale could possibly be completed outside the territorial scope of the French patent (in that case, the sale could be completed with the parent company located abroad or with one of the different subsidiaries located in France or abroad). The court considered that the restriction, placed on some of the seized documents, according to which the products protected by a patent in a country were not offered or were not supplied for this country, was of no significance insofar as the offering itself had taken place in France so that it constituted an infringement of the French patent. The *Cour de Cassation* thus revealed an indubitable indifference towards the concrete circumstances of the subsequent supply of the products offered under the territorial and temporal scope of the French patent.

And from this point of view, French case law seems closer to German and Dutch case laws than to English case law. In Germany, the federal Court of Justice (5 Dec. 2006, *Simvastatin*, Patent World, No. 192, pp. 11-12; *Journal of Intellectual Property Law & Practice*, 2007, vol. 2, No. 6, pp. 357-358), decided that the publicity made in various specialised newspapers but also the mention of the generic medicine in a private compilation indexing the whole of the drugs marketed or to be marketed soon in the country (Lauer-Taxe) constituted an infringing offer regardless of whether the distribution of the products was to take place only after the expiry of the originator title. And in the Netherlands, the Court of Appeal of The Hague (2 Nov. 2010, *Glaxo Group Limited v. Pharmachemie B.V.* (a member of the Teva group)) decided in a similar way that the mention of the generic medicine in a private compilation indexing the whole of the drugs marketed or marketed soon in the country (G-standaard) constituted an infringing offer while at the same time the dissemination of the products was to take place only after the expiry of the originator title. In these two last cases, the courts have also both referred to the Community Patent Convention adopted in 1975 and modified in 1989, whose Article 25 defines the infringing acts among which one finds in particular the offering. The offering is envisaged as a sufficient use to constitute by itself the infringement. And the offering is obviously

understood as a broad concept, broader than the offering for sale covering any offer in general.

In England, in *Gerber v. Lectra*, the High Court (Lord Justice Robin Jacob) decided that the fact of offering for sale a patented product during the period of validity of the patent for a supply after the expiry of the patent did not constitute an infringement of the patent.

Another dimension of the question is approached by one of the orders which had to rule especially on a priority question of constitutionality raised by one of the defendants. The company Intas had raised a priority question of constitutionality relating to the provisions of Articles L. 613-3 and L. 615-1 of the French Intellectual Property Code claiming that they violated Articles 1, 4, 6 and 14 of the French *Déclaration des Droits de l'Homme et du Citoyen* of 20-26 August 1789 and Article 1 of the French 1958 Constitution, all together the principles of freedom of access to public procurement, of equal treatment of candidates, of free enterprise, of contractual freedom and free competition. Intas claimed that the prohibition of the offering ruled by Article L. 613-3 of the French Intellectual Property Code led to prevent a company from tendering for a public procurement contract even if the conclusion of this contract and its execution should take place only after the expiry of the patent.

The Judge in preliminary proceedings refuses to refer the priority question of constitutionality to the *Cour de Cassation* on the ground that the judge's freedom in respect of the appreciation of the facts, when he is seised in preliminary proceedings on the ground of Article L. 615-3 (he then appreciates the adequacy of the requested measure with the claimed infringement and resulting damage) as when he is seised by a claim for calculation of the damages on the ground of Article L. 615-1 (he then appreciates the reality and the extent of the damage resulting from the infringement), allows him to take into account the reality and the seriousness of the damage, and in a case similar to this case allows him to take into account the absence of any exclusive right at the date of conclusion and execution of the contract, to decide either not to authorise the requested provisional measure, or to grant only very low damages, ensuring thus concretely the respect of balances between the rights of the parties.

However, we may wonder about the quality of this argument. If the fact that the supply of the products must take place after the expiry of a patent or a SPC is of no significance regarding the qualification of infringement for an offer made before, in the temporal and territorial scope of this title, how could the judge take account of this circumstance to refuse or even adapt the preliminary injunction requested because of the imminence of the infringement? As for the remedy to the damage resulting from the committed infringement, a judge should decide on the contrary that because of the infringement through offer in the scope of an intellectual property right (right expired at the day of conclusion of the contract or supply of the products), the holder of the intellectual property right was prevented, because of the offer and as of the day of its formulation, from concluding the contract or from the possibility to conclude the contract (loss of a chance). It should also be possible to see there a pure and simple example of a springboard effect resulting from the infringement: the infringing act made before the expiry of the title continue to have effect, to provide to its author a competitive advantage, a favourable position in the market even after the expiry of the title.

[Original French decision.](#)

[English translation.](#)

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