

**T R I B U N A L
D E G R A N D E
I N S T A N C E
O F P A R I S**

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**ORDER IN PRELIMINARY PROCEEDINGS
issued on 19 August 2010**

Docket No.:
10/56889

No. : 1/FB

By Marie-Claude Hervé, Vice-Presiding Judge of the *Tribunal de Grande Instance* of Paris, in open court, in the form of preliminary proceedings, on behalf of the Presiding Judge of the *Tribunal*.

Summons of:
27 and 28 July 2010

Assisted of Christelle Le Guen, Court Clerk

CLAIMANTS

S.A. AVENTIS PHARMA
20 avenue Raymond Aron
92160 Antony

S.A. SANOFI – AVENTIS FRANCE
9-13 boulevard Romain Rolland
75014 Paris

represented by Ms Patricia Ghozland, attorney-at-law, member of the Paris Bar – P569

DEFENDANTS

S.A.S TEVA SANTÉ
Le Palatin 1 – 1 Cours du Triangle
Paris La Défense
92800 Puteaux

represented by Mr Grégoire Desrousseaux, attorney-at-law, member of the Paris Bar - #W03

Société TEVA PHARMA B.V.
Computerweg
10 3542 DR Utrecht
The Netherlands

represented by Mr Grégoire Desrousseaux, attorney-at-law, member of the Paris Bar - #W03

DISCUSSION

At the 16 August 2010 hearing, held publicly and presided by Ms Marie-Claude Hervé, Vice-Presiding Judge,

We, Presiding Judge,

After hearing the appearing parties or their attorney-at-law,

OVERVIEW OF THE DISPUTE:

Aventis Pharma is the holder of supplementary protection certificate (SPC) No. 960006 related to European patent EP 253 738, 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.

On 26 January 2010, the Dutch company Teva Pharma B.V. which is represented in France by Teva Santé France, was granted a market authorisation (MA) for the pharmaceutical product Docetaxel Teva, a generic of Taxotere, authorised throughout the European Union.

On 30 June 2010, Sanofi-Aventis France sent a letter to Teva Santé France drawing its attention to the existence of its intellectual property rights and the provisions of Article L 613-3 of the French Intellectual Property Code.

Several tendering procedures related to public contracts for the supply of medicines, including Docetaxel, for the year 2011, and even 2012, are pending and have a deadline for filing the bids prior to 28 November 2010.

Thus, the *groupement interdépartemental* of Auvergne¹ issued an invitation to tender for the period from 1 January 2011 to 31 December 2012 with a deadline for receiving the tenders on 16 August 2010; the *Assistance Publique – Hôpitaux de Marseille*² issued an invitation to tender for the period from 1 January to 31 December 2011, renewable once for a 12 months' period, with a deadline for receiving the tenders on 19 August 2010.

¹ Translator's note: group of administrative divisions of the Auvergne region

² Translator's note: the public hospital system of the city of Marseilles

In a letter dated 13 July 2010, Aventis Pharma and Sanofi-Aventis France requested that Teva Santé France confirm that it would not submit a tender for Docetaxel until the expiry of Aventis Pharma's rights.

In the absence of a satisfactory reply, on 27 and 28 July 2010, Aventis Pharma and Sanofi-Aventis France summoned Teva Pharma B.V. and Teva Santé France to appear before the Judge in preliminary proceedings at the *Tribunal de Grande Instance* of Paris, on the basis of Article L. 615-1, L. 615-3 and L. 613-3 of the French Intellectual Property Code and on the basis of Article 5 of the Regulation (EC) No. 469/2009 of 6 May 2009, to enjoin them 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.

Aventis Pharma and Sanofi-Aventis France also request that the proprietary medicines containing Docetaxel be handed to a bailiff, with the package leaflets and technical and commercial documentation held by Teva Pharma B.V. and Teva Santé France; that the infringing products be recalled to be destroyed and that the order be notified to the authorities concerned.

Finally, Aventis Pharma claims a €30,000 compensation under Article 700 of the French Civil Procedure Code.

In support of their requests, Aventis Pharma and Sanofi-Aventis France set out that European patent EP 738 has never been challenged. They also explain that offering an infringing product, regardless of the forms of this offer and even if it is not linked to an actual commercialisation, constitutes an act of infringement. They add that providing specimens, as required by certain invitations to tender, constitute acts of infringement distinct from the offer. They therefore allege that Teva Pharma B.V. and Teva Santé France's submission of a tender in response to the invitations to tender at issue, with specimens being provided, infringes Aventis Pharma's intellectual property rights. They also argue that the fact that Teva holds an MA and all the authorisations required for marketing its product in France and that it failed to reply explicitly to the letters dated 30 June and 13 July 2010, is sufficient to deduce an imminent infringement of its rights.

The defendants raise the invalidity of the summons owing to insufficient legal and factual arguments being set out. The Dutch company Teva Pharma also raises the invalidity and the lateness of the service of this summons which it refused to receive as it was written in English.

Then they raise the inadmissibility of the requests made by Sanofi-Aventis France which has no standing and legal interest in initiating an action under Article L.615-3 of the French Intellectual Property Code.

The defendants also dispute the existence of an infringement. First, they explain that they are unable to set forth arguments as to whether or not the SPC is reproduced since Aventis Pharma and Sanofi-Aventis France have not provided the previous market authorisation which defines the limits thereto. They add that pursuant to Article 4 of Regulation (EC) 469/2009, the scope of the SPC is limited to the use of the product as a medicine so that the response to an invitation to tender which will result in the use of the product only after the rights conferred by SPC have expired, does not constitute an infringement. In the same way, the defendants argue that providing specimens which are not intended for consumption neither constitute an infringement.

The defendants then raise the absence of imminent infringement of Aventis Pharma's rights. They set out that the silence or the reply to the various letters received by Teva Santé France is not sufficient to deduce a will to respond to the invitations to tender at issue.

The defendants contend that the requests should be dismissed and add that the injunction appears inappropriate while it would have the effect of conferring on Aventis Pharma a monopoly after its rights have expired. They claim a €30,000 compensation under Article 700 of the French Civil Procedure Code.

The claimants reply that Sanofi-Aventis France has an interest in initiating an action since it is the licensee and producer of Taxotere. They add that the summons was served on 28 July 2010 in a language that Teva Pharma B.V. understands, pursuant to the provisions of Article L. 615-3 of the French Intellectual Property Code.

The claimants then reply that the effects of the SPC are identical to those of the patent and prohibit the same acts and in particular the offer with the supply of specimens.

REASONS FOR THE DECISION

1/ On the lawfulness of the procedure:

The summons served upon Teva Pharma B.V. and Teva Santé France contains a clear presentation of the legal grounds (rights related to the SPC, response to an invitation to tender constituting an act of infringement, imminent infringement of the intellectual property rights) and the facts (existence of an MA and other administrative authorisations issued to the defendants, behaviour further to the different letters) mentioned by the claimants; Teva Pharma B.V. and Teva Santé France were in a position to reply thereto with arguments.

The summons should therefore be considered lawful in the light of the provisions of Article 56 of the French Civil Procedure Code.

On 28 July 2010, the bailiff sent to the Dutch authority, designated for that purpose, the request for summons in preliminary proceedings against Teva Pharma B.V. On 30 July 2010, the receiving authority received this request and effected the requested service on 9 August 2010. Teva Pharma B.V. did not accept the document on the ground that the language used was English and not Dutch.

Pursuant to Article 8 of Regulation (EC) No. 1393/2007 of 13 November 2007, the addressee of the document may refuse to accept it if it is not in a language which he understands or in the official language of the Member State addressed.

It emerges from those provisions that the document to be serviced upon Teva Pharma B.V. did not necessarily have to be written in Dutch but could have been so in another language as long as it was understood by the addressee.

In this particular case, Teva Pharma B.V. which is part of an Israeli Pharmaceutical group and uses English in the context of its activity, does not contend that it does not understand it.

The delivery of a summons written in English was thus valid and the service of the summons was therefore lawfully effected on 28 July 2010. The fact that its effective delivery took place on 9 August 2010 cannot affect the validity of the procedure since the circumstances establish that the defendant was in a position to ensure its defence in satisfactory conditions.

Finally, the summons was delivered upon authorisation of the delegate of the President of the *Tribunal de Grande Instance* of Paris pursuant to the requirements of sub-paragraph 2, Article 485 of the French Civil Procedure Code. This special text is distinct from the provisions relating to *ex parte* orders and does not refer to Article 494 of the French Civil Procedure Code. Consequently, the absence of a written request does not call into question the validity of the authorisation granted.

Thus, Teva Pharma B.V. was lawfully summoned to appear before the Judge in preliminary proceedings of the *Tribunal de Grande Instance* of Paris.

2/ On the admissibility of Sanofi-Aventis France's requests

Under Article L. 615-3 of the French Intellectual Property Code, any person with authority may bring proceedings for infringement.

It is not disputed that Sanofi-Aventis France is not the holder of the intellectual property rights at issue. Also, it has acquired no licence. Yet, its possible authority as a distributor, of which it does not provide evidence, does not confer upon it the right to bring an action for infringement.

Therefore, Sanofi-Aventis France does not establish having authority to bring proceedings for infringement so that an action brought before the Judge in preliminary proceedings on the basis of Article L. 615-3 of the French Civil Procedure Code is inadmissible.

3/ On Aventis Pharma's requests

- on the scope of the SPC:

Article 5 of Regulation (EC) No. 469/2009 provides that subject to Article 4, the SCP confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations.

Article 4 of that same Regulation relating to the scope of the SPC, sets out that within the limits of the protection conferred by the basic patent, the protection extends only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

It results from those provisions that the SPC which aims at sustaining innovation in the field of health, grants a protection to a product as a medicinal product in any forms enjoying the protection of the basic patent.

This text does not have as a consequence to alter the definition of the infringement of a protected invention as laid down in Article L. 613-3 of the French Intellectual Property Code.

Consequently, the fact that Aventis Pharma's rights are based on a SPC and not on a patent does not have the effect of excluding the offer from the acts of infringement.

- on the imminent infringement:

Pursuant to Article L. 615-3 of the French Intellectual Property Code, the person having the authority to bring an action for infringement, may bring preliminary proceedings in order to obtain the implementation of measures intended to prevent any imminent infringement of its rights or to prevent the allegedly infringing acts from being continued.

In order to establish the existence of an imminent infringement of its rights, Aventis Pharma mentions an MA granted to Teva as well as various administrative approvals and the absence of an explicit reply to its letters dated 30 June and 13 July 2010. It adds that considering the confidentiality that surrounds the tendering procedures for public contracts, it is unable to supply further evidence and that only reasonably accessible elements rendering likely the alleged facts may be requested from it.

Nonetheless, the law authorised the pharmaceutical laboratories to file MA applications for generic medicines and to obtain their inclusion on the list of refundable drugs and the repertory of generics despite the existence of intellectual property rights; during the drafting of the 29 October 2007 Act, the legislator did not consider that the requests for prices to the *Comité Économique des Produits de Santé*³ constituted an imminent infringement.

It thus appears that the law authorises the generic companies to take all the relevant steps to put on the market their products before the intellectual property rights over the originator product are extinguished. Therefore it cannot be inferred from the steps taken by the defendants in accordance with the legal provisions that they intend to commercialise their generic product before the expiry of Aventis Pharma's rights.

Also, it should be noted that the letter dated 30 June 2010 informing Teva Santé France of the existence of intellectual property rights did not call for a reply and that Teva Santé Pharma replied to the 16 July 2010 letter by confirming its respect for intellectual property rights. In any case, Aventis Pharma cannot force Teva to make statements of intention, and the defendant's silence following the service of the summons, as to its will to submit a tender in response to the invitations to tender at issue and in particular to that of the *Assistance Publique-Hôpitaux de Marseille*, is not sufficient to characterise the likelihood of an imminent infringement whereas Teva can legitimately be opposed to legal proceedings intended to oblige it to reveal its commercial strategy.

Therefore, there is no evidence of the defendants' will to submit a tender in response to the invitations to tender whose deadline expires before 28 November 2010. Therefore, there is no ground for initiating preliminary proceedings upon Aventis Pharma's requests owing to the absence of an imminent infringement sufficiently established.

The defendants will be awarded the sum of €15,000, on the basis of Article 700 of the French Civil Procedure Code.

ON THESE GROUNDS

Ruling publicly, by delivery of the order to the Court Clerk's office, after due hearing of the parties, in first instance,

Hold that the summonses serviced upon Teva Pharma B.V. and Teva Santé are lawful,

Hold that an action brought by Sanofi-Aventis France before the Judge in preliminary proceedings on the basis of Article L. 615-3 of the French Civil Procedure Code is inadmissible,

Hold that there is no ground for initiating preliminary proceedings upon Aventis Pharma's requests,

³ Translator's note: Economic Committee on Health Products

Order severally and jointly Sanofi-Aventis France and Aventis Pharma to pay Teva Pharma B.V. and Teva Santé the overall sum of €15,000 on the basis of Article 700 of the French Civil Procedure Code.

Order jointly and severally Sanofi-Aventis France and Aventis Pharma to pay the legal costs.

Drafted in Paris, on **19 August 2010**

The clerk,

signature

Christelle Le Guen

The Presiding Judge,

signature

Marie-Claude Hervé