

FRENCH REPUBLIC
IN THE NAME OF THE FRENCH PEOPLE
COUR D'APPEL DE PARIS

Division 1 – Chamber 3
DECISION OF 11 DECEMBER 2012
(No. 689, 6 pages)

Docket Number: **11/20113**

Decision referred to the *cour d'appel*: order of 31 October 2011 – *tribunal de grande instance de Paris* –
Docket No. 11/15302

APPELLANTS

SANOFI-AVENTIS FRANCE *société anonyme*, represented by its legal directors domiciled for that
purpose at the said registered office,

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75014 PARIS

SANOFI WINTHROP INDUSTRIE *société anonyme*, represented by its legal directors domiciled for
that purpose at the said registered office,

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94250 GENTILLY

ZENTIVA K.S, represented by its legal directors domiciled for that purpose at the said registered
office,

U Kabelovny 130, 102, 37
PRAGUE (CZECH REPUBLIC)

Represented by: Ms Nathalie LESENECHAL (attorney-at-law, member of the PARIS Bar, court box
D2090)

assisted by: Mr Arnaud CASALONGA of SELAS CASALONGA AVOCATS (attorney-at-law, member of
the PARIS Bar, court box K0177)

RESPONDENTS

NOVARTIS AG, represented by its legal directors domiciled for that purpose at the said registered
office,

Lichtstrasse 35
4058 BASEL – SWITZERLAND

NOVARTIS PHARMA SAS, represented by its legal directors domiciled for that purpose at the said registered office,

2-4 rue Lionel Terray
92500 RUEIL MALMAISON

Represented by: SCP MONIN – D’AURIAC (Mr Patrice Monin) (attorneys-at-law, members of the PARIS Bar, court box J071)

assisted by: Ms Laetitia BENARD of SDE ALLEN & OVERY LLP (attorney-at-law, member of the PARIS Bar, court box J022)

COMPOSITION OF THE COUR D’APPEL:

The case was discussed on 22 October 2012, in public hearing, before the *cour d’appel* composed of:

Ms Joëlle BOURQUARD, Presiding Judge
Ms Martine TAILLANDIER-THOMAS, Judge
Ms Sylvie MAUNAND, Judge

who deliberated

Court Clerk, during the discussion: Ms Véronique COUVET

DECISION:

- AFTER HEARING ALL THE PARTIES

- made available at the Court Clerk’s office, the parties having been previously notified under the conditions laid down in the second subparagraph of Article 450 of the French Code of Civil Procedure.

- signed by Ms Joëlle BOURQUARD, Presiding Judge, and by Ms Véronique COUVET, Court Clerk.

Novartis AG, holder of European patent EPO 443 983 which expired on 12 February 2011, was granted a supplementary protection certificate (SPC) for valsartan on 17 September 1999. This SPC No. 97C0050 was in turn the subject of a paediatric extension, which expired on 13 November 2011.

Novartis Pharma holds a licence for this SPC and its paediatric extension registered in the French patent register. It holds several marketing authorizations for proprietary drugs containing Valsartan marketed under the name Tareg or Cotareg.

Citing the infringement of the European patent and the SPC by the product Valsartan hydrochlorothiazide, Zentivalab 80mg/12.5mg 160mg/12.5mg and 160mg/25mg, Novartis requested an interim injunction against Sanofi-France Aventis, Sanofi Winthrop Industrie and Zentiva KS before the Presiding Judge of the *tribunal de grande instance de Paris* who, by order of 27 October 2011, granted the request and also ordered information to be made available as well as the communication and publication of a report in the medium of choice of the claimants.

Sanofi-France Aventis, Sanofi Winthrop Industrie and Zentiva KS served a summons on Novartis in an attempt to have the ruling revoked and in the alternative, obtain the obligation to provide security.

By order of 31 October 2011, the Judge ruling in preliminary proceedings upheld the injunction in all its provisions except for those relating to the communication of information that would identify the origins and distribution networks of the pharmaceutical products reproducing the claims of patent EP 0443983 and SPC No. 97C0050.

Sanofi-France Aventis, Sanofi Winthrop Industrie and Zentiva KS, appellants, in their pleading of 28 September 2012, request that the *cour d'appel* state that the conditions of Article L 615-3 of the French Intellectual Property Code were not met and that provisional measures must be limited to acts of marketing the allegedly infringing products, and not those relating to manufacturing, holding, using or importing the products, and therefore, reverse the ruling in all its provisions except those that reverse the obligation to communicate information that would identify the origins and distribution networks of the pharmaceutical products reproducing the claims of patent EP 0443983 and SPC No. 97C0050, dismiss Novartis's requests and order them jointly and severally to pay them the sum of €100,000 pursuant to Article 700 of the French Code of Civil Procedure.

Novartis, in its pleading of 12 October 2012, seeks that the order be confirmed, that the appellants be ordered to pay it the sum of €100,000 for damages for abuse of process, that the decision to be handed down be published in its entirety according to the terms laid out in its pleadings, and that the appellants be ordered to pay it the sum of €250,000 in irrecoverable costs.

WHEREUPON, THE *COUR D'APPEL*

Considering that Novartis claims to act on the basis of Article L 615-3 of the French Intellectual Property Code;

Considering that Article L 615-3 paragraph 1 of the French Intellectual Property Code states that "Any person with authority to bring an action for infringement may, in preliminary proceedings request the competent civil court to order, under a penalty of a daily fine if necessary, against the alleged infringer or intermediaries whose services it uses, any measure aimed at preventing an infringement about to be committed against rights conferred by the title or aimed at stopping any further allegedly infringing act. The competent civil court may also order *ex parte* urgent measures when the circumstances require that such measures should not be taken in the presence of both parties, in particular when any delay would be likely to cause an irreparable damage to the claimant. The court, in preliminary or *ex parte* proceedings, may order the requested measures only if evidence, reasonably accessible to the claimant, make it likely that its rights are infringed or that such infringement is about to be committed."

Considering that Novartis sought, by means of a request, to obtain injunction and communication measures, that the order that resulted was the subject of a request for revocation upon which the Judge ruled by way of the order referred to the *cour d'appel*;

Considering that it is for the present jurisdiction to now verify whether or not the case was duly submitted to the Judge by checking if the request or the order characterize circumstances justifying that the measure sought be exceptionally considered outside of all discussions in *ex parte* proceedings, that these circumstances must be appreciated on the day that the Judge statutes on a request and may not be the result of facts revealed later and notably of records of the ordered measures;

Considering that the *cour d'appel* notes that Novartis, which submitted 68 exhibits to the discussion, did not deem it necessary to communicate the request at the origin of these proceedings; that this exclusion is detrimental to the examination of the file; that it constitutes negligence on Novartis' behalf and a lack of seriousness towards the *cour d'appel*;

Considering nonetheless that the *cour d'appel* has access to this request as it was produced by Novartis' adversaries;

Considering that this request comprises 64 pages and a list of 54 exhibits;

Considering that this request presents the invoked rights, then the allegedly infringing products and then the violations of those rights; that page 48 mentions the sale of infringing products in pharmacies and tangible elements establishing the infringement on 26 and 27 October 2011 in a pharmacy and a *saisie-contrefaçon* of 26 October 2011;

Considering that the *cour d'appel* notes in this respect that both the request and the list of exhibits annexed to Novartis's latest pleading mention exhibit 54 as "evidence of infringement"; that this statement is not detailed and is not explained in a precise and exhaustive manner and therefore does not respect the principle of validity and transparency in providing elements of evidence; that the *cour d'appel* is unable to identify the evidence that was presented before the motions judge and does not know whether the evidence submitted to the arguments before it under number 54 as "evidence of infringement" is the same which was submitted to the motions judge;

Considering that in any case, the *cour d'appel* notes that in the case of an appeal, there are two requests under No. 54 seeking *saisies-contrefaçon* in a Gambetta pharmacy and in the production and distribution premises of Sanofi in Montargis; that it must thereby note that the two requests do not explicitly state grounds for making an exception to the due process and that they were followed by reports, the first of which reveals the absence of the commercialized product and the impossibility of putting the product up for sale, the proprietary drug present in the office software having neither sale price nor purchase price and the second of which mentions the presence of palettes of Valsartan products; that the bailiff does not mention having noted a receiver for these palettes; that there is therefore a doubt as to the imminent marketing of the products in question;

Considering that there is also a copy of a treatment form from a TASSE pharmacy for a Valsartan product following a prescription of 26 October 2010 written by a doctor Alain Francillon; that these documents are not accompanied by a certificate of authenticity from the pharmacist, doctor or patient and that the conditions in which they were obtained are unknown;

Considering that these are the only exhibits at the disposition of the *cour d'appel* and that they are those which were presented as evidence of infringement to the motions judge in support of the request for an injunction;

Considering finally that the request specifies on page 60 that "these measures may not be usefully ordered in the context of *inter partes* proceedings considering the expiry date of SPC No. 97C0050 and the non-working days, it is not possible for a judgment to be rendered before a significant part of the remaining duration of the SPC has already passed. One may imagine that the premature launch of the allegedly infringing products is precisely the result of a hope that it would not be possible to take efficient measures before the expiration of the SPC. It is relevant to note that, in addition to considerable financial damage, the presence of infringing generic products would cause Novartis truly irreparable damage due to the elements recalled above",

Considering that it is pertinent to stress that the text is set out so that the circumstances require that measures not be taken in *inter partes* proceedings, notably when any delay would be likely to cause irreparable damage to the appellant.

Considering that the request was presented on 27 October 2011 when the SPC was set to expire on 13 November 2011, that is to say 17 days later; that it claims that this short period of time made it impossible to obtain a decision rendered *inter partes* within this time period; that, in their latest pleading, Novartis felt it necessary to add that there were weekends and non-working days and school holidays;

Considering however that one might remind them that there exist preliminary proceedings with an emergency motion to be heard on very short notice that make it possible to respect due process in a short timeframe; that moreover, jurisdictions may grant urgent hearing dates on weekends or on holidays and that school holidays have no bearing on this possibility, much less in November when there are no court holidays; that the truth of the matter is demonstrated by the fact that immediately after the injunction order, the defendants immediately submitted to the Judge a petition, which was admitted, for an urgent hearing of their revocation request; that the Judge heard the parties on 29 October 2011 and rendered his judgment on 31 October 2011, exactly 14 days before the expiry of the SPC; that the *cour d'appel* notes that 29 October was a Saturday and that the day of deliberations was the eve of a public holiday;

Considering that it follows that these grounds are not serious and could not justify having recourse to *ex parte* proceedings.

Considering that the comment about the adversary's hope that it would not be able to resort to efficient measure before the expiry of the SPC is hypothetical;

Considering that Novartis cites irreparable damage; that the case is stated like a hypothesis which would allow for the possibility of having recourse to *ex parte* proceedings as long as this is stated after the adverb "notably"; that this does not signify that it is sufficient;

Considering that the irreparable damage that is cited is linked, according to Novartis, to their massive investments in the development of pharmaceutical products, a cost which the producer of generic drugs does not bear, that the establishment of generics leads to a loss of market share for them, that generic producers' sales benefit from an illegitimate springboard effect if they begin to sell before the expiry of a product's rights;

Considering that the investments made to discover the branded products were compensated by the protection extended by the patent and the SPC for several years; that the existence of generic products is favoured by public powers concerned with public health and that the damage resulting from marketing such products that necessarily leads to a loss of market share for Novartis is the result of this authorization and this marketing independently of whether the marketing is recognized to have been premature by 17 days; that moreover, this damage is not irreparable but rather can be resolved through the payment of damages;

Considering that the grounds cited in support of the request to authorize the non-respect of due process are insufficient; that they could not allow resorting to *ex parte* proceedings, while *inter partes* proceedings were essential, the issues at stake were important and the injunction measures that were sought entailed heavy consequences for the opposing parties;

Considering that it follows that the grounds presented to justify the exception to due process were not serious, the referred order that was to examine the grounds for justifying the exception to this principle could do no other than to revoke the request and that it must therefore be reversed concerning this head of claim;

Considering that fairness requires that the request of Sanofi and Zentiva be acceded to

pursuant to Article 700 of the French Code of Civil Procedure; that the respondent companies are jointly and severally condemned to pay the sum laid out in this decision;

Considering that, yielding, Novartis will not argue the existence of abusive proceedings nor claim the allocation of irrecoverable expenses and must bear the entire costs of the proceedings;

ON THESE GROUNDS

Reverses the appealed order;

Ruling again,

Revokes the *ex parte* order of 27 October 2011;

Rejects all of the requests of Novartis AG and Novartis Pharma;

Orders, jointly and severally, Novartis AG and Novartis Pharma to pay the sum of €60,000 to Sanofi-Aventis, Sanofi Winthrop Industrie and Zentiva KS pursuant to the provisions of Article 700 of the French Code of Civil Procedure;

Orders, jointly and severally, Novartis AG and Novartis Pharma to bear the entire costs of the proceedings which may be recovered pursuant to the provisions of Article 699 of the French Code of Civil Procedure.

THE COURT CLERK

THE PRESIDING JUDGE