

Court of Appeal

Brussels

Judgment

8<sup>th</sup> Chamber

Civil cases

Sandoz v. Sanofi

**SANDOZ**, having its registered offices in 2870 Puurs, Lichterveld 7,

Appellant,

Represented by Mr. Christian DEKONINCK, in his own name, and loco Mr. Kristof ROOX, lawyer, in 1000 Brussels, Joseph Stevensstraat 7;

Against

**SANOFI NV**, company under French law, having its registered in 75008 Paris-FRANCE, Rue de la Boétie 54,

Defendant,

Represented by Mr. Liesbeth WEYNANTS, lawyer in 1040 BRUSSELS, Nervierslaan 9-31.

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The appeal is lodged against a decision of 18 December 2012 of the president of the commercial court in Brussels.

This decision was notified to Sandoz NV on 28 May 2013 at the request of Sanofi SA.

The appeal was lodged with the registry of the court on 28 June 2013 in time. It is regular as to its form.

## **I. Facts and procedural precedents**

1. Sandoz NV is part of the Novartis group. Novartis is active in the area of pharmaceuticals, consumer health, OTC medicines (freely available without prescription) and generic medicines and is established in Basel, Switzerland.

The French Sanofi SA is a pharmaceutical company that is part of the Sanofi-Aventis group of companies and that sells its medicines in Belgium through its subsidiary Sanofi-Aventis Belgium.

2. Sanofi was the owner of the European Patent EP 0 454 511 (hereinafter "EP '511") that was applied for on 20 March 1991, indicating *inter alia* Belgium. This patent, which expired on 20 March 2011, was titled "N-substituted heterocycle derivatives, their preparation, and compositions containing them".

Based on the invention protected by this patent, Sanofi developed the medicine Aprovel®, with as only active substance irbesartan, which treats essential hypertension.

After being granted the marketing authorization for this medicine, Sanofi applied for a supplementary protective certificate ("SPC"). This application was filed based on EP '511 and the marketing authorization obtained for Aprovel®. An SPC was granted on 2 February 1999, with reference BE 98 C 0028 ("SPC'028"). The SPC '028 came into effect on 20 March 2011, after the expiry of EP '511, and was valid in Belgium until 15 August 2012.

Sanofi also developed the medicine CoAprovel®, consisting of irbesartan in combination with the hydrochlorothiazide (hereinafter "HCTZ"), also to treat essential hypertension.

After being granted a marketing authorization for its medicine based on irbesartan and HCTZ, Sanofi applied for an SPC for the combination of irbesartan and HCTZ. This application was filed based on EP '511 and the market authorization obtained for CoAprovel®. The SPC was granted on 5 October 1999, with reference BE 99 C 009 ("SPC'009"). The SPC '009 became valid on 20 March 2011, after the expiry of EP '511, and was valid in Belgium until 15 October 2013.

Based on this SPC, Sanofi claimed exclusive rights on all medicines that contain the combination of irbesartan and HCTZ, and this until 15 October 2013.

3. Sandoz was granted different marketing authorizations and reimbursement decisions for medicines with irbesartan as the only active substance and medicines that contain a combination of irbesartan and HCTZ.

Sandoz was put on notice on 4 May 2012 by (the Belgian legal counsel of) Sanofi not to launch the concerned medicines on the market.

This letter was followed by a non-confidential correspondence between the legal counsels of the parties, in which Sandoz confirmed that it would not commercialize medicines based *only on irbesartan* before 15 August 2012 (date on which the term of protection of the SPC for the mono-product irbesartan expired).

As to the combination irbesartan and HCTZ, the parties could however not come to an agreement, since Sandoz was of the opinion that the SPC '009 of Sanofi for this combination was invalid in light of the most recent case law of the Court of Justice.

4. Sanofi filed an *ex parte* request with the president of the commercial court in Brussels on 25 July 2012 to obtain a counterfeit seizure.

The applied for counterfeit seizure (including the seizure measures that also apply to "future stock" of the alleged infringing products) was granted by decision of 27 July 2012. Sanofi then continued the negotiations with Sandoz.

5. On 22 August 2012, Sanofi notified and enforced the decision of 27 July 2012. Not only Sandoz, but also several its distributors were involved.

## **II. The claims of the parties in first instance and the contested decision**

6. On 24 September 2012, Sandoz lodged third party opposition against this decision, *inter alia* because it was of the opinion that the validity of the right invoked by Sanofi was questionable.

Sanofi argued that the third part opposition of Sandoz was inadmissible, at least unfounded and asked the first instance judge to condemn Sandoz to the costs of the proceedings.

In the framework of the third party opposition, the first instance judge ruled that the invoked SPC was *prima facie* valid, that a patent or SPC "*even granted without pre-examination*" should be deemed *prima facie* valid as such, as long as it is not invalidated by a final decision. On 18 December 2012, Sandoz' third party opposition was rejected. Against this decision of 18 December 2012 Sandoz lodged the present appeal.

### **III. Facts that took place after the decision under appeal**

7. On 28 August 2012 (even before the court appointed expert had filed his report) Sanofi also initiated accelerated proceedings on the merits against Sandoz before the president of the commercial court of Brussels, in order to obtain final injunction measures.

By interim decision of 19 December 2012 these proceedings were suspended pending the decision of the Court of Justice concerning a preliminary question asked by the English High Court of Justice in the framework of English proceedings that also related to co-irbesartan.

Sanofi's claim for preliminary injunction measures based on Article 19 (2) Jud.C., pending a decision on the merits, was rejected in the same decision. The president was of the opinion that the validity of the SPC invoked by Sanofi was highly questionable.

8. By writ of summons of 12 February 2013 Sandoz claimed that the decisions of 27 July and 18 December 2012 would be revoked because of "changed circumstances" (Article 1369bis/1, §7, (2) Jud.C.). Sandoz referred in this regard to the interim decision of 19 December 2012 according to which the right invoked by Sanofi did not justify preliminary measures.

Sandoz was indeed of the opinion that the interim decision of 19 December 2012 constituted a "changed circumstance" within the meaning of Article 1369bis/1, §7, (2) Jud.C., justifying the amendment or revocation of the decisions of 27 July (*ex parte* grant of the counterfeit seizure) and 18 December 2012 (confirmation of the counterfeit seizure in the framework of the third party opposition).

According to Sandoz the conditions of Article 1369bis/1, §5 Jud.C. were no longer met. The actual seizure measures and the consequences thereof thus had to be lifted / revoked. More in particular the prohibition to part with the goods and every sealing of the medicines had to be undone immediately.

Sanofi concluded that the claim of Sandoz was unfounded and asked the president to condemn them to pay the legal fees.

9. The decision of 26 March 2013 was declared admissible but unfounded.

10. On 2 September 2013 Sandoz wrote the legal counsel of Sanofi asking him to confirm that Sanofi agreed with the release of the seized products at the moment of the expiry of the SPC of Sanofi, on 15 October 2013.

Sanofi replied that it did not object to this and that it would cooperate with all formalities that would be useful to release the products on 15 October 2013 (but not earlier).

On 4 October 2013, Sandoz contacted the bailiff with respect to the release, with the request to release the products either in the afternoon of 14 October 2013, or at midnight since its wholesalers were waiting to deliver the products to hospitals and pharmacies in the early morning of 15 October.

Sanofi agreed with a release in the night of 14 to 15 October, at midnight, and the bailiff thus released the goods.

#### **IV. The claims of the parties before court**

11. Sandoz requests the court:

- to join the (limited) appeal of Sandoz with its appeal against the decision of 26 March 2013 (2013/KR/156, claim of Sandoz to revoke the decision of 27 July 2013 due to changed circumstances);

- to declare the appeals admissible and well-founded and hence, to revoke the decisions under appeal of the president of the Brussels commercial court of 18 December 2012 (C/12/00162) and 26 March 2013 (C/13/00018);

- to decide on the third party opposition of Sandoz and declare it admissible and well-founded to the following extent:

- to decide that in the decision of the president of the Brussels commercial court of 27 July 2012 (RR/12/00522), which replaces the decision of 26 July 2012 (RR/12/00521) and which was notified to Sandoz on 22 August 2012, seizure measures under the payment of penalties were unjustly granted with regard to *“every future stock of Sandoz’ combination products based on irbesartan and HCTZ which NV SANDOZ would manufacture, import, market, commercialize, stock or use in Belgium”*;

- to decide that the decision must be revoked on that point;

- hence, to order that all seizure measures (including the imposed penalties) which relate to *“every future stock of Sandoz’ combination products based on irbesartan and HCTZ which NV SANDOZ would manufacture, import, market, commercialize, stock or use in Belgium”* and all accompanying advertising, must be immediately revoked under payment of a penalty of 10.000,00 Euro for each hour that there are consequences, as from from two hours after the notification of the order to revoke the seizure measures;

- in any case, to declare that all seizure measures are lifted as of 15 October 2013, the date on which the invoked SPC BE 99 C 009 expires;

- to condemn Sanofi to pay all costs of the counterfeit seizure as well as the third party opposition proceedings in first instance and in appeal, including the costs of the writ of summons and the legal costs which amount to 1.310 Euro.

12. Sanofi requests the court :

- to declare Sandoz’ claim inadmissible, at least unfounded and hence to reject it;

- to decide that the costs of the decisions under appeal remain with Sandoz;

- to condemn Sandoz to pay the costs of these proceedings, including the legal costs.

## **V. Legal assessment**

### V.1. The joinder of both cases

13. The court assesses discretionarily whether or not cases are related. The court decides in this case that there is no reason to join both proceedings in appeal.

The request of Sandoz is rejected.

### V.2. The standing and the capacity of Sandoz

14. The party who claims to be holder of a subjective right, has, even though this right is challenged, the standing and the capacity to file a claim. The examination on the existence or the scope of the invoked subjective right, therefore, does not concern the admissibility but the merits of the claim (see Cass. 26 February 2004 (C.01.402.N), *Arr. Cass.* 2004, 334, *Pas.* 2004, 335, *R.A.B.G.* 2004, 612 with note P. VANLERSBERGHE, *R.H.A.* 2004, 291, *J.T.* 2005, 437 with note and *R.W.* 2006-07, 133 (shorter version) ; Cass. 2 April 2004 (C.02.609.N), *Arr.Cass.* 2004, 597, *Pas.* 2004, 573, *Eur. Vervoerr.* 2004, 417 and *R.H.A.* 2005, 13 ; Cass. 28 September 2007 (C.06.180.F), *Arr. Cass.* 2007, 1798, *Pas.* 2007, 1658; Cass. 16 November 2007 (C.06.144.F), *Arr. Cass.* 2007, 2193, *Pas.* 2007, 2043 and *R.W.* 2009-10, 532; Cass. 4 February 2011 (C.09.420.N), *Arr.Cass.* 2011, 399, *Pas.* 2011, 427 and *R.W.* 2011-12, 370 with note J. VANROYE and Cass. 23 February 2012 (C.11.259.N), *Arr.Cass.* 2012, 457, *Pas.* 2012, 429 and *R.W.* 2012-13, 1106).

The standing mentioned in Article 17 Jud.C. can be described as every material or moral advantage that anyone, who files a claim or conducts a defense, can expect at the time of the legal action and which may change and improve his current legal position.

The Articles 17 and 18 Jud.C. do not require that a precise and material damage is proven. Standing can result from merely moral elements (Cass. 18 December 1980, *J.T.* 1981, 550) or from a potential damage (Cass. 29 February 1996, *Arr.Cass.* 1996, 210; K. Wagner, *Artikelsgewijze commentaar gerechtelijk recht*, Kluwer, 2002, 170; Cass. 1 March 1993, *Arr.Cass.* 1993, 238).

The concept of “prejudice” is wider than “damage”. Prejudice contains actual or possible material or moral damage, serious disadvantages, and more generally, any indirect, actual or possible negative influence on the legal position of the third party.

15. Sanofi contests that Sandoz, with respect to its claim, still has standing in the sense of Article 17 Jud.C., given that the intellectual property right on which Sanofi based its request for a counterfeit seizure, has expired and that the goods that were seized in the framework of the counterfeit seizure have been released.

According to Sanofi, Sandoz’ claim is therefore without relevance.

16. A request to revoke a decision granting a counterfeit seizure, is not inadmissible for lack of standing merely because the decision no longer has any consequences or because it was already enforced.

At the time of lodging the third party opposition on 24 September 2012, and also at the time of the lodging of the appeal against the decision of 18 December 2012, on 28 June 2013, Sandoz had the

standing required by Article 17 Jud.C. The annulment/revocation of the decisions of 18 December 2012 and 27 July 2012 would change and improve its legal position.

Moreover, Sandoz still has the necessary standing to obtain a decision on its claims notwithstanding the circumstances invoked by Sanofi (cfr. supra). The “revocation” of a counterfeit seizure could indeed, in certain circumstances, give rise to the application of Article 1369bis/3, §2 Jud.C.

V.3. The claims of Sandoz regarding the seizure measures which concern “every future stock of SANDOZ’ combination products based on irbesartan and HCTZ which NV SANDOZ would manufacture, import, market, commercialize, stock or use in Belgium”.

17. Sandoz requests the court to revoke the decision of 18 December 2012 under appeal to the extent that it confirms the injunctions granted by decision of 27 July 2012, regarding “*every future stock of Sandoz’ combination products based on irbesartan and HCTZ which NV SANDOZ would manufacture, import, market, commercialize, stock or use in Belgium*” and to revoke all measures relating to this future stock.

Sandoz correctly argues that, in the framework of a (unilateral) counterfeit seizure, no seizure measures can be granted concerning future stock or products which are not yet in the possession of the seized party at the time of the enforcement of the seizure.

Such a seizure only relates to products at a given moment in time, which cannot concern future products.

Some legal scholars argue correctly:

*“The legislator has limited the possible measures to a prohibition of the disposal, displacement or modification of the infringing goods, respectively of the elements that are used in the production or distribution hereof. Because of their nature, these measures only concern the objects that are, at the time of enforcement of the counterfeit seizure, [found to be] in the possession of the seized party. When enforcing that decision, the applicant must confine himself to the boundaries of the law, and the court appointed expert as well as the bailiff must control this. Hence, it is not possible to obtain injunctions for any other (whether or not infringing) practices, such as (in case of a patent infringement) a prohibition to manufacture, offer, market, use, import or keep in stock the infringing products, or the use or offering for sale of an infringing process through a counterfeit seizure. This can only be obtained within the frame of summary proceedings, injunction proceedings or proceedings on the merits.”*

(C. RONSE with cooperation of G. FROIDBISE, “Intellectuele rechten: beslag inzake namaak” in X, Bestendig Handboek Deskundigenonderzoek, Mechelen, Kluwer, VI.2-501).

Granting a measure such as the one against which Sandoz initiated third party opposition proceedings, is contrary to the text of Article 1369bis/1, §4 Jud.C. which only allows to grant an injunction to “*dispose of, displace or modify [certain goods] which affect their efficacy*”.

The measures mentioned in the act can, due to their nature (“dispose of”, “displace” or “modify”), only concern those goods that were already in possession of the seized party at the time of the seizure.

To argue that a possible injunction to “dispose” of the allegedly infringing goods also concerns every future stock of the allegedly infringing goods, which would be manufactured, imported, marketed,

commercialized, stocked or used in Belgium by the seized party, is an overly broad interpretation of Article 1369bis/1, §4 Jud.C., contrary to the intentions of the legislator.

The judge in first instance therefore has, in his decision of 18 December 2012 mistakenly confirmed the measure of 27 July 2012 which related to *“every future stock of Sandoz’ combination products on the basis of irbesartan and HCTZ which would be manufactured, imported, marketed, commercialized, stocked or used in Belgium”* by Sandoz NV and this under the payment of a penalty *“for each package that is found on the market, for each sample and carrier which contains advertisement documents that are relevant to the description of the infringement”*.

This measure goes far beyond the measures mentioned in the law (“dispose of”, “displace” or “modify”) and results in a general prohibition to commercialize the allegedly infringing goods in Belgium. By imposing penalties for each package *“found on the market”* which concern also the packages that, after enforcement of the counterfeit seizure, were manufactured, imported or commercialized, a general commercialization prohibition has been mistakenly granted.

The measures, determined by Article 1369bis/1, §4 Jud.C., which the legislator has limited to the possible measures prohibiting the disposal of, displacement or modification of the allegedly infringing goods, found at the time of enforcement of the seizure, cannot be extended to a general injunction, prohibiting the commercializing of even future stock.

18. Given the above, the measure which concerns *“every future stock of Sandoz’ combination products on the basis of irbesartan and HCTZ which would be manufactured, imported, marketed, commercialized, stocked or used in Belgium”*, while imposing penalties *“for each package that is found on the market, for each sample and carrier that contains advertisement documents that are relevant for the description of the infringement”* has been mistakenly confirmed by the judge in first instance in the decision under appeal of 18 December 2012.

The first instance judge mistakenly did not revoke the decision of 27 July 2012 to the extent that it has granted the aforementioned measure.

19. Sandoz requests the court to order that all seizure measures (including the penalties) which concern *“every future stock of Sandoz’ combination products on the basis of irbesartan and HCTZ which would be manufactured, imported, marketed, commercialized, stocked or used in Belgium”* and all accompanying advertising, must be revoked under payment of a penalty of 10.000,00 Euro for each hour there are any consequences, as from two hours after the notification of the order to lift the seizure measures.

This claim is no longer relevant, as Sanofi has (voluntarily) lifted on the night of 14 to 15 October 2013 all seizure measures mentioned above. As a consequence all seizure measures were revoked at that time.

#### V.4 Sandoz’ claim concerning all seizure measures

20. Sandoz requests the court to declare that all seizure measures are in any case lifted as from 15 October 2013, the date on which the SPC BE 99 C099 invoked by has expired.

To the extent that this claim extends or amends Sandoz’ original request, it is inadmissible, given that it does not meet the requirements of Article 807 Jud.C.



In any case, within the framework of a third party opposition against a counterfeit seizure, the court cannot take into account a fact that occurred (long) after 26/27 July 2012 (27 July 2012 being the date of the decision which has corrected the initial decision of 26 July 2012).

To rule whether the third party opposition against a counterfeit seizure is well-founded, the judge has to place himself at the moment on which the decision that granted the counterfeit seizure was pronounced.

Even if this claim of Sandoz would be admissible, it would for these reasons (within the framework of the third party opposition of Sandoz) be unfounded.

21. All other factual elements, arguments and means invoked by the parties are not relevant in the current case and in any case do not outweigh the above mentioned reasoning.

FOR THESE REASONS :

THE COURT, ruling after contradictory proceedings,

With regard to Article 24 of the law of 15 June 1935 on the use of language in judicial proceedings;

Declares the request to join the present proceedings with the appeal known under the court registry number 2014/KR/156 admissible, but not founded;

Declares the appeal of Sandoz NV admissible and well founded;

As a consequence:

Revokes the decision under appeal of 18 December 2012 to the following extent:

Declares the third party opposition of Sandoz NV admissible and well founded to the following extent:

Declares that the first instance judge has mistakenly granted seizure measures upon penalties relating to *“every future stock of Sandoz’ combination products on the basis of irbesartan and HCTZ which would be manufactured, imported, marketed, commercialized, stocked or used in Belgium”* in the decision of 27 July 2012 (RR/12/00522), which replaces the decision of 26 July 2012 (RR/12/00521) and which was notified to Sandoz on 22 August 2012,

Revokes the decision of 27 July 2012, which replaces the decision of 26 July 2012 (RR/12/00521), to the extent that it affirms the aforementioned;

Declares that the request of Sandoz NV to revoke all seizure measures (including the penalties) which relate to *“every future stock of Sandoz’ combination products on the basis of irbesartan and HCTZ which would be manufactured, imported, marketed, commercialized, stocked or used in Belgium”* and all accompanying advertising, under payment of a penalty of 10.000,00 Euro for each hour that there are consequences, as from two hours after the notification of the order to lift the seizure measures, has become irrelevant;

Declares the claim of Sandoz NV to order that all seizure measures are lifted as from 15 October 2013, the date on which the SPC BE 99 C 099 invoked by Sanofi has expired, is inadmissible;

Orders Sanofi SA to pay the costs of these third party opposition proceedings, in first instance as well as in appeal;

Establishes the costs as follows: for NV Sandoz at 320,11 Euro (writ summons and third party opposition) + 1.320 Euro (procedural indemnity third party opposition in first instance) + 160 Euro (application in appeal) + 1.320 (procedural indemnity appeals procedure).

**This was decided and pronounced at the public hearing of the 8<sup>th</sup> civil chamber of the Brussels court of appeal on 1 December 2014 where the following were present and seated:**

Els HERREGODTS,

Judge,

Kaatje BATSELIER

Registrar.

[signatures]