COMM. CH.B

COUR DE CASSATION
[French highest civil court]

Public hearing of 1st February 2023

Quashing

Mr VIGNEAU, President

Ruling No. 97 FP-D

Appeal in law No. M 21-13.664

FRENCH REPUBLIC

IN THE NAME OF THE FRENCH PEOPLE

RULING ISSUED BY THE *COUR DE CASSATION*, COMMERCIAL, FINANCIAL, AND ECONOMIC CHAMBER, OF 1ST FEBRUARY 2023

1°/ Ono Pharmaceutical co.Ltd, a company incorporated under the laws of Japan, with registered office at 8-2, Kyutaromachi 1-Chome, Chuo-Ku, Osaka 541-8564 (Japan), with an address for service in these proceedings at 1-5 Doshomachi 2 - Chome, Chuo-Ku, Osaka-Shi 541-8526 (Japan),

2°/ Mr X, residing at 19-4 Osagi-Cho Iwakura, Sakyo-Ku, Kyoto-Shi, Kyoto 606-0001 (Japan),

lodged appeal No. M 21-13.664 against judgment No. RG: 18/10540 handed down on 19 January 2021 by the *cour d'appel de Paris* [Paris Court of Appeal] (division 5, chamber 1) in the dispute between the appellants and the General Director of the *Institut national de la propriété industrielle* [French National Institute for Industrial Property] (INPI), with registered office at 15 rue des Minimes, CS 50001, 92400 Courbevoie, the respondent to quashing.

In support of their appeal, the appellants rely on the two arguments for quashing appended to this ruling.

The case file was sent to the Prosecutor General.

On the report of Ms Bessaud, Reporting Judge, on the observations of SCP Thomas-Raquin, Le Guerer, Bouniol-Brochier, lawyer for

Ono Pharmaceutical co. Ltd and Mr X, of SCP Marlange et de La Burgade, lawyer for the General Director of the *Institut national de la propriété industrielle*, and on the opinion of Mr Debacq, Advocate General, following which the President asked the lawyers if they wished to submit further observations, after discussion at the public hearing of 6 December 2022, in the presence of Mr Vigneau, President, Ms Bessaud, Reporting Judge Referee, Ms Darbois, Senior Judge of the Chamber, Ms Vaissette, Senior Judge of the Section, Mr Mollard, Senior Judge of the Section, Ms Vallansan, Ms Poillot-Peruzzetto, Ms Graff-Daudret, Ms Bélaval, Ms Champalaune, Ms Daubigney, Judges, Mr Guerlot, Ms Barbot, Judges Referees, Mr Debacq, Advocate General, and Ms Labat, Chamber Registrar,

the Commercial, Financial, and Economic Chamber of the *Cour de cassation*, composed, pursuant to Articles R. 421-4-1 and R. 431-5 of the French Judicial Organisation Code, of the aforementioned President and Judges, after having deliberated in accordance with the law, has issued this ruling.

Facts and procedure

1. According to the judgment under appeal (Paris, 19 January 2021, No. RG 18/10540), on 15 December 2015, Ono Pharmaceutical (Ono) and Mr X jointly filed an application for supplementary protection certificate (SPC) No. 15C0088 for nivolumab, on the basis of Regulation (EC) No. 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

2. This application was based on the European patent filed on 2 July 2003, published under No. EP 1 537 878 (patent EP 878) and granted on 22 September 2010, entitled “Immunopotentiating compositions”, of which Ono and Mr X are holders.

3. It also referred to a Community marketing authorisation (MA) granted on 19 June 2015 under No. EU/1/15/1014 to Bristol-Myers Squibb Pharma EEIG for a proprietary medicine named “Opdivo-Nivolumab” with nivolumab as the active ingredient.

4. By decision of 2 March 2018, the General Director of the *Institut national de la propriété industrielle* (INPI) denied the application for SPC No. 15C0088 on the basis of Article 3(a) [and (c)[TN]] of the aforementioned Regulation on the grounds that, first, Ono was already the holder of an SPC for the same product granted based on another patent and, second, the product, the subject-matter of this application, was not protected by patent EP 878.

[TN] The reference to Article 3(c) was omitted in the judgment.

5. Ono and Mr X lodged appeal against this decision.

Examination of the arguments

On the second part of the first argument appended hereto

6. Pursuant to Article 1014(2) of the French Civil Procedure Code, there is no need to rule by a specially reasoned decision on this argument, which is clearly not of a nature to lead to quashing.

And on the first and third parts of the first argument

Statement of the argument

7. Ono and Mr X criticise the judgment under appeal for dismissing their appeal against the decision handed down on 2 March 2018 by the INPI General Director denying SPC application No. 15C0088, whereas:

"1°/ under Article 6 of Regulation (EC) No. 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products, an SPC shall be granted to the holder of a basic patent or their successor in title; pursuant to Article 3(c) of Regulation (EC) No. 469/2009, in the light of Article 3(2), second sentence, of Regulation (EC) No. 1610/96 of 23 July 1996 concerning the creation of an SPC for plant protection products, an SPC may be granted to the holder of a basic patent for a product for which, at the time of filing of the application for a certificate, one or more certificates have been already granted to one or more holders of one or more other basic patents; if the regime of the undivided joint ownership in the French Civil Code is not applicable to the joint ownership of a patent, which can be used by each joint owner for their own benefit, subject to fairly compensating the other joint owners, the patent is nevertheless held by all joint owners in an undivided joint ownership and not by each joint owner taken individually; ruling in the present case that an SPC for nivolumab could not be granted to Ono and Mr X based on patent EP 878, of which they are joint owners since SPC 15C0087 for nivolumab had been already granted to Ono and Squibb & Sons LLC based on patent EP 336, of which both companies are joint owners, and that "Ono, which alone can use both patents EP 336 and EP 878, of which it is a joint owner under the conditions laid down in Article L. 613-29 of the French Intellectual Property Code, is the holder of these same patents within the meaning of Article 3(3) of the aforementioned Regulation No. 1610/96", while, regardless of the operating rules of the joint ownership of a patent, the latter remains nevertheless the undivided property of all joint owners, preventing any of them from alleging to be the holder individually as each joint owner is only the holder of a share of the patent,

the *cour d'appel* violated by misapplication Articles L. 613-29, L. 613-20 of the French Intellectual Property Code, Article 6 of Regulation (EC) No. 469/2009 of 6 May 2009, Article 3(c) of Regulation (EC) No. 469/2009 in the light of Article 3(2), second sentence, of Regulation (EC) No. 1610/96 of 23 July 1996;

3°/ an SPC shall be granted to the holder of a basic patent or their successor in title; the joint owner of a patent is not the holder thereof, but only of a share thereof; ruling nevertheless that an SPC might have been granted to Mr X alone based on patent EP 878, of which he is only a joint owner, the *cour d'appel* violated Article 6 of Regulation (EC) No. 469/2009 of 6 May 2009."

Court's response

8. It follows from Article 3(c) of Regulation (EC) No. 469/2009, which reiterates the provisions of Article 3(c) of Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, in the light of Article 3(2) of Regulation (EC) No. 1610/96 of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products, as interpreted by the Court of Justice of the European Union (CJEU), that more than one SPC may be granted for a same product based on different basic patents on the condition that these SPCs are granted to distinct holders of the basic patents to reward them for research they carried out separately and which led to patented innovations (CJEU, judgment of 3 September 2009, AHP Manufacturing, C-482/07, paragraph 25).

9. The regime of patent joint ownership is defined in Articles L. 613-29 to L.613-32 of the French Intellectual Property Code, Article L. 613-30 specifying that the ordinary law regime of the undivided joint ownership coming from the French Civil Code is not applicable to the joint ownership of a patent application or a patent.

10. The judgment under appeal points out that Ono, together with ER Squibb & Sons, were granted SPC No. 15C0087 for nivolumab based on patent EP 2 161 336 (patent EP 336) filed on 2 May 2006, of which they are joint owners, and rules that it precludes the grant of a second SPC to Ono for the same product based on patent EP 878, although it is joint owner of this other patent together with Mr X, who does not already have an SPC for nivolumab.

11. It considers that the circumstance that the undivided joint ownership between Ono and Squibb & Sons, the holders of patent EP 336, is different from that between Ono and Mr X, the holders of patent EP 878, is

irrelevant insofar as the rules of civil law on undivided joint ownership are not applicable. Lastly, it notes that Ono, which alone can use both patents EP 336 and EP 878, of which it is joint owner under the conditions laid down in Article L. 613-29 of the French Intellectual Property Code, is “holder” of these same patents under Article 3(2) of the aforementioned Regulation (EC) No. 1610/96 and that an SPC might have been granted to Mr X to reward him for his own investment expenditure without violating the provisions of Article 3(c) of Regulation (EC) No. 469/2009.

12. In this state and since the condition laid down in Article 3(c) of Regulation (EC) No. 469/2009 shall be assessed considering each joint owner of a patent on the basis of which an SPC is applied for for a same product and not the undivided joint ownership composed of the joint owners, which has no legal personality, the *cour d’appel* rightly denied the new SPC application submitted by Ono for the product for which it already had an SPC based on another basic patent.

13. The argument, which is based on a false premise, is therefore unfounded.

But on the third part of the second argument

Statement of the argument

14. Ono and Mr X criticise the judgment under appeal for the same, whereas “an action for annulment of a decision of the INPI General Director has no devolutive effect; the *cour d’appel*, before which such action is brought, should determine the case under the conditions existing at the time the disputed decision was handed down and cannot ground its judgment on new exhibits that had not been adduced or mentioned in the proceedings before the INPI General Director; relying, to determine the case as it did, on a paper entitled “*Introduction aux techniques utilisées en biochimie - Préparation des anticorps*” [Introduction to techniques used in biochemistry - Preparation of antibodies], adduced by the INPI General Director, while this exhibit had not been adduced in the proceedings before the latter nor referred to in the disputed decision, the *cour d’appel* violated Article L. 411-4 of the French Intellectual Property Code.”

Court’s response

Having regard to Article L. 411-4 of the French Intellectual Property Code, in the wording prior to Order No. 2019-1169 of 13 November 2019:

15. It follows from this text that the *cour d'appel*, before which an action for annulment of a decision of the INPI General Director was brought and which should determine the case under the conditions existing at the time that decision was handed down, cannot take account of the newly adduced exhibits.

16. To rule that the identification of nivolumab in the basic patent required an independent inventive step and to dismiss consequently the appeal lodged against the decision of the INPI General Director, who denied the grant of an SPC for this product, the *cour d'appel* relied in particular on a scientific paper adduced for the first time before it.

17. In so determining, the *cour d'appel* violated the aforementioned text.

And on the fourth part of the second argument

Statement of the argument

18. Ono and Mr X criticise the judgment under appeal for the same, whereas "a product is protected by a basic patent in force within the meaning of Article 3(a) of Regulation (EC) No. 469/2009, if it corresponds to a general functional definition used by one of the claims of the basic patent and necessarily comes within the scope of the invention covered by that patent, but is not otherwise indicated in individualised form as a specific embodiment of the method of that patent, provided that it is specifically identifiable, in the light of all the information disclosed by that patent, by a person skilled in the art, based on that person's general knowledge in the relevant field at the filing date or priority date of the basic patent and on the prior art at that date; conversely, a product cannot be considered as protected by the basic patent when it has been developed after the filing date of the patent application following an "independent inventive step"; however, a product requires such "independent inventive step" only if, at the filing or priority date of the basic patent, a person skilled in the art was not able to achieve this product by implementing the teachings of the patent based on their common general knowledge in the relevant field and on the state of the art at the same date; stating irrelevantly that, first, it allegedly emerges from a paper dated from the year 2007 that "the preparation of monoclonal antibodies requires a complex process for producing (by screening, isolating, cloning), seeding, most of the time *in vivo*, and selecting them, all these steps requiring technologies that are "very expensive in terms of equipment, reagents, time, and workforce" and, second, this analysis is allegedly supported by the fact that Ono, in partnership with ER Squibbs & Sons, needed three years to file patent EP 2 161 336 on nivolumab specifically, which allegedly constitutes "a strong indicator of the complexity of the research to be carried out and of

the need to demonstrate, starting from patent EP 878, an “independent inventive step” within the meaning of the Royalty Pharma case”, without examining, as it should, the wording of the description of the basic patent EP 1 537 878, which specified that the methods for manufacturing antibodies were “well-known” and described in detail the steps for producing an anti-PD-1 antibody and the screening method for identifying those inhibiting the PD-1 immunosuppressive signal, and which taught accordingly all necessary information for a person skilled in the art to achieve the antibodies covered by claim 1, including nivolumab, the *cour d’appel* deprived its judgment of a legal basis having regard to Article 3(a) of Regulation (EC) No. 469/2009 of 6 May 2009 concerning the supplementary protection certificate.”

Court’s response

Having regard to Article 3(a) of Regulation (EC) No. 469/2009 and Articles 69(1) and 83 of the European Patent Convention (EPC), signed in Munich on 5 October 1973:

19. According to the first of these texts, an SPC shall be granted if, in the Member State in which the application is submitted and at the date of that application, the product is protected by a basic patent in force.

20. Under the second one, the extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

21. Under the last one, the European patent application shall disclose in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

22. In the judgment of 30 April 2020, Royalty Pharma Collection Trust (C-650/17), the Court of Justice ruled that “Article 3(a) of Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that a product is protected by a basic patent in force, within the meaning of that provision, if it corresponds to a general functional definition used by one of the claims of the basic patent and necessarily comes within the scope of the invention covered by that patent, but is not otherwise indicated in individualised form as a specific embodiment of the method of that patent, provided that it is specifically identifiable, in the light of all the information disclosed by that patent, by a person skilled in the art, based on that person’s general knowledge in the relevant field at the filing date or

priority date of the basic patent and on the prior art at that date."

23. The Court of Justice specifies in that respect that, in order to ascertain whether a particular product is protected by a basic patent in force, within the meaning of Article 3(a) of Regulation No. 469/2009, it is necessary to ascertain, where that product is not expressly mentioned in the claims of that patent, whether that product is necessarily and specifically covered by one of those claims. To that end, two cumulative conditions must be satisfied. First, the product must, from the point of view of a person skilled in the art and in the light of the description and drawings of the basic patent, necessarily come under the invention covered by that patent. Second, the person skilled in the art must be able to identify that product specifically in the light of all the information disclosed by that patent, on the basis of the prior art at the filing date or priority date of the patent concerned (judgments of 25 July 2018, Teva UK and others, C-121/17, paragraph 52, and aforementioned Royalty Pharma Collection Trust, paragraph 37).

24. After having found that nivolumab was implicitly and necessarily covered by the patent in that it comes within the functional definition contained in the patent claims, the judgment under appeal notes that Ono, in partnership with another company, needed three years to file patent EP 336 on nivolumab specifically, the said patent mentioning seven inventors and comprising 25 claims specifying the antibody sequences that link to human PD-1, consisting of six hypervariable regions defining precisely the entire microstructure of nivolumab. It deduces therefrom that the time required to file this patent is a strong indicator of the complexity of the research to be carried out and of the need to demonstrate, starting from patent EP 878, an "independent inventive step" within the meaning of the Royalty Pharma Collection Trust case. It adds that evidence is not brought that nivolumab was specifically identifiable by a person skilled in the art from their knowledge and the state of the art at the filing date.

25. In so determining, without ascertaining, as it was invited thereto, first, whether the methods for manufacturing monoclonal antibodies were well known to the person skilled in the art at the filing date of the application for patent EP 878 and whether the latter described in the description how to screen the relevant antibodies to identify those that fulfil the function of the invention, namely those that inhibit "the PD-1 immunosuppressive signal", and, second, whether the person skilled in the art could accordingly, upon reading the patent and using their common general knowledge, achieve through routine operation all the antibodies fulfilling the function covered by the patent, including nivolumab, the *cour d'appel* did not provide its judgment with a legal basis.

26. In the absence of any reasonable doubt as to the interpretation of the European Union law on the questions raised by the argument, there is no need to refer to the Court of Justice for a preliminary ruling.

ON THESE GROUNDS, and without it being necessary to rule on the other arguments, the Court:

QUASHES AND SETS ASIDE, in all its provisions, the judgment handed down on 19 January 2021 (RG No. 18/10540) between the parties by the *cour d'appel de Paris*;

Returns the case and the parties to the status existing prior to the said judgment and refers them to the *cour d'appel de Paris* in a different composition;

Orders the Public Treasury to pay the costs;

Pursuant to Article 700 of the French Civil Procedure Code, dismisses the claims;

Thus decided by the *Cour de cassation*, Commercial, Financial, and Economic Chamber, and pronounced by the President at a public hearing on the first day of February in the year two thousand and twenty-three.