COMM. CH.B

COUR DE CASSATION
[French highest civil court]

Public hearing of **1st February 2023**

Quashing

Mr VIGNEAU, President

Ruling No. 96 FP-D

Appeal in law No. K 21-13.663

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) and 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. K 21-13.663 against judgment No. RG: 18/10522 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 single argument 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 18/10522), on 6 January 2016, Ono Pharmaceutical (Ono) and Mr X jointly filed an application for supplementary protection certificate (SPC) No. 16C0001 for pembrolizumab, 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 17 July 2015 under No. EU/1/15/1024 to Merck Sharp & Dohme (MSD) for a proprietary medicine named “Keytruda” with pembrolizumab 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. 16C0001 on the basis of Article 3(a) of the aforementioned Regulation on the grounds that the product, the subject-matter of this application, was not protected by patent EP 878.

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

Examination of the argument

On the third part of the argument

Statement of the argument

6. 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, 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 issued 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:

7. 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.

8. To rule that the identification of pembrolizumab 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.

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

And on the fourth part of the argument

Statement of the argument

10. 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 the said 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 MSD needed five years to file patent EP 2 170 959 on pembrolizumab 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 pembrolizumab, 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:

11. 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.

12. 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.

13. 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.

14. In the judgment of 30 April 2020, Royalty Pharma Collection Trust (C-650/17), the Court of Justice of the European Union 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.”

15. 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).

16. After having found that pembrolizumab was implicitly and necessarily covered by the patent in that it comes within the functional definition

of the product, the judgment under appeal notes that a third party needed five years to file a patent on pembrolizumab specifically, this patent mentioning three inventors and comprising 21 claims specifying the antibody sequences that link to human PD-1 and correspond to pembrolizumab. 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 pembrolizumab was specifically identifiable by a person skilled in the art from their knowledge and the state of the art at the filing date.

17. 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 pembrolizumab, the *cour d’appel* did not provide its judgment with a legal basis.

18. 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. 18/10522) 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;

States that at the request of the Prosecutor-General at the *Cour de cassation* this ruling is to be forwarded for transcription in the margin or after the quashed judgment;

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.