COMM. CH.B

COURT OF CASSATION
[French highest civil court]

Public hearing of **1st February 2023**

Dismissal

Mr VIGNEAU, President

Ruling No. 102 FP-D

Appeal in law No. C 21-17.773

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°/ Wyeth LLC, a limited liability company governed by the laws of Delaware, with registered office at 235 East, 42nd Street, New York, NY 10017 (United States),

2°/ The General Hospital Corporation, a non-profit organization governed by the laws of Massachusetts, with registered office at 55 Fruit Street, Boston MA 02114 (United States),

lodged appeal No. C 21-17.773 against the judgment handed down on 9 February 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, 92677 Courbevoie cedex, 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 Wyeth LLC and The General Hospital Corporation, and on the opinion of Mr Douvreleur, 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 Douvreleur, 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, 9 February 2021), Wyeth LLC (Wyeth) develops cancer drugs. The General Hospital Corporation (GHC) is a non-profit organization responsible for the management of a US teaching hospital, Massachussets General Hospital, specialised in research and in particular in the field of cancer treatment.

2. On 26 July 2016, Wyeth and GHC jointly filed the application for supplementary protection certificate (SPC) No. 16C1004 for osimertinib on the basis of Regulation (EC) No. 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

3. This application was based on European patent EP 1 848 414 (patent EP 414) entitled “Method for treating gefitinib resistant cancer”, filed on 2 February 2006 and granted on 4 April 2011, claiming priority from two US patents, US 649483 of 3 February 2005 and US 671,989 of 15 May 2005. It referred to a marketing authorisation (MA) in France granted to Astrazeneca on 2 February 2016 under No. EU/1/16/1086 for the proprietary medicine “Tagrisso” with osimertinib as the active ingredient, which active ingredient was the subject-matter of patent No. EP 2736895 filed on 25 July 2012 by Astrazeneca.

4. By decision of 1st August 2019, the General Director of the *Institut national de la propriété industrielle* (INPI) denied this SPC application.

5. Wyeth and GHC lodged appeal against this decision.

Examination of the arguments

On the first argument and the second, third, fourth, fifth, and seventh parts of the second 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 these arguments, which are clearly not of a nature to lead to quashing.

On the sixth part of the second argument

Statement of the argument

7. Wyeth and GHC criticise the judgment under appeal for dismissing their appeal against the decision handed down on 1st August 2019 by the INPI General Director, whereas "while it pointed out that the basic patent EP 414 indisputably contributed to the research on EGFR [epidermal growth factor receptor] inhibitor and this basic patent is mentioned in the patents relating to osimertinib filed by Astrazeneca, the *cour d'appel* ruled that the evidence provided by the appellants does not establish that the osimertinib active ingredient is not the fruit of an independent inventive step since fifteen other patents are also mentioned as prior art references in Astrazeneca's patents; admittedly, the 2008 Avizienyte publication mentions the 2005 Kwak study, but it further mentions thirty-one other references in its bibliography; "the same finding should be made regarding the other publications put forward by the appellants (Cumming of 2014 and Heydt of 2018)"; in so ruling on grounds that failed to establish that osimertinib was developed after the filing of the basic patent application following an independent inventive step, the *cour d'appel* violated Article 3(a) of Regulation (EC) No. 469/2009 of 6 May 2009 concerning the supplementary protection certificate."

Court's response

8. In the judgment of 30 April 2020 (Royalty Pharma Collection Trust, C-650/17), the Court of Justice of the European Union, interpreting Article 3(a) of Regulation (EC) No. 469/2009 of 6 May 2009 ruled "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."

9. It specified that "*a product can be regarded as being protected by a basic patent in force, within the meaning of Article 3(a) of Regulation No 469/2009, only if, from the point of view of 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 that patent, and on the basis of the prior art at that date, that product is specifically identifiable in the light of all the information disclosed by that patent*", which "*is not the case for a product which was developed after the filing date or priority date of the basic patent, following an independent inventive step*" (paragraphs 48 and 49).

10. In this same judgment, it also ruled that "*a product is not protected by a basic patent in force, within the meaning of that provision, if, although it is covered by the functional definition given in the claims of that patent, it was developed after the filing date of the application for the basic patent, following an independent inventive step*" [paragraph 50].

11. The judgment under appeal, after having retained that osimertinib corresponds to the general functional definition used by claim 23 of patent EP 414 and necessarily comes within the scope of the invention covered by that patent, considered nevertheless that this product was unknown to the person skilled in the art at the filing date of the patent and the latter could not deduce it directly and unambiguously from the said patent, making it clear that osimertinib was not specifically identifiable by the person skilled in the art based on their common general knowledge in the relevant field and on the state of the art at the filing or priority date of the patent.

12. On these grounds, from which it is clear that osimertinib does not come within the extent of the protection conferred by the asserted patent, the *cour d'appel* legally justified its decision on this head.

13. The argument, which criticises extra grounds, is therefore inoperative.

And on the first part of the second argument

Statement of the argument

14. Wyeth and GHC criticise the judgment under appeal for the same, whereas "claim 23 of the basic patent EP 1 848 414 covers a "pharmaceutical

composition for use in treating cancer in a subject with a cancer having a mutation in EGFR (SEQ ID NO: 1), wherein the mutation is substitution of a methionine for a threonine at position 790; and wherein the pharmaceutical composition comprises an irreversible EGFR inhibitor"; according to paragraph 31 of the description of this patent, EGFR inhibitors "covalently crosslink the receptor" and have therefore a covalent bond with the targeted protein; accordingly, claim 23 of the basic patent covers the combination of a functional element (namely the irreversible EGFR inhibitor) with a structural element (namely the covalent bond between the irreversible EGFR inhibitor and the EGFR target protein); stating that the appellants failed to show that claim 23 was the combination of a functional element with a structural element for specifically targeting osimertinib, on the grounds that the presence of a Michaël acceptor is only mentioned in a 2012 "Carmi" publication and the Michaël acceptor is only a small part of the osimertinib molecule, without investigating whether the structural element of this claim lies in the existence of a covalent bond between the irreversible EGFR inhibitor and the EGFR target protein, the *cour d'appel* deprived its judgment of a legal basis having regard to Article 69 of the European Patent Convention of 5 October 1973, together with Article 3(a) of Regulation (EC) No. 469/2009 of 6 May 2009 concerning the supplementary protection certificate."

Court's response

15. The judgment under appeal rules that, if it is acknowledged that the common feature of irreversible EGFR inhibitors is that they comprise a Michaël acceptor in their molecule, such feature comes from neither the description nor the claims of the patent, but from a publication dated from June 2012, posterior to the patent application filed on 2 February 2006 and granted on 4 April 2011.

16. The *cour d'appel*, which had not to make investigation that its findings rendered inoperative, legally justified its decision.

ON THESE GROUNDS, the Court:

DISMISSES the appeal;

Orders Wyeth LLC and The General Hospital Corporation to pay the costs;

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

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.