Repertoriumnummer

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23 DEC. 2024

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A/24/02113

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M1

Dutch-speaking business court Brussels

Judgment

Offered on

Not to be registered

President, hearing the case as in summary proceedings

In the case of:

1.

Company incorporated under US law Amgen Inc., having its registered office in the United States of America, One Amgen Center Drive, 91320-1799 Thousand Oaks, CA,

Company incorporated under US law Amgen Fremont Inc, having its registered office in the United States of America, One Amgen Center Drive, 91320-1799, Thousand Oaks, CA,

Plaintiff,
hereinafter together "Amgen",

whose lawyers are Christophe Ronse, Kirian Claeyé and Julie Peeters, with offices at 1000 Brussels, Havenlaan 86C, box 414 (e-mails: christophe.ronse@altius.com, kirian.claeye@altius.com and julie.peeters@altius.com).

Against:

Samsung Bioepis NL BV, having its registered office in the Netherlands, NL-2616 LR Delft, Olaf Palmestraat 10, kvk no. 71719652

Defendant,
hereinafter "SB",

whose lawyers are Kristof Roox, Jurgen Figys and Christopher Dumont, with offices at 1000 Brussels, rue Joseph Stevensstraat 7 (e-mails: kroox@crowell.com, jfigys@crowell.com and cdumont@crowell.com).

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1. PROCEDURE

1. The President noted among other things:

- The writ of summons dated 17 May 2024;
- Amgen's summary submissions of 12 September 2024 (59 pages);
- SB summary submissions of 26 September 2024 (87 pages);
- The exhibits filed by the parties;

At the public hearing on 3 October 2024, the President heard the counsel of the parties. Afterwards, she closed the debates and took the matter in consideration. This judgment is rendered after having heard both parties. The proceedings were conducted in Dutch in accordance with the Act of 15 June 1935 on the use of languages in judicial matters.

2. FACTS

2.1 Parties

2. Claimants Amgen Inc. and Amgen Fremont Inc. (hereinafter collectively "Claimants" or “Amgen") belong to the Amgen group of companies controlled by Amgen, which develops and manufactures, among other things, biologics and biosimilar medicines [1] (Amgen's Exhibit 1.1).

3. SB is the Dutch subsidiary of the Korean biotechnology company Samsung Bioepis Co, Ltd, which is part of the Samsung Group (piece 1.2 of Amgen). SB is a biopharmaceutical company that develops and manufactures biosimilar drugs.

2.2 SPC039 and EP016

4. Amgen has denosumab, a human monoclonal antibody. Denosumab is the active ingredient in Prolia® and XGEVA® (hereinafter “Prolia" and "Xgeva") marketed by Amgen NV, a subsidiary of the Amgen Group, in Belgium.

Both denosumab and the processes used to manufacture this active ingredient are protected by a portfolio of patents owned by Amgen or its affiliates.

5. Claimants are co-holders of the supplementary protection certificate (hereinafter "SPC") with No 2010C/039 obtained on 7 June 2016 (hereinafter "SPC039", Amgen's Exhibit 11.3 and SB's Exhibit 1.1) that provides an additional protection period for medicinal products containing denosumab as an active substance. Initially, SPC039 was to expire on 28 May 2025, but due to an additional paediatric extension, if the paediatric extension is granted and the annual fees are paid on time, this SPC will expire on 28 November 2025. SPC039 protects the active ingredient denosumab for use until that date.

[1] I.e. a biological medicine that is an original biological medicine (the reference medicine) and whose functioning and safety are the same.

6. SPC039 is based on European patent EP1 409 016 (hereinafter "the Basic Patent" or EP016") entitled "antibodies for OPLG" which was granted on 14 April 2010 and expired on 25 June 2022 (Amgen's Exhibits 11.1 and 11.6 and SB's Exhibit 1.2).

7. Amgen also holds the corresponding patents in third countries protecting the active ingredient denosumab, including in particular patent No. 7,364,736 (hereinafter US 736") in the United States America and the corresponding patent in South Korea No. KR10-1038585 (hereinafter "KR585"). Amgen also holds several patents in various countries protecting the manufacturing process of biological molecules, including denosumab in particular.

8. Prolia is authorised in the EU as a biological medicinal product by European Commission decision(s) No EU/1/10/618. Xgeva was authorised by European Commission decision(s) No EU/1/11/703.

2.3 The dispute between the parties: SB's notification of 13 March 2024

9. SB intends to manufacture its biosimilar denosumab medicinal product under the SPC manufacturing waiver under the SPC Manufacturing Waiver Regulation No 2019/933 of the European Parliament and of the Council 20 May 2019 amending Regulation (EC) No 469/2009 as regards the SPC for medicinal products (hereinafter "the SPC Manufacturing Waiver Regulation" and "the SPC Regulation", respectively) during the protection period of SPC039, with a view to exporting it from the EU.

10. According to Amgen, SB has not as yet complied with the requirements and obligations to lawfully rely on the SPC manufacturing waiver and Amgen is at risk of serious damage due to the imminent, if not existing, infringement of SPC039 and the concomitant violation of fair commercial practices in relation to the (threat of) infringement of KR585 in South Korea and US736 in the US in particular.

11. By letter dated 13 March 2024, SB notified the Belgian Intellectual Property Office (hereinafter "BIPO") of its intention to proceed with the manufacture of products containing denosumab in Belgium (and with related acts in the Netherlands) and to export them to third countries in accordance with Article 5(2)(b) SPC Regulation (Exhibit V.1 of Amgen and Exhibits 11.1, 11.2 and III.1 of SB).

    SB used the standard form of Annex 1a of the SPC Regulation for this purpose, on which it stated that the manufacture was for export purposes and that the information regarding the reference number of the MA or the equivalent of such licence in each exporting third country "*will be provided as soon as it is publicly available, in accordance with Article 5(5)(e) of Regulation (EC) No 469/2009 (as amended)*" (Amgen's Exhibit V.1 and SB's Exhibit 11.1).

12. The same day, SB also informed Amgen regarding this notification (SB's Exhibit III.1).

13. By letter dated 29 March 2024, Amgen's counsel informed SB's counsel that Amgen considered the notification dated 13 March 2024 incomplete under Article 5(2)(b) of the SPC Regulation due to the lack of a reference number or equivalent or lack of identification of a third country of export. Amgen requested SB to complete the notification and to refrain from any manufacture until three months after such completed notification (Amgen's

Exhibit V.2 and SB's Exhibit III.2).

14. By letter dated 11 April 2024, SB, through its counsel, replied that it was not inclined to the same position as Amgen, that it believed that the notification was complete (given that Article 5(5)(e) of the SPC Regulation provides that the reference number should be communicated "*as soon as it publicly available*") and was therefore valid and effective as of that date (Amgen's Exhibit V.3 and SB's Exhibit III.3).

15. On 17 May 2024, Amgen sued SB before the President of the Dutch-speaking Business Court of Brussels, hearing the case in summary proceedings, to obtain a cease and desist order.

16. By letter dated 28 May 2024, Amgen's counsel requested SB to refrain from direct or indirect infringements of SPC039, with in particular the manufacture and export of products containing denosumab as an active ingredient to any country where the counterpart of EP016 has not expired (Amgen's Exhibit V.4).

17. By letter dated 4 June 2024, SB's counsel reiterated SB's initial position and disputed Amgen's claims (Exhibits V.4 and V.5 of Amgen and Exhibits III.4 and III.5 of SB).

18. On 12 June 2024, Amgen filed a petition pursuant to Article 19, paragraph 3 of the Judicial Code to obtain interim measures. With regard to these interim measures, the parties reached an agreement to suspend consideration of those measures.

19. Amgen explains that it has taken legal action in third countries (such as South Korea and the United States) to protect its IP rights.

2.4 Amgen's accusations to SB

20. According to Amgen, SB's attitude regarding the progress and launch of the biosimilar drug SB16 is ambiguous, SB is withholding information and this is especially so in light of SB's alleged collaboration with Catalent Belgium NV.

In essence, Amgen's allegations can be summarised as follows:

- First, Amgen accuses SB of not falling under the manufacturing waiver given that:
  - The 13 March 2024 notification does not mention the reference number of the MA in the countries to which SB wants to export;
  - The 13 March 2024 notification does not mention the third countries for export;
  - In the export countries targeted by SB, Amgen's patent rights would apply;
- Second, Amgen argues that SB is guilty of unfair commercial practices.

SB disputes these allegations by Amgen and argues that it can legitimately rely on the manufacturing waiver for export, it therefore does not infringe Amgen's SPC039 and that the manufacturing does not constitute an act contrary to fair commercial practices. In subsidiary order, SB requests that the cease and desist order would be limited to when SB communicates the information about the third country of export and to the extent that

there are alleged unfair commercial practices, that the periodic penalty payments claimed by Amgen would be reduced.

3. CLAIMS

21. The operative part of Amgen's summary submissions reads as follows:

"*Declare Plaintiffs' claim admissible and well-founded and, accordingly:*

- *Declare that the Defendant, by manufacturing, having manufactured, offering, marketing or using, or stocking or importing for that purpose, medicinal products containing denosumab as an active ingredient, infringes the Supplementary Protection Certificate No. 2010C/ O39;*
- *Order the defendant to refrain from any direct or indirect infringement of the Supplementary Protection Certificate No. 2010C/O39, in particular by manufacturing, having manufactured, offering, placing on the market or using such products, or stocking or importing such products for that purpose, under penalty of a fine of EUR 10,000 per infringing product and EUR 100,000 per day of infringement after service of the intervening judgment;*
- *Order that the above prohibition be dropped as far as the manufacture (i.e., the manufacture or performance of related operations strictly necessary for such manufacture) of products containing denosumab is concerned:*
  (a) three months after Samsung's notification of the exporting country to the Belgian Intellectual Property Office and to Plaintiffs and their Belgian counsel, for the purpose of exportation to that country and related acts strictly necessary for such exportation, or for the actual exportation of such products to that country, provided that Amgen lnc. or its affiliates cannot claim market exclusivity in that country by virtue of their intellectual property rights;
  (b) six months before the expiration of the said supplementary protection certificate, for the purpose of stocking such products in Belgium or any related act strictly necessary for the actual stocking, in order to market such products in the Member States of the European Union after the expiration of such certificate;
  (c) upon the expiration of said supplementary protection certificate, with respect to all other infringing acts;

Moreover:
- *Find that the manufacture for and export to the United States of America of products containing denosumab constitute acts contrary to fair market practices so long as Amgen lnc. can claim market exclusivity for such products based on U.S. Patent 7,364,736;*
- *Order the defendant to cease and desist from such acts, under penalty of a fine of EUR 10,000 per infringing product and EUR 100,000 per day of infringement after service of the intervening judgment;*
- *Order that the above order shall lapse in the event of a res judicata declaration of invalidity by a competent U.S. court, or upon the expiration of U.S. Patent 7,364,736;*

- *Acting on Plaintiffs' reservation to extend the claim to other U.S. patents held by them and allegedly infringed, and generally with respect to exports to other third countries where they hold enforceable intellectual property rights;*
- *Order the defendant to pay court costs, including court fees, provisionally assessed at the base amount of EUR 1,800.*"

22. The operative part of SB's summary submissions reads as follows:

"In the main order, declare Amgen's claim admissible but unfounded, as Samsung Bioepis' manufacture - given proper notification under Article 5(2)(b) of the SPC Regulation - cannot infringe SPC 039;

Accordingly, manufacture under the SPC Manufacturing Waiver Regulation also cannot constitute an act contrary to fair market practices, and Amgen's claim should be dismissed as unfounded in this regard as well;

In any event, Amgen's reservation to extend its claim to any other US patents (in addition to the identified US patent 7,364,736) of which it holds should also be rejected, as Samsung Bioepis cannot be expected to take into account (or be required to take into account) foreign patents that even Amgen cannot identify today;

Subordinate, to the extent Amgen's claim is found to have some merit,

- *limit the injunction to when Samsung Bioepis communicates the information about the third country of export*

- *Dismiss the penalty payments claimed by Amgen, at least substantially reduce to*

    - *EUR 500 per infringing product and*
    - *EUR 1,000 per day that a breach occurs after service of the intervening judgment,*
    - *with a maximum amount to be forfeited capped at EUR 50,000;*

and this for both Amgen's claim based on the alleged infringement of SPC 039 and its claim based on the alleged violation of fair market practices.

In any event, order Amgen to pay the costs of the proceedings, including court fees, provisionally estimated at the basic amount of EUR 1,800."

4. ASSESSMENT

4.1 Claims

23. Amgen argues that SB is wrong to claim the benefit of the manufacturing waiver for export because it does not comply with the notification requirement as provided under Art. 5 of the SPC Regulation and that consequently, by manufacturing (or performing related acts in respect of) SB's biosimilar medicines containing the active ingredient denosumab (hereinafter "Biosimilar Medicines") in South Korea, importing these medicines to Belgium for further processing and then exporting these Biosimilar Medicines to countries not yet disclosed by SB, is an infringement of SPC039.

    Accordingly, Amgen requests the President hearing this case in summary proceedings imposes a cease and desist order on SB to prevent the damage it would suffer as a result of Amgen's alleged infringement of SPC039 and the concomitant violation of fair commercial practices in connection with (the threat of) infringement of KR585 in South Korea and US736 in the United States of America in particular.

24. According to SB, its activities fall under the exception to protection under SPC039, specifically the manufacturing waiver for export. SB concludes that Amgen's claim is unfounded.

25. Between the parties, the validity of Amgen's patent or SPC is not in dispute. However, the parties disagree on whether SB, with its notification of 13 March 2024, made a formal notification that meets the conditions as stipulated under the SPC Regulation (introduced by the SPC Manufacturing Waiver Regulation) and thus falls (or not) under the manufacturing waiver.

    The parties rely on a different interpretation of the manufacturing waiver provisions of the SPC Regulation, as introduced by the SPC Manufacturing Waiver Regulation.

4.2 Jurisdiction

26. The President of the Dutch-speaking Enterprise Court of Brussels has, pursuant to art. XVII.14, §2 of the Code of Economic Law, art. XI.337 of the Code of Economic Law and art. 633quinquies §4 of the Judicial Code, material and territorial jurisdiction to hear this case.

4.3 Assessment

4.3.1 Whether or not SB's reliance on the manufacturing waiver for export is valid

27. Admissibility

    SB raises no plea of inadmissibility on Amgen's claim insofar as it relies on the interpretation of Article 5 of the SPC Regulation as amended by the SPC Manufacturing Waiver Regulation. Nor did the President identify any ground of

inadmissibility for her to raise *ex officio*. This part of Amgen's claim is therefore admissible.

28. First plea: the notification obligation (application of Article 5(2) SPC Regulation)

Supplementary protection certificates ("SPCs") extend patent protection for a product or drug within the limits of the protection granted by the basic patent. The system of SPCs was introduced to compensate for the time lost by patent holders in marketing medicinal products for which patent protection was also sought.

The SPC legislation attempts to balance the competing interests of companies pursuing research and development into new drugs, on the one hand, and companies developing generic and biosimilar drugs, on the other.

The SPC Manufacturing Waiver Regulation has created additional exceptions to the rights of SPC holders because it was noted that markets have undergone significant development and there has been tremendous growth in the manufacture of generic and biosimilar medicines, especially in countries outside the Union (third countries) where there is no protection or it has lapsed. The SPC Manufacturing Waiver Regulation seeks, inter alia, to accommodate the situation whereby Union-based manufacturers of generic and biosimilar medicines (characterised by complex manufacturing processes and lengthy authorisation periods) were prevented from manufacturing these generic and biosimilar medicines in the Union, even when intended for export to third-country markets where there is no protection or it has lapsed, and to promote the competitiveness of manufacturers within the Union, but taking into account the rights of certificate holders.

Accordingly, Article 5(2) of the SPC Regulation (as amended by the SPC Manufacturing Waiver Regulation) provides an exception to the protection of the SPC if the following conditions are met :

> "*2. By way of derogation from paragraph 1, the certificate referred to in paragraph 1 shall not confer protection against certain acts which would otherwise require the consent of the holder of the certificate ("the certificate holder"), if the following conditions are met:*
>
> *(a) the acts comprise:*
>
> > *(i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; or*
> > *(ii) any related act that is strictly necessary for the making, in the Union, referred to in point (i), or for the actual export; or*
> > *(iii) the making, no earlier than six months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate; or*
> > *(iv) any related act that is strictly necessary for the making, in the Union,*

referred to in point (iii), or for the actual storing, provided that such related act is carried out no earlier than six months before the expiry of the certificate.

(b) the maker, through appropriate and documented means, notifies the authority referred to in Article 9(1) in the Member State in which that making is to take place, and informs the certificate holder, of the information listed in paragraph 5 of this Article no later than three months before the start date of the making in that Member State, or no later than three months before the first related act, prior to that making, that would otherwise be prohibited by the protection conferred by a certificate, whichever is the earlier;

(c) if the information listed in paragraph 5 of this Article changes, the maker notifies the authority referred to in Article 9(1) and informs the certificate holder, before those changes take effect;

(d) in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex -I, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging;

(e) the maker complies with paragraph 9 of this Article and, if applicable, with Article 12(2).”

Art. 5(4) of the SPC Regulation (as amended by the SPC Manufacturing Waiver Regulation) states:

“*The information provided to the certificate holder for the purposes of points (b) and (c) of paragraph 2 shall be used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance*.”

Art. 5(5) of the SPC Regulation (as amended by the SPC Manufacturing Waiver Regulation) further stipulates what information must be :

“5. *The information to be provided by the maker for the purposes of point (b) of paragraph 2 shall be as follows:*

(a) the name and address of the maker;

(b) an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;

(c) the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place;

(d) the number of the certificate granted in the Member State of making, and the

number of the certificate granted in the Member State of the first related act, if any, prior to that making; and

(e) for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available."

Art. 5(7) of the SPC Regulation (as amended by the SPC Manufacturing Waiver Regulation) states:

"*Failure to comply with the requirements of point (e) of paragraph 5 with regard to a third country shall only affect exports to that country, and those exports shall, therefore, not benefit from the exception.*"

The crux of the dispute between the parties concerns whether, in the specific circumstances, SB can validly rely on the manufacturing waiver of Article 5(2) SPC Regulation (as amended by the SPC Manufacturing Waiver Regulation) and whether its notification of 13 March 2024 meets the requirements of notifications:

- According to Amgen, SB cannot rely on the manufacturing waiver because SB did not mention in its notification the reference number of the MA nor the countries of export (i.e. information as presupposed under Article 5(5)(e) of the SPC Regulation) and the three-month period only starts after SB has complied with these presupposed notification requirements;
- According to SB, it can indeed rely on the manufacturing waiver and did fulfil the conditions of the notification. In particular, it refers to the statement "*the reference number of the MA or of the equivalent of such a licence in any exporting third country, as soon as it is publicly available.*"

Both parties hold a different interpretation and interpretation of Article 5 of the SPC Regulation.

According to the case-law of the Court of Justice, when interpreting provisions of EU law, account must be taken of the wording of the provision, its context and the objectives of the legislation of which it forms part. The genesis of the provision, which is gaining importance[2], can also be relevant information for interpretation.

The President, hearing this case in summary proceedings, notes that:

- The wording of Article 5 of the SPC Regulation is clear regarding the information to be provided (i.e. the list under Article 5(5a) to (e) of the SPC Regulation) and that SB, through its notification of 13 March 2024, provided the information listed under Articles 5(5)(a) to (e) of the SPC Regulation:

[2] See, inter alia, CJEU 19 December 2019, C-263/7-18, no 38; K. LENAERTS and J.A. GUTIERREZ-FONS, " To say what the Law of the EU is: Methods of interpretation and the European Court of ", Academy of European Law 2013/9, European Institute Working Papers.

- It does not follow from the provision that when the manufacturer makes the notification provided for in Art 5(2) of the SPC Regulation as amended by the SPC Manufacturing Waiver Regulation, it must already have the marketing authorisations in the exporting countries (or the equivalent of such licence) in order to obtain a valid waiver. According to the text of the provision, the manufacturer must provide the reference number of the marketing authorisation *"as soon as it is publicly available";*

- It does not follow from the provision either that (in the absence of a reference number), the exporting countries should be mentioned in the notification. This is also confirmed by the genesis of the provision, which shows that the European legislator, in striking a balance between the interests of the SPC holder, on the one hand, and the manufacturer of the biosimilar medicinal product, on the other hand, deliberately chose the wording of Article 5 as it is currently before us (omitting the indication of third countries to which the export is planned, as this potentially adversely affect competition and to avoid having to provide confidential, business-sensitive information before it is public and not with a view to simplifying the notification procedure) (Exhibits IV.1 to IV.8 of SB);

- This (restrictive) reading is also confirmed by:

  (i) The objective of the SPC Manufacturing Waiver Regulation to allow EU-based manufacturers to compete fairly with non-EU-based manufacturers who can also start manufacturing biosimilar medicines before a marketing authorisation is granted and to guarantee a timely access of generic and biosimilar medicines to the Union market, in particular to ensure ore competition, lower prices and both the sustainability of national health care systems and better access to affordable medicines for patients in the Union;
  (ii) The genesis of the provision as preempted by the SPC Manufacturing Waiver Regulation (Exhibits IV.1 to IV.8 of SB);
  (iii) The possibility of supplementing/updating the standard notification form (Exhibit VI.2 of SB) that provides a box "*update an existing notification*" and the lack of a framework on the standard notification form for indicating to which third countries the export is planned;

- The recitals of the Regulation(s) may also serve as an interpretative element, which may shed light on the objective and/or will of the legislator. In this context, based on the recitals of the SPC Regulation and of the SPC Waiver Manufacturing Regulation, the President notes that the aim was to strike a balance between*, on the one hand,* the protection of IP rights to encourage research, investment and innovation and to provide effective protection by granting a sufficiently long period of effective patent protection (e.g. recitals 3, 4, 5 and 9 of the SPC Regulation and 2, 12, 13 of the SPC Waiver

Manufacturing Regulation) and*, on the other hand,* public health interests and need for a level playing field between Union-based manufacturers and third-country manufacturers to promote Union competitiveness and to protect the viability of Union-based generic and biosimilar drug manufacturers (inter alia, recitals 10 of the SPC Regulation and 3, 4, 5, 6, 7, 8, 29 of the SPC Waiver Manufacturing Regulation). While the President notes that a balance is sought between the competitive position of the manufacturers within the Union and the exclusive rights of certificate holders, it should be noted that recitals have no binding force and, contrary to what Amgen tries to imply, cannot be invoked to deviate from the provision(s) or interpret them in a sense that is manifestly contrary to their wording.[3] It follows that the President cannot conclude from the considerations raised by Amgen that the non-disclosure of the reference number and/or identity of the exporting countries would lead to the non-compliance with the notification requirement.

Consequently, the President does not accede Amgen's position, where she argues that Article 5 of the SPC Regulation should be interpreted to mean that "*the manufacturer (must) disclose the MA number of each exporting third country as soon as it is publicly available. If the MA number is not yet publicly available, the manufacture must at least indicate the countries of destination of the export*" and that "*according to the wording of Article 5(2)(b) of the SPC Regulation, the manufacture may not start the manufacturing activities earlier than three months after full notification*". The provision does not provide for these conditions, and since a recital has no binding legal force and no positive effect of its own, it cannot be invoked to derogate from the provision itself or to interpret it in a sense that is manifestly inconsistent with its wording.

29. Second plea: "export to countries where patent rights do not (or no longer) apply"

Amgen further raises that the manufacturing waiver for export to third countries would only apply if no relevant intellectual property rights apply in those countries. Among other things, Amgen relies on recitals 4, 8, 11, 18 and 30 of the SPC Manufacturing Waiver Regulation to defend its position.

SB disputes this view of Amgen and, according to the President, rightly raises the point that the SPC Manufacturing Waiver Regulation does not provide for this condition in its provisions and that such an interpretation would be contrary to the SPC Manufacturing Waiver Regulation's objective of promoting the competitive position of EU-based manufacturers vis-à-vis global competition if EU-based manufacturers were allowed to manufacture only for export to countries that are right-free, as they would then be put at a serious disadvantage compared to non-EU-based competitors who are not subject to such restrictions. Incidentally, while legal recitals can be important in determining the purpose of the Regulation, they are not legally binding and cannot be used to derogate of the provisions of the Regulation itself or to interpret these provisions in a manner contrary to their wording.

[3] CJEU 19 December 2019, case C-418/18P, nos 75 and 76.

The President hearing this case in summary proceedings does not read from the provision, nor from the recitals, that manufacturing under the waiver would only be allowed if no relevant (patent) rights apply in the export countries. Indeed, this condition is not included in the literal wording of the provision and, moreover, such an interpretation would also be contrary to the purpose of the SPC Manufacturing Waiver Regulation.

30. Third plea: "strict necessity for actual export"

Amgen further argues that the European legislator has deliberately chosen to allow storage in manufacture for export only in accordance with Article 5(2a)(i) and (ii) if it is strictly necessary for the actual export and, although no specific time period is mentioned in this respect, long-term storage is not allowed under any circumstances.

SB raises that nowhere in the SPC Manufacturing Waiver Regulation nor in the preparatory works does it state that the export should be done immediately, or in the short term, at least nowhere does it state that stockpiling for export would violate the SPC Manufacturing Waiver Regulation.

It follows from the wording of Article 5(2)(a) SPC Regulation as amended by the SPC Manufacturing Waiver Regulation that the waiver also allows related acts that are strictly necessary for the actual export. It is clear from recital 9 of the SPC Manufacturing Waiver Regulation that related acts, for example, may relate to the possession, offering for supply, delivery, importation, use or synthesis of an active substance for the manufacture of a medicinal product containing it, or the temporary stocking or advertising activities aimed exclusively at exports to third-country destinations. The SPC Manufacturing Waiver Regulation also does not provide a maximum period for temporary storage other than that it must be strictly necessary for the actual export. Given the objectives of the SPC Manufacturing Waiver Regulation, this will be subject to a period that is customary within a normal business operation (taking into account the specificity for the manufacture of biosimilars and supply chains), which does not put the manufacturer at a disadvantage compared to manufacturers outside of the Union. The time for this storage falls under the permitted related operation under the waiver.

31. The foreign decisions

The President hearing this case in summary proceedings took note of the two foreign decisions which also ruled on the interpretation of the SPC Manufacturing Waiver Regulation and more specifically the notification requirements (see the decision of 20 October 2023 by the Munich Regional Court and the decision of 23 January 2024 by the Hague District Court).

The Munich Regional Court ruled that the manufacturing waiver for export should be interpreted restrictively in the sense that the manufacturer must mention the reference number of the market authorisation in the notification before it can claim the manufacturing waiver. The President does not join the view that from the genesis of the provision, the requirement to mention the countries of export in the notification was removed for the purpose of simplifying the notification procedure.

In interpreting the SPC Manufacturing Waiver Regulation, the Hague court correctly took into account not only the wording of the provision, but also its context and the objectives of the regulation, also taking into account the genesis from which it can be seen that the information regarding the identity of the exporting third countries was deliberately omitted in order to avoid having to provide commercially sensitive information before public disclosure.

32. Decision

It follows from the above that with its notification of 13 March 2024, SB has complied with the notification requirements for the manufacturing waiver for export (to the extent that it provides the reference number(s) as soon as they are publicly available).

4.3.2 Assessment of unfair commercial practices

33. Art. VI.104 of the Code of Economic Law prohibits any act contrary to fair commercial practices by which a company harms or may harm the professional interests of one or more other companies.

Amgen alleges that the infringement of the SPC039 and SB's threat to manufacture biosimilar drugs for export to a country where Amgen enjoys patent protection, such as South Korea and the United States in particular, is an act contrary to fair commercial practices.

SB first argues that there is no infringement of SPC039 and raises the plea of inadmissibility on Amgen's claim insofar as it relies on unfair commercial practices due to manufacturing for and exporting to South Korea and the United States.

It follows from the requirement of an immediate and already acquired standing that an *ad futurum* claim cannot be admitted. Art. 18(2) of the Judicial Code provides for an exception to this rule, more specifically when the claim is brought to prevent the infringement of a seriously threatened right. The President finds that Amgen, by referring to alleged ambivalent communications from SB and documents from the FDA that Catalent had shipped denosumab from Belgium to the United in the past, does not provide evidence of an infringement by SB of Amgen's patent rights or of a grave and serious threat causing a defined interference. To the extent that this part of Amgen's claim does not meet the requirements of Article 17 and Article 18 of the Judicial Code, due to the lack of an actual, or imminent standing, the President dismisses this part of its claim as inadmissible.

4.3.3 Other reservations

34. The reservations formulated by Amgen are not claims within the meaning of Articles 12 and 14 of the Judicial Code so the President did not take this question into account.

4.4 The measures claimed by Amgen

35. The President hearing this case in summary proceedings does not find any infringements alleged by Amgen, so there are no grounds to order the measures claimed by Amgen.

5. COURT COSTS

36. Since the President dismissed Amgen's claim, Amgen has to bear SB's legal costs.

    This gives SB the right to pay the court fee at the basic legal amount (€1,800.00), as claimed. Subpoena costs (including € 24.00 contribution to the Second Level Legal Assistance Budget Fund) remain at Amgen's expense.

6. PROVISIONAL ENFORCEMENT

37. This judgment is enforceable by operation of law (Article XVII.18 Code of Economic Law).

7. DECISION OF THE COURT

38. The President, hearing this case as in summary proceedings:

- Declares itself competent to rule on the dispute;
- Declares Amgen's claim regarding compliance with the notification requirement and -conditions admissible but unfounded and dismisses it;
- Declares Amgen's claim relating to the unfair commercial practices inadmissible and dismisses it;
- Orders Amgen to pay to SB the legal costs assessed on SB's behalf at €1,800 (basic legal costs);
- Places the docket fee of € 165.00 at the charge of Amgen, which must pay this amount to the Federal Public Service of Finances at its first request.

This judgment was rendered by H. Yu, serving President sitting as in summary proceedings. She pronounced the judgment with the assistance of Registrar M. Vanden Eycken at the public hearing (in application of Article 6(1) of the Convention for the Protection of Human Rights and Fundamental Freedoms) of 23 December 2024.

M. Vanden

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H. Yu

H. Yu.