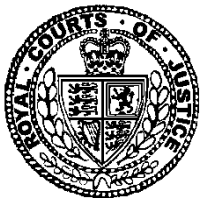

Neutral Citation Number: [2025] EWHC 3050 (Pat)
Case No: HP-2025-000047

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

Royal Courts of Justice
Rolls Building, Fetter Lane,
London, EC4A 1NL
Date: 24 November 2025

Before :
MR JUSTICE MEADE

- -

Between:

(1) REGENERON PHARMACEUTICALS, INC.
(a company incorporated under the laws of the State of New York)
(2) BAYER PLC

Claimants

- and -

(1) ALVOTECH HF
(a public limited company incorporated under the laws of the Republic of Iceland)
(2) FISHER CLINICAL SERVICES UK LIMITED

Defendants

- -

Tom Mitcheson KC and **Alice Hart** (instructed by **Allen Overy Shearman Sterling LLP**) for the **Claimants**
Andrew Lykiardopoulos KC and **Thomas Lunt** (instructed by **Bird & Bird LLP**) for the **Defendants**

Hearing dates: 3 and 4 November 2025

- -

APPROVED JUDGMENT

Remote hand-down: This judgment will be handed down remotely by circulation to the parties or their representatives by email and release to The National Archives. A copy of the judgment in final form as handed down should be available on The National Archives website shortly thereafter but can otherwise be obtained on request by email to the Judicial Office (press.enquiries@judiciary.uk).

Mr Justice Meade:

Introduction

1. This is my judgment following a two-day trial that I expedited by my order of 29 September 2025 ([2025] EWHC 2623 (Pat)).

2. The action concerns SPC/GB13/028 (the "**SPC**"). The SPC protects the drug Eylea, which has as its active ingredient the fusion protein aflibercept. Aflibercept is a clinically and commercially highly successful therapy used to treat "wet" macular degeneration by injection into the eye.

3. I heard a trial earlier this year relating to two formulation patents concerning aflibercept ([2025] EWHC 2527 (Pat)), with different defendants and different issues. There, as here, the parties relying on exclusive rights were Regeneron Pharmaceuticals, Inc ("**Regeneron**") and Bayer Plc ("**Bayer**") (collectively the "**Claimants**", though I note in passing that the validity of Bayer's alleged exclusive licence was not admitted by the Defendants in these proceedings).

4. The Defendants in this action, Alvotech Hf ("**Alvotech**") and Fisher Clinical Services UK Limited ("**Fisher**") (collectively, the "**Defendants**") propose to participate in bringing to market a biosimilar of aflibercept, AVT06 (it is called Mynzepli by one of Alvotech's commercial partners and was referred to by that name in some of the papers at trial). As part of an international plan, they want to manufacture in the UK. They do not challenge the validity of the SPC, and they do not say that their product is outside the scope of the SPC in the sense of patent-style non-infringement. But they do say that what they propose is permitted by what is sometimes called the "**SPC manufacturing waiver**". This provides for two exceptions to infringement in the UK by third party "makers" of medicinal products otherwise protected by an SPC. It allows for (i) making products for export outside of the UK and the EU, and (ii) making and storing products during the last six months of the SPC's lifetime for sales in the UK and EU after SPC expiry. Purely for brevity I will call them the "**export waiver**" and the "**storage waiver**".

5. Both exceptions require the provision of certain information to the SPC owner three months in advance of manufacture. The Defendants say that they provided the requisite information to Regeneron in two notifications and so are entitled to manufacture AVT06 in the UK during the SPC's life (to the extent permitted by the waivers).

6. The SPC will expire on 22 November 2025.

7. The two notifications were given on 30 April 2025 (the "**First Notification**") and on 12 August 2025 (the "**Second Notification**"). The Second Notification was given by the Defendants to seek to protect themselves against alleged shortcomings of the First Notification raised by the Claimants on 29 July 2025 (just inside the permitted three-month period for an SPC holder to object).

8. The Claimants contend that both notifications are invalid, with the resulting collective effect being that any manufacturing of AVT06 in the UK prior to the

SPC's expiry would infringe it. The Claimants thus say that the Defendants should be injuncted.

9. The rationale for expedition of the trial was mainly to enable the Claimants, if successful, to get an injunction before SPC expiry. I agreed to expedite the trial for three main reasons: first, that the period just before the expiry of a patent (or related right such as an SPC) can be the most profitable for the right-holder (provided exclusivity is maintained) since all the hard work of product and market development has been done and sales may be at their height; second, because the Defendants did not oppose expedition and were willing to cooperate to establish whether or not there was (a) valid notification(s); and third, because there was time in the Patents Court's diary that could be allocated to the trial without prejudicing other litigants. Militating against these factors was the fact that I thought the Claimants had acted extremely tactically in delaying their objections to the First Notification until the very last minute. Objectively speaking it looked very much like that was done to give the Defendants the minimum possible time to rectify any problems with the First Notification. Although the Claimants put in evidence explaining what was said generally to be delay on their parts and denied in a very general way having behaved abusively, they did not deny acting to minimise the Defendants' time for responding. So to an extent the time pressure on having a trial was caused by the Claimants themselves, but I thought the factors in favour of expedition outweighed this, and the point which remains for me to decide would have been live whatever the Claimants' motives and approach, since the objection it concerns could not be rectified by the Second Notification, if the Claimants were right about it.

10. The Claimants' bases for alleging the notifications to be invalid are that:

    i) In so far as they are relied on for making for export outside the UK and EU, both notifications failed to provide marketing authorisation ("**MA**") reference number(s) for the intended territory of export (Japan). This is the "**Export Issue**". No Japanese MA number was publicly available at the date of either Notification, and, by the time it was available, there was less than three months left to SPC expiry. This objection applies to both Notifications, and it was not argued that the Second Notification remedied it; and

    ii) The First Notification was not made in the name of a "maker" that is "established in the United Kingdom": the "**Maker Issue**". This alleged shortcoming, which the Defendants did not accept to be correct, is accepted by the Claimants to have been remedied by the Second Notification.

11. The Claimants also advanced timing arguments based on the exact reckoning of the three-month notice period that is required. Explaining these points and their significance in this judgment would involve disclosing confidential information about the Defendants' commercial plans and I do not consider that necessary or appropriate. Suffice it to say that had the Claimants succeeded on the main Maker Issue (so as to knock out the First Notification) and all the timing points on the three month period for the Second Notification, they would have been

able to argue that the Defendants were starting manufacture for sales in the UK, EU, and/or export countries fractionally too early, if, in addition, certain confidential matters relating to the Defendants' commercial activities came to pass. Those matters were, on the evidence, unlikely.

12. This meant that the Maker Issue and associated timing points were extremely unlikely to lead to any really material relief but were going to make it nigh-on impossible to conclude the trial within the two days allotted, and very difficult for me to give judgment before SPC expiry (because there would be a lot more to cover in a judgment). I was also concerned about the overall justice of this aspect of the situation given that the time pressure in relation to it lay at the door of the Claimants, for reasons explained above. After a discussion on the first day of the trial the Claimants pragmatically accepted that the way forward was to argue only the Export Issue as a means for obtaining an injunction prior to SPC expiry. The Maker Issue and timing points can be revived and argued for the purpose of getting damages, if the confidential matters referred to above come to pass on the Defendants' side. If they do not, there will be nothing additional to argue about.

13. There was also an issue to do with final relief, i.e., whether the Claimants would be entitled to injunctive relief (and/or delivery up and destruction) if I held that that the SPC manufacturing waiver did not apply so that there was an infringement (the "**Relief Issue**"). The Defendants said that an injunction would be disproportionate and/or that the Claimants had disentitled themselves from seeking it by their delay.

14. The upshot is that the only issues remaining for decision at the start of the trial before me were the Export Issue and, if the Claimants were to win on that, the Relief Issue. I heard the Export Issue first, and although the parties' detailed arguments going to it are numerous and in some ways quite complex, with good time for pre-reading and the bulk of the oral submissions taking place on the first day of trial I was able to reach a decision in which I was sufficiently confident that I could announce it on the second day, after all argument on the issue, with reasons to follow; this judgment gives those reasons. That meant that I did not need to hear the Relief Issue: I would have gone on to hear it had there been any prospect of an interim injunction pending appeal, but for reasons that I do not need to go into the Claimants had agreed, in order to promote the chances of getting expedition, not to seek any such interim relief pending appeal.

15. The law going to the Export Issue has been considered by courts in Germany, the Netherlands and Belgium (between different parties and on somewhat different facts). The decision in Germany (a first instance one) was in line with the Claimants' case and all the other decisions (first instance and on appeal) support the Defendants' case.

16. Although, as I have said, the Export Issue has a considerable number of potentially somewhat complex sub-issues, it is at the end of the day a short point of legislative interpretation: can a party seeking an SPC export waiver give a valid notification prior to having an MA in the export country (or the number of the MA) so long as they provide the MA number later, or is a notification

without an MA number inherently invalid, which would have the effect that the three month period would not start until an MA was granted and the number publicly available?

17. Answering this point from within the four corners of the SPC Regulation (see below), including its recitals and overall agreed purpose can be done fairly shortly and I think it is clear that the Defendants are right. What lengthened the hearing of this trial, and will lengthen this judgment, is arguments over the travaux préparatoires and over the European decisions referred to above. I found the travaux of no real assistance, for reasons given below, and the arguments on the foreign decisions were overengineered in the sense that the parties sought to pick them apart at an unjustified level of detail.

Legal principles

The relevant legislation

18. Prior to Brexit, the medicinal product SPC regime operated under Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 (the "**SPC Regulation**").

19. Under the European Union (Withdrawal) Act 2018, EU-derived domestic legislation and direct EU legislation in force in the UK at 11pm on 31 December 2020 (in the form that it was in effect at the time) was saved (s.2) or incorporated (s.3) into domestic law ("**IP Completion Day**"). By virtue of being direct EU legislation, pursuant to s.3 of the 2018 Act, the SPC Regulation was incorporated into domestic law and became retained EU law.

20. The SPC manufacturing waiver was given effect by a new EU Regulation, Regulation (EC) No 2019/933 of the European Parliament and of the Council of 20 May 2019 (the "**Amendment Regulation**"), which introduced the waiver by amending the SPC Regulation. The Amendment Regulation came into effect on 1 July 2019, and thus the waiver provisions in the SPC Regulation were automatically incorporated into UK law as retained EU law.

21. There has been subsequent tidying up of the manufacturing waiver provisions (e.g., to change references to the "Union" to the "United Kingdom") through the Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020/1050). Nothing of substance turns on these tidying up changes in this case.

22. Pursuant to the Retained EU Law (Revocation and Reform) Act 2023, retained EU law ceased to exist as a special category of domestic law on 1 January 2024. Pursuant to s.5 of that Act, any retained EU law which remained on the UK statute book became "assimilated law". Thus, we now have the **assimilated SPC Regulation**.

23. I have reproduced in full Art. 5 of the assimilated SPC Regulation below (emphasis added by me as explained further below):

> "Article 5

Effects of the certificate

1. Subject to the provisions of Article 4 and paragraphs 1a and 1b, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

1a. The protection conferred by a certificate in accordance with paragraph 1 shall extend only to the territory in respect of which a valid, UK, GB or NI authorisation has been issued and where the authorisation—

(a) is the first authorisation for the product in the territory in accordance with Article 3(b) and (d), and

(b) has been issued before the certificate takes effect in accordance with Article 13(1).

1b. Where after the submission of an application for a certificate in accordance with Article 7(1) or (2) and before the certificate takes effect in accordance with Article 13(1), a GB or NI authorisation is granted in respect of the same product and the authorisation would have met the requirements of Article 3(b) and (d) had it been granted on the date of submission of the application, the protection conferred by a certificate in accordance with paragraph 1 shall extend to the territory of England and Wales and Scotland or the territory of Northern Ireland as the case may be.

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 countries outside the United Kingdom, the Isle of Man and the Member States of the European Union; or

(ii) any related act that is strictly necessary for the making, in the United Kingdom, 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 United Kingdom, in order to place that product, or a medicinal product containing that product,

on the market of the United Kingdom, the Isle of Man or one or more Member States of the European Union after the expiry of the corresponding certificate; or

(iv) any related act that is strictly necessary for the making, in the United Kingdom, 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 comptroller, 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 the United Kingdom, 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 that certificate, whichever is the earlier;

(c) if the information listed in paragraph 5 of this Article changes, the maker notifies the comptroller 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 countries outside the United Kingdom, the Isle of Man and the Member States of the European Union, the maker ensures that the words 'UK export' are affixed so as to be sufficiently clear and visible to the naked eye 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.

3. The exception referred to in paragraph 2 shall not apply to any act or activity carried out for the import of products, or medicinal products containing those products, into the United Kingdom merely for the purpose of repackaging, re-exporting or storing.

4. 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.

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) [omitted]

(d) the number of the certificate; and

(e) for medicinal products to be exported to countries outside the United Kingdom, the Isle of Man and the Member States of the European Union, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each country of export, as soon as it is publicly available.

6. For the purposes of notification to the comptroller under points (b) and (c) of paragraph 2, the maker shall use the standard prescribed form.

7. Failure to comply with the requirements of point (e) of paragraph 5 with regard to a country outside the United Kingdom, the Isle of Man and the Member States of the European Union shall only affect exports to that country, and those exports shall, therefore, not benefit from the exception.

8. [omitted]

9. The maker shall ensure, through appropriate and documented means, that any person in a contractual relationship with the maker who performs acts falling under point (a) of paragraph 2 is fully informed and aware of the following:

(a) that those acts are subject to paragraph 2;

(b) that the placing on the market, import or re-import of the product, or the medicinal product containing that product, referred to in point (a)(i) of paragraph 2 or the placing on the market of the product, or the medicinal product containing that product, referred to in point (a)(iii) of paragraph 2 could infringe the certificate referred to in paragraph 2 where, and for as long as, that certificate applies.

10. Paragraph 2 shall apply to certificates that are applied for on or after 1 July 2019.

Paragraph 2 shall also apply to certificates that have been applied for before 1 July 2019 and that take effect on or after that date. Paragraph 2 shall only apply to such certificates from 2 July 2022.

Paragraph 2 shall not apply to certificates that take effect before 1 July 2019.

> 11. The Secretary of State may by regulations make further provision as to the manner and form (including design and colour) of affixing the words "UK export" to the outer packaging of the product, or the medicinal product containing that product, referred to in paragraph 2(a)(i) of this Article, and, where feasible, to its immediate packaging.
>
> 12. Those regulations are to be made by statutory instrument which is subject to annulment pursuant to a resolution of either House of Parliament."

24. The key provisions relating to the waiver for present purposes are those at Arts. 5(2)(a) (i) and (ii), 5(2)(b) and 5(5), especially 5(5)(e), and I have underlined them above simply for that reason. Art. 5(2)(a) defines the permitted acts under the waiver, Art. 5(2)(b) contains the requirement for three months' notice, and Art. 5(5) defines the information that the notification must contain. The information required by Art 5(2)(a) to (d) is clearly mandatory. As I have already said, the real point arises under Art. 5(2)(e) where it says the reference number of the marketing authorisation in the export country must be given "*as soon as it is publicly available*". In line with the statute, and for brevity, I will refer to the person giving the notification as the "**maker**" throughout this judgment.

25. The Amendment Regulation includes at Annex 1a the standard form for notification under Art. 5(2):

Standard form for notification pursuant to points (b) and (c) of Article 5(2)

Tick the appropriate box	☐ New notification ☐ Update of an existing notification	
(a) Name and address of the maker	…	
(b) Purpose of making	☐ Export ☐ Storing ☐ Export and storing	
(c) Member State in which making is to take place and Member State in which first related act (if any) prior to making is to take place	Member State of making	…
	(Member State of first related act (if any))	…
(d) Number of certificate granted in the Member State of making and number of certificate granted in Member State of first related act (if any) prior to making	Certificate of Member State of making	…
	(Certificate of Member State of first related act (if any))	…
(e) For medicinal products to be exported to third countries, reference number of marketing authorisation, or the equivalent of such authorisation, in each third country of export	…	
	…	
	…'	

26. Some minor arguments were made about this: it explicitly provides for an "Update of an existing notification" as one tick-box option, and entry (e) required the MA numbers for the "third country of export" with no reference to whether or not they are available. I do not think anything turns on either point. Those standard form features are just for convenience.

Facts about the First and Second Notifications

27. When the First and Second Notifications were made, no MA for Japan was granted, and no MA numbers were publicly available. Notification of the grant of the Japanese MA was given to Alvotech's commercial partner there on 19 September and there was expected to be a further time lag before MA numbers were made publicly available. In advance of that, the Defendants' UK lawyers sent a confidential letter to the Claimants' UK lawyers with the numbers.

28. Annex A to this judgment is the Second Notification as given.

The parties' positions on the Export Issue

29. The Claimants' position is that under Art. 5(5), no valid notification can be given until there actually is a granted MA for the export territory in question and that the three-month period does not begin to run until the MA number(s) is/are given.

30. The Defendants' position is that a valid notification can be given prior to the grant of an MA in the export territory and that the MA numbers can be given by way of update without restarting the three-month time period.

The purpose of the SPC manufacturing waiver

31. The parties differed in their approaches to how the purpose(s) of the waiver should be identified and the relative importance in that exercise of the operative provisions and recitals on the one hand, and the travaux préparatoires on the other. I need to refer to those points in a little more detail below, but it is possible and useful to identify the general issues behind the waiver at this stage.

32. Without the waiver:

    i) Manufacturers outside the EU located in a country where there was no SPC (or similar exclusive right) could make a drug and export it to another country (I will call this the "**export country**") where again there was no SPC or similar exclusive right (or at least no valid exclusive right that would be infringed – see below). Manufacturers inside the EU could not do that because the SPC (in EU member states where there was one) would be infringed. So, EU companies were at risk of being disadvantaged when it came to competing for sales in the export country.

    ii) On the expiry of an SPC in the EU, manufacturers in the EU could not start to sell effectively on "day 1" (the first day after expiry) because they would not have had a chance to make any stock, as to do so would have infringed the SPC during its life. Manufacturers outside the EU could stockpile, by contrast, and import freely and effectively into the EU on day 1. So again, EU companies were at risk of being disadvantaged.

33. In broad terms, these scenarios are what the legislation was aimed at and were intended to be addressed by appropriate waivers. But at the same time, it could

be seen that there would be a serious problem if enterprises in the EU were given *carte blanche* to start manufacturing there pre-SPC expiry, without the SPC owner having some appropriate visibility of what was being done to try to enforce their rights if the waivers were abused or did not apply. Hence the notification provisions.

The travaux préparatoires

34. I was provided with and taken through some of a 780-page bundle containing the travaux préparatoires to the Amendment Regulation. It contains 38 documents from various EU institutions spanning from March 2018 to May 2019.

35. Neither side's primary case depended on recourse to the travaux; the Claimants were particularly negative about their usefulness because they said that nothing in them actually resolved any ambiguity in Art. 5. Despite this, I was taken to a dozen different documents within the bundle to scrutinise the language in great detail.

36. There is no doubt that two particular things changed materially during the legislative process. One was that the early draft legislation did not provide for stockpiling for "actual 'day 1 entry'"; that came in later. The other was that for much of the time when the proposed Regulation was under consideration there was a proposal that the party seeking a waiver should have to include in their notification the identities of the countries to which they intended to export, even before that was public via an MA being published for those countries. There were argued to be two related problems with that: one was that that information would usually be commercially sensitive, and the other was that if its confidentiality was to be protected in some way that might mean that national patent offices would have different information from the SPC owners when a notification was given. In the end, the argument that the information was confidential and should not have to be disclosed carried the day.

37. I think these significant changes make it impractical and wrong in principle to try to spell out of the travaux prior to or during the making of those changes, the sort of very detailed analysis of nuances of legislative purpose that the parties aimed at. The recitals to the Amendment Regulation are so much better as a way to identify the actual purposes of the legislation as it was eventually made.

Statutory interpretation

38. There was nothing between the parties on the applicable principles for interpreting assimilated law (and they agreed that for the purposes of this case assimilated law was to be interpreted in harmony with the approach of the CJEU after Brexit just as before).

39. The Defendants in their skeleton said the following:

> 40. The general principles of European interpretation were set out in *Srl Cilfit v Minister of Health Case* 283/81 [1982] ECR

3415, where the Court of Justice gave the following guidance on the interpretation of directives:

> "20. Finally, every provision of Community law must be placed in its context and interpreted in the light of the provisions of Community law as a whole, regard being had to the objectives thereof and to its state of evolution at the date on which the provision in question is to be applied."

41. In *IDT Card Services* [2006] EWCA Civ 29, the Court of Appeal considered the principles of interpreting of domestic legislation implementing European directives. Having cited the above paragraphs from *Cilfit* at [69] of its judgment, it explained the significance of the travaux and the objectives of the statute at [70]-[71]:

> "70. When European Union legislation has to be examined, the courts often have no difficulty in finding that the meaning is clear on any basis. The English courts have with practice also become accustomed to looking at the travaux préparatoires and asking advocates to produce them. They are also becoming more accustomed to looking at a few of the different language versions of directives. However, the guidance in the *Cilfit* case is not always easy to apply. The number of different language versions that the court can examine is limited. The court also rarely has the benefit of decisions on European Union legislation in other member states […]
>
> 71. On the other hand, the *Cilfit* case makes a point that is of particular importance on this appeal, and that is that the court should have regard to the objectives of the legislation. English statutes rarely contain statements of their objectives because they are often found not to be reliable guides to the detailed points of interpretation that tend to arise on English statutes. However European Union directives frequently have long preambles setting out the purposes or reasons for the measures and what it is intended to achieve. This point is an indication that the objectives of a measure have a greater normative force under Community law than they would under English law."

42. Tools to aid the purposive interpretation of European legislation include the terms of the legislation, including its preamble, the preparatory documents, the usual meaning of expressions used, comparison of different language texts of the instrument, and the purpose and general scheme of the legislation (*RTL Television v NLM* [2004] 1 CMLR 5 at [97]-[99]).

40. At my request the Claimants (who had cited other authorities which I thought were to very similar effect) considered whether they disputed this, and they confirmed they did not.

41. These statements emphasise the elevated importance of legislative purpose to this sort of exercise of interpretation, but they also specifically emphasise the significance of recitals. They leave room for the travaux but they do not, in my view, put them on an equal footing with recitals, and the present case may illustrate why not.

42. On top of the agreed general approach to which I have just referred, the Claimants reminded me of the *Infopaq* canon of construction (*Infopaq International A/S v Danske Dagblades Forening*, C-5/08, EU:C:2009:465): that where I have to interpret and apply a derogation from a general principle established by EU legislation, that derogation should be interpreted narrowly. Counsel for the Defendants quite rightly pointed out that the *Infopaq* principle is just one canon of construction that I should take into account, though, and it is not a licence to rewrite clear language. The *Infopaq* principle is also not a completely easy fit with the present situation. That is because there is one general principle at play from the SPC Regulation itself, which is the grant of an important intellectual property right in the nature of a monopoly, and a second general principle at play from the waiver amendment, which is to limit that right so as to achieve further, different purposes, including levelling the playing field between EU/UK-based manufacturers and manufacturers outside the EU/UK. The exercise of interpretation that I have to conduct ought, in my view, to be regarded in the light of an intended balance between these two principles. If application of the *Infopaq* canon of interpretation were to lead to unduly denying the effectiveness of the second principle very severely or altogether in favour of the first, then something will have gone wrong.

The Recitals

43. To aid with ascertaining the purpose behind some of the requirements for the export waiver, I was taken to the recitals to the Amendment Regulation. (17) and (18) were the focus:

> (17) If a local marketing authorisation, or the equivalent of such authorisation, in a specific third country, for a given medicinal product, is published after the authority is notified, the notification should be promptly updated to include the reference number of that marketing authorisation, or the equivalent of such authorisation, as soon as it is publicly available. If the reference number of that marketing authorisation, or the equivalent of such authorisation, is pending publication, the maker should be required to provide, in the notification, that reference number as soon as it is publicly available.
>
> (18) For reasons of proportionality, failure to comply with the requirement regarding a third country should only affect exports to that country, and exports to that country should, thus, not benefit from the exception provided for in this Regulation. It

> should be the responsibility of the maker established in the Union to verify that protection does not exist or has expired in a country of export, or whether that protection is subject to any limitations or exemptions in that country.

44. These are explanatory of the operative provisions rather than broad statements of overall purpose, but nonetheless clearly still relevant to interpretation. As to the more general purpose behind the SPC manufacturing waiver, I was taken to the following recitals during the course of oral submissions:

> (3) Since the adoption in 1992 of the predecessor to Regulation (EC) No 469/2009, markets have evolved significantly and there has been huge growth in the making of generics and especially of biosimilars, and in the making of their active ingredients, in particular in countries outside the Union ('third countries') in which protection does not exist or has expired.
>
> (4) The absence in Regulation (EC) No 469/2009 of any exception to the protection conferred by the certificate has had the unintended consequence of preventing makers of generics and biosimilars established in the Union from making generics and biosimilars in the Union, even for the purpose of export to third-country markets in which protection does not exist or has expired. Likewise, makers are prevented from making generics and biosimilars for the purpose of storing them for a limited period before the expiry of the certificate. Those circumstances make it more difficult for those makers, in contrast to makers located in third countries where protection does not exist or has expired, to enter the Union market immediately after expiry of the certificate, given that they are not in a position to build up production capacity for the purpose of export or for the purpose of entering the market of a Member State until the protection provided by that certificate has expired.
>
> (5) Those circumstances put makers of generics and biosimilars established in the Union at a significant competitive disadvantage in comparison with makers based in third countries that offer less or no protection. The Union should strike a balance between restoring a level playing field between those makers and ensuring that the essence of the exclusive rights of holders of certificates ('certificate holders') is guaranteed in relation to the Union market.
>
> (7) The timely entry of generics and biosimilars into the Union market is important, particularly in order to increase competition, to reduce prices and to ensure that national healthcare systems are sustainable and that patients in the Union have better access to affordable medicines. The importance of such timely entry was underlined by the Council in its conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the Union and its Member States.

Regulation (EC) No 469/2009 should, therefore, be amended so as to allow the making of generics and biosimilars for export and storing, while bearing in mind that intellectual property rights remain one of the cornerstones of innovation, competitiveness and growth in the internal market.

(8) The aim of this Regulation is to promote the competitiveness of the Union, thereby enhancing growth and job creation in the internal market and contributing to a wider supply of products under uniform conditions, by allowing makers of generics and biosimilars established in the Union to make in the Union products, or medicinal products containing those products, for the purpose of export to third-country markets in which protection does not exist or has expired, thereby also helping those makers to compete effectively in those third- country markets. This Regulation should also allow such makers to make and store products, or medicinal products containing those products, in a Member State for a defined period pending the expiry of the certificate, for the purpose of entering the market of any Member State upon expiry of the corresponding certificate, thereby helping those makers to compete effectively in the Union immediately after protection has expired ('EU day-one entry'). This Regulation should also complement the efforts of the Union's trade policy to ensure open markets for makers of products, or medicinal products containing those products, established in the Union. Over time, this Regulation should benefit the entire pharmaceutical sector in the Union, by allowing all players, including newcomers, to reap the benefits of the new opportunities opening up in the fast-changing global pharmaceutical market. Furthermore, the general interest of the Union would be promoted given that, by reinforcing Union-based supply chains for medicines and by allowing storing with a view to entry into the Union market upon expiry of the certificate, medicines would become more accessible to patients in the Union after the expiry of the certificate.

(9) In those specific and limited circumstances, and in order to create a level playing field between makers established in the Union and third-country makers, it is appropriate to provide for an exception to the protection conferred by a certificate so as to allow the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or of storing, and any related acts in the Union strictly necessary for that making or for the actual export or the actual storing, where such acts would otherwise require the consent of a certificate holder ('related acts'). For instance, such related acts could include: possessing; offering to supply; supplying; importing; using or synthesising an active ingredient for the purpose of making a medicinal product; or temporary storing or advertising for the exclusive purpose of export to third-country destinations.

That exception should also apply to related acts performed by third parties who are in a contractual relationship with the maker.

(12) By limiting the scope of the exception to making for the purpose of export outside the Union or to making for the purpose of storing, and to acts strictly necessary for such making or for the actual export or the actual storing, the exception provided for in this Regulation should not conflict with the normal exploitation of the product, or the medicinal product containing that product, in the Member State in which the certificate is in force, namely with the core exclusive right of the certificate holder to make that product for the purpose of placing it on the Union market during the term of the certificate. In addition, that exception should not unreasonably prejudice the legitimate interests of the certificate holder, whilst taking account of the legitimate interests of third parties.

(13) Effective and proportionate safeguards should apply in relation to the exception in order to increase transparency, to help the holder of a certificate enforce its protection in the Union and check compliance with the conditions set out in this Regulation, and to reduce the risk of illicit diversion onto the Union market during the term of the certificate.

(14) This Regulation should impose an information obligation on the maker, namely the person established in the Union, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export or storing, is carried out. It is possible that the maker directly carries out the making. That information obligation should consist of requiring the maker to provide certain information to the competent industrial property office, or another designated authority, which granted the certificate ('the authority') in the Member State where the making is to take place. A standard form for notification should be provided for this purpose. The information should be provided before the making of a product, or a medicinal product containing that product, starts for the first time in that Member State, or before any related act prior to that making, whichever is the earlier. The information should be updated as and when appropriate. The making of a product, or a medicinal product containing that product, and the related acts, including those performed in Member States other than the one of making in cases where the product is also protected by a certificate in those other Member States, should only fall within the scope of the exception where the maker has sent the notification to the authority of the Member State of making, and where the maker has informed the holder of the certificate granted in that Member State. Where making takes place in more than one Member State, a notification should be required in each of those Member States. In the interests of transparency, the

> authority should be required to publish, as soon as possible, the information received, together with the date of notification of that information. Member States should be allowed to require that notifications, and updates to notifications, be subject to the payment of a one-off fee. That fee should be set at a level which does not exceed the administrative cost of processing notifications and updates.
>
> (15) The maker should also inform the certificate holder, through appropriate and documented means, of the intention to make a product, or a medicinal product containing that product, pursuant to the exception, by providing the certificate holder with the same information as notified to the authority. That information should be limited to what is necessary and appropriate for the certificate holder to assess whether the rights conferred by the certificate are being respected, and should not include confidential or commercially sensitive information. The standard form for notification could also be used to inform the certificate holder, and the information provided should be updated as and when appropriate.
>
> (23) This Regulation is without prejudice to other intellectual property rights that could protect other aspects of a product, or a medicinal product containing that product. This Regulation does not affect the application of Union acts that aim to prevent infringements, and facilitate enforcement, of intellectual property rights, including Directive 2004/48/EC and Regulation (EU) No 608/2013 of the European Parliament and of the Council.
>
> (29) Since the objective of this Regulation, namely to promote the competitiveness of the Union, in a manner that creates a level playing field for makers of generics and biosimilars in relation to their competitors in third- country markets in which protection does not exist or has expired, by laying down rules enabling the making of a product, or a medicinal product containing that product, during the term of the corresponding certificate, and also by providing for certain information, labelling and due diligence obligations for makers that use those rules, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

45. I think these are in line with the general summary of the purposes that I have identified above. They explain the level playing field issue (e.g. (4), (9)), the need to balance that with the essence of the SPC right (e.g. (5)), the desirability of day 1 entry (e.g. (8)), the need for the SPC owner to have appropriate

information to help police the SPC (e.g. (13)-(15)), and the desires that confidential information should not be required, with the same information going to the SPC owner as to the national authority (also at (15)).

Are the export waiver provisions also to protect exclusive rights in export countries?

46. The Claimants argued that under the export waiver provisions, if there were in fact an SPC (or other similar right) in the export territory, then not only would there be an infringement of that right in that territory, but there would *necessarily* be an infringement of the SPC in the EU/UK country of manufacture, i.e. the waiver would definitely be invalid.

47. The Defendants on the other hand said that whether or not there was a right, or infringement of it, in the country of export was a matter only for that country; it did not affect the validity of any waiver.

48. The point does not arise directly on the facts of this case: there is no relevant SPC (or other similar right) in Japan. But the Claimants sought to use it as a lever on interpretation of the export waiver provisions, arguing that it implied that those provisions would attach a high degree of importance to the SPC owner's ability to know the situation as to the export country as early as possible, because the existence there of an SPC would necessarily imply an infringement of the SPC in the EU/UK state where the waiver was sought.

49. To support their argument that the existence of a right in the export territory necessarily implied infringement in the EU/UK, the Claimants relied on an entry by Judge Klaus Grabinski in *Benkard, The European Patent Convention*, 4th Ed 2023:

> Although this is not expressly stated in the wording of the Regulation, according to the spirit and purpose of the Amendment Regulation 2019/933, which is intended to allow the **export to third-country markets where there is no protection or protection has expired** (recital 8), the making of a product or a medicinal product containing this product for the purpose of export to a third country that is not without protection is to be regarded not only as an infringement of the patent or certificate protection effective in that third country, but also as an infringement of the relevant protection certificate according to Regulation 469/2009 (v. Czettritz/Kau GRUR-Prax 2018, 396 (397).
>
> If the maker, when making for third countries of export, does not provide to the authority and the certificate holder the reference number of the marketing authorisation, or the equivalent of such authorisation, for one or more third countries of export, as soon as this is available, the privilege of making can not be claimed with respect to these third countries of export, Art. 5 (7) of Regulation 469/2009. Conversely, a violation of the information obligation according to Art. 5 (5) a)-d) of Regulation 469/2009 does not result in the loss of the privilege of making. Yet the

> certificate holder can assert this obligation in court, and if adjudicated, can enforce it by compulsory execution according to Sec. 888 ZPO [German Code of Civil Procedure].

50. There was some debate at trial about when this text came into being given that it relies on a 2018 journal article in the first paragraph above (i.e., when the Amendment Regulation was still being developed). I was told by counsel for the Claimants that the legal team for the Claimants had checked, and the 2019 edition of the book does not have any commentary on the waiver. So, it seems that this material appeared for the first time in the 2023 edition.

51. What is said in the first paragraph is indeed in line with the Claimants' submissions, but the degree of reliance that can be placed on it is significantly limited by the fact that the authority relied on for the proposition in the first paragraph (the 2018 Czettritz/Kau article in GRUR) was written well before the final text of the Amendment Regulation.

52. As will be seen, the Dutch and Belgian courts reached a different conclusion on this question and I prefer their point of view, which was fully argued before them and which they supported by more detailed analysis. If the mere existence of a right in the export territory which was arguably infringed meant that the export waiver automatically did not apply, then EU/UK manufacturers would continue to be disadvantaged relative to manufacturers in non-EU/UK countries, who would be free to manufacture in preparation for export to the territory in question and would be free to sell there if they could successfully challenge the validity or scope of the right in question.

53. I also think the Claimants' argument is inconsistent with the second sentence of Recital (18) to the Amendment Regulation: "It should be the responsibility of the maker established in the Union to verify that protection does not exist or has expired in a country of export, or whether that protection is subject to any limitations or exemptions in that country". I accept that there are various references throughout the Amendment Regulation to third countries (taking the example of Recital (4)) "in which protection does not exist or has expired", but in my view those references just focus on the clearest cases where the export waiver makes sense. Those references do not preclude waivers for export countries where protection is open to serious challenge, or is obviously invalid, or does not cover the product of the maker for some reason (see the reference to "subject to any limitations or exemptions in that country" in Recital (18)).

54. As to the second paragraph in the Benkard extract above, the Defendants argued that what is set out there is effectively what is said in Art. 5(5)(e): that the maker needs to provide the MA reference numbers as soon as they are publicly available. The Defendants said that there is no suggestion by the authors that the maker cannot actually make the notification until they have been granted an MA or that the three-month time period only starts to run once they have provided the reference numbers. I accept this.

SPC owner's ability to police

55. One clear purpose of the notification required by Art. 5 is to help the SPC owner to assess whether the rights under the SPC are being respected (Recital (15) to the Amendment Regulation). The information should be limited to what is appropriate and necessary for that purpose. However, it is clear that the information required under Art. 5 would not be enough on its own for a definite answer to whether the maker would be operating within the waiver(s) or not. For example, a notification of intention to export outside the EU/UK, even with all the information required by Art. 5 (including MA numbers of the export territory), would not reveal that the maker was in fact intending to export to another EU/UK member state, or was going beyond acts strictly necessary for export outside the EU/UK.

56. What the notification could be expected to do, in my view, would be to put the SPC owner on inquiry and/or in a position to make a provisional assessment of whether the maker intended fully to respect the limits of the waiver or not, especially when the information in the notification was put in the context of knowledge of the relevant drug market, commercial intelligence, knowledge of the business of the maker, and so on. There is nothing in the Amendment Regulation or the assimilated SPC Regulation to stop the SPC owner asking the maker for information, including confidential information. The maker might give this information under terms of confidence, and a national court considering a claim for infringement of the SPC on the basis that the waiver was not going to be respected might draw conclusions from such confidential discussions as appropriate, including a failure to answer reasonable questions. The ability to ask for confidential information on terms which would preserve its confidentiality is not in my view inconsistent with the fact that the Amendment Regulation does not require the making public of information that would otherwise be confidential, so destroying its confidentiality.

57. The circumstances of the present case and of the German, Dutch and Belgian cases all show that the information required under Art. 5 (whether or not it includes the details of the export country MA) can be enough, with other inquiries and public information, to allow a sufficient likelihood of infringement to be established that the SPC owner can initiate proceedings in a national court to explore the matter further with the procedural tools available there. But the information required will not be, and cannot be expected to be, enough on its own to make a definite decision.

58. The relevance of this is that the Claimants argued that without the export country MA details the SPC owner could not be certain whether or not the maker was operating within the waiver(s). In my view the SPC owner could not be certain either way. It is not the purpose of Art. 5 to require the giving of enough information for the SPC owner to be certain, only to begin meaningful assessment.

59. In addition, for reasons given above, in my view it is not the purpose of Art. 5 to allow the SPC owner to decide whether or not there is infringement of any export territory SPC or other similar right. It is directed to whether the SPC in the EU/UK is potentially being infringed.

Analysis

60. In my view the ordinary meaning of Art. 5(5) is that certain information is mandatory and must be provided in any event, but that the information at Art. 5(5)(e) (the export country MA number) only has to be provided once it becomes publicly available. There is nothing to say that a notification is not valid until the Art. 5(5)(e) information is given. Nor is there anything to say that the three-month notice period in Art. 5(2) does not run until the reference number of the export country MA is provided.

61. This view is clearly supported by Recital (17) to the Amendment Regulation: the notification has to be *updated* once the reference number is available. This clearly connotes that the notification is valid when given but may be updated later, not that it is invalid until then.

62. The Claimants argued that "*the* marketing authorisation" and "*such* authorisation" in Art. 5(5)(e) necessarily imply that an MA must already exist, but this is far too slender a linguistic support for their position. If the legislators had intended that the export waiver should only be available once an MA was actually obtained it would have been spelled out in much clearer terms and not by this extremely oblique wording in a provision which is about the detail of what information should be provided and not the more basic questions of whether and when a waiver should be available at all. Textually speaking "the marketing authorisation" is simply subject to the same conditionality/futurity as the reference number thereof, by virtue of the words "as soon as … publicly available".

63. Legislative purpose also supports the Defendants' position. Competing makers in non-EU/UK countries without SPC protection could start manufacture without an MA in the export country. EU/UK makers would be disadvantaged relative to them if they could only obtain a waiver three months after they had an MA and were able to give its number. So the Claimants' position is clearly contrary to the level playing field objective. I appreciate that that objective has to be balanced against the substance of the SPC right in the EU/UK (Recital (5) to the Amendment Regulation). However, levelling the playing field by not requiring EU/UK makers to have an export country MA from the outset of providing a notification does not compromise the SPC right in the EU/UK materially.

64. The Claimants argued that the proper solution was for makers to apply for their MAs in the export country early (i.e. before normal commercial considerations and regulatory processes would dictate) so as to be able to notify the SPC owner of the MA reference number in good time to get the export waiver when they wanted it. There is nothing in the Amendment Regulation to support this, in my view, and it is indirectly or tacitly contrary to the decision that was plainly made in the course of development of the legislation that makers should not have to reveal their intentions as to which countries to operate in early, because that information is generally confidential. If the argument were accepted, makers would have to make unnaturally early MA applications not for the usual regulatory and commercial purposes but just in order to make public the export territories they were interested in.

65. The Claimants also argued that the Defendants' position would lead to the "wild west" because makers would be incentivised to notify in support of export waivers absurdly early, when they had no idea of the export countries they were interested in and/or were far from getting an MA in any of them. Then it would be possible, the Claimants said, that MA reference numbers were not publicly available until much too late and the first that the SPC owner would know would be when the maker was imminently about to be on the market in the export country, too late to check or do anything there.

66. I reject this for three reasons. The first is that it represents merely an edge case and even if made out it does not reveal any basic flaw in the situation that would apply on the ordinary working of Art. 5. The second is that I do not think it is a practical reality because a person giving a premature notification in such a situation would rapidly draw the attention of the owner of the SPC and would be unable to give any good account of themselves, leading to litigation if necessary. It would not be practical for them to stay under the radar. The third is that the whole argument is based on an alleged inability to enforce the export country SPC, but for reasons already given I do not think that is the concern of the Amendment Regulation.

67. The Claimants also made an argument on Recital (18), first sentence, and Art. 5(7). I agree that they have the effect that where a notification relates to more than one country of export (as is specifically allowed) a failure with one would not invalidate the notification for the others. But I do not see how that is any more than neutral on the question of whether a valid notification can be given without an MA yet having been granted in the country of export. It just means that the Claimants do not have to confront the still more difficult argument that they would have to make if failure to be able to give MA reference numbers for one export country prevented the waiver applying to export countries where they could be given.

Foreign decisions

General

68. As I have already mentioned, a national court in Germany gave a (first instance) decision which favours the Claimants on the law, while courts in the Netherlands and Belgium have given decisions (at first instance and on appeal) going the other way. Since there are decisions going both ways I am bound to agree with at least one court and disagree with (an)other(s). So these decisions cannot be decisive. Nonetheless, a lot of time was spent picking over the fine details of the decisions. Since I heard those arguments I will deal with them, but doing so will take some pages, and it will help the reader of this judgment who is interested in my overall logic but not the excessive detail, for me to summarise:

    i) All the courts, including the German court, held that the ordinary meaning of Art. 5 is not what the Claimants say. I agree with this.

ii) The German court said that the purposes of the Amendment Regulation nonetheless led to a conclusion in line with what the Claimants argued before me.

iii) The relevant purpose relied on by the German court was the ability of the SPC owner to enforce its exclusive right in the export territory. The Dutch and Belgian courts disagreed with this, and I also disagree, for reasons given above.

iv) The Defendants said that the German court made a mistake about the legislative history/intent of the Amendment Regulation, in that the court thought that the requirement for the maker to notify the SPC owner of the countries of intended export was removed from the legislation only for simplicity and that such information was not really confidential. The Claimants accepted that was a mistake. Below, I conclude that it was a material mistake which vitiates the reasoning appreciably.

v) The Claimants retaliated by arguing that the reasoning of the other courts consistently muddled up the export waiver with the storage waiver. In my analysis below I reject that.

69. Thus I have four decisions in the Defendants' favour on the law with whose reasoning I agree, versus one decision in the Claimants' favour which is accepted to contain an error that I believe is material. In addition, two of the decisions in the Defendants' favour are from appeal courts (albeit that the Belgian appeal decision contains relatively little analysis, for understandable procedural reasons given below).

70. So overall the foreign decisions give me additional confidence in my conclusions, although I would have reached them anyway.

71. I move on to the detail.

Germany

72. I was taken to the decision of the District Court Munich I in *Janssen Biotech v. Formycon* dated 20 October 2023 (Case no. 21 O 12030/23). This appears to have been the first publicly available decision that addresses the export waiver.

73. The relevant parts of the headnote are:

> **1. According to the wording of Article 5(2)(b) of Regulation (EC) No. 469/2009, it is not necessary for the number of the marketing authorisation to be available for each third country of export when the information is conveyed. According to the intention and purpose of the Regulation, however, derogation in Art. 5 of the Regulation must be interpreted restrictively to the effect that the manufacturer cannot invoke this if it has not conveyed the authorisation number for at least one country and has not declared to**

> **which third country an export is to take place. (marginal note 17) (key point of judgement)**
>
> **2. It is true that the wording of Article 5 of Regulation (EC) No. 469/2009 makes no distinction between third countries with and without existing intellectual property rights. Instead, only third countries are mentioned, in general terms. From the recitals of the Regulation, however, the objective arises that an export should only take place to third countries without conflicting property rights. (marginal note 20) (key point of judgement)**
>
> […]
>
> **4. The manufacturer cannot benefit from the privilege of Art. 5 of Regulation (EC) No 469/2009 if an authorisation number has not been conveyed for any third country and it has not been declared to which third country the export is to be made. (marginal note 26) (key point of judgement)**

74. Thus, it appears that the Munich Court accepted that the ordinary wording of Art. 5 is against the Claimants' position before me, but held that the purpose of the export waiver provisions was sufficiently clear to overcome that.

75. The facts of that case, as stated by the Munich Court, were as follows:

> **3** In a notification to the Applicant and the German Patent and Trade Mark Office dated 31/05/2023, received by the Applicant on 07/06/2023, the Defendant stated its intention to produce a biosimilar of ... in Germany for export to third countries. The Defendant did not provide an authorisation number, nor did it explain to which third countries the export was to take place. No application has been made for marketing authorisation in a third country. The Applicant then made its request in the proceedings. (the file for which has been consulted by the Chamber) by letter dated 30/06/2023, for the issuance of an interim injunction, whereby the Defendant shall be prohibited from producing.... ... The Defendant then sent a further notification dated 27/07/2023 to the German Patent and Trade Mark Office and the Applicant and changed the production purpose from "export and storage" to "storage" with regard to the original notification dated 31/05/2023. Subsequently, the parties unanimously declared procedure ... to be completed.
>
> **4** In a notification to the Applicant and the German Patent and Trade Mark Office dated 23/08/2023 (Annex PM1), the Defendant again stated its intention to produce a biosimilar of ... in Germany for export to third countries. In turn, the Defendant did not provide an authorisation number, nor did it explain to which third countries the export is to take place. No third-country authorisation has thus far been applied for.

76. The Munich Court, in holding the notification to be invalid, reasoned as follows:

> **15** 2. The Defendant cannot validly make use of the manufacturing privilege under Article 5(2)(a(i) and (ii) of Regulation (EC) No 469/2009 on supplementary protection certificates for medicinal products (as amended by Regulation (EU) 2019/933 amending Regulation (EC) No 469/2009) because it has neither conveyed an authorisation number nor has it declared to which third country the export is to be made.
>
> […]
>
> **17** Pursuant to Article 5(5)(e) of the Regulation, it is a prerequisite that the manufacturer convey the number of the marketing authorisation or something equivalent to this authorisation in each third country of export as soon as it becomes publicly available. It is true that, according to the wording of the provision, it is not necessary for the authorisation number to be available at the time the information is conveyed, in accordance with Article 5(2)(b) of the Regulation. According to the intention and purpose of the Regulation, however, derogation from Article 5 of the Regulation must be interpreted restrictively to the effect that the manufacturer cannot invoke this if it has not conveyed the authorisation number for at least one country and has not declared to which third country an export is to take place.

77. On the purpose of the Amendment Regulation, the Munich Court had this to say:

> **19** The aim of amending Regulation 2019/933 (hereinafter also referred to as the Regulation) is to promote the competitiveness of the European Union by allowing manufacturers of generics and biosimilars to manufacture - in the EU - medicinal products and products for export to the markets of third countries in which there is no protection or in which protection has expired (Recital 8 of the Regulation). Contrary to the opinion of the defendant, the purpose of the Regulation is not to fully equate manufacturers within the EU with manufacturers in third countries and that European manufacturers should at all times be able to produce biosimilars and generics that infringe a protective right, largely without restriction. Looking at the Regulation as a whole, its aim is rather to achieve an appropriate balance between the conflicting interests of the IPR holder and the manufacturer and to allow only a selective exception in the event of export to third countries free of intellectual property rights.
>
> **20** In particular, the Regulation seeks only to enable exports to those third countries without protective rights. Although the wording of Article 5 of the Regulation, as the Defendant rightly

notes (Reply, marginal note E.2.2), is makes no distinction between third countries with and without existing property rights. Rather, the only reference made is to third countries in general. However, recitals 3, 4, 8, 29 and 30 each state the objective that exports should only take place to third countries without conflicting property rights. Recital 18 further clarifies that the manufacturer should make sure that there is no protection in an export destination country. Finally, it follows from recitals 4 and 5 of the amending Regulation that the derogation in Article 5 of the Regulation is intended to eliminate competitive disadvantages for manufacturers in the EU with respect to manufacturers in third countries where no protection exists. However, this competitive disadvantage exists only with regard to third countries in which there are no conflicting intellectual property rights. In third countries, however, in which intellectual property rights are opposed, manufacturers may not act in any case, so that there is no threat of discrimination against manufacturers in the European Union in this respect.

[…]

22 According to the stated protective purpose of the Regulation, the three-month period referred to in Article 5(2 (b) of the Regulation is to be applied, contrary to the opinion of the Defendant (Reply to application, marginal note 10.2), not only for the purpose of enabling the IPR holder to check whether the requirements of the Regulation have been complied with and, in particular, whether there is a risk of the products being diverted to the EU market. However, in the opinion of the Chamber, the three-month period is also intended to make it possible for the IPR holder to check whether a market authorisation has been granted in the intended third country of export and whether export to the designated third country is authorised. Otherwise, it would be incomprehensible why Article 5(4)(e) of the Regulation requires that the authorisation number be conveyed at all. This understanding is also supported by recital 15, in which the following is expressly stated.

"This information should be limited to what is necessary and appropriate to enable the certificate holder to assess whether the rights conferred by the certificate are being complied with (...)"•

[…]

25 Contrary to the opinion of the Defendant, it does not follow from recital 18 that the manufacturer alone is responsible for compliance with intellectual property rights in the third country. All that is clarified is that the manufacturer is responsible for ensuring that there is no conflicting protection in the third country. Thus does not mean however that the IPR holder's legal protection options are limited. The Defendant has not

> demonstrated and it is also not clear why the IPR holder would have to accept the generally prohibited production of the product and should only be referred to a claim for legal protection in the third country concerned. In particular, the IPR holder would hardly have the option of obtaining a ban on production within the European Union by resorting to the courts in a third country. In this respect, the right to effective legal protection (Article 47 of the Charter of the Fundamental Rights of the European Union) also requires that the IPR holder must in principle be able to defend itself, within the EU, against the potential infringement of an IPR by the production of a product, even if it is intended for export to a third country.

78. The Munich Court thus drew the following conclusions on the law:

> **26** cc) It follows from this that the manufacturer cannot claim the privilege of Article 5 of the Regulation if an authorisation number has not been conveyed for any third country and no explanation has been given as to which third country the export is to take place, as this is the only way for the IPR holder to check whether the export to the third country is contrary to an IPR. Whether - in accordance with the opinion of the claimant (Reply, marginal note 40) - it is imperative that the manufacturer has provided an authorisation number for at least one third country, or that it is sufficient to state to which third country the export is intended, can be omitted, because the Defendant has not provided any further information on the intended export.
>
> **27** If it were sufficient for the manufacturer, as in the present case, to merely convey the intention to manufacture without any information on the intended country of export, the purpose of the three-month period would be (too) easily undermined. The manufacturer could commence manufacturing after the three-month period and submit the application in the third country. Since there is no explicit obligation to give notice of the application in the third country, it could convey the authorisation number at a later date, after receiving the authorisation, and enter the third country's market directly. Under certain circumstances, the IPR holder would only be informed of this at the time it entered the market and would not have sufficient opportunity to examine whether the imminent market entry in the third country precludes IPRs. It would also be deprived of the possibility of effective legal protection, because it would only be able to take action against production and export as well as distribution in the third country after market entry if it were not a third country free of intellectual property rights. At this point, however, the risk that already completed facts would have been created by production and distribution would have been realised and the damage (usually difficult to repair) would have occurred. According to the Defendant's understanding, the mere

announcement of the production for the purpose of export would ultimately be sufficient to claim the manufacturing privilege. However, this contradicts Article 5(5)(e) of the Regulation, which as a rule provides for the notification of the authorisation number.

28 The Chamber's view is also supported by the comparison with Article 5(2)(a)(i) of the Regulation. In Article 5(2)(a), the Regulation distinguishes between two cases in which, in exceptional circumstances, use is permitted despite the existing intellectual property right: on the one hand, in (a)(i) and (ii) production for the purpose of export or related actions, and on the other hand, in (a)(iii) and (iv) production of products in order to place them on the market in the Member States following expiry of the certificate (day 1 market entry), or related actions. In principle, storage of the products is only permitted at the earliest six months before the expiry of the protection certificate in accordance with Article 5(2)(a)(iii) if the intention is to place the products on the market in a Member State following expiry of the protection certificate. In the case of production for the purpose of export, however, storage is permitted only in accordance with Article 5(2)(a)(i) and (ii) insofar as this is absolutely necessary for the actual export. Even if a specific time frame is not mentioned in this respect, this means - contrary to the opinion of the Defendant (Reply to marginal note 21.3.1) - unlike lit. a) iii), that, in any event, longer-term storage is not permissible. Production for long-term storage in stock is therefore not covered by the manufacturing privilege if the manufacturer only has the general intention of exporting the products to a third country, but it has not even been determined to which specific third country the export is to take place. On the other hand, such long-term storage would be at risk were the manufacturer to commence production three months after notification without knowing and/or having made appropriate (regulatory) arrangements as to the specific third country to which the export is to take place.

29 The Chamber does not overlook the fact that Article 5(5)(e) of the Regulation only provides for notification of the authorisation number "as soon as it is publicly available". Moreover, in the legislative procedure, the obligation provided for in the fourth revised proposal of the Council, 15777/18, to designate the third country of export in the absence of an authorisation (see Annex rop13 in the procedure ... P. 21), no longer included in the final text of the amending regulation. Further, in contrast to the original amendment proposed by the Commission, COM(2018) 317 final, the text of the Regulation no longer provides for notification of a provisional list of the third countries to which the product is to be exported (see Annex ROP10 in the procedure . p. 19). However, in the Chamber's

> view, the aim of the amendments made within the framework of the legislative procedure was to simplify the obligation to notify the national patent authority, but not to impair the examination rights of the IPR holder. It follows from the legislation that identification of the country of export is essential in order to assess whether the conditions for effective use of the derogation are met (as stated in the fifth revised Council proposal, 5130/19, Annex ROP14 in the procedure ... p. 5). Although the consideration of trade secrets of the manufacturer that are worthy of protection is also one of the objectives of the Regulation to be observed (cf. recital 15; first revised proposal of the Council, 12514/18, Annex rop11 in the procedure ... P. 3; fourth revised Council proposal, 15777/18, Annex rop13 in the procedure ... P. 4) As a rule, however, no sensitive trade secrets are disclosed through the mere notification of the intended third country of export. In addition, in accordance with Article 5(4)(e), the Regulation generally provides for the notification of the authorisation number. This also follows from Annex I of the Regulation, which contains a standard notification form in accordance with Article 5(2)(b) and (c) of the Regulation and provides for the notification of the authorisation number under (e). The Regulation itself therefore assumes that the implicit notification of the export destination country is a prerequisite for use of the manufacturer's privilege and, in this respect, attaches greater importance to the interests of the IPR holder in the knowledge of the export destination country than to the interest of the manufacturer in the confidentiality of the country of export.

79. There was some debate during the trial as to what the Munich Court was saying in the final sentence in paragraph 17 of the decision (reproduced above). It is not entirely clear whether the Munich Court meant that giving the authorisation number would necessarily give the identity of the country concerned or whether the authorisation number and the country were said to be separate and cumulative requirements. I mention that it is not entirely clear without any disrespect, since I believe any ambiguity may may well turn on the nicety of translation and whether "and" connotes "and thereby". I was referred to the German version which uses the words "*und auch*" but I cannot hope to decide the nuances of what that means, if anything, above and beyond just "*und*". In any case, the Munich Court clearly attached importance to the party seeking the waiver having to identify the intended country of export (see paragraph 29 which also refers to the identity of the country not being a sensitive trade secret).

80. I was informed by counsel for the Claimants that the German case settled before any appeal.

81. I agree with the Munich Court that the ordinary words of Art. 5 do not require provision of the MA authorisation number to be given for a valid notification, but I respectfully disagree with its other reasoning. Its understanding that the amendments during progress of the legislation removing the requirement to give

the identity of the intended countries of export was "to simplify" as stated in paragraph 29 is simply wrong, as counsel for the Claimants had to, and did, accept. Likewise, the statement in the same paragraph that the intended third county of export is not a trade secret is squarely inconsistent with the legislative intent. These are not minor matters, and I think the erroneous understandings are closely related to the whole chain of reasoning of the Munich Court. I am of course not hearing an appeal from that Court and could never do so, but given that I am being asked by the parties to choose between rival foreign decisions I think I am compelled to assess the criticisms they make where they are relevant to the questions before me.

The Netherlands

82. I was taken to the decision of the District Court of the Hague in *Janssen Biotech v. Samsung Bioepis* dated 23 January 2024 (C/09/657817). As will appear below this went on appeal and the District Court's decision was upheld. So, it is the appeal decision that really matters as to the legal analysis, but it is convenient to set out some of the first instance decision for context.

83. The Hague District Court summarised the facts as follows (I omit footnotes):

i) 2.8. On 24 October 2023, Samsung Bioepis submitted a notification within the meaning of Article 5(2)(b) of the SPC Regulation to the Danish and the Italian authority respectively in copy to Janssen, in which Samsung Bioepis announces that it intends to manufacture and stockpile its biosimilar in Denmark and Italy, respectively:

ii) - for exports to third countries (the manufacturing-for-export waiver ex Art. 5(2)(a), under i and ii, SPC Regulation);

- to place the product on the market in the European Union after the SPC has expired (the EU stockpiling waiver ex Art. 5(2)(a,) under iii and iv, SPC Regulation).

On 30 October 2023, Samsung Bioepis announced in an updated notification for the targeted export countries (for Denmark: the UK and for Italy: Canada, South Korea and the UK). In doing so, Samsung Bioepis has again stated that the reference numbers of the marketing authorisations shall be provided as soon as these are publicly available.

84. In holding the notification to be valid, the Hague District Court reasoned as follows:

> 4.13. Janssen first argues that Samsung Bioepis in its notifications must mention the reference number of the marketing authorisations granted in the export countries in order to obtain a valid manufacturing waiver. However, it does not follow from the Manufacturing Waiver Regulation [i.e., the Amendment Regulation] that at the time the manufacturer makes the notification ex Art. 5(2)(b) Manufacturing Waiver

Regulation, it must already be granted a marketing authorisation in the country to which it wants to export. According to the text of the regulation, the manufacturer only has to provide 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. This means, in the preliminary opinion, that if this number is not yet publicly available, the manufacturer has the option to supplement the notification with the reference number of the marketing authorisation as soon as that is publicly available, as evidenced by Article 5(5)(e) Manufacturing Waiver Regulation.

4.14. The European legislator thereby gave the manufacturer the opportunity to make the notification at the time that it does not yet have a marketing authorisation and to provide the reference number later as soon as it has obtained this number, which in practice is equal to the time when the licence was granted to it. This is also stated in so many words in the recitals under no. 17:

"If a local marketing authorisation, or the equivalent of such authorisation, in a specific third country, for a given medicinal product, is published after the authority is notified, the notification should be promptly updated to include the reference number of that marketing authorisation, or the equivalent of such authorisation, as soon as it is publicly available. If the reference number of that marketing authorisation, or the equivalent of such authorisation, is pending publication, the maker should be required to provide, in the notification, that reference number as soon as it is publicly available."

The establishment history shows that this has been deliberately chosen with the aim of allowing manufacturers located in the EU to compete fairly with manufacturers located outside the EU who can (also) start manufacturing biosimilars before a marketing authorisation has been granted. It also opted for a clearly defined information obligation whereby manufacturers do not have to provide certificate holders with company confidential or commercially sensitive information.

4.15. In addition to the fact that it follows from the literal wording of the Manufacturing Waiver Regulation that the marketing authorisation does not yet have to be granted at the time of the notification, this is also not necessary, contrary to what Janssen argues, to be able to determine the properties of the biosimilar in order to determine whether it falls under the scope of protection of a patent/SPC in a third country. After all, these properties are often already known after phase III clinical trials and it follows from the legal requirements for biosimilars that the Summary of Product Characteristics (SmPC) must largely correspond to the reference medicinal product in question.

> 4.16. The fact that the manufacturer can only submit a notification as referred to in Article 5(2)(b) Manufacturing Waiver Regulation after the marketing authorisation has been granted, as Janssen argues, (and thus can only start manufacturing three months after that) does not follow from the regulation and also does not relate to the purpose of the regulation, namely the creation of a level playing field so that manufacturers located in the European Union can effectively compete with manufacturers outside the European Union. In this context, the Preliminary Relief Judge notes that the European legislator with regard to the EU *stockpile* waiver acknowledges that the possibility of day-one entry is important in order to be able to compete effectively (recitals under 8). It is not clear why this would be different in order to compete effectively in countries outside the EU. In this context, it is also important that Samsung Bioepis, by stating the intended export countries, enables Janssen to check whether patent or SPC rights still apply in the respective country and whether it can initiate proceedings about this, as can be explained below.

85. The Hague District Court addressed the Munich Court decision that I referred to above:

> 4.17. The Landgericht München considered that the manufacturing-for-export waiver should be interpreted restrictively in the sense that the notification must give the reference number of a market authorisation before the manufacturing-for-export waiver can be invoked. In this context, the Landgericht found:
>
> […]
>
> In the English translation:
>
> "The Chamber does not fail to recognize that Article 5 para. 5 lit. e) of the Regulation only provides for the notification of the marketing authorization number "as soon as it is publicly available". Furthermore, in the legislative procedure the obligation to name the third country of export in the absence of a marketing authorization, which was still provided for in the fourth revised Proposal of the Council, 15777 /18 (see exhibit rop13 in proceedings 21 O 8059/23, p. 21), was not included in the final text of the Amending Regulation. Also, in contrast to the Commission's original Amending Proposal, COM(2018) 317 final, the wording of the Regulation no longer provides for the notification of a provisional list of third countries to which the product is to be ex-ported (see exhibit rop10 in proceedings 21 O 8059/23, p. 19). However, in the view of the Chamber, the amendments made during the legislative procedure were intended to simplify the notification obligation towards the

> national patent authority, but not to impair the examination rights of the property right holder."
>
> The Preliminary Relief Judge does not find any support in the history of the Manufacturing Waiver Regulation for the consideration that the requirement to mention the export countries in the notification was removed with the aim of simplifying the notification obligation. In this context, reference is made to the comments to the Third revised proposal, which states:
>
> "Information to the SPC holder aims to provide the latter with the information needed to enforce its SPC. It should not contain commercially sensitive information relating, for example, to export countries, as this could potentially have the unwanted effect of negatively affecting competition."
>
> and the Fourth revised proposal, which states:
>
> "Most diverging views have been expressed on the requirement to notify third country export destinations (point (f) of Article 5(3)). This point, therefore, has now been re-engineered, to essentially remove confidential and sensitive details of future export intentions. Instead, the maker must now provide the reference number of the corresponding market authorization (or equivalent) obtained in the third country of export in respect of a given medicinal product, so that the country in question is identifiable."
>
> The removal of the requirement to mention the export countries in the notification appears to be motivated by concerns about having trade secret information provided by manufacturers and not by the wish to simplify the notification procedure.

86. I agree with what the Hague District Court said about the Munich Court's decision, as will be apparent from my own analysis, above.

87. The Hague District Court also addressed what it termed to be Janssen's "rights free" argument:

> 4.19. In addition, Janssen argues that Samsung Bioepis may not manufacture a biosimilar under the manufacturing-for-export waiver because the countries to which it wants to export them are not "rights free". However, no requirement follows from the Manufacturing Waiver Regulation that no relevant patent rights apply in the intended export countries and/or that the manufacturer must demonstrate this in advance. For the question whether manufacture is permitted under the manufacturing waiver, this is not necessary for the time being. If the manufacturer subsequently opts to market the biosimilar in a third country where patent rights apply, it is up to the

> patent/certificate holder to file infringement proceedings in that country if necessary.
>
> 4.20. Although Janssen rightly argues that in the considerations (3, 4 and 8) of the DCCP, reference is made to "biosimilars intended for export to third countries where there is no protection or where said protection has expired", the Preliminary Relief Judge does not infer from that that the intention of the European legislator was that manufacturing under this waiver would only be permitted if no relevant (patent) rights apply in the export countries. After all, the literal wording of the provisions of the DCCP does not include such a requirement. Moreover, it would be contrary to the objective of the Manufacturing Waiver Regulation to achieve a level playing field with global competition, if manufacturers based in the EU could only manufacture for export to countries that are "rights-free", because they are then seriously disadvantaged compared to competitors based outside the EU who are not bound by such restrictions. After all, this would mean that the European manufacturer, unlike a competitor in a country where there is no (or no longer) protection, could only start manufacturing the medicinal product concerned after the patents in the export country have expired or been revoked. The manufacturing of medicinal products, and certainly biosimilars, as Samsung Bioepis has argued undisputedly, takes considerable time (six months or more). The explanation proposed by Janssen would effectively make day-one entry impossible and thus undermine the purpose of the Manufacturing Waiver Regulation.

88. Again, this aligns with my own analysis, above.

89. The Claimants' central criticism of the Hague Court's decision, which is very similar to its criticism of the decision on appeal from it, which I cover next, is that the decision muddles up the export waiver and the storage waiver (e.g. at 4.16 where it refers to "day-one entry"), despite there being a specific permission for making for storage in relation to the latter and not the former. I reject this. The judgment clearly recognises the two waivers as being different. "Day-one entry" is in a sense relevant both to EU/UK countries where there is an SPC and what is allowed is stockpiling in the last 6 months of the life of *that* SPC for EU/UK sales, and to export country exclusive rights where a level playing field ought to allow EU/UK makers to get on the market straight away after the expiry of *that* (non-EU/UK) exclusive right. The "day-ones" and the rights whose expiry determine when those days are, as well as the acts permitted under the waivers, are different, but I am clear that the Hague Court had all this well in mind. There is no error that affects its reasoning.

90. The Hague District Court's decision was appealed and was upheld by the Hague Court of Appeal on 11 February 2025 (200.337.844/01). I was taken to the following passages from that judgment (I omit the quotations of the Amendment Regulation, and footnotes):

6.8 According to SB, this requirement does not imply more or less than that a reference number must be communicated at the time that this is publicly available, and it is not clear anywhere that the manufacturer must already have a marketing authorisation in the intended country of export at the time of the notification, or at the start of the manufacturing. According to Janssen, it is evident, on the other hand, that the manufacturer must already have a marketing authorisation at the time of the notification, or at the latest at the start of the manufacturing. With reference to Article 5(2)(b), 4 and 7 of the SPC Regulation, recitals 17 and 18 of the MW Regulation [i.e., the Amendment Regulation] and the establishment history and objective of the MW Regulation, Janssen argues that the three-month period of Article 5(2)(b) of the SPC Regulation is intended to enable the SPC holder to check whether the requirements for the waiver have been met and whether the intended country of export is free of rights before the start of manufacturing, so that the SPC holder can start proceedings if necessary. According to Janssen, this objective would not be achieved if the notification is made long before a marketing authorisation is issued, manufacturing is started and a stock is created, since the SPC holder can only assess based on the marketing authorisation whether the maker actually intends to enter the market in the export country and whether in the export country there is a risk of an infringement of the exclusive rights of the SPC holder. The risk of diversion of products to the Union market would be enormous without a marketing authorisation. According to Janssen, the provision that the reference number of the marketing authorisation must be specified *"as soon as this is publicly available"* is therefore only included in case a marketing authorisation has already been granted, but the reference number has not yet been published. Janssen also points out that manufacturing for export before a marketing authorisation is obtained requires stockpiling. The latter is not permitted under the manufacturing-for-export waiver. It also sees an indication in this that a marketing authorisation must be obtained for a valid reliance on the manufacturing-for-export waiver.

6.9 The Court of Appeal does not follow Janssen in its argument. First, the interpretation of Janssen does not find support in the wording of Article 5 of the SPC Regulation. Only Article 5(5)(e) of the SPC Regulation mentions the marketing authorisation. The only requirement of this provision is that the reference number is communicated as soon as it is publicly available. If the reference number is not yet publicly available, according to the literal wording of Article 5(5)(e) of the SPC Regulation, this does not prevent reliance on the manufacturing-for-export waiver. The wording does not provide grounds for the opinion that this is different if the reference number is not yet publicly

available because a marketing authorisation has not yet been obtained.

[…]

6.11 Secondly, Janssen's interpretation is not supported in the considerations of the MW Regulation. The requirement to provide the marketing authorisation reference number is only discussed in recital 17 of the MW Regulation. This recital states, insofar as relevant:

[omitted]

This does not show that that manufacturing may not take place if the reference number has not been provided because there is no marketing authorisation yet. This consideration also does not show that the reference number, in the eyes of the legislator, plays an essential role in the conditions for the waiver. All of this is also not apparent from any other consideration.

6.12 Thirdly, an interpretation of Article 5(5)(e) which means that at the time of the notification, at least no later than before the start of manufacturing, there must already be a marketing authorisation, is not in accordance with the purpose of the obligation to notify and the purpose of the MW Regulation. The purpose of the notification is shown from recital 15 of the MW Regulation (underlining Court of Appeal):

[omitted]

The purpose of the notification is therefore only to enable the SPC holder to verify that its rights granted by the SPC are guaranteed for the Union market, and not to verify that IP rights in force in third countries are respected. This is in line with the purpose of the MW Regulation (see recitals 6.4 and 6.5). The purpose of the 3-month period is to enable the control of those rights (and, if necessary, their enforcement). The argument of Janssen that the marketing authorisation must already have been granted before notification, or at least manufacturing, because the SPC holder can only assess based on the marketing authorisation or if the export country threatens to infringe the exclusive rights of the SPC holder that apply there, therefore fails.

6.13 Janssen's argument that the notification becomes pointless if the maker can start manufacturing and stockpiling without it being clear whether the maker actually intends to enter the market in the intended export country, also fails. With this argument, Janssen disregards the fact that based on Article 5(5) of the SPC Regulation other information must also be provided to the SPC holder than the reference number of the marketing

authorisation. This information informs the SPC holder which maker intends to manufacture in which countries under the waiver. Janssen also disregards the fact that the manufacturer must ensure, based on Article 5(8) of the SPC Regulation, that the products do not have an active unique identifier within the meaning of Delegated Regulation (EU) 2016/1617, and that the manufacturer must apply a logo on the products intended for export based on Article 5(9) of the SPC Regulation. These measures aim to prevent the diversion of the products and their entry into the Union market. According to Article 5(5) MW Regulation, the notification of Article 5(4) MW Regulation also has the purpose of enabling the SPC holder to check whether these obligations are met (see recital 6.12).

[…]

6.17 Moreover, the proposal for the MW Regulation was further amended because the European Parliament (EP) considered that mentioning an export country before the marketing authorisation reference number was publicly available was undesirable because it concerns commercially valuable confidential information. The explanation to the revised proposal for the MW Regulation of 18 February 2019 states about this: *"Lengthy discussions at technical meetings were needed to convince the EP of the Councils approach of having symmetry between the information notified to the competent patent office and the information provided to the SPC holder and to explain to the EP that under the Council approach no confidential or commercially sensitive information would be disclosed and that the publication of all information given to the patent office would be in the interest of fair competition and would avoid any burden on or liability of the national offices. At the end, the EP was willing to accept the Council's approach. However, as part of the overall compromise, one adaptation in the information to be made in the notification as regards export countries needed to be made, as a concession to the EP (). The reference to the third country of export was dropped, as the EP insisted that this would be commercially sensitive information and the EP, although it had moved a long way from its initial mandate, would not accept to include it."*

[Emphasis added by the Dutch Court in the original]

This shows that the EU legislator no longer required that the maker, if he did not already have a reference number, must provide the intended export country. This information was considered too confidential. The requirement was therefore replaced by the requirement to provide the reference number as soon as it was publicly available.

6.18 In Janssen's explanation, the maker could only rely on the manufacturing-for-export waiver if he possesses an export license at the time of notification. SB rightly argues that this does not align with the intention of the EU legislator mentioned in the citation to reach a compromise between the desire to provide the authority and the SPC holder with equal information and the desire not to share confidential information with the SPC holder in the interest of fair competition.

After all, it would force the maker to apply for a marketing authorisation at an earlier stage (Janssen argues that SB should have done so), so that it can start manufacturing after granting it. Applying for this earlier and subsequently specifying the marketing authorisation reference number would have the same effect as the removed obligation to specify the intended export countries in the absence of a marketing authorisation reference number: competitors would become familiar with the maker's plans at an early stage. This is contrary to the interest of fair competition explicitly mentioned by the EU legislator and the purpose of the MW Regulation to create a level playing field with competitors of third countries, who can already start manufacturing before they have a marketing authorisation (see recital 6.4) and who do not have to disclose their market strategy at an early stage. Furthermore, Janssen acknowledges that the marketing authorisation reference number usually becomes publicly available a few days and no more than a few weeks after the date it was obtained. It is not clear that the debate of the Union legislator on the confidentiality of data pertained to this short period between granting the marketing authorisation and the reference number becoming public. This is also, as SB rightly argues, an indication that the EU legislator was concerned with finding a solution to the conflicting interests of the SPC holder and the generic pharmaceutical companies in the period between the notification and the granting of the marketing authorisation.

[…]

6.30 Janssen states that the manufacturing-for-export waiver does not allow a stockpile to be created for export. In this context, it argues the following, in summary:

- The creation of a fully level playing field as such is not an objective of the MW Regulation. The aim is to strike a fair balance between the importance of a more level playing field and the exclusive rights of the SPC holders.

- A legal basis to allow the creation a stockpile for export is missing. Article 5(2) of the SPC Regulation permits stockpiling only for a *"Day-1 entry"* in the EU. Article 5(2)(a) under ii of the SPC Regulation only exempts the strictly necessary actions

for actual export. This does not include stockpiling for *"Day-1 entry"* in third countries.

- Recital 9 of the MW Regulation shows that temporary stockpiling necessary for actual export is permitted. This means, for example, temporary stockpiling until a container is loaded or until a carrier picks up the container. Storage until a trade permit is obtained or the intended export countries are free of rights, is not necessary for actual export.

- Recital 11 of the MW Regulation stipulates that the manufacturing-for-export waiver may not apply to keeping products in stock for purposes other than those mentioned in the MW Regulation.

- The Union legislator, according to the establishment history of the MW Regulation, was against keeping products in stock, due to the risk that these products would be diverted to the Union market. The Union legislator ultimately allowed stockpiling only for *"Day-1 entry"* in the EU. No basis can be found in the legislative history for a (wider) waiver for stockpiling for *"Day-1 entry"* outside the EU.

- A *"Day-1 entry"* outside the EU does not exist; a maker can export as soon as they have a marketing authorisation.

- Allowing manufacturing by SB on a larger scale than foreseen by the EU legislator is contrary to Article 52 of the EU Charter, since the (constitutional) right of the SPC holder is too limited. After all, this restriction does not meet the public interest objectives recognised by the Union and is also not proportionate, even though exceptions should in fact be interpreted in a limited manner.

6.31 SB argues against this, in summary, that the intention of the EU legislator was in fact to enable *"Day-1 entry"* for outside the EU. In this context, it refers to the purpose of the MW Regulation to improve the global competitive position of manufacturers in the EU. In order to be able to compete effectively in the global markets, according to SB, it is necessary to enter those markets first (the first mover effect) with generic and biosimilar medicinal products. SB states that this is only possible if the manufacturers can build up a stock. According to SB it cannot be inferred from the fact that *"Day-1 entry"* for countries outside the EU is not explicitly mentioned that it was not the intention to enable *"Day-1 entry"* outside the EU. An explanation for this is that there is no uniform *"Day-1"* worldwide; the *"Day-1 entry dates"* can be different for all countries. SB also points out that the MW Regulation does not set a maximum period for the *"temporarily in stock"* made possible by Article 5(2)(a) under ii MW Regulation. According to SB, the Preliminary Injunction

Judge rightly interpreted this concept as maintaining a stock for a period that is customary within a normal operation.

[…]

6.34 However, the Court of Appeal derives from the objective of the MW Regulation that under the manufacturing-for-export waiver it is permitted to create a stockpile for the export, more specifically for *"Day-1 entry"* on the market of the intended export country. The Court of Appeal explains this as follows.

[…]

6.36 For the time being, the Court of Appeal does not deem it plausible that real competition on the global market is possible if only stockpiling of a very temporary nature is permitted, as Janssen argues (for example, temporary stockpiling pending the filling of a container or pending the transporter). Only with a stockpile is it possible to achieve a *"Day-1 entry"* in the intended export country and thus to actually compete with manufacturers outside the EU. It is thus consistent with the intention of the EU legislator to allow manufacturers in the EU to also maintain such stockpile for export that they can enter the intended export market on *'Day-1'*.

6.37 In contrast to the above, Janssen's argument that the term *"Day-1 entry"* and *"stockpiling"* was only used in the context of the EU stockpiling waiver in the establishment of the MW Regulation, is not convincing. It is not clear that the Union legislator considered the possibility of a *'Day-1 entry'* for the competitive position of makers for the Union market important, but not for the markets in third countries. It is illogical that, in Janssen's view, SB was already allowed to create a *"stockpile"* for *"Day-1 entry"* in the EU, but not for, for example, the UK.

6.38 Janssen's argument that *"Day-1 entry"* does not exist in the global market, because there is no global *"Day-1"* or because the market in third countries is already freely accessible to any party that wants to sell its product there and has the relevant licence, also fails. IP rights may also exist in third countries that prevent market entry. If those rights expire, a *"Day-1"* applies to the market of the third country concerned.

6.39 The Court of Appeal also does not follow Janssen in its argument that it is not the prohibition to stockpile, but the own timing of SB leads to that it cannot use the *"first mover effect"*. According to Janssen, SB should have applied for a marketing authorisation earlier. This argument disregards the fact that a valid reliance on the manufacturing-for-export waiver does not require that a marketing authorisation has already been obtained

> (see recital 6.21). The present case also does not affect the systematic interpretation of the exception given above.
>
> 6.40 Recital 11 of the MW Regulation does not lead to a different opinion. This consideration determines, insofar as relevant here:
>
> *(11) () In addition, the exception should not cover any storing of products, or medicinal products containing those products, for any purpose other than those specified in this Regulation.*
>
> In the above it has already been considered that stockpiling for a *"Day-1 entry"* is in accordance with the purposes of the MW Regulation. There is therefore no conflict with recital 11 of the MW Regulation. For the same reason, Janssen's argument that allowing a stock for export in violation of Article 52 of the EU Charter allows manufacturing on a larger scale than foreseen by the EU legislator fails.
>
> 6.41 Finally, the Court of Appeal rejects Janssen's argument that maintaining a stockpile for export increases the risk that products manufactured for export are marketed in the EU. The MW Regulation provides for measures to overcome this risk. The Court of Appeal refers to recital 6.13.
>
> 6.42 The conclusion is that, in the preliminary opinion of the Court of Appeal under the manufacturing-for-export waiver, SB is permitted to stockpile for the export of its biosimilar of Ustekinumab, more specifically for the purpose of *"Day-1 entry"* on the market of the intended export country.

91. I am informed by counsel for the Claimants that Janssen are seeking to take this case to the Supreme Court of the Netherlands. This makes no difference to my task.

92. I agree with the Hague Court of Appeal; its analysis essentially matches mine. Again, the Claimants' criticism of it focused on an alleged confusion between the storage waiver and the export waiver, the respective "day ones", and the associated right to store product. As with the Hague District Court and for essentially the same reasons, I reject that. There are both relevant parallels and also differences between the waivers, but the Hague Court of Appeal was well aware of them and was not at all in a muddle.

Belgium

93. I was shown two decisions from the Belgian courts. The first in time was from the Court of Appeal of Brussels, on 4 November 2024, (2024/QR/44) in the *Amgen v. Samsung Bioepis* litigation. It was an appeal on an interim *saisie* order. Probably for this reason the reasoning on the substantive question equivalent to the one I have to decide is short, although it was clearly in favour of the Defendants' arguments in this case, and explicitly disagreed with the Munich Court on the arguments before it.

94. The second Belgian decision was from the Enterprise Court of Brussels dated 23 December 2024 (A/24/02113). This was in main proceedings on the merits, hence why it comes after the above Appeal decision. The main parts of the Enterprise Court decision to which I was referred are as follows:

> The acting president, seated as in preliminary relief proceedings, determines that:
>
> - The wording of Art. 5 of the SPC Regulation is clear regarding the information that must be provided (i.e. the list under Art. 5(5), a) through e), of the SPC Regulation) and that SB by its notification of 13 March 2024 has provided the information as listed under Art. 5(5), a) through e), of the SPC Regulation:
>
> • It does not follow from the provision that the maker, if he already makes the notification as provided in Art. 5(2) SPC Regulation as amended by the Waiver Regulation [i.e., the Amendment Regulation], must already have the marketing authorisations in the export countries (or the equivalent of such permit) in order to obtain a valid waiver. According to the text of the provision, the maker must specify the authorisation reference number *"as soon as it is publicly available";*
>
> • The provision also does not show that (in the absence of a reference number), the export countries must be mentioned in the notification. This is also confirmed by the history of the provision, showing that the European legislator, when seeking a balance between the interests of the SPC holder on the one hand and the maker of the biosimilar medicinal product on the other hand, deliberately opted for the wording of Art. 5 as currently presented (with the omission of the mention of third countries to which the export is planned, because this could potentially negatively affect competition and to avoid confidential, commercially-sensitive information must be provided before it becomes public and not for the purpose of simplifying the notification procedure) (Exhibits IV.1 to IV.8 of SB);
>
> - This (restrictive) interpretation is also confirmed by:
>
> (i) The objective of the Waiver Regulation to allow manufacturers established in the EU to compete fairly with manufacturers established outside the EU who can also start manufacturing biosimilar medicinal products before a marketing authorisation is granted and to ensure timely access of generics and biosimilar medicinal products to the Union market, in particular to increase competition, reduce prices and ensure both the sustainability of national health systems and better access to affordable medicinal products for patients in the Union;

> (ii) The history of the provision as predetermined by the Waiver Regulation (Exhibits IV.1 through IV.8 of SB);
>
> (iii) The possibility of supplementing/updating the standard notification form (Exhibit VI.2 of SB) that provides for a box *"updating an existing notification"* and the lack of a framework on the standard notification form for specifying to which third countries the export is planned;

95. The Enterprise Court went on:

> 30. Third ground: "strict necessity for the actual export"
>
> […]
>
> It follows from the wording of Art. 5(2)(a) SPC Regulation as amended by the Waiver Regulation that the waiver also allows for related actions that are strictly necessary for the actual export. Recital 9 of the Waiver Regulation shows that related acts, for example, may concern the holding, offering for supply, supplying, importing, using or synthesising an active substance for the manufacture of a medicinal product containing this product, or the temporary stockpiling or advertising activities aimed exclusively at exports to destinations in third countries. The Waiver Regulation also does not provide for a maximum period for the temporary stockpiling, other than it must be strictly necessary for the actual export. In view of the objectives of the Waiver Regulation, this will be subject to a period that is customary in the normal course of business (taking into account the specificity for the manufacture of biosimilars the supply chains), as a result of which the maker is not disadvantaged compared to makers outside the EU. The time for this stockpiling is covered by the permitted related act under the waiver.

96. The Enterprise Court also made reference to the Munich Court and Hague District Court decisions I referred to above (the Hague Appeal Court decision not having been given yet):

> 31. The foreign decisions
>
> The acting president, seated in preliminary relief proceedings, took note of the two foreign decisions which also ruled on the interpretation of the Waiver Regulation and more specifically the notification requirements (i.e. the decision of 20 October 2023 of the Regional Court of Munich and the decision of 23 January 2024 of the Court of The Hague).
>
> The Regional Court of Munich considered that the manufacturing waiver for exports should be interpreted restrictively in that the maker must indicate the reference number of the market authorisation in the notification before he can

> invoke the waiver. The acting president does not agree with the opinion that the requirement to mention the exporting countries in the notification has been removed from the historical origin of the provision with a view to simplifying the notification procedure.
>
> The District Court of The Hague correctly took into account the wording of the provision in the interpretation of the Waiver Regulation, but also in the context thereof and with the objectives of the scheme, taking into account the historical origin from which it can be established that the information regarding the identity of the third countries was intentionally omitted for export in order to avoid that commercially sensitive information should be provided before public disclosure.

97. Basically the same points apply to this decision as to the Dutch decisions: the Court found that Art. 5 of the SPC Regulation has the same meaning as I have decided it does as a matter of language, and rejected the Claimants' arguments about purpose. The Court also noted the same error on the part of the Munich Court about "simplify". The Claimants before me said relatively little about the Belgian decisions but I assume they would make a parallel point to that on the Dutch decisions about confusion between the storage and export waivers, which I reject for like reasons, *mutatis mutandis*.

Conclusion

98. The Claimants fail on the Export Issue. The First and Second Notifications are not invalidated by reason of the fact that they did not contain MA reference numbers for Japan. I refuse the Claimants' claim to an injunction.

ANNEX A

Intellectual Property Office

Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

Patents Form SP5
Patents Act 1977 (Rules 116(A)(1))

Notification under the Supplementary Protection Certificate 'manufacturing waiver'

(Article 5(2) of Regulation 469/2009)

1. This notification is for:	✓	A new notification (Article 5(2)(b))
		An update of an existing notification (Article 5(2)(c))
2. SPC number	SPC/GB13/028	
3. Full name, address and postcode of the maker: *(underline all surnames)*	Fisher Clinical Services UK Limited, 3rd Floor, 1 Ashley Road, Altrincham, Cheshire, WA14 2DT.	
4. Purpose of making:		Export
		Storing
	✓	Export and storing
5. For medicinal products to be exported to countries outside the United Kingdom, the Isle of Man and the Member States of the European Union, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each country of export, as soon as it is publicly available.		