Intellectual Property Office

BL O/1160/25

12 December 2025

COUNCIL REGULATION (EC) 469/2009 CONCERNING THE CREATION OF A SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICINAL PRODUCTS

and

THE HUMAN MEDICINES REGULATIONS 2012

APPLICANT	DANA-FARBER CANCER INSTITUTE, INC. & GENETICS INSTITUTE LLC
ISSUE	Whether the application for an extension to certificate SPC/GB17/072 satisfies Article 8(1)(d)(i) of the SPC Regulation
HEARING OFFICER	Dr Rowena Dinham

DECISION

Background

1 This decision relates to the issue of whether the application for a six-month extension to the period of protection provided by supplementary protection certificate SPC/GB17/072 ("the SPC"), filed in the name of Dana-Farber Cancer Institute, Inc. & Genetics Institute LLC ("the Applicant"), meets the requirements of Article 8(1)(d)(i) of Council Regulation (EC) No 469/2009[1] ("the SPC Regulation") for the territorial scope of the whole of the UK or merely for Northern Ireland.

2 The SPC was granted on 17 August 2018 for the product atezolizumab, relying upon basic patent EP (UK) 1210428 B1 filed on 23 August 2000, and centralised European marketing authorisation ("MA") (EU/1/17/1220), granted to Roche Registration Limited on 25 September 2017 and relating to the medicinal product Tecentriq[2]. The basic patent expired on 22 August 2020, and the SPC entered into force on 23 August 2020. The SPC expired on 22 August 2025.

3 On 18 August 2023 the Applicant applied for a six-month extension to the UK SPC. In support of their application, the Applicant provided:

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[2] Tecentriq is a Registered Trade Mark in the United Kingdom

a. the relevant Patents Form SP4;

b. a copy of the statement of the European Medicines Agency (EMA) dated 13 February 2020 indicating compliance with the agreed completed Paediatric Investigation Plan for the medicinal product “Tecentriq/atezolizumab”;

c. copies of the updated current marketing authorisations for GB and NI comprising:

i. Commission Decision C(2020)5804 (final), dated August 2020, amending the marketing authorisation granted by Decision C(2017)6512(final) for “Tecentriq–atezolizumab”;

ii. the associated amended Summary of Product Characteristics (SmPC);

iii. an extract from the OJEU (indicating a 20 August 2020 notification date for Commission decision C(2020)5804);

iv. the SmPCs for “converted EU MAs” PLGB 00031/09098 and PLGB 00031/0915 (both indicating 25 April 2022 as the “Date of first authorisation/renewal of the authorisation” and both now listing the holder as Roche Products Limited);

d. the MA documents for “Tecentriq-atezolizumab” as they existed prior to the above-mentioned amendments by the Commission;

e. an EMA document listing the procedural steps taken and scientific information after the initial authorisation of Tecentriq;

f. a copy of the grant certificate for the original SPC in UK.

4 The Examiner set out his objections in an examination report on 18 June 2024, subsequent to which were a number of rounds of correspondence. The examiner is of the opinion that the application does not meet the requirements of Regulation 58A(2)(a) of the Human Medicines Regulations 2012 (“HMR”) because a statement in the MA, indicating compliance with an agreed completed Paediatric Investigation Plan (“PIP”), has not been provided. Whilst not explicitly set out by the examiner, a lack of a compliance statement in the MA does not meet the requirement of Article 8(1)(d)(i) of the SPC Regulation, and as such the application for an extension to the SPC should be refused. These rounds of correspondence did not lead to agreement and thus this matter came before me at a hearing on 6 November 2025.

5 The Applicant was represented at the hearing by Mr Mike Snodin of Park Grove IP and Mr Gareth Morgan and Ms Natalie Coan of Pinsent Masons. DeAnn Smith, from Foley Hoag LLP, and Steve Caltrider, of Dana-Farber Cancer Institute, Inc., joined remotely as observers.

6 In their skeleton arguments, the Applicant helpfully clarified that the application for an SPC extension is based on the completion of PIP P/0207/2019, which was submitted to the EMA as part of the centralised authorisation procedure, (and led to the resulting statement of compliance issued by the EMA), and not that before the

Medicines & Healthcare products Regulatory Agency (MHRA) with reference number MHRA-100131-PIP01-21.

7 Prior to the hearing I wrote to the Applicant requesting that I be addressed briefly on Council Regulation (EC) No 1901/2006[3] ("the Paediatric Regulation"), particularly Articles 36 and 28(3) and Recital 17, and *E I du Pont Nemours*[4] ("*du Pont*"), particularly paragraphs 28-38. In view of the very short time period between this request and the hearing, I did not request that the skeleton argument should be modified accordingly.

8 In addition to the points made during the hearing, this decision will draw on the final version of the Applicant's thorough and helpful skeleton arguments provided on 3 November 2025 and the report serving as a pre-hearing report provided by the Examiner on 20 August 2025.

Issues to be decided

9 This decision will consider whether the application satisfies Article 8(1)(d)(i) of the SPC Regulation, which requires that the Applicant provides a copy of an MA which includes the statement indicating compliance with an agreed paediatric investigation plan. In practice this amounts to determining whether the EMA compliance statement, issued on 13 February 2020, meets this requirement, or whether a further compliance statement issued by the MHRA post IP completion day[5] is required.

10 It is not at issue that an extension of the SPC with territorial scope of Northern Ireland alone can be granted[6].

11 It is also not at issue that the Applicant met the requirements with regard to the marketing authorisation for a paediatric extension prior to 11pm on IP completion day, and therefore had an application for the paediatric extension to the SPC been made at any time prior to 11pm on 31 December 2020, then the requirements of Article 8(1)(d)(i) would have *prima facie* been met.

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[3] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004. Following the end of the transition period provided by the Agreement on the Withdrawal of the United Kingdom from the European Union, relevant provisions of The Paediatric Regulations were incorporated into the HMR. In particular, Articles 28(3) and 36, setting out the paediatric extension to an SPC, were replaced by Regulation 58A of the Human Medicines Regulations.

[4] *E I du Pont Nemours & Co v The UK Intellectual Property Office* [2009] *EWCA Civ 966*; for the full decision see https://www.bailii.org/ew/cases/EWCA/Civ/2009/966.html

[5] IP completion day ("Implementing Period Completion Day") refers to the end of the transition period during which EU legislation continued to apply in the UK after formally leaving the EU on 31 January 2020. IP completion day is 11:00pm 31 December 2020. After this date UK legislation replaced certain EU-based legislation, and "retained EU law" came into effect.

[6] This is because certain provisions of EU law continued to apply to Northern Ireland under the Windsor Framework, including how Marketing Authorisations issued by the EMA continued to have effect in Northern Ireland until 1 January 2025.

12 In this decision I am restricting my considerations specifically to the arguments presented as to whether the available documentation in support of the Applicant's application for an extension to the SPC satisfies the legal requirements for one to be granted. Whilst the Applicant has commented upon the actions of the MHRA in relation to compliance statements in MAs issued by the EMA prior to IP completion day, it is not appropriate for me to discuss practice at the MHRA.

The law

13 The SPC Regulation provides a patent-like right extending the period of exclusivity in the pharmaceutical field. The period of the extension is determined in relation to the dates of grant of the basic patent and the appropriate marketing authorisation, with a maximum period of five years following expiry of the basic patent. In turn an extension to that period of six months' duration is possible if certain conditions with regard to paediatric testing (governed by a PIP agreed between the MA holder and the relevant regulatory authority) are met.

14 Article 8(1) of the SPC Regulation sets out the requirements for the content of an application for a certificate (including extensions) stating (my emphasis added to the quotes throughout, where appropriate):

> *1. The application for a certificate shall contain:*
>
> *(a) …;*
>
> *(b) a copy of the UK, GB or NI authorisation or, where there is more than one such authorisation, of each authorisation to place the product on the market, as referred to in Article 3(b) and (d), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC, Article 14 of Directive 2001/82/EC, Article 35 of Regulation (EU) 2019/6, Part 2 to Schedule 8 of the Human Medicines Regulations 2012 or Part 1 of Schedule 1 to the Veterinary Medicines Regulations 2013;*
>
> *(c) …;*
>
> ***(d) where the application for a certificate includes a request for an extension of the duration:***
> ***(i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in regulation 58A(2)(a) of the Human Medicines Regulations 2012;***
> *(ii) details of the territory in respect of which the statement referred to in sub-paragraph (i) has been made.*

15 With EU exit, relevant provisions of Council Regulation (EC) No 1901/2006 were incorporated into the Human Medicines Regulation 2012 (HMR), with appropriate modification to take account of the Northern Ireland Protocol. These changes were achieved through the statutory instrument The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020/1488). Regulation 58A of the HMR as amended in this respect states:

Paediatric rewards

58A.—(1) Paragraph (2) applies if—

(a) an application—
(i) to which regulation 50A (requirement for certain applications to include the results of a paediatric investigation plan) applies, and in relation to which there is an agreed paediatric investigation plan; or
(ii) to which Article 7 or 8 of the Paediatric Regulation applies, and in relation to which there is an EU agreed paediatric investigation plan,
is granted by the licensing authority; and
(b) the licensing authority is satisfied that the material provided by the applicant pursuant to—
(i) regulation 50A(3), where paragraph (1)(a)(i) applies; or
(ii) Article 7 or 8 of the Paediatric Regulation, where paragraph (1)(a)(ii) applies,
demonstrates compliance with the agreed paediatric investigation plan.

(2) Where this paragraph applies, the licensing authority must—
(a) include in the UK marketing authorisation a statement to the effect that it is satisfied as set out in paragraph (1)(b); and
(b) ensure that the results of all studies referred to in the paediatric investigation plan are included in the summary of product characteristics and, if the licensing authority considers that the information would be useful to patients, in the package leaflet.

(3) Where—
(a) paragraph (2) applies; or
(b)an application to which Article 7 or 8 of the Paediatric Regulation applies—
(i) includes the results of all studies conducted in compliance with an EU agreed paediatric investigation plan; or
(ii) confirms completion of an EU agreed paediatric investigation plan which failed to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, the package leaflet of the medicinal product,

the holder of a patent or supplementary protection certificate covering the medicinal product to which the application relates is entitled to a six month extension of the period referred to in Articles 13(1) and 13(3) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (subject to paragraphs (4) to (5)).

(4) Paragraph (3) does not apply if the grant of the application referred to in paragraph (1)(a)—
(a) relates to a new paediatric indication; and
(b) the holder of the UK marketing authorisation is entitled to a one year extension of the ten year period referred to in regulation 51A(6), under regulation 51A(12).

(4A) Paragraph (3) does not apply where—
(a) the territorial protection conferred by the supplementary protection certificate referred to in paragraph (3) does not cover the whole of the United Kingdom; and
(b) the UK marketing authorisation in which the statement of compliance is included is not in force in the same part of the United Kingdom as the supplementary protection certificate.

(4B) Where—
(a) the territorial protection conferred by the supplementary protection certificate referred to in paragraph (3) does cover the whole of the United Kingdom; and
(b) the UK marketing authorisation in which the statement of compliance is included is in force in in Great Britain only or in Northern Ireland only,
the extension provided for in paragraph (3) only applies in relation to Great Britain only or Northern Ireland only (as appropriate).

16 Schedule 33A includes the transitional provisions for converted EU MAs, stating at paragraph 6 (my emphasis):

PART 3
Transitional provision in respect of conversion of EU marketing authorisations in force immediately before IP completion day

Conversion of EU marketing authorisations in force before IP completion day

6.—(1) This paragraph applies in relation to an EU marketing authorisation which was in force immediately before IP completion day.

(2) An EU marketing authorisation to which this paragraph applies—

(a) insofar as it authorises sale or supply of a medicinal product in Great Britain, has effect on and after IP completion day as a UKMA(GB) granted under regulation 49(1) of these Regulations (but, insofar as it authorises sale or supply of a medicinal product in Northern Ireland, continues to operate in Northern Ireland as an EU marketing authorisation); and

(b) is referred to in this Part as a "converted EU marketing authorisation".

(3) If the holder of an EU marketing authorisation to which this paragraph applies notifies the licensing authority in writing before the end of the period of 21 days beginning with IP completion day that it does not wish to be the holder of a converted EU marketing authorisation, the licensing authority must revoke the converted EU marketing authorisation with effect from the date of receipt of the notification.

(4) A converted EU marketing authorisation—

(a) is treated as if it had been granted by the licensing authority under regulation 49(1) on the same terms as those on which the EU marketing authorisation was granted, including any conditions

or restrictions subject to which the EU marketing authorisation was granted and which remain in force immediately before IP completion day;

(b) is treated, for the purposes of regulations 65 or 65B (validity of UK marketing authorisation), as if it had been granted by the licensing authority on the date that the EU marketing authorisation took effect;

(c) is treated for the purposes of regulation 67(1) (failure to place on the market) as if it had been granted on IP completion day, and the period of three years referred to in regulation 67(2) is treated as having started on IP completion day;

(d) is treated for the purposes of determining the relevant fee period for the purposes of Schedule 4 to the Fees Regulations (periodic fees for marketing authorisations) as if it had been granted by the licensing authority on the date that the EU marketing authorisation took effect;

(e) is treated, for the purposes of the reference to the date of grant in regulation 27A(a) of the Fees Regulations (fees for renewals of a marketing authorisation) as if it had been granted on the date that the EU marketing authorisation took effect;

(f) retains, for the purposes of regulation 51A(1) and (6), the benefit of any remaining periods of data or marketing exclusivity (if any) from which the holder benefitted immediately before IP completion day;

(g) retains the benefit of any decision by the EMA to exempt the holder from Articles 14(4) or (5) of Regulation (EC) No 726/2004 (failure to place on the market), and that decision is treated as if it had been made by the licensing authority under regulation 67(3); and

(h) remains subject to—

(i) any suspension of the EU marketing authorisation that is in force immediately before IP completion day,

(ii) any post-authorisation obligations imposed after it was granted, and which remain in force immediately before IP completion day, and

(iii) any variation to its terms which were granted or accepted before IP completion day.

(5) For the purposes of this paragraph, an EU marketing authorisation is in force, even if that authorisation is suspended immediately before IP completion day.

(6) A converted EU marketing authorisation to which this paragraph applies which—

(a) was granted as a conditional marketing authorisation within the meaning of Article 1 of Regulation (EC) No 507/2006; and

(b) remains such a conditional marketing authorisation immediately before IP completion day,

has effect on and after IP completion day as a UK marketing authorisation granted under regulation 58F.

(7) A converted EU marketing authorisation to which this paragraph applies which relates to a medicinal product which—

(a) was designated as an orphan medicinal product by the European Commission pursuant to Article 5 of the Orphan Regulation; and

(b) remains in the Community register of Orphan Medicinal Products as referred to in that Article immediately before IP completion day,

has effect on and after IP completion day as a UK marketing authorisation granted under regulation 58C and retains, for the purposes of regulation 58D, the benefit of any period of marketing exclusivity from which the holder benefitted immediately before IP completion day under Article 8 of the Orphan Regulation.

17 In relation to the Paediatric Regulation, Schedule 33A paragraph 41 of the HMR covers further transitional arrangements:

PART 6

Transitional provision in relation to the Paediatric Regulation

Transitional provision in relation to applications made to EMA before IP completion day under the Paediatric Regulation

41.*—(1) Where a paediatric investigation plan has been agreed by the EMA in accordance with the Paediatric Regulation before IP completion day, that plan, including any modifications agreed by the EMA before IP completion day, has effect on and after IP completion day as an agreed paediatric investigation plan.*

(2) Sub-paragraph (3) applies where—

(a) a paediatric investigation plan has been submitted to the EMA with a request for agreement before IP completion day;

(b) the proposed paediatric plan is valid in accordance with the provisions of Article 15(2) of the Paediatric Regulation; but

(c) the EMA has not adopted a decision to agree the plan before IP completion day.

(3) Where this sub-paragraph applies, the licensing authority must—

(a) where an opinion favourable to agreeing the paediatric investigation plan has been given by the Paediatric Committee before IP completion day, treat the plan as an agreed paediatric investigation plan;

(b) where an opinion against agreeing the paediatric investigation plan has been given by the Paediatric Committee before IP completion day, decide that it cannot agree the plan under regulation 50B(5) (agreement and modification of paediatric investigation plan); or

(c) where before IP completion day no opinion in relation to the paediatric investigation plan has been given by the Paediatric Committee treat it as a request for agreement under regulation 50B(1) and determine that request as soon as reasonably practicable, unless the applicant notifies the licensing authority in writing that they do not

want the application to proceed as a request for agreement of a paediatric investigation plan under these Regulations.

(4) Sub-paragraph (5) applies where—

(a) a paediatric investigation plan has been agreed by the EMA in accordance with the Paediatric Regulation before IP completion day;

(b) the person to whom the EMA's decision to agree the plan was addressed has, before IP completion day, made a proposal under Article 22 of the Paediatric Regulation to modify the plan, or to request a waiver; but

(c) the EMA has not adopted a decision to agree to the modification or waiver before IP completion day.

(5) Where this sub-paragraph applies, the licensing authority must—

(a) where an opinion favourable to agreeing the modification or waiver has been given by the Paediatric Committee before IP completion day, agree to the modification or waiver as if it had been requested under regulation 50B(6);

(b) where an opinion against agreeing the modification or waiver has been given by the Paediatric Committee before IP completion day, decide that it cannot agree to the modification or waiver as if it had been requested under regulation 50B(6); or

(c) where before IP completion day no opinion in relation to the modification or waiver has been given by the Paediatric Committee treat the proposal as one made under regulation 50B(6) and consider it accordingly, unless the applicant notifies the licensing authority in writing that they do not want the proposal to proceed as a proposal under regulation 50B(6).

(6) Where the EMA has adopted a decision to grant, and has not revoked, a waiver of the obligation to produce the information in Article 7(1)(a) of the Paediatric Regulation before IP completion day, that waiver has effect on and after IP completion day as a waiver granted by the licensing authority under regulation 50D (waiver of production of information in a paediatric investigation plan).

(7) Sub-paragraph (8) applies where—

(a) an application has been made to the EMA for a waiver of the obligation to produce the information in Article 7(1)(a) of the Paediatric Regulation before IP completion day;

(b) the application has been accepted as valid by the EMA; but

(c) the EMA has not adopted a decision to grant the waiver before IP completion day.

(8) Where this sub-paragraph applies, the licensing authority must—

(a) where an opinion favourable to agreeing the waiver has been given by the Paediatric Committee before IP completion day, grant the waiver under regulation 50D(2);

(b) where an opinion against agreeing the waiver has been given by the Paediatric Committee before IP completion day, decide that it cannot grant the waiver under regulation 50D(2); or

(c) where before IP completion day no opinion in relation to the waiver has been given by the Paediatric Committee treat the proposal as one made under regulation 50D and consider it accordingly, unless the applicant notifies the licensing authority in writing that they do not want the proposal to proceed as a proposal under regulation 50D.

Relevant guidance

18 Paragraph SPM8.09.3 of the IPO Manual of Patent Practice ("MoPP") sets out the current understanding of the interpretation of the transitional arrangements:

> *SPM8.09.3 Authorisations granted under the centralised procedure of Regulation 726/2004 that were converted into a GB authorisation on 31 December 2020 (see SPM1.07.2) are not taken to contain a compliance statement compatible with regulation 58A upon conversion, even if such a statement was made on the corresponding centralised authorisation before that date. Regulation 58A requires such a statement to be made by "the licensing authority"; i.e., the MHRA. Under paragraph 41(1) of Schedule 33A to the Human Medicines Regulations (Transitional provision in relation to EU Exit), an agreed EU PIP is taken to be accepted by the MHRA and applied to the converted authorisation; however, the provision does not include adoption of the compliance statement itself. Therefore, in order for a paediatric extension to be granted based on the converted authorisation, it will be necessary for the applicant to demonstrate that a compliance statement has been made on the converted authorisation by the MHRA based on an agreed completed EU PIP. This remains the case where the converted authorisation has become a transitioned-UK authorisation under Schedule 33B of the Human Medicines Regulations.*

19 The UK government guidance "Procedures for UK paediatric investigation plan (PIPs)" ("PIP Procedures Guidance") on GOV.UK[7], in particular paragraphs 7(3) and 7(5), states:

> ***7.3 Adopted compliance check (CC) prior to 1 January 2021***
>
> *Where there is a positive PDCO partial CC prior to 1 January 2021.*
>
> - *this has been adopted as the UK partial CC outcome*
> - *a new MHRA compliance check submission is not required for these unless subsequent modifications have led to divergence between the UK and EU PIPs*
> - *the adopted PDCO compliance report should be submitted with the subsequent UK full or final compliance check submission*

[7] Available at https://www.gov.uk/guidance/procedures-for-uk-paediatric-investigation-plan-pips

Where there is a positive PDCO full /final CC prior to 1 January 2021, and there is a PDCO opinion on compliance (that is, the PIP is considered to be completed):

- *this has been adopted as the UK full/ final CC outcome*
- *a new MHRA compliance check submission is not required*
- *the adopted PDCO opinion on compliance should be submitted with the relevant regulatory application*

7.5 Statements of compliance

An MHRA statement of compliance is required for any applications to the UK's Intellectual Property Office (IPO) to claim paediatric rewards.

The full / final compliance report and decision letter issued at conclusion of the compliance check assessment is not the same as the statement of compliance for the product and cannot be used to claim relevant paediatric rewards associated with successful completion of the UK PIP.

Where appropriate, an MHRA statement of compliance will be issued with the grant letter of the relevant MA or variation application, when all of the agreed PIP measures have been completed, as follows:

- *the development of this product has complied with all measures in the agreed paediatric investigation plan < reference number >*
- *the summary of product characteristics and, where applicable, the package leaflet will include the results of the studies referred to in the PIP*

In cases where the expected statement of compliance has not been issued with the grant letter, the applicant/MA holder can contact RIS.NA@mhra.gov.uk to request re-issue of the grant letter. Alternatively, applicants can consider submission of a product licence variation via the Human Medicines portal, for the purpose of issuing the PIP compliance statement alone, as a Type IB (under C.I.z.).

For orphan rewards which are conferred on successful completion of a PIP, a statement of compliance will be issued for applicant records and case file. The extension of orphan exclusivity will be granted by the MHRA.

If an EU compliance statement is available, this should be included.

The Examiner's view

20 The Examiner considers that an extension cannot be granted for the territory of Great Britain, because the Applicant has not provided a corresponding compliance statement, as required by Regulation 58A(2)(a) of the HMR. He argues that whilst the Manual of Patent Practice is not itself a legal authority, the practice at paragraph SPM8.09.3 should be followed and suggests that paragraph 41(1) of Schedule 33A to the Human Medicines Regulations 2012 is applicable as it relates to the scenario

where a paediatric investigation plan has been agreed with the EMA in accordance with the Paediatric Regulation before IP completion day. It is this provision that he suggests is referred to in paragraph SPM8.09.3. He asserts that, while paragraph 41(1) says that a PIP agreed before IP completion day has effect after IP completion day, it makes no mention of the adoption of the compliance statement itself. Furthermore, Regulation 58A(2)(a) of the HMR makes it clear that the licensing authority (which he suggests must be the MHRA) must provide a compliance statement to the effect that it is satisfied that the application demonstrates compliance with an agreed PIP (as per Regulation 58A(1)(b)(i)). Therefore, in the absence of any clear guidance in the transitional provisions on this matter, the Examiner concludes that an application caught by paragraph 41(1) still needs to have an MHRA compliance statement with regard to the territory of Great Britain.

21 In relation to paragraph 6(4)(a) of Schedule 33A to the HMR, which states that a converted EU marketing authorisation is treated as if it had been granted by the licensing authority under regulation 49(1) "…on the same terms as those on which the EU marketing authorisation was granted, including any conditions or restrictions subject to which the EU marketing authorisation was granted…", the Examiner agrees with the Applicant that the completed PIP was a condition attached to the MA at IP completion day, but maintains that this does not extend to the statement of compliance itself. The statement of compliance, the Examiner asserts, is entirely separate to the MA and forms no part of it and thus it is not a "condition" or a "restriction" according to paragraph 6(4)(a) and consequently "[i]t forms no part of the authorisation itself, nor does it form part of the Annexes to the authorisation."

22 Furthermore, the Examiner points to paragraph 7.5 of the PIP Procedures Guidance (reproduced above), and suggests that the lack of any mention of transitional provisions supports his view that a statement of compliance issued by the MHRA is necessary, even if there existed an agreed PIP at IP completion day. The Examiner goes on to state that MHRA compliance statement is longer possible because a full product specific waiver has been granted under Regulation 50A(5)(a)(ii)[8]. Therefore, as a compliance statement is not applicable the conditions set out in Regulation 58A cannot be met. I shall only give this point consideration if I conclude that a compliance statement issued by the MHRA is needed.

The Applicant's view

23 The Applicant frames the issue at hand as two questions:

1. "*Can the legal status afforded to Statements of Compliance issued by the EMA prior to IP Completion Day be deduced from other, more general provisions of the laws that entered into force on IP Completion Day (viewing each such law as a whole, and taking into account legislative intent and other aids to statutory interpretation)?";*

and,

[8] In relation to PIP MHRA-100131-PIP01-21 before the MHRA, and not PIP P/0207/2019 submitted to the EMA as part of the centralised authorisation procedure.

2. "*If the answer to the first question is "no", should the law be interpreted so that it has the effect of stripping away any and all legal significance afforded to such Statements of Compliance prior to IP Completion Day (and hence also the effect of stripping away rights to paediatric rewards that flow from such Statements of Compliance)?* "

24 The Applicant submits that the answer to the first question is "yes" and, even if the IPO does not agree, asserts that the answer to the second question must be "no", summarising their answers as follows:

> *"for converted EU MAs, the legal status afforded to a Statement of Compliance issued by the EMA prior to IP Completion Day can be deduced from the laws that entered into force on IP Completion Day, with the consequence that such a Statement of Compliance can provide basis for the grant of a paediatric SPC extension for the whole of the UK, even for extension applications filed after IP Completion Day. Conversely, the interpretation of the relevant legislation that has been adopted by the UKIPO cannot be correct even in the context of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 ("EU Withdrawal Regulations") [Document 13 in hearing bundle] as a whole."*
>
> *"To the extent the UKIPO disagrees with Dana-Farber's position as set out [above] then it is submitted that the removal of rights from a class of SPC holders is both a serious action to contemplate enacting with retrospective effect and perverse in its outcome that other aids to the interpretation of the EU Withdrawal Regulations should be adopted by the UKIPO. These sources show the UKIPO's interpretation cannot be correct."*
>
> *"A review of the Explanatory Memorandum to the EU Withdrawal Regulations [Document 14 in hearing bundle], Impact Assessment [Document 15 in hearing bundle] or relevant Hansard extract [Document 16 in hearing bundle] reveals that the removal of rights from a class of SPC holders was not in the contemplation of the legislator when the EU Withdrawal Regulations were being passed. The UKIPO should, therefore, adopt an interpretation of the EU Withdrawal Regulations that does not have this effect. Indeed, the view of the relevant Minister was that the intent of the EU Withdrawal Regulations was meant to "provide continuity for businesses" in the event of a "no deal" Brexit."*
>
> *"Finally, Dana-Farber submits that its interpretation of the EU Withdrawal Regulations is the only interpretation that does not breach the Human Rights Act 1998 ("HRA") [Document 17 in hearing bundle]."*

25 I will consider each question in turn and only consider question 2 should I find that I disagree with the Applicants' position in relation to question 1.

Analysis

Question 1: Can the legal status afforded to a compliance statement issued by the EMA prior to IP Completion Day be deduced from the laws that entered into force on IP Completion Day?

26 At the hearing Mr Morgan ascertained my familiarity with the statement in Article 28(3) of the Paediatric Regulations, stating that the compliance statement "becomes part of the technical dossier" and asked that I bear that in mind whilst considering the HMR. Turning to Schedule 33A, he referred to these transitional provisions and drew my attention to Section 6 of the HMR applying to EU MAs that were in force. Mr Morgan suggested that there is no question that this provision applied to Tecentriq immediately before IP completion day. Highlighting subsection 4A which states:

> *6-(4) A converted EU marketing authorisation—*
> *(a) is treated as if it had been granted by the licensing authority under regulation 49(1) on the same terms as those on which the EU marketing authorisation was granted, including any conditions or restrictions subject to which the EU marketing authorisation was granted and which remain in force immediately before IP completion day*;

He asserted that it is the Applicant's position that this includes both the Section 28(3) statement and the amended product literature. He then asserted that the Human Medicine Regulations give "a route through". To expand on this, he referred to Regulation 58A subsection (3)(b) (see above) and asserted that this gives the legal basis for the grant of the extension on Tecentriq without any further action from the MHRA (the process of conversion excepted). Regulation 58A (3)(b) relates to an application under whichever of Article 7 or 8 of the Paediatric Regulation applies and he suggested that Tecentriq was obviously covered by that provision. Thus, he argued that the Applicant had both the results of the paediatric investigation plan and the required statement of compliance in place.

27 Mr Morgan then concluded on this first question by stating "So our very simple primary case is it does go further than that - we can find a route through the Human Medicine Regulations simply through a contextual reading of what was in the MA at IP completion date". This he suggested was what was apparent from Schedule 33 subsection 6. Then "Regulation 58A (3)(b) gives you the route through without the MHRA doing anything further, and of course, why would the MHRA do anything further? It doesn't need to, because it's all part of marketing authorisation already."

28 Prior to the hearing, Mr Snodin helpfully provided a timeline for the MA in relation to the EU exit-associated regulatory changes:

Date	**Event**
25 Sep 2017	Grant of centralised MA (EU/1/17/1220)
01 Apr 2019	The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/775)
04 Apr 2019	The Patents (Amendment) (EU Exit) Regulations 2019 (SI 2019/801)

13 Feb 2020	EMA Statement of Compliance
19 Aug 2020	Commission Decision C(2020)5804 (final) Amends SmPC sections 4.2, 4.8, 5.1 and 5.2 in the light of the outcome of PIP studies.
20 Aug 2020	Notification of Commission Decision C(2020)5804 (final)
07 Dec 2020	The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 (SI 2020/1471)
08 Dec 2020	The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020/1488)
31 Dec 2020 at 23:00: IP Completion Day	
01 Jan 2021	EU MA converted to PLGB 00031/0908 and PLGB 00031/0915
18 Aug 2023	Filing of application for extension of SPC/GB17/072

29 This timeline clearly shows that the EMA statement of compliance, the corresponding changes to the summary of product characteristics ("SmPC") of this centralised MA and the associated notification by Commission Decision all took place before 31 December 2020. As stated above, it is clear that the Applicant met the requirements with regard to the MA for a paediatric extension prior to 11pm on IP completion day, and as a consequence had the United Kingdom not left the European Union the Applicant would have had no difficulty obtaining an extension to the duration of the SPC.

30 However, the argument put forward by the Examiner is that an extension to the SPC with GB scope cannot be granted now because no compliance statement has been provided by the MHRA so as to satisfy Regulation 58A(2)(a) of the HMR (i.e. the HMR as amended by statutory instrument The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020/1488)). Furthermore, the EMA compliance statement cannot be used because, whilst the completed PIP is a condition attached to the MA at IP completion day, this does not extend to the EMA compliance statement.

31 At its heart this position is dependent on the omission of clear references to the situation in which the Applicant finds themselves in the transitional arrangements for both the HMR and the SPC Regulation. In other words, whilst it is clear that a completed PIP agreed by the EMA prior to IP completion day is taken to be accepted

by the MHRA and applied to the converted MA[9], there is no explicit indication that a statement of compliance issued by the EMA prior to IP completion day in relation to that accepted PIP is considered to be applied to the converted MA.

32 There is no dispute between the Applicant and the Examiner that the Statutory Instruments containing the amendments[10] that entered into force on IP completion day do not contain any transitional provisions which make specific mention of the legal status (or significance) of statements of compliance issued by the EMA prior to IP completion day. However, guided by the Manual of Patent Practice guidance at paragraph SPM8.09.3 (reproduced above), the Examiner considers Schedule 33A paragraph 41(1) to be relevant:

> *41.—(1) Where a paediatric investigation plan has been agreed by the EMA in accordance with the Paediatric Regulation before IP completion day, that plan, including any modifications agreed by the EMA before IP completion day, has effect on and after IP completion day as an agreed paediatric investigation plan.*

This, the Examiner suggests, applies to the current situation and therefore indicates that although the PIP is carried across, as the wording is silent on the compliance statement, it should be interpreted as indicating that the EMA compliance statement itself is not carried across post IP completion day. As such, the Examiner regards it as not being possible to treat the EMA compliance statement as being covered by Schedule 33A paragraph 6(4)(a) of the HMR. This is as a result of the compliance statement being neither a condition nor a restriction to the MA.

33 I agree that the omission of a clear indication regarding the status of the EMA compliance statement allows the inference that an MHRA compliance statement is needed, if the compliance statement is not part of the MA as the examiner suggests. However, and equally, the Applicant's position is also, as they state, reliant on what can be inferred by this omission, and not what is set out in legislative provisions.

34 I will therefore look at the law both pre- and post-IP completion day regarding the status of the compliance statement in relation to the MA.

35 Prior to EU Exit, Article 8(1)(d) of the SPC Regulation stated:

> *"where the application for a certificate includes a request for an extension of the duration:*
> *(i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006; …"*

36 In turn Article 36 of the Paediatric Regulation (in its original form) stated (my emphasis):

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[9] See Paragraph 41(1) of Schedule 33A to the Human Medicines Regulations (Transitional provision in relation to EU Exit)

[10] to the Human Medicines Regulations 2012 or to The Patents (Amendment) (EU Exit) Regulations 2019 (SI 2019/801)

"1. Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92…

*"2. **The inclusion in a marketing authorisation** of the statement referred to in Article 28(3) shall be used for the purposes of applying paragraph 1 of this Article."*

37 Article 28(3) stated (my emphasis):

*"If the application complies with all the measures contained in the agreed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, **the competent authority shall include within the marketing authorisation a statement indicating compliance** of the application with the agreed paediatric investigation plan. …"*

38 Therefore, it is clear to me that the Paediatric Regulation states that the compliance statement was **within** the marketing authorisation and **was not separate** to it. Indeed, Jacob LJ's discussion of these provisions in *du Pont* appears to support this interpretation, and at paragraph 30 he considered Miss Charlotte May's arguments with approval, stating:

"The key provision is Article 36(2) of the Paediatric Regulation. It says that inclusion of an Article 28(3) statement in a MA "shall be used". Miss May says that is the only way of proving compliance with Article 36(1). And for a range of convincing reasons."

39 After IP completion day, the Paediatric Regulation was replaced by Regulation 58A of the HMR, and so I must ask whether the status of compliance statements changed with these new Regulations. Whilst Regulation 58A of the Human Medicines Regulation 2012 has been laid out above, it is useful to look again at some of its provisions in this context (my emphasis):

Paediatric rewards

58A.—(1) Paragraph (2) applies if—

(a)an application—
(i)to which regulation 50A (requirement for certain applications to include the results of a paediatric investigation plan) applies, and in relation to which there is an agreed paediatric investigation plan; or
(ii)to which Article 7 or 8 of the Paediatric Regulation applies, and in relation to which there is an EU agreed paediatric investigation plan,
is granted by the licensing authority; and
(b)the licensing authority is satisfied that the material provided by the applicant pursuant to—
(i)regulation 50A(3), where paragraph (1)(a)(i) applies; or

(ii)Article 7 or 8 of the Paediatric Regulation, where paragraph (1)(a)(ii) applies,
demonstrates compliance *with the agreed paediatric investigation plan.*

(2) Where this paragraph applies, ***the licensing authority must—***
(a)include in the UK marketing authorisation a statement to the effect that it is satisfied as set out in paragraph (1)(b); *and*
(b)ensure that the results of all studies referred to in the paediatric investigation plan are included in the summary of product characteristics and, if the licensing authority considers that the information would be useful to patients, in the package leaflet.

(3) Where—
(a)paragraph (2) applies; or
(b)an application to which Article 7 or 8 of the Paediatric Regulation applies—
(i)includes the results of all studies conducted in compliance with an EU agreed paediatric investigation plan; or
(ii)confirms completion of an EU agreed paediatric investigation plan which failed to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, the package leaflet of the medicinal product,

the holder of a patent or supplementary protection certificate covering the medicinal product to which the application relates is entitled to a six month extension of the period referred to in Articles 13(1) and 13(3) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (subject to paragraphs (4) to (5)).

(4) …..

(4A) Paragraph (3) does not apply where—
(a)the territorial protection conferred by the supplementary protection certificate referred to in paragraph (3) does not cover the whole of the United Kingdom; and
*(b)****the UK marketing authorisation in which the statement of compliance is included*** *is not in force in the same part of the United Kingdom as the supplementary protection certificate.*

(4B) …..

It therefore appears to me, that, similar to the situation with Article 28(3) of the Paediatric Regulation, any new compliance statement also clearly forms part of the MA. Nevertheless, I also need to consider whether there is anything in the transitional arrangements that make it explicit that the status of pre-existing EMA compliance statements changes post IP-completion day?

40 The only statements making explicit reference to the need for a new MHRA compliance statement are MoPP SPM8.09.3 and paragraph 7.5 of the PIP Procedures Guidance. These are both merely guidance, and thus whilst useful for

interpreting the law, they are not binding on me. Indeed, paragraph 7.5 of the PIP Procedures Guidance states that "*the full/final compliance report and decision letter… is not the same as the statement of compliance for the product and cannot be used to claim relevant paediatric rewards associated with successful completion of the UK PIP*". This paragraph goes on to state that an MHRA statement of compliance will be issued when all the agreed PIP measures have been completed[11]. Neither of these statements explicitly refer to the situation where a statement of compliance was present in the MA prior to IP completion day. Nevertheless, this paragraph concludes with the statement that if "an EU compliance statement is available, this should be included", but again this does not explicitly refer to the availability of the EU compliance statement prior to IP completion day

41 The Applicant has further pointed to a number of sources which stressed that the aim of the transitional arrangements was the preservation of rights and the minimisation of disruption to business. For example, the Explanatory Memorandum to the EU Withdrawal Regulations stated at section 5 that "The Minister of State for Health, Stephen Hammond, has made the following statement regarding Human Rights: "*In my view the provisions of the Human Medicines (amendments etc.) (EU Exit) Regulations 2019 are compatible with the Convention rights*"" and at section 7.1 that "*The instrument makes a large number of changes to make sure that the MHRA can operate in a No Deal EU Exit and to provide continuity for businesses and the public*". Similarly, the Applicant drew my attention to the Hansard record of a debate held before the House of Lords on 7 March 2019 where The Baroness Manzoor stated:

> *"In developing these regulations, my department's priorities have been to make sure that timely availability of safe, effective medicines and devices continues whilst minimising disruption to patients, businesses and ongoing trials, and to ensure that the UK regulator is able to continue to protect public health" and*
>
> *"I end by stating very clearly that the effect of these three sets of regulations is to ensure continuity in the area of medicines, medical devices and clinical trials in a no-deal EU exit. The department has sought to minimise any disruption to patients and industry; to make sure that UK regulators can still protect public health; and to ensure that the UK's life sciences sector contributes, and continues to be a world leader in clinical research and the pharmaceutical sector."*

42 Thus, I am faced with guidance suggesting that the transitional arrangements change the status of the EMA compliance statement, with sources stating that the intention of these arrangements was to "provide continuity", and with actual Statutory Instruments and Regulations that allow an inference either way. There is nothing explicit in relation to the loss of status regarding the compliance statement in any of these sources.

43 This being the case, I do not think I am dealing with a situation which is evenly balanced in terms of whether or not I consider that the Application satisfies Article

[11] i.e. the development of the product has complied with all measures in the agreed PIP; and the SmPC (and where appropriate package leaflet) will indicate the results of the studies referred to in the PIP.

8(1)(d)(i). The Examiner's interpretation of the transitional arrangements is predicated on the compliance statement not forming part of the MA. Prior to EU Exit, Article 28(3) of the Paediatric Regulation makes it clear that this was not the case- at this point in time, the compliance statement was part of the MA. Nothing has been presented to me, nor have I located anything explicitly stating that the situation pre-IP completion day had changed as a result of the transitional arrangements, and that the compliance statement does not form part of the MA. Indeed, Article 58A(2)(a) of the HMR states that the compliance statement is included in the MA. To quote Mr Snodin at the hearing "there is no reason to believe that the amendments entering into force on IP completion date were intended to introduce an additional and purely bureaucratic hurdle to the eligibility to the reward of an extension for GB." On this basis I conclude that the EMA compliance statement still formed part of the MA immediately post-IP completion day and thus paragraph 6(4)(a) of Schedule 33A of the HMR is pertinent:

> *"(4)* ***A converted EU marketing authorisation—(a) is treated as if it had been granted by the licensing authority under regulation 49(1) on the same terms as those on which the EU marketing authorisation was granted,*** *including any conditions or restrictions subject to which the EU marketing authorisation was granted and which remain in force immediately before IP completion day".*

44 Therefore, in light of the above assessment, I consider the EMA compliance statement is carried across on conversion of the MA, and is read as such for the purposes of the extension to the duration of the SPC.

45 With this interpretation I consider that the other transitional arrangements to which the Examiner referred may be read in a consistent fashion. Paragraph 41 of Schedule 33A describes a series of different situations with regard to EU PIPs, whether they have been agreed and thus how the MHRA must treat them. It was agreed by the Applicant and the Examiner that none of the situations of paragraph 41(2) to 41(8) applied, but the Examiner considered that 41(1) applied and suggested a new compliance statement was needed due to the lack of its mention. However, if we consider that the compliance statement is part of the grandfathered MA (or indeed any MA – EU, UK, GB or NI) there is no need to refer to something inevitably part of the MA in paragraph 41 of Schedule 33A. Therefore, only the status of the PIP, not forming part of the MA as such, need be referred to, and this is the case with paragraph 41. Such an interpretation would also not appear to be inconsistent with paragraph 7.5 of the PIP Procedures Guidance, because again this guidance does not explicitly define the present situation where both the EU statement of compliance is present in the MA and the SmPC has been updated to include the results of the PIP prior to IP completion day.

46 At the hearing, Mr Snodin also suggested that if the legal status of the EMA compliance date cannot be inferred from the general provisions of the law, as amended, and especially taking into account the object and purpose of the amendments, legislative intent and other aids to statutory interpretation, then a gap in the law would be left. If there is indeed a legislative oversight then he suggested that could not be held against the Applicant "because you cannot use that an absence of something explicit to strip rights away".

47 Having considered the law and the various aids to interpretation, I am satisfied that the status of the EMA compliance statement can be inferred and thus I do not need either to consider the presence or absence of a legislative oversight, or indeed to consider the current practice of the MHRA. Therefore, my answer to the first question posed by the Applicant referred to above is “yes” and as such I do not need to consider their second question. I also note here that, in their skeleton arguments, the Applicant also drew to my attention a number of paediatric extension applications which the IPO had granted. I do not believe it is necessary to consider these specific cases in this decision.

Conclusion

48 Having determined that the EMA compliance statement issued prior to IP completion day forms part of the grandfathered MA, and it being established that the grandfathered MA SmPC includes any changes that were associated with the completed PIP, I conclude that the application satisfies Regulation 58A(2)(a) of the HMR, as the MA is a converted EU MA having effect after IP completion day as a UKMA(GB) granted under Regulation 49(1) of the HMR. As a result, the requirements of Article 8(1)(d)(i) are met and thus an extension to the SPC may be granted to the Applicant with both GB and NI territorial scope. I therefore remit the application back to the Examiner for further processing.

Dr Rowena Dinham

Patent Examination Group Head, acting for the Comptroller