

## **Decision in Respect of an Application by Shire International GmbH for Reinstatement of the Deadline for Filing an Application for an Extension of the Duration of Supplementary Protection Certificate (SPC) No. 2009/040**

### INTRODUCTION

1. This case concerns an application for reinstatement of the deadline for filing an extension of the duration of SPC No. 2009/040.
2. The primary legislation governing SPCs in Ireland is *Council Regulation (EEC) No. 1768/92*. This was transposed into Irish Law by Statutory Instrument (S.I.) *No. 125/1993, (European Communities (Supplementary Protection Certificate) Regulations, 1993)*. In January 2007, *Regulation (EC) No. 1901/2006 on medicinal products for paediatric use* came into force and aimed at promoting the development of medicinal products for use in the paediatric population. Amongst the incentives for the pharmaceutical industry introduced by this Regulation was that of a 6-month period of extension to the duration of an existing SPC - commonly known as a “paediatric extension”. In 2009, the original 1992 Regulation was amended to provide for this further period of extension and was codified as *Regulation (EC) 469/2009* – hereinafter the ‘*SPC Regulation*’.
3. On 21 December 2009, Movetis N.V. (‘Movetis’) submitted an SPC application No. 2009/040 for the product “*Prucalopride or a pharmaceutically acceptable acid addition salt thereof*” (the active ingredient in the medicinal product RESOLOR) and the corresponding certificate was granted on 1 April 2010 with an expiry date of 15 November 2020.
4. On 1 February 2019, the agent, FRKelly, filed an application for a paediatric extension on behalf on Shire International GmbH (‘Shire’), to whom the original SPC had been assigned on 5 February 2019. The agent simultaneously submitted an application for reinstatement of the deadline for the filing of this extension application. He explained this was necessary because, under Article 7(4) of the *SPC Regulation*, the latest date for lodging this application had already passed on 15 November 2018 (i.e. not later than two years before the expiry of the original certificate).

5. In accounting for the failure to meet the statutory filing deadline, the agent stated that Shire had only become aware of this fact on 5 December 2018. He also said that this failure had not only been completely inadvertent but had occurred despite reasonable care having been taken by the applicant in the monitoring of such deadlines over a considerable period of time.

6. In support of the application the agent enclosed additional documents as follows: (i) a statement signed by Ramy Riad on behalf of Shire; (ii) a statutory declaration by Kevin McGough of Takeda Pharmaceutical Company Ltd. (the present owners of Shire) and Annexes 1,2(a), 2(b), 3, 4, 5 and 6; and (iii) a declaration by Bart Laenen of LC Patents and Annexes 1(a), 1(b), 2 and 3.

7. The agent also quoted Article 12 of *S.I. No. 125/1993*: "*Wherever a procedure in relation to an SPC or an application for an SPC is not laid down in these Regulations ... the procedures of the Act of 1992 and the Rules of 1992 in relation to patents and patent applications shall apply...*". On this basis the agent argued that it was appropriate to apply for reinstatement of this application under Section 35A of the *Patents Act, 1992* (as amended).

8. In a communication to the agent on 12 April 2019, the examiner stated her opinion that Section 35A applied to existing applications which had either been refused or were treated as having been withdrawn. It did not, in her view, allow for the extension of a deadline prescribed in legislation such as the 2-year deadline in Article 7(4) and she proposed to refuse the reinstatement application. On 16 April 2019 the agent requested a hearing on the matter which was subsequently arranged for 16 May 2019. Prior to the hearing the agent filed a further written submission providing additional supporting background information, case law and argumentation in support of the applicant's case.

## HEARING

9. At the hearing the applicant was represented by Dr. Luke Maishman and Mr. Donal Kelly from FRKelly, accompanied by Mr. Simon Keevey-Kothari from Carpmiels & Ransford (UK). In addition to myself, Dr. Dolores Cassidy, the examiner who handled the case, also attended.

10. Dr. Maishman reiterated that the failure by Shire to meet the filing deadline of 15 November 2019 had occurred despite reasonable care having been taken in the monitoring of such deadlines. He emphasised that Shire had completed all the additional studies in compliance with an agreed paediatric investigation plan (PIP) as required under the *SPC Regulation*, and he pointed out that these studies had necessitated considerable additional investment by Shire. He explained that a 6-month extension of the duration of the existing SPC represented an economically significant continuation of the monopoly right at a commercially important stage in the lifetime of RESOLOR and that the loss of this right would severely disadvantage the applicant.

11. He then referred in some detail to the supporting information provided by the applicant, in particular the declarations by Mr. Kevin McGough and Mr. Bart Laenen which give a detailed account for the failure to comply with the statutory time limit. A brief summary of these declarations and the related annexed material follows.

12. In his declaration, Kevin McGough outlined his role within Shire and explained that, at the time of the development of RESOLOR, the company had around 11,000 US and foreign patent applications on hand, including some related SPCs, and was filing and prosecuting hundreds of applications annually.

13. He stated that the SPC for RESOLOR was based on a European patent, EP 0 807 110. This patent was filed on 16 November 1995 by Janssen Pharmaceutica NV in Belgium and granted by the EPO on 8 May 2002. On 27 May 2007 the patent had been assigned to Movetis, a spin-out company from Janssen. He explained that responsibility for managing the company's SPC applications in Europe were being managed by LC Patents, a well-established patent agent partnership also based in Belgium. In 2010 Movetis and its IP portfolio were then acquired by Shire (under the name of Shire-Movetis) who continued the relationship with LC Patents for managing its SPC portfolio.

14. In his declaration, Bert Laenen, a partner at LC Patents, confirmed he was responsible for coordinating SPC filings in Europe related to the RESOLOR patent and for instructing other national attorneys across Europe. He outlined how, in 2014, Shire-Movetis had taken back responsibility for the renewal fee payments (annuities) for its SPCs from LC Patents (this task was subsequently handled by Shire's annuity service

provider, CPI). He stated that LC Patents now understood it was no longer required to report any SPC-related deadlines to Shire-Movetis. He added that, as deadlines linked to possible SPC extensions had never been automatically logged in the company's docketing system, there would have been no other deadlines for the company to report back on. He confirmed that the LC Patents had closed its files on all the SPCs in its Shire-Movetis portfolio at this point in time.

15. He then referred to an email request from Kevin McGough on 26 May 2017 (see Annex 2) requesting LC Patents to continue to preserve all Shire's patent and SPC rights. On 29 May 2017, his colleague, Ann Vander Borght, replied on his behalf seeking clarification as to whether this request had been sent mistakenly given the understanding of LC Patents that annuity payments were all being dealt with by CPI (on Shire's behalf). As LC Patents never received a reply to Ann Vander Borght's follow-up email, it was assumed that Kevin McGough's email had been sent in error and no further action was taken. He summed up by emphasising that in all his time LC Patents had never missed an SPC or paediatric extension deadline nor had it ever needed to file a reinstatement request at any patent office. He also pointed out that its internal systems had been in full compliance with the ISO 9001:2008 Management System Standard since 2012.

16. At this point, Mr. Keevey-Kothari raised the issue of reinstatement of rights in patent law to highlight the opportunity afforded to applicants to reinstate lost rights arising from the inadvertent missing of a deadline. In support of his argument he cited Article 12 of the Patent Law Treaty (PLT), Article 48 of the Patent Cooperation Treaty (PCT) and Article 122 of the European Patent Convention (EPC) as examples of provisions in international patent law which allowed for the reinstatement of lost rights in such a situation.

17. Referring to Irish legislation in this area, he argued that Section 35A of the *Patents Act*, together with the corresponding Rule 33A, did provide a sound legal basis for the reinstatement of an application such as in the present case. In his opinion, prior to 15 November 2018, there had clearly existed on the side of the applicant a right to apply for a paediatric extension to SPC No. 2009/040 and that this right was only lost as a result of the inadvertently missed deadline. He also emphasised how Shire, on being made aware of the missed deadline on 5 December 2018 by way of an email from

a Senior Associate at Carpmaels in London, had reacted swiftly to rectify the situation by submitting the extension application together with an application for reinstatement of the deadline to the Irish Office on 1 February 2019.

## ANALYSIS

18. The evidence presented and summarised above does indicate that it was Shire's intention to take back only the responsibility for annuity payments from LC Patents. Unfortunately for Shire, LC Patents' understanding was that it no longer had any responsibility for reporting back any SPC-related deadlines and that it could now close its Shire SPC portfolio. This does explain why a paediatric extension application was not filed within the statutory deadline because of this misunderstanding.

19. However, given that Shire had not only agreed a PIP with the European Medicines Agency (EMA), but had also performed the necessary studies (as shown by the document "Positive Opinion of the Paediatric Committee on compliance with a Paediatric Investigation Plan" issued by the EMA on 6 December 2013), it had clearly been Shire's intention all along to apply for a paediatric extension for RESOLOR.

20. As pointed out both in the pre-hearing submission and at the hearing itself, the principle of "reinstatement of rights" is a well-established one in patent law worldwide. This was one of many issues addressed by the PLT in 2000, which provided for the harmonisation and streamlining of certain formal procedures in respect of patent applications and granted patents. Subsequently, many of these provisions, including one dealing specifically with the issue of reinstatement of rights, have been incorporated directly into regional patent treaties such as the PCT and the EPC, and into national patent legislation across the globe.

21. The legislative position in Ireland on reinstatement was originally provided for in Rule (99)(1) of the *Patents Rules, 1992* as follows: "*If an application for a patent is refused by the Controller arising from an omission by the applicant to reply to a communication within a time limit specified by the Controller for so doing, the applicant may apply to the Controller for reinstatement of the application.*"

22. As mentioned earlier in paragraph 3, the 1992 *SPC Regulation* was transposed into Irish Law by S.I. No. 125/1993. Article 4(2) of this S.I. provided for reinstatement of an SPC request: “(2) *A request may be reinstated in accordance with the provisions of Rule 99 of the Rules of 1992 as if, in that Rule, there were substituted references to a request for reference to an application for a patent.*”

23. One of the aims of the *Patents (Amendment) Act 2006* was to give effect to certain provisions of the PLT. Of relevance in the present case was the introduction of Section 35A: “(2) *Where an application for a patent is refused or is treated as having been withdrawn, as a direct consequence of a failure by the applicant to comply with a requirement of this Act or rules made thereunder within a period which is prescribed or specified by the Controller, subject to subsection (3), the Controller shall reinstate the application only if—*

- (a) the applicant requests the Controller to do so,*
- (b) the request complies with the prescribed requirements, and*
- (c) the Controller is satisfied that the said failure to comply occurred despite reasonable care having been taken to so comply.”*

24. Another piece of legislation, S.I. No. 194/2009 – *Patents (Amendment) Rules 2009*, was then introduced to revoke Rule 99 and replace it with a new Rule as follows: “*Rule 33A. (1) The time limit for making a request under section 35A for reinstatement shall be the earlier to expire of the following periods:*

- (a) two months from the date on which the removal of the cause of non-compliance occurred, or*
- (b) twelve months starting from the date the application was terminated.*

*(2) The request for reinstatement shall state—*

- (a) the name and address of the applicant for reinstatement and the number of the patent application in question, and*
- (b) the circumstances which led to the failure to comply with the time limit, and it shall be accompanied by the prescribed fee and by evidence verifying any statement made in relation to the circumstances mentioned in subparagraph (b).”*

25. The Explanatory Note to the S.I. provides the context for this amendment: - “... *Certain rule amendments are necessary to allow for the commencement of some sections*

*of the Patents (Amendment) Act 2006, in particular, the provisions relating to the Patent Law Treaty.*” It was the provision in the PLT dealing with reinstatement, namely *Article 12 - Reinstatement of Rights After a Finding of Due Care or Unintentionality by the Office*, which Section 35A, in conjunction with the replacement of Rule 99 by Rule 33A, was introduced to support.

26. However, whilst the PLT provides the means for the reinstatement of rights related to a failure by an applicant to comply with a time limit, the amendment to Section 35A uses language – possibly influenced by the text in the old Rule 99 – which is more restrictive in that it refers merely to the reinstatement of an application rather than the reinstatement of the right as such.

27. In this context the corresponding amendment made to the EPC in the light of the PLT is also of relevance: *“Article 122 - Re-establishment of rights An applicant for or proprietor of a European patent who, in spite of all due care required by the circumstances having been taken, was unable to observe a time limit vis-à-vis the European Patent Office shall have his rights re-established upon request if the non-observance of this time limit has the direct consequence of causing the refusal of the European patent application or of a request, or the deeming of the application to have been withdrawn, or the revocation of the European patent, or the loss of any other right or means of redress.”* This provision more clearly reflects the focus on the re-establishment of lost rights and also sets a threshold of “all due care” as compared with that of “reasonable care” in Section 35A(2)(c) of the Irish Act.

28. Mr. Keevey-Kothari did make specific reference to this threshold issue in arguing that the reason given for Shire’s failure to comply with the filing deadline did meet this “reasonable care” threshold in Irish Law. As support for this, he pointed out in five other EU Member States namely, Belgium, Czech Republic, France, Luxembourg and Sweden Shire had been similar applications for reinstatement and that, to the best of his knowledge, these states applied either a “*due care*” or “*all due care*” threshold.

29. The more restrictive language of Section 35A is also reflected in the language of the request from Shire namely, “... *reinstatement of the deadline for filing an application for extension ...*”. Likewise, this language may have influenced the examiner to propose

rejection of the reinstatement application based on her interpretation that this provision related solely to existing applications which had either been refused or treated as having been withdrawn. Whilst I can see her logic in arriving at this conclusion, I believe it may have been unduly restrictive.

30. It is clear to me that Shire had earned the right to file a paediatric extension application by virtue of having a valid SPC for RESOLOR and having successfully completed the required studies for PIP compliance. Shire lost this right through its failure to file the extension application within the statutory deadline owing to the circumstances described in detail above. Despite the language of the reinstatement application, what was clearly being sought was a reinstatement of its right to file this application.

31. In relation to the “reasonable care” threshold, I have noted that the “all due care” requirement has been addressed by one of the EPO Boards of Appeal in paragraph 10 of the decision in case T 0529/09 (10 June 2010): *“By “all due care” in this context is meant all reasonable care, i.e. the standard of care that the notional reasonably competent patentee, applicant or representative would employ in all the relevant circumstances (see T 30/90 of 13 June 1991, point 3 of the reasons). According to the established case law of the boards of appeal, an isolated mistake in a normally satisfactory system is excusable”*.

32. From the evidence presented in this case it is clear to me that the applicant was unable to file the extension application in time due to an isolated error, caused by a misunderstanding in the handing over of responsibilities between Shire and LC Patents, in what had previously been a well-proven system for monitoring patent and SPC deadlines over a period of years. In my opinion this satisfies the “reasonable care” requirement in Section 35A(2)(c) of the *Patents Act*.

33. Furthermore, I accept that once Shire became aware of the missed deadline on 5 December 2018 i.e. the date on which the removal of the cause of non-compliance occurred, it acted promptly to remedy the situation by submitting the paediatric application together with the reinstatement request to the Irish Office on 1 February 2019. This falls within the 2-month period prescribed in Rule 33A(1)(a) of the *Patents Rules*.



34. Finally, I do not believe that any third party would be adversely affected if the application for reinstatement is allowed as the SPC for RESOLOR itself is not due to expire until 5 November 2020.

## DECISION

Notwithstanding the somewhat restrictive wording of Section 35A(2) of the *Patents Act*, and Rule 33A(1)(a) of the *Patents Rules*, the application to reinstate the applicant's right to file an extension of the duration of SPC No. 2009/040 is allowed.

As a consequence of this, the application for the paediatric extension application to SPC 2009/040 submitted on 1 February 2019 is now deemed to have been filed within the period provided for under Article 7(4) of the *SPC Regulation*.

Therefore, the application may now proceed for examination in the normal manner.

Dr. Michael Lydon  
Hearing Officer  
23 August 2019