



**THE COURT OF APPEAL
CIVIL**

**Court of Appeal Record No. 2020/52
High Court Record No. 2018/1080 JR
Neutral Citation No. [2022] IECA 109**

**APPROVED
NO REDACTION NEEDED**

**Murray J.
Costello J.
Haughton J.**

BETWEEN

ARTHROPHARM (EUROPE) LIMITED

APPLICANT/APPELLANT

- AND -

THE HEALTH PRODUCTS REGULATORY AUTHORITY

RESPONDENT

- AND -

CHANELLE PHARMACEUTICALS MANUFACTURING LIMITED

NOTICE PARTY

JUDGMENT of Mr. Justice Murray delivered on the 10th day of May 2022

The basic facts

1. Cartrophen Vet 100 mg/ml solution for injection ('Cartrophen') is a veterinary medicinal product. It is used in the treatment of osteoarthritis in dogs. As a medicinal product, it can only be placed on the market in an EU Member State if it is the subject of a marketing authorisation. The respondent ('HPRA') is the competent authority responsible for the grant in the State of such authorisations. In October 1991 HPRA¹ granted the applicant ('Arthroparm') a relevant authorisation in respect of Cartrophen.
2. The legal regime governing such authorisation is now found in the provisions of the European Communities (Animal Remedies) (No. 2) Regulations 2007 (SI No. 786 of 2007) ('the 2007 Regulations') as amended. The 2007 Regulations transposed into domestic law Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products ('the 2001 Directive').²
3. On 20 July 2018 HPRA granted a marketing authorisation³ to Chanelle in respect of Osteopen 100 mg/ml solution for injection ('Osteopen'). This product is also used in the treatment of musculoskeletal disorders in dogs. That authorisation was granted on the basis that Osteopen was a generic of Cartrophen. The 2007 Regulations and 2001

¹ At the time the respondent was known as the Irish Medicines Board.

² The requirement for a marketing authorisation in respect of a veterinary medicinal product before such a product is put in the market in a member state is imposed by Article 5 of the 2001 Directive, and Article 3 of the 2007 Regulations.

³ The term used in the 2007 Regulations is '*veterinary product authorisation*'. Having regard to the language used in those parts of the 2001 Directive relevant to these proceedings I will, as did the trial judge, refer throughout to '*marketing authorisation*'.

Directive provide that a ‘generic’ medicinal product is one that has the same qualitative and quantitative composition and active substances in the same pharmaceutical form as a reference product that has been previously authorised.

4. Because HPRA was satisfied that Osteopen was a generic of Cartrophen, and because Cartrophen had at the time of the application made by Chanelle been authorised for not less than eight years in a Member State of the European Union, the relevant regulatory regime provided that to obtain the authorisation Chanelle did not – as it would otherwise have been required to do – have to provide the results of safety and residue tests or of pre-clinical and clinical trials in respect of the product.⁴ Instead, Chanelle was able to ‘piggyback’ on the earlier authorisation granted in respect of Cartrophen.
5. Arthroparm was not aware that Chanelle was seeking an authorisation of this kind, and neither the 2001 Directive nor the 2007 Regulations made provision for Arthroparm to be advised that a process to obtain authorisation as a generic by reference to one of its products was in train. Nor is there provision for the holder of an authorisation in respect of a reference product to be advised of the fact of the grant of a generic marketing authorisation.
6. Three days after it was made (23 July 2018), the decision to grant the marketing authorisation in respect of Osteopen was published by the HPRA on its website. At the same time a number of documents related to the decision were published in the same way. These included a product authorisation assessment. One month after this

⁴ The obligation to provide this information is imposed by Article 12 of the 2001 Directive, and the modification of that obligation in respect of generic products is enabled by Article 13. The equivalent provisions in the 2007 Regulations are Regulations 5 and 6.

publication (23 August 2018) Arthroparm learnt of the grant of that authorisation to Chanelle. It was so informed by its United Kingdom distributor.

7. On 20 December 2018 an *ex parte* application was brought by Arthroparm for leave to apply for judicial review of the decision of the HPRA to grant the marketing authorisation to Chanelle. That application was acceded to and leave was granted on that date.
8. While there are a large number of complaints made in the proceedings, central to the action is the claim made by Arthroparm that Osteopen is not properly viewed as a generic of Cartrophen. It makes three essential points. First, Arthroparm says that the quantitative and qualitative compositions of the two products are not the same. Second, it contends that HPRA erred in accepting, in the course of the process, the omission of bioequivalence data in circumstances where the active substance in the manufacturing processes for the two products are not the same. Third, it complains that the active ingredient is a biological substance and that Osteopen ought to have been assessed in accordance with Article 13(4) of the Directive. This requires HPRA to take account of differences relating to raw materials or in the manufacturing processes of the two products. It says that variations in the manufacturing processes of the active substance used in Osteopen and Cartrophen result in significant differences between the two products.
9. At the time leave was sought and granted HPRA had not complied with the statutory obligation imposed upon it by Regulation 46 of the 2007 Regulations to publish notice of the grant of a veterinary product authorisation in *Iris Oifigiúil*. HPRA did not do this until 8 January 2019.

The issues

10. On its face, the timing of all of this gave rise to an issue. Order 84 Rule 21(1) of the Rules of the Superior Courts ('RSC') provides that an application for leave to apply for judicial review shall be made '*within three months from the date when grounds for the application first arose*'. The court is empowered under certain conditions to extend this time. The application for leave was moved five months after the decision to grant the marketing authorisation was made and published to the world at large, and four months after Arthroparm became aware of it. In their opposition papers HPRA and Chanelle asserted that Arthroparm was out of time to seek the relief it claimed.

11. When granting leave to apply for judicial review the High Court directed that any questions as to whether it was necessary to extend time for seeking such relief and, if so, whether such an extension should be granted, should be left to the trial judge. Shortly before the full action was due to come on for trial, the High Court judge managing the judicial review list directed the trial of an issue as to whether the proceedings had been brought within the period specified in Order 84 Rule 21(1) and, if not, whether time should be extended (as enabled by Order 84 Rule 21(3)). The trial of that issue came before Simons J. For reasons explained in a detailed and careful reserved judgment, ([2020] IEHC 16) he answered both of these questions in the negative. In this appeal from that decision, the following issues arise:

- (i) Whether the trial judge erred in finding that the date from which the three month period ran is 23 July 2018 (as HPRA contended) or whether (as Arthroparm argued) it ran either (a) from the point at which HPRA complied with its statutory obligation to publish notice of the grant of the licence in *Iris Oifigiúil*, or (b) from 30 October 2018, this being the point at which HPRA responded to

an ‘objection’ to the registration made by Arthroparm on 12 October 2018⁵ which, *inter alia* requested HPRA to suspend the authorisation.

- (ii) If the answer to (i) is in the negative, whether the trial judge erred in refusing to extend the time for bringing the application for leave having regard to (a) the fact that Arthroparm did not learn of the decision until 23 August 2018, (b) the claim made by Arthroparm that even then the information available about Osteopen was (it claims) limited, (c) the contention that it was only after the launch of Osteopen on the market on 8 November 2018 that Arthroparm was in a position to obtain a sample of the product for comparative analysis, (d) that correspondence from HPRA responding to complaints from Arthroparm did not come to the latter’s attention until 14 December 2018, (e) the fact that there were ongoing exchanges between the parties as of the date of the application for leave to seek judicial review and (f) the fact that the decision had not been published in *Iris Oifigiúil* as of the date of that application.
- (iii) Irrespective of the answer to the first two of these questions, whether a fresh decision was made by HPRA when, by letter dated 6 March 2019, it refused to accede to Arthroparm’s request that it withdraw or suspend the product licence.

The point from which time began to run under Order 84 Rule 21(1)

⁵ There is some confusion as to whether this letter was sent on 10 October (the letter sent bears this date) or 12 October (the e-mail sending it seems to bear this date); as with the trial judge I will refer throughout to the letter of 12 October.

(a) *The provisions governing publication of the decision.*

12. In the High Court, much of the argument around when time began to run for the bringing of a challenge became meshed with the issue of when and how the decision of HPRA was and ought to have been published; indeed, Arthroparm argued that when leave was sought time had not started to run at all by reason of the failure of HPRA to publish the decision in Iris Oifigiúil until 8 January 2019.

13. At least some of the difficulty arose from the fact – to which I have referred earlier – that the regulatory scheme governing the grant of authorisations of this kind does not envisage the holder of the authorisation for the reference product being either advised of or involved in the process leading to the grant of a generic marketing authorisation, as well as from the fact that no provision is made for informing them of an authorisation once granted. Instead, the assumption appears to be that the holder of the authorisation for the reference product will learn of the grant of the generic marketing authorisation through public notification of such a decision once made. This was, Simons J. believed, a *‘surprising feature of the legislative regime’* (at para. 9).

14. The Directive addresses public notification in two provisions, Article 25 and Article 94. Article 25(3) provides (emphasis added):

*‘The competent authority shall make the marketing authorisation **publicly available without delay**, together with the summary of product characteristics for each veterinary medicinal product that it has authorised.’*

15. Article 25(4) makes it clear that the relevant obligation is not limited to publication of the authorisation, but that it also extends to the assessment report. This is a report regarding the results of the pharmaceutical, safety and residue tests and the pre-clinical and clinical trials of the veterinary medicinal product concerned. Article 25(4) states *inter alia*:

‘The competent authority shall make the assessment report and its reasons for the opinion publicly available without delay, after deleting any information of a commercially confidential nature.’

16. Article 94 imposes an overlapping obligation:

‘Any decision referred to in this Directive, taken by the competent authorities of the Member States, may only be taken on the grounds set out in this Directive and shall state in detail the reasons on which it is based.

Such a decision shall be notified to the party concerned who shall at the same time be informed of the remedies available to him under current legislation and the time allowed for seeking such remedies.’

Decisions to grant or revoke a marketing authorisation shall be made publicly available.’

(Emphasis added).

17. These provisions are given effect to in the 2007 Regulations in a somewhat indirect way. Regulation 9(4) states:

*‘[The HPRA] except in the case of a homeopathic animal remedy referred to in Regulation 7(2), shall **have regard to** Article 25 of the Directive.’*

(Emphasis added)

18. Regulation 46 states:

‘[The HPRA] shall publish notice of the grant or revocation of a veterinary product authorisation in Iris Oifigiúil’

19. Regulation 47 then addresses notification obligations *vis-à-vis* the European Medicines Agency (referred to throughout the Regulations as ‘the Agency’):

‘The Board shall inform the Agency of a decision to grant, refuse, suspend or revoke a veterinary product authorisation or a manufacturer’s licence, or to prohibit the sale or supply, or to recall an animal remedy and the reasons for the decision.’

20. It will be noticed that the provision prescribing the form of publication (Regulation 46) imposes neither a requirement that the publication occur ‘*without delay*’ as required by Article 25 of the Directive, nor does it comply with the obligation under Article 25 to publish the assessment report. The provision that does specifically refer

to Article 25 (Regulation 9(4)) appears to view it as something to be taken into account (*'have regard to'*) rather than as generating a clear and binding obligation. That provision does not prescribe how the obligation it imposes will be complied with, and indeed Regulation 9(4) refers to the *entirety* of Article 25, not just to the mandatory obligation provided for in Article 25(4).

21. These provisions should be viewed in the light of the broader regulatory context. The overall effect of that regime is that authorisation for certain types of drugs can be sought and granted centrally by the European Commission, or in other cases by the regulatory authority in a member state. In the former situation, the authorisation is valid throughout the European Union. The latter is administered by the authorities of one member state (the Reference Member State or 'RMS'), an application being made to use either the mutual recognition procedure (in which the relevant authorities of other concerned states are requested to mutually recognise an authorisation granted by the RMS of another State) or a decentralised procedure (appropriate where a marketing authorisation has not been granted for the product in any member state). In the case of the decentralised procedure (which was the procedure in issue here) the applicant for an authorisation requests the RMS to act as such, submitting an application to it and, simultaneously, to all member states involved. The authority in the RMS takes the lead in the running of the procedure and assessment of the application with the relevant authorities in those states having consultative and supporting roles in the process of assessment.

22. Essentially, the RMS represents the other concerned states in making the detailed assessment and operates in conjunction with them: while in one sense all of the

member states act independently, they use their best endeavours to reach a common position and, if a point is reached such that a concerned member state cannot approve an application, the matter is referred to a body called the Co-ordination Group for Mutual Recognition and Decentralised Procedures. If the RMS grants the authorisation, it is then granted in other states. Here, the application was made to Ireland as the RMS, and it was in that context that HPRA assumed the function of granting the authorisation. The point is that the decentralised procedure availed of by Arthroparm involved the expert regulators of twelve other member states (each of whom concluded that Osteopen was a generic of Cartrophen) and the grant of the authorisation by HPRA had an important consequence in those other concerned jurisdictions.

- 23.** HPRA determined to effect immediate publication in what the trial judge described as an '*ad hoc*' and '*pragmatic*' way by publishing the decision and associated documentation on its website (a form of publication for which no legal provision is made anywhere), and by doing so three days after the making of the decision. That publication comprised the summary of product characteristics and public assessment report for the product. On the date it made its decision, it also notified the communications and tracking system used by national competent authorities involved in the licensing of human and veterinary products. The summary of product characteristics and public assessment report for Osteopen were then published on the product index maintained by the Heads of Medicines Agencies (the VMRI). The VMRI contains information on veterinary products authorised under the mutual recognition and decentralised procedures provided for in the 2001 Directive and is publicly available on the Heads of Medicines Agencies websites. An RSS web-feed

of the latest products added or changed on the VMRI may be subscribed to without charge. On 16 August, HPRA published on its website a list of updates made to authorised veterinary products during the previous month. That update included the marketing authorisation granted in respect of Osteopen.

(b) The decision of the trial judge as to the running of time

24. Simons J. shortly rejected the suggestion that the time period specified in Order 84 Rule 21(1) ran from the date of the impugned decision. He explained (at para. 53):

‘It would undermine the purpose of the requirement for public notification and the right to effective judicial protection were the three month time-limit under Order 84, rule 20(1) to begin to run prior to the date of the publication of the decision. To interpret the rule otherwise could produce a scenario whereby the time-limit for judicial review proceedings would have already expired before the public were notified of the decision.’

25. Having so concluded, Simons J. noted the restriction on the constitutional right of access to the courts entailed by Order 84 Rule 21, observing that it was arguable that the time limits should be construed in strict accordance with the relevant statutory regime, and that this contention – if well placed – would suggest that time only began to run from the date that the relevant decision had been published in the prescribed form (i.e. in *Iris Oifigiúil*). Ultimately, he rejected this conclusion, preferring to find that time should instead be calculated from the date of the *ad hoc* posting of the decision on the HPRA website. He explained this (at paras. 57 and 58), as follows:

‘This conclusion is reached on the basis that the posting of the decision and associated documentation on the website represents an effective form of public notification, and that the wording of regulation 9(4) of the 2007 Regulations is flexible enough to authorise this form of public notification. The Directive mandates that the reasoned decision and assessment report be made publicly available without delay. The Authority is obliged, under regulation 9(4), to have regard to these requirements, and this obligation is satisfied by publication on the website. The formal publication of the decision alone in Iris Oifigiúil provides less rather than more information, and it would seem pedantic to defer the running of the time-limit until the date of this publication.

My conclusion is informed, in part at least, by the particular circumstances of this case whereby the Objector had actual knowledge of the making of the decision by 23 August 2018, i.e. well within three months of the date of the posting of the decision on the website. Given its actual knowledge, it is difficult for the Objector to argue convincingly that the running of time should have been postponed until the date of the subsequent publication in Iris Oifigiúil (8 January 2019). This is especially so where there is no suggestion that the Objector or its officers ever examined Iris Oifigiúil or relied on same as a source of information.’

26. Simons J. rejected the contention advanced by Arthroparm that time ran from the point at which HPRA delivered its response on 30 October 2018. He explained (at para. 59):

‘The nature and extent of the information which must be made publicly available is set out at article 25 of the Directive. On the facts of the present case, the requisite information was made available on the Authority’s website on 23 July 2018. Once the legislative requirements had been complied with, time began to run. If and insofar as the Objector wishes to argue that further information was required in order to allow it to institute judicial review proceedings, this is a matter which goes towards the separate question of an extension of time. It does not affect the date upon which time begins to run.’

27. He expressed his conclusion as follows (at paras. 60 and 61):

‘... I have concluded that the time-limit for the purposes of Order 84, rule 21 began to run from the date upon which the decision and associated documentation was first published on the Authority’s website, i.e. 23 July 2018. This was the date upon which compliance with the requirements of articles 25 and 94 of the Directive had been achieved. The decision to grant a marketing authorisation had been published, together with a copy of the assessment report. A person inspecting the website would thus be aware of the nature of the decision, i.e. a decision to grant marketing authorisation, and would also understand the basis upon which the decision had been reached.

Whereas the hypothetical person inspecting the website might wish to argue that more expansive reasons should have been provided, or that certain information which had been omitted on the grounds of its “commercially confidential nature” by reference to article 25(4), should have been published, that person

would nevertheless already be armed with sufficient material to allow proceedings to be prepared and drafted. This is borne out by the facts of the present case where, of course, the Objector had been in a position to put together a detailed objection to the decision by reference to the materials available as of 23 July 2018. It will be recalled that the detailed objection of 12 October 2018 had been prepared without any necessity for an analysis of a sample of the generic product.'

28. To summarise and repeat the trial judge's reasoning and conclusions on this issue:

- (i) In the view of the trial judge to hold that time would begin to run from a point that pre-dated the publication to the world at large of the decision in question would potentially breach principles of effective judicial protection.
- (ii) Therefore, the commencement of time should depend upon the publication of the decision in accordance with the applicable regulatory regime.
- (iii) The identification of that point was therefore related to when publication in accordance with the requirements of the 2007 Regulation occurred: *'[o]nce the legislative requirements had been complied with time began to run'* (at para. 59).

- (iv) Publication in accordance with the 2007 Regulations occurred on 23 July 2018 as the posting of the decision and associated documentation on the HPRA website was authorised by Regulation 9(4).
- (v) To run time from the point at which publication occurred in Iris Oifigiúil would be pedantic and involved the provision of less rather than more information.
- (vi) The fact that Arthroparm was aware of the decision by 23 August 2018 was relevant to this conclusion, and that knowledge made it difficult for Arthroparm to contend that the running of time ought to have been postponed until the date of subsequent publication in Iris Oifigiúil.
- (vii) The request made by Arthroparm on 12 October that HPRA suspend the authorisation was not relevant to the running of time having regard to the fact that the decision was made publicly available in accordance with Article 25 of the Directive before this. Insofar as is relevant, this went to discretion to extend time rather than to the point at which time began to run.

29. As I explain, I agree with the essential conclusion reached by the trial judge that Arthroparm had a period of three months from the date of publication of the decision to grant the marketing authorisation, within which to bring its challenge. However, I have reached that conclusion for reasons that differ from those adopted by the trial judge. While the difference between the trial judge's reasons and mine may itself appear pedantic, having regard to the arguments advanced by Arthroparm in this appeal as to the point from which time ran it is necessary to outline in some detail what

I believe to be the correct analysis of the relationship between the date of the decision, the date of actual publication, the date on which Arthroparm actually learnt of the grant, the terms of Order 84 Rule 21(1) and the provisions of the Directive and Regulation mandating publication of decisions to grant marketing authorisations.

(c) The legal characterisation of Arthroparm's interest in the impugned decision.

30. It is impossible to address these issues without making some reference to the nature (and source) of Arthroparm's right to bring the action at all. The invocation by the trial judge of principles of effective judicial protection suggest a conclusion on his part that Arthroparm enjoyed rights in European law to challenge the impugned decision, and indeed at one point he observed that a decision to grant a marketing authorisation was in principle justiciable (at para. 52). For reasons I will shortly explain, I have decided that it would not be appropriate to determine finally in this application whether Arthroparm enjoyed such a right. Nonetheless, in explaining my approach to the point at which time should be viewed as beginning to run, it is necessary to say something about the question. The Directive makes no reference of any kind to such an interest, and neither it nor the 2007 Regulations make any provision for the holder of a marketing authorisation to participate in the procedure by which a generic marketing authorisation is granted, to be advised of such a decision if it is made, nor to challenge such a decision when made. Instead, it envisages what all parties accept to be a bilateral procedure involving HPRA and the applicant for the authorisation. Here I should stress that it was *not* part of the case advanced by Arthroparm that it had any implied right to have the grant of the marketing authorisation reviewed *de novo* and, having regard to the terms of the Directive and indeed the CJEU case law to

which I will shortly refer, it is hard to see how such a contention – had it been advanced – could have been sustained.

- 31.** In any event, the 2001 Directive proceeds on the basis that where a market authorisation is granted in respect of a veterinary medicinal product, a generic veterinary medicinal product shall not be placed on the market until a period of ten years have elapsed from the initial authorisation of the reference product (Article 13(1)). The reference product must have been authorised for at least eight years in a member state or in the European Union before it can be relied upon in the generic authorisation process. These provisions thus afford the holder of the authorisation a period of data exclusivity of eight years, and ten years of market protection. After the expiry of these periods, the holder of that authorisation can have no expectation of exclusivity. In this case Arthroparm has enjoyed a period of twenty-seven years of market exclusivity prior to the placing on the market of a competing generic product.
- 32.** In addressing the legal interest of Arthroparm in the process of authorisation of the generic product, its counsel referred the court to the decision of the CJEU in Case C-104/13. *Olainfarm AS v. Latvijas Republikas Veselibas ministrija* ECLI:EU:C:2014:2316, contending that in that case the court recognised a right on the part of a party in the position of Arthroparm to challenge the marketing authorisation. This may be, but is not necessarily, correct. It is certainly *not* accurate to assert, as counsel did, that the case law was '*clear*'.
- 33.** *Olainfarm* concerned not the 2001 Directive, but Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ('Directive 2001/83'). Nonetheless, it is

of relevance here as Article 10 of Directive 2001/83 similarly enabled by way of derogation from some of the requirements normally imposed on an applicant for such authorisation, the grant of a marketing authorisation in respect of a generic product where there is an authorised reference product. As with the 2001 Directive, this could only be done where the reference product had been authorised for not less than eight years, it being permissible to place the generic product on the market only when ten years had elapsed from the initial authorisation of the reference product.

34. Article 10a of Directive 2001/83 contained another derogation from certain requirements normally imposed upon an applicant for a marketing authorisation, introducing a similar simplified authorisation procedure. It operated to exempt an applicant for such an authorisation from the obligation otherwise arising to provide the results of pre-clinical tests or clinical trials if it could demonstrate that the active substances of the medicinal product had been – subject to certain conditions – in well-established medicinal use within the Community within ten years.⁶

35. In 2008 Olainfarm obtained a marketing authorisation in Latvia for a product called NEIROMIDIN. It did so in accordance with Article 10a of Directive 2001/83, having demonstrated that the active substances of the product had been in well-established medicinal use within the Community for at least ten years. In 2011, another pharmaceutical company, Grindeks AS, obtained a generic marketing authorisation under Article 10 of Directive 2001/83. It did so, purporting to use NEIROMIDIN as its reference product. Olainfarm sought to challenge the grant of the generic product authorisation by application brought before the relevant authority in Latvia. Its case was that that the documents submitted for registration of the reference product did not

⁶A similar provision appears in Article 13a of the 2001 Directive.

comply with EU law requirements for generic medicinal products. The complaint was rejected on the basis that the holder of a marketing authorisation did not enjoy an individual right to challenge an authorisation granted for a generic of the reference product.

36. That decision was challenged in annulment proceedings, Olainfarm contending that as the manufacturer of the reference product it enjoyed an individual right to challenge what it claimed was the unjustified advantage which, it contended, had been granted to Grindeks. Its substantive case was that a medicinal product for which a marketing authorisation had been granted in accordance with Article 10a did not constitute a reference medicinal product for the purposes of Article 10. The Senate of the Latvian Supreme Court referred two questions to the CJEU by way of an application for a preliminary ruling. One of these was as to the substantive issue regarding the use of Article 10 in respect of a product authorised in accordance with Article 10a. The other was as to whether the manufacturer of a reference medicinal product enjoys an individual right to bring an action challenging the decision of a competent authority by which a generic medicinal product of another manufacturer of medicinal products was registered, using as a reference the registration of its product.

37. In addressing the second of these questions, Advocate General Wahl drew a distinction between two situations. One was where it was arguable that the effect of the decision granting the marketing authorisation which it was sought to challenge would be to allow the manufacturer of the generic product to market a competing product within the period of exclusivity envisaged by the Directive (which was ten, or in certain circumstances eleven, years). In that situation, he said, if the holder did not have the right to challenge that decision this would run counter to the objective of ensuring that

no competing generics are placed on the market during the ten-year protection period. However, he could not read into the Directive any more far-reaching right that would extend beyond that period of time. He said (at para. 50):

‘Once the ten-year protection period has expired, the holder no longer enjoys market exclusivity and is, accordingly, in the same position as any other third party. In fact, extending the right to challenge a decision to grant a marketing authorisation for a generic beyond the ten-year period expressly provided for in Article 10 of the directive would enable the holder to block the entry into the market of competitors by restricting the use of information already in the public domain.’

38. It is arguable that the CJEU formulated a broader entitlement on the part of the holder of the marketing authorisation in respect of the reference product. Noting that the procedure for the grant of a marketing authorisation under Directive 2001/83 was conceived as bilateral and did not contain an express provision to the effect that a judicial remedy was available to the holder of a marketing authorisation whose reference product was used to avail of the authorisation procedure for a generic, the court observed the effect of Article 47 of the Charter of Fundamental Rights of the European Union (‘the Charter’) and consequent right to a judicial remedy for any person whose rights as guaranteed by the law of the European Union were violated.

39. In stating – without apparent qualification – that the holder of a market authorisation did enjoy the right to such a remedy, the court proceeded on the basis that the holder of that authorisation was obliged to accept that the manufacturer of another medicinal product was entitled to refer to the results of pre-clinical tests and clinical trials

contained in the dossier relating to the application for the marketing authorisation for the former product rather than to perform those tests or trials himself for the purposes of obtaining an authorisation for the other medicinal product. It was that obligation, the court held, which gave rise to the entitlement to a judicial remedy (at para. 37):

‘It is apparent that that provision confers a concomitant right on the holder of the MA for the former medicinal product to demand that the rights attaching to him by virtue of those conditions are observed’.

40. It is arguable that at paragraph 38 of its judgment the court identified two distinct circumstances in which the holder might have such a right. The first was phrased thus:

‘... the holder of a MA for a medicinal product has the right to demand, pursuant to the second and fifth subparagraphs of Article 10(1) of Directive 2001/83, that that medicinal product is not to be used as a reference product for the purpose of authorising the placing on the market of a medicinal product of another manufacturer until a period of 8 years has elapsed from the date on which that MA was granted, or to demand that a medicinal product authorised to be placed on the market on the basis of Article 10 is not to be marketed until a period of 10 years — which may be extended, where appropriate, to 11 — has elapsed from the date on which that MA was granted.’

41. The second was, it might be said, broader:

‘Similarly, that holder may demand that his medicinal product is not to be used for the purpose of obtaining, under Article 10, a MA for another medicinal

product in relation to which his own product cannot be regarded as a reference product within the meaning of Article 10(2)(a), as contended by Olainfarm before the referring court, or for a product which does not fulfil the requirement, laid down in Article 10(2)(b) of the directive, that it should be similar to the reference product in terms of its composition in active substances and pharmaceutical form.'

42. Some aspects of the submissions of HPRA and Chanelle suggested that the rationale of the CJEU's judgment in *Olainfarm* was limited to challenges which were, or might arguably have been, derived from the exclusive right of the holder of the manufacturing licence within the ten-year period of exclusivity (and each has maintained a challenge to the *locus standi* of Arthroparm to challenge the decision to grant the authorisation). If that were correct, this would have consequences not merely for Arthroparm's standing (although it would not necessarily deprive it of standing, which it might independently enjoy under domestic law – see for example *Scotia Pharmaceuticals Ltd. v. National Drugs Advisory Board and anor* (Unreported, High Court, 30 June 1995, Barron J.), but it would also have a potential implication for its position in extending time, as it would enjoy no *right* under European law to bring the action. The interpretation suggested by HPRA and Chanelle is supported by the approach of the Advocate General in *Olainfarm*.

43. However, as I have noted, the language of the second part of paragraph 38 of the CJEU judgment in *Olainfarm* might suggest, in its second part, a broader right. Moreover, it might be said that the rationale for the right to challenge identified by the court invites a more extensive entitlement than was adopted by the Advocate General. Arguably, the rationale is not rooted in the rights of the holder of the product authorisation to

exclusivity but is presented as a consequence of the obligation imposed by Article 10. That might be thought to have been reflected in the unqualified terms of the answer provided by the court to the first question asked of it (at para. 40):

‘...on a proper construction of Article 10 of Directive 2001/83, read in conjunction with Article 47 of the Charter, the holder of a MA for a medicinal product used as a reference product in an application for a MA under Article 10 of the directive for a generic product of another manufacturer has the right to a judicial remedy enabling him to challenge the decision of the competent authority which granted the MA for the generic product, provided that that holder is seeking judicial protection of a right conferred on him by Article 10. Such a judicial remedy exists, inter alia, where the holder demands that his medicinal product is not to be used for the purpose of obtaining, under Article 10, a MA for another medicinal product in relation to which his own product cannot be regarded as a reference product within the meaning of Article 10(2)(a) of the directive.’

44. That said, the CJEU in *Olainfarm* was concerned with a case in which the period of exclusivity was engaged, and it is quite possible that insofar as it referred to Article 10 in the second part of paragraph 38, it was addressing only a right to such exclusivity, and not any broader right vested in the holder of the reference product authorisation (this, certainly as I read his judgment, being the interpretation suggested by Lewis J. in *Orion Corporation v. Secretary of State for Health and Social Care* [2019] EWHC 689 (Admin.) at para. 13).

45. The parties did not in terms request the court to determine conclusively the issue of whether in the circumstances of this case Arthroparm had a right under Article 47 of the Charter to bring a challenge of the kind in issue here (although counsel for Arthroparm did focus in some detail on the decision in *Olainfarm* in the course of his reply). I believe it would be wrong to decide the issue on this application to extend time under Order 84 Rule 21(3), not least of all in circumstances where it would involve determining by way of a preliminary issue around timing a matter going to the merits of the case that is not usually appropriate when addressing the application of Order 84 Rule 21. This was not obviously envisaged by the High Court when the issue was fixed. Moreover, determining this issue finally might require a reference to the CJEU (a possibility, I should say, on which I am not expressing a final view). However, the question cannot simply be ignored, as the issue of whether Arthroparm enjoys a right under EU law to bring this challenge has implications for how the court approaches the operation of the time limits in Order 84 RSC.

46. The proper way to proceed, it appears to me, is to note that having regard to the manner in which the CJEU expressed itself in *Olainfarm*, it is arguable that there is such a right, and that having regard to the actual facts of that case and for the reasons explained by the Advocate General, it is arguable that there is not. However, to assume that there is no such right could operate unjustly to Arthroparm's detriment as the rules governing time in a challenge in an EU law right may well be more generous than those applicable in the case of a purely domestic remedy. To assume that there is such a right does not result in prejudice of the same degree to HPRA and Chanelle, as they remain free at the trial to agitate the question of Arthroparm's standing to bring the case. Therefore, I will determine this application on the assumption that such a right is indeed enjoyed by Arthroparm. This does, as I explain, have implications for how

the issue of an extension of time should be approached. However, I stress, this is not to determine finally the question of whether Arthrofarm had a right under Article 47 of the Charter to bring this claim.

(d) Order 84 Rule 21(1)

47. The first conclusion reached by Simons J. has an obvious initial appeal – it seems counterintuitive that time would run against a person seeking to challenge the legal validity of a decision before they might reasonably know of it and, indeed, that that time could in theory expire before they knew or could reasonably have known that the decision had been made. However, it is my view that this conclusion was mistaken – at least in the way it was expressed. Ultimately, as I have earlier suggested, the error is at least to some extent *nihil ad rem* as on the facts here the court must in this case exercise its discretion to extend time so that Arthrofarm is afforded a period of three months from the point at which it knew or ought to have known of the decision to bring its challenge – and indeed it may well be that this is what Simons J. intended. However, as I have already noted, it is important to explain the precise basis on which I have reached this conclusion.

48. In this regard, four points should be noticed at the outset. First, albeit most obviously, if time is not fixed to run from the point a decision is made or takes effect, any alternative needs to be accommodated within the language of the relevant rule. Second, and related to this, if publication is to be the trigger for the running of time, there must be some basis, if not in Order 84, then in the particular regulatory regime governing the decision in question for concluding not merely that publication but also

the particular mode of publication relied upon, has this effect. Third, it is to be borne in mind that irrespective of when time begins to run, the court has a discretion to extend time which, one would expect, would be exercised in such a manner as to take account of the fact (where the issue arises) that the applicant neither knew nor could have known of the impugned decision when it was made.

49. Fourth, if public administration is properly, fairly, and transparently conducted, there should not often be a divergence between the point at which a person having a legitimate interest in challenging the decision of a statutory body becomes, or ought to reasonably become aware of that decision, and the date of that decision taking effect. Often, persons directly affected by the decision of a statutory body will have participated in the process leading to the decision and will in the course of that process be notified of the decision when it takes effect. Where this is not the case the law should – and usually does – clearly prescribe a method of publication to which those interested in the decision can be expected to refer so that they can be reasonably taken to have been in a position to appraise themselves of it (whether or not they actually do so). This case is thus less than usual: Arthroparm had the right to market the reference product, but no right to be advised when a generic sought to ‘piggyback’ on that product so as to enter the market to compete with it. It was therefore neither aware of the process, nor the decision when it was made. The law prescribes a method of publication of the decision (but neither the reasons therefor nor the assessment report) in *Iris Oifigiúil*, but HPRA postponed complying with that requirement in favour of a different form of immediate publication which did include the assessment report. Nowhere was it provided by law that this was how such decisions would be publicised. I should state – albeit obviously – that if Arthroparm had no right to challenge the

decision, all of this would be academic and the omissions I have identified would not present any particular difficulty.

50. The starting point in resolving these various questions is the background to and language of the relevant rule. The first generally applicable requirement that proceedings by way of judicial review be commenced within specific time periods was introduced by the 1986 Rules of the Superior Courts. Prior to the overhaul of the procedure for obtaining relief by way of judicial review effected by Order 84 of those Rules, the only such requirement applicable to the old state side orders arose in relation to applications for orders of *certiorari* of certain decisions of the District and Circuit Court, with Order 84 Rule 10 of the 1962 Rules of the Superior Courts imposing a period of six months for the bringing of such applications, and the court having a general power in an appropriate case to extend that time. Delay in the bringing of other state side applications was addressed under the umbrella of the court's power to withhold relief on discretionary grounds (see, in particular, *State (Furey) v. Minister for Defence* [1988] ILRM 89 at p. 93 to 94 (per Griffin J.)). It is not unimportant that the 1962 Rules specifically provided that in those cases in which the stipulated time limit did arise, time ran from the date of making of the relevant order, not from its publication.

51. The language used by the rule-maker in the 1986 iteration of Order 84 Rule 21(1) mirrored that appearing in the similar reforms to judicial review procedure introduced in England and Wales in Order 53 of the Rules of the Supreme Court in 1980:

'An application for leave to apply for judicial review shall be made promptly and in any event within three months from the date when grounds for the

application first arose, or six months where the relief sought is certiorari unless the court considers that there is good reason for extending the period within which the application shall be made.'

52. From the introduction of the identically worded provision in the English Rules, the courts in that jurisdiction concluded that the rule meant exactly what it said. Time ran from the point at which grounds for the application first arose, and the grounds for seeking judicial review of an administrative decision arise when the decision is made and takes legal effect, not when the applicant learns of it or when it had sufficient information to bring a claim (*R v. Secretary of State for Transport Ex Parte Presvac Engineering Ltd.* (1992) 4 Admin LR 121 at pp. 133 to 134). This position has been consistently reiterated in that jurisdiction (*R v. Cotswold District Council ex parte Barrington Parish Council* (1998) 75 P&CR 515 at p. 523; *Springer v. University Hospitals of Leicester NHS Trust* [2018] EWCA Civ. 436 at para. 52). The law in England is authoritatively summarised in Lewis '*Judicial Remedies in Public Law*' (6th Ed, 2021) at para. 9-016:

'The time-limit runs from the date when the grounds of challenge arose and not from the date when the claimant first learned of the decision or action under challenge nor from the date when the claimant considered that he had sufficient information or evidence to apply for judicial review, although these matters, together with all the other facts, will be relevant to the question of whether there is good reason for extending the time-limit.'

53. I mention the English decisions because the case law in that jurisdiction was relied upon by Clarke J. (as he then was) in *Veolia Water UK plc v. Fingal County Council*

(No. 1) [2007] 1 IR 690 (*Veolia*). While *Veolia* was a public procurement case, and thus concerned a decision within a category of proceeding long recognised as requiring particular rapidity, the applicable time limit was defined in similar terms to those now appearing in Order 84 Rule 21(1), Order 84A Rule 4 RSC fixing the obligation to commence such proceedings ‘*at the earliest opportunity and in any event within three months of the date when grounds for the application first arose*’. There, the proceedings were brought four and a half months after the applicants learnt that they had been unsuccessful in the procurement process they sought to challenge but they said that they had acted within three months of their learning of the alleged deficiencies in that process of which they sought to complain in their proceedings. The respondent contended that the rule meant that the proceedings had to be brought within three months of the decision irrespective of knowledge (while acknowledging that knowledge was relevant to an extension of that time): the applicants said that such a construction of the rule would be *inter alia* contrary to European law.

54. Following an analysis of English case law addressing similarly worded requirements in the applicable legislation in that jurisdiction, Clarke J. concluded that the language of Order 84A ‘*requires that time begins to run in relation to the making of an application for judicial review when the events giving rise to the grounds upon which the challenge is intended to be brought occur*’ (at para. 48). He continued:

‘Those events may be said to have occurred when any formal adverse consequence has crystallised to the extent of a formal step in the process being taken adverse to the interests of the applicant concerned.’

55. It is of some importance that while *Veolia* was, as I have observed, a public procurement case to which particular requirements of urgency have always applied, it was also – for that same reason – a decision reached in the context of domestic legislation implementing EU law. Clarke J. found that neither that fact, nor the implications of the constitutional right to litigate, affected the conclusion reached by the court as to when time began to run. Potential unfairness arising where a litigant found that time began running before they were or could have been aware of a decision affecting their rights were mitigated by the power of the court in an appropriate case to extend time. He explained (at p. 707):

‘amongst the matters that must properly be taken into account by the court in considering whether to extend time is to ensure that time will be extended in any case where a refusal to extend time could be said to establish a breach of the principle of effectiveness.’

56. The underlying test formulated by Clarke J. – whether a formal adverse consequence has crystallised to the extent of a formal step in the process being taken adverse to the interests of the applicant – has been applied since outside the specific context of procurement challenges (*O’Rourke v. Department of Education and Skills* [2019] IEHC 938 at para. 25) and is acknowledged as the applicable analysis in the texts (see Hogan and Morgan *Administrative Law in Ireland* (5th Ed. 2019) at para. 18-161 fn. 401; De Blacam *Judicial Review* (3rd Ed. 2017) at para. 36.15; Biehler et al *Delaney and McGrath Civil Procedure* (4th Ed. 2018) at paras. 31-76 and 77 and fn. 188). This also reflects the intendment of Order 84 Rule 21(2), which provides that where relief is sought by way of *certiorari* in respect of *inter alia* ‘any proceeding’ the date when

grounds for the application first arose shall be taken to be the date of that proceeding. It is unsurprising therefore that there are many authorities in which the courts have stressed that time for seeking judicial review runs from the date of the decision and not from the date on which the applicant first becomes aware of or fully understands the substance of the relevant decision (*Irish Skydiving Club Ltd. v. An Bord Pleanála* [2016] IEHC 448 at para. 50; *SC SYM Fotovoltaic Energy SRL v. Mayo County Council* [2018] IEHC 20 at para. 72(4)).

57. This case shows the difficulty of using any other starting point. Once Simons J. decided that because Order 84 Rule 21(1) could not be interpreted so that time began to run before '*the public were notified of the decision*' it followed that the options were (a) the point at which an *ad hoc* notification was posted on the HPRA website or (b) the point at which the notification was published in *Iris Oifigiúil*. He chose the former because that publication '*represents an effective form of public notification*' and because the language of the applicable domestic regulation was '*flexible enough to authorise this form of public notification*'.

58. While fully accepting the sense of this conclusion, it could only be correct if one of two things were true – either that Order 84 Rule 21(1) does not mean what it says ('*grounds first arose*'), instead running time from the point where there has been '*an effective form of public notification*', or because it was publication of the decision rather than the making of it that resulted in what Clarke J. described in *Veolia* as a formal consequence adverse to the interests of the applicant. For reasons I have explained, the first is not correct. The second could only be so (a) if the decision did

not take legal effect until it was published and (b) that publication in a form that is referred to nowhere in the 2007 Regulations was the trigger for its legal efficacy.

(e) Publication

59. It is obviously open to the Oireachtas or, in the case of rules provided for by Statutory Instrument, the relevant Minister, to predicate the legal efficacy of a decision on its publication to the world at large or, for that matter, delivery to specific persons. Where that occurs, the point at which time runs for the purposes of Order 84 and the publication of the decision will be coincident because it is only upon such publication that there is a decision impacting adversely on the applicant's interests. Where there is no such connection publication is irrelevant to the running of time – although, again, it will be potentially relevant to the extension of that time.

60. In the absence of an express provision rendering the legal effect of a decision dependent upon its publication or delivery, the issue of whether there is a connection between the two will depend on the proper construction of the legal instrument providing for publication. In some cases, it may be that publication obligations are conditions precedent to the validity of subsequent steps so that a failure to publish may vitiate a decision (*Keogh v. Galway Corporation* [1995] 3 IR 457). However, the authorities confirm the common-sense consideration that generally if the Oireachtas has not expressly related publication to validity, a failure to comply with an obligation to publish will only invalidate a prior decision if the purpose of that obligation is in some way referable to the efficacy of the decision (see for an example of an analysis to that effect *Casey v. Minister for Housing, Planning and Local Government and*

others [2021] IESC 42). This might arise, for example, where the legislation precludes the taking of steps on foot of the decision in advance of publication.

61. There is nothing of that kind in the regulatory scheme in issue in this case, and indeed it was accepted by counsel for Arthroparm in oral argument before this court that publication was not required for the authorisation to have legal effect. Certainly, the Directive is clear in mandating that the authorisation and reasons for the opinion publicly available ‘*without delay*’, and it is equally clear that this serves the purpose of ensuring that the public generally are aware of the fact of the authorisation and reasons for it. It also enables the holder of an authorisation for a reference product to know where a generic has been authorised, and to equip it with the basic information required to challenge the legality of the decision to grant the authorisation. To hold, however, that a failure to comply with that obligation meant that the authorisation was legally ineffective would require clear words, not least of all because of the impact on the entity to which the authorisation has been granted. Far from containing such a clear stipulation, Regulation 10(1) of the 2007 Regulations strongly suggests that the intention was that the decision takes effect when it is made:

*‘Without prejudice to Regulations 9(3) and 11, a veterinary product authorisation is, unless previously revoked, valid for five years, **commencing on the date of the grant of the authorisation.**’*

(Emphasis added)

62. For this reason, I cannot accept that it was the intention of either the Directive or implementing Regulations that the decision would be effective only upon publication.

The decision takes effect when made, not when it is published, and publication is therefore irrelevant to the point at which the ‘*grounds*’ for an application to review the decision ‘*first arose*’. If that is correct, the language of Order 84 Rule 21(1) precludes time running from the point of publication.

(f) *The decisions in Uniplex and Commission v. Ireland*

63. I have already noted that in *Veolia*, Clarke J. rejected the contention advanced in that case that for time to run before a party became aware of a decision would be contrary to principles of effectiveness because the court retained a discretion to extend time. In two public procurement cases judgment in which was delivered subsequent to that decision, the CJEU considered the compatibility with particular rules of EU law of the Irish Order 84A (Case C-456/08 *Commission v. Ireland* ECLI:EU:C:2010:46) and the similarly worded English equivalent (Case C-406/08 *Uniplex (UK) Ltd v. NHS Business Services Authority* ECLI:EU:C:2010:45 (*‘Uniplex’*)). In each of these judgments, the CJEU stressed the importance of legal certainty in the imposition of time limits for the bringing of legal challenges. In *Commission v. Ireland* (to which counsel for Chanelle referred in the course of her submissions) the CJEU found that the original version of Order 84A (which required that legal proceedings challenging a decision reached in the course of a procurement process be brought ‘*at the earliest opportunity and in any event within three months*’) was contrary to the applicable public procurement directives as it meant that legal proceedings could become barred before the expiry of the three month period if not brought ‘*at the earliest opportunity*’ and because the effect of the language used was to render it impossible for parties to predict what the limitation period would be if this were left to the discretion of the

competent court (at para. 74). Insofar as Ireland had relied upon the power of the courts under Order 84A to extend this time where there was ‘*good reason*’ for so doing, the CJEU refused to accept that this remedied the difficulty arising from the uncertainty introduced by the term ‘*at the earliest opportunity*’. It explained (at para. 81):

‘... the possibility for national courts to extend periods for bringing actions as provided for in Order 84A(4) of the RSC, is not such as to compensate for the shortcomings in that provision, having regard to the clarity and precision which Directive 89/665 requires in respect of the system of limitation periods. Even if the candidate or tenderer concerned takes into account the possibility that periods may be extended, it will still not be able to predict with certainty which period will be accorded to it for the purpose of bringing proceedings, in view of the reference to the obligation to bring an action at the earliest opportunity’.

(Emphasis added).

64. In *Uniplex* (to which attention was drawn during the hearing of this appeal) the question before the CJEU was framed in an Article 267 Reference issued by the English High Court in proceedings brought to challenge the rejection of a tender by the applicant. An issue under the time bar arose because while the proceedings were brought within three months of the provision to the applicant of reasons for its exclusion, the application was brought more than three months after it had been advised of that exclusion. In determining whether, as the CJEU had been asked in the reference, the English time bar was consistent with EU law principles of effective judicial protection, the court noted that it was only once a concerned candidate or

tenderer has been informed of the reasons for its elimination from the public procurement procedure that it could come to an informed view as to whether there had been an infringement of the applicable provisions and as to the appropriateness of bringing proceedings. It continued (at paras. 32-33):

'...the objective laid down in Article 1(1) of Directive 89/665 of guaranteeing effective procedures for review of infringements of the provisions applicable in the field of public procurement can be realised only if the periods laid down for bringing such proceedings start to run only from the date on which the claimant knew, or ought to have known, of the alleged infringement of...the provisions applicable in the field of public procurement'.

65. The court observed that it was incumbent on the national court to interpret the domestic time limit so as to accord with this mandate of European law. It continued (at para. 48):

'If the national provisions at issue do not lend themselves to such an interpretation, that court is bound, in exercise of the discretion conferred on it, to extend the period for bringing proceedings in such a manner as to ensure that the claimant has a period equivalent to that which it would have had if the period provided for by the applicable national legislation had run from the date on which the claimant knew, or ought to have known, of the infringement of the public procurement rules.'

(Emphasis added)

66. In other words, where an EU law right is engaged the court *must* exercise its discretion so as to allow the applicant three months from the point at which it knew or ought to have known of the decision in question. I do not think there can be any doubt but that this principle applies not merely to EU public procurement challenges, but to any case engaging rights of an applicant protected by EU law (in this case, the right I am assuming to vest in Arthroparm under Article 13 of the 2001 Directive) and I note that this reflects the view adopted in the leading texts (see in particular De Smith *'Judicial Review'* (8th Ed. 2018) at para. 16-056; Lewis *'Judicial Remedies in Public Law'* (6th Ed. 2021) at para. 9-019).⁷ Nor do I believe that the interpretation of the time limits so mandated by the CJEU can be imposed on Order 84 Rule 21(1) without re-writing the provision: as I have explained earlier the rule envisages the running of time from the point at which grounds first arose, not from the point at which an applicant might have become aware of them. Therefore, the EU case law does not strictly speaking affect the point at which time starts under Order 84 Rule 21(1).

67. What it does do, however, is to mandate the court to extend time under Order 84 Rule 21(3) so as to give effect to the requirement that time should run from the point at which the applicant knew or ought to have known of the decision it seeks to challenge.

⁷*Uniplex* has been applied in a number of High Court decisions, most often in interpreting the provisions applicable to procurement challenges, *Baxter Healthcare Ltd. v. Health Services Executive* [2013] IEHC 413, *Gaswise Ltd. v. Dublin City Council* [2014] IEHC 56, and *Newbridge Tyre and Battery Co. Ltd T/A Fleet Service Centre v. Commissioner of An Garda Síochána* [2018] IEHC 365. In *Harrington v. Environmental Protection Agency* [2014] IEHC 307 Barrett J. applied *Uniplex* in the context of a challenge to decisions to amend an Integrated Pollution Prevention and Control Licence to find that time under Order 84 Rule 21(1) ran from the point at which the applicant knew or ought to have known of the decision. As is clear from paragraph 42 of the judgment in *Uniplex* in the light of my conclusion as to the interpretation of Order 84 Rule 21, strictly speaking the correct analysis is that time runs from the date of the decision, the discretion to extend being exercised in cases engaging rights conferred by EU law from the point of actual or constructive knowledge. When the applicant *'ought to have known'* should be determined in the light of the applicable regulatory regime, and the language of Order 84 Rule 21 itself.

That is the same essential conclusion reached by Simons J., and as I have noted it might be thought that the difference between our respective analysis is pedantic. That said, I have felt compelled to explain why I have reached this conclusion at some length. First, it is for this reason that the contention advanced by Arthroparm that time ran from 12 October 2018 or 8 January 2019 cannot be correct. Second, the explanation gives important context to the limb of the test '*or ought to have known*'. This, rather than whether a form of publication is authorised by statute, defines the legal test. The two will, of course, coincide in many cases: a person ought to know of a decision when it is published in accordance with a governing statutory regime. That will not always, however, be the earliest point at which knowledge of the decision should be imputed and, obviously, if a party learns of a decision before publication, they cannot contend that time should only be computed from the point of publication.

(g) Conclusion on the running of time

68. In summary:

- (i) Time runs for the purposes of Order 84 Rule 21(1) from the point at which there is a formal consequence adverse to the interests of the applicant, this being, in this case, when a decision having legal effect is made. That may coincide with the date of the publication of the decision if the relevant legal provisions have this effect, expressly or by necessary implication.
- (ii) There is nothing in the provisions of the Directive or in the 2007 Regulations that postpones the legal efficacy of a decision granting a market authorisation

to the point at which that decision is published in accordance with Article 25(4) of the Directive.

- (iii) It follows that publication of the decision did not affect the running of time under Order 84 Rule 21(1).
- (iv) However, because (for the reasons I have outlined earlier) I am approaching this case on the basis (but without finally so deciding) that Arthroparm enjoyed a right under Article 47 of the Charter to challenge the decision to grant a marketing authorisation the court must, following the decision of the CJEU in *Uniplex*, operate its discretion so that Arthroparm is given a three month period from the point at which it either knew or ‘*ought to have known*’ of that decision.

Extending time: some general considerations

(a) *The proceedings.*

69. Critical to Arthroparm’s challenge is the meaning of ‘*generic medicinal product*’.

This defines the precondition to the use of the procedure provided for by Article 13.

Article 13(2)(b) is as follows:

“‘*generic medicinal product*’ shall mean a medicinal product which had the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by

appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes, or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy ... Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.'

70. Article 13(3) then provides that where a veterinary medicinal product does not fall under the definition of a generic medicinal product as defined in para. 2(b) *or* where bioequivalence cannot be demonstrated through bioavailability studies or in the case of changes to the active substance, therapeutic indications, strength, pharmaceutical form or route of administration *vis-à-vis* the reference product, the results of the appropriate safety and residue tests and pre-clinical tests or clinical trials shall be provided.

71. Article 13(4) of the Directive essentially provides that if the active ingredient of the product is a biological substance, the assessment must in certain circumstances take account of '*differences relating to raw materials or in manufacturing processes*' of the two products:

'Where a biological veterinary medicinal product which is similar to a reference biological veterinary medicinal product does not meet the conditions in the definition of generic medicinal products owing to, in particular, differences related to raw materials or in manufacturing processes of the

biological veterinary medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to those conditions must be provided'

72. These provisions define the objection Arthroparm has to the use by HPRA and Chanelle of Cartrophen as a reference product for Osteopen. As is clear from the assessment report, HPRA accepted the omission of in-vivo bioequivalence data based upon the essential similarity between the generic and reference product formulations, and in particular because the application was a generic application pursuant to Article 13 of the 2001 Directive and bioequivalence with the reference product had been accepted by HPRA, a number of tests, data and studies were not required. The report records that it was accepted *'based upon satisfactory demonstration of essential similarity between the generic and reference product formulations'* that no difference in terms of safety for the user is anticipated between Osteopen and Cartrophen. It also makes clear that a user safety assessment was provided in the course of the application process.

73. In seeking orders quashing the decision of HPRA that Osteopen is a generic of Cartrophen and of the authorisation granted by HPRA, Arthroparm presents some general complaints that HPRA failed to take material considerations into account and failed to give reasons for its decision but makes three core points. It says:

- (i) That the quantitative and qualitative compositions of the two products are not the same. There are, it claims clear structural and molecular weight differences between the active substance in the two products, those differences relating to both the content and the arrangement of key active chemical groups.

- (ii) That the manufacturing process for the active substance in each (Pentosan Polysulfate Sodium ('PPS')) are not identical so that there are varying toxicity and potency levels in the PPS used by Arthroparm when compared with that in Osteopen. So, because of these differences in the manufacturing processes of PPS as between the two products, Osteopen was not a bioequivalent of Cartrophen. Therefore, it is said, HPRA ought not to have accepted the omission of bioequivalence data in respect of the alleged generic, and;
- (iii) That PPS is a biological substance which ought to have been (but was not) assessed in accordance with Article 13(4).

74. Insofar as the first of these contentions is concerned, it is to be noted that the claim that the products did not have the same qualitative and quantitative composition is rooted in the different manufacturing processes used for PPS. The essential point is made at paragraph 10 of the Amended Statement of Grounds, as follows:

'Osteopen is not a generic of Cartrophen in circumstances where the manufacturing processes for the active ingredient in both products ... [PPS] are different and this difference in the manufacturing process results in a product that may have similar chemical compounds, but has varying toxicity/potency levels. This gives rise to safety issues and may also impact on the efficacy of Osteopen'.

75. Paragraph 29 of the Amended Statement of Grounds puts the matter thus:

‘Osteopen does not have the same qualitative and quantitative composition in active substances as Cartrophen. The effect of the difference in the manufacturing process of the active ingredient, PPS, is such that Osteopen is not a bioequivalent of Cartrophen. The difference in the manufacturing process of PPS has the result that Osteopen and Cartrophen have different potency and toxicity’.

76. It is clear from the remainder of the Statement of Grounds that all references to differences in the manufacturing processes are concerned with the active ingredient (at paras. 39, 46 and 53). Based upon these core contentions, Arthroparm contends that HPRA did not have the power to grant the authorisation in accordance with Article 13(1), and that in concluding that Osteopen is a generic medicinal product of Cartrophen, HPRA effected an error on the face of the record. It seeks an order of *certiorari* quashing the authorisation and four declaratory orders to the effect that (i) the grant of the authorisation on the basis that Osteopen was a generic of Cartrophen was null, void and of no effect, (ii) in determining the application for that authorisation HPRA failed to comply with the 2001 Directive and 2007 Regulations, (iii) that HPRA failed to take into account relevant considerations in deciding to grant the authorisation and, (iv) that HPRA erred:

‘ ... in failing to suspend or withdraw the veterinary product authorisation on the 6th day of March 2019 granted ... in respect of Osteopen on becoming aware that the qualitative and quantitative composition of a product is not as stated

and/or that the risk-benefit assessment of the veterinary medicinal product is unfavourable’.

(b) The pre-action correspondence

77. What Arthroparm knew about this claim, and when it knew it, is critical to the application for an extension of time, and it is thus convenient to compare this pleaded case with what went before. On 12 October 2018 Dr. David Cullis-Hill, a director of Arthroparm, wrote to HPRA recording what the letter described as an ‘*objection*’ to the generic registration of Osteopen ‘*due to procedural omissions and deviations*’. Neither the 2001 Directive nor the 2007 Regulation make any provision for an ‘*objection*’ of this kind: the decision had by this time been made and the authorisation granted. The letter – which appears to have been prepared before Arthroparm had obtained legal advice (at least in Ireland) – assumes otherwise, and proceeds on the basis that Arthroparm had a right to a *de novo* determination based upon representations it wished to make in respect of the grant.

78. The e-mail with which the letter was sent summarised and attached a detailed objection to the marketing authorisation. It sought ‘*a review of the registration process*’, observing:

- (i) A generic product registration had been approved for a country where the comparator product was not registered.

- (ii) Differences in manufacturing processes for the active substance (or ‘API’) were not taken into account.
- (iii) The API from different manufacturers is known to have widely varying biological activity and potency. In this regard it is said that the active ingredient in Osteopen (PPS) was produced in a different factory and by a different process from that used for Cartrophen. PPS batches from different manufacturing facilities were, it was contended, demonstrably not structurally identical and hence each batch may have very different biological properties.
- (iv) Consideration to different structures and molecular weights and sulfation patterns from different manufacturing processes was not evaluated.

79. The letter itself was detailed. It included the following assertions:

- (i) The active ingredient PPS in Osteopen was produced in a different factory to the active PPS in Cartrophen and was produced by a different process.
- (ii) The process did not reference details in the Arthroparm Vet file for the raw material and finished specification and stability studies for ‘biological activity’ as presented for PPS.
- (iii) The applicant did not appear to have taken account of a recent similar or identical application for an active ingredient PPS which had been ruled

deficient both by the FDA and EU authorities. It said that a generic application should not short cut this refusal to grant an application of a similar or identical substance.

- (iv) Different suppliers of PPS had different profiles of structures and different biological potency.
- (v) Published studies indicated a dose window for efficacy, with higher and lower doses or potencies being less effective.
- (vi) Well studied data on heparin, said to be a closely related pharmaceutical family to PPS, support the concept of different manufacturers producing products of different structure and potency having distinctly different potency and safety.

80. The letter supported these propositions with a lengthy list of references from the relevant literature and specifically elaborated by reference to that review on the proposition that not all PPS are the same, noting that if the PPS preparation used is more potent than that used in Cartrophen there is a risk of toxicity and a higher incidence of side effects, while if it is less potent this could be ineffective for the treated condition. An objection in the same terms was sent at the same time to the relevant authorities in the United Kingdom, France, Germany and Spain in which jurisdictions, as a result of the authorisation of Osteopen in this country, marketing authorisations had also been granted. Those authorities were also asked to suspend these authorisations, and to review same.

81. On 16 October 2018, HPRA sent an email acknowledging receipt of the email of 12 October 2018. That mail recorded that HPRA would respond as soon as possible. On 30 October 2018 it sent a detailed substantive response. That response (which was also sent by e-mail) was deleted by a junior staff member in Arthroparm with the result that Arthroparm was under the impression that no response had been received. However, on 26 October 2018 the United Kingdom authority responded to the objection submitted to it, *inter alia* referring Arthroparm to the more detailed response that would be received from HPRA. On 2 November 2018 the German authority responded to the objection it had received, referencing that it had been in touch with HPRA, and stating:

'We have been informed by the RMS (Ireland) that you have addressed your questions also to the RMS and that you have already received an answer regarding your objection to the registration of Osteopen MA.'

82. Thereafter, Osteopen was placed on the market on 8 November 2018, following which Arthroparm obtained a sample of the product and arranged for comparative testing to be carried out. It obtained the results of this on 9 December 2018. On 13 December 2018 a firm of solicitors acting on its behalf wrote to HPRA. That letter referred to the objection of 12 October 2018 and said that Arthroparm had now obtained a sample of Osteopen and contended that there were major structural differences between it and Cartrophen. The comparative analysis was enclosed with that letter.

83. HPRA responded on 14 December 2018 pointing out that a substantive response had been sent on 30 October 2018. Arthroparm's solicitors replied to the effect that that correspondence had not been received and asking for a copy of it. The response was

resent by HPRA on 17 December 2018. On 18 December 2018, Arthroparm's solicitors indicated that they wished to consider the email of 30 October 2018 and to reply to it, and the following day the solicitors for HPRA recorded that HPRA was happy to consider any response from Arthroparm to the email of 30 October 2018 and confirmed that they would respond to the letter dated 13 December 2018 by 21 December 2018. In circumstances in which HPRA made it clear that it would take what Arthroparm characterised as '*a delay point*', the application for leave was moved on 20 December 2018, although there remained at that point correspondence outstanding from HPRA.

(c) The Rule

84. I have earlier quoted the original incarnation of Order 84 Rule 21(1). It notably provided – in addition to the requirement that leave to seek judicial review be sought within a specified period of the grounds first arising – that proceedings be brought '*promptly*', providing in general terms that the court could, if satisfied that there were good reasons for doing so, extend the period within which the relief could be sought. In 2011 the Rules were amended, first by the deletion of the requirement that the proceedings be initiated promptly, second by the removal from Order 84 Rule 21(1) of any reference to a power to extend time, third, by the relocation of that power in a new rule, and finally by the addition of new requirements for the grant of such an extension. The first of these changes was made to eliminate any uncertainty perceived as attending the over-riding requirement that the proceedings be brought promptly and to give effect to the decision in *Commission v. Ireland*, while the others reflect an intention to tighten the conditions under which time will be extended.

85. The new provisions appear in Order 84 Rule 21(3) to (6), as follows:

(3) Notwithstanding sub-rule (1), the Court may, on an application for that purpose, extend the period within which an application for leave to apply for judicial review may be made, but the Court shall only extend such period if it is satisfied that:

(a) there is good and sufficient reason for doing so, and

(b) the circumstances that resulted in the failure to make the application for leave within the period mentioned in sub-rule (1) either:

(i) were outside the control of, or

(ii) could not reasonably have been anticipated by the applicant for such extension.

(4) In considering whether good and sufficient reason exists for the purposes of sub-rule (3), the court may have regard to the effect which an extension of the period referred to in that sub-rule might have on a respondent or third party.

(5) An application for an extension referred to in sub-rule (3) shall be grounded upon an affidavit sworn by or on behalf of the applicant which shall set out the reasons for the applicant's failure to make the application for leave within the

period prescribed by sub-rule (1) and shall verify any facts relied on in support of those reasons.

(6) Nothing in sub-rules (1), (3), or (4) shall prevent the Court dismissing the application for judicial review on the ground that the applicant's delay in applying for leave to apply for judicial review (even if otherwise within the period prescribed by sub-rule (1) or within an extended period allowed by an order made in accordance with sub-rule (3) has caused or is likely to cause prejudice to a respondent or third party'.

86. While there is a substantial body of case law addressing the application of the power conferred by the 1986 version of Order 84 Rule 21(1), the judgment of Finlay Geoghegan J. (with whom MacMenamin and O'Malley JJ agreed: O'Donnell and Irvine JJ diss.) in *MO'S v. The Residential Institutions Redress Board* [2018] IESC 61, [2019] 1 ILRM 149 ('*MO'S*') was the first occasion on which the Supreme Court addressed the new rule. In her judgment Finlay Geoghegan J. iterated the changes introduced in 2011 (at para. 35): (a) the addition of the requirement that the reason given be '*sufficient*' as well as '*good*', (b) the specific requirements of Order 84 Rule 21 (3)(b)(i) and (ii), (c), the power of the court to take account of the effect an extension of time may have on the respondent or a third party, and (d) the obligation now imposed upon an applicant where seeking an extension of time to specifically aver as to the reason for its failure to make the application for leave within the specified period. The new rule had earlier been considered by this court in *Heaphy v. Governor of Cork Prison* [2018] IECA 125, and was subsequently addressed in *AB v. XY* [2019] IECA 326 and *Nugent v. PSRA* [2021] IECA 250. It was also considered in some detail by

Barniville J. in *SC SYM Fotovoltaic Energy SRL v. Mayo County Council* [2018] IEHC 20.

87. The text of the rule when viewed in the light of those decisions and the law as it developed around the original form of Order 84 Rule 21(1) suggests that the following are now clear:

- (i) The period fixed by Order 84 Rule 21(1) is not a limitation period properly so called (*Sfar v. Revenue Commissioners* [2016] IESC 15 at para. 19 (per McKechnie J.)). The requirement to proceed within that time instead derives from a rule of court which, while having the force of law, is subject to the possibility of an extension if the court is satisfied, in accordance with the relevant law, that time should be extended (*MO'S* at para. 69 per Finlay Geoghegan J.).
- (ii) The effect of the rule is clearly to place an obligation on the party seeking an extension of time to identify on oath the reasons the application was not brought during the period fixed by Order 84 Rule 21(1) *and* during the time between the expiry of that point and the date on which the application was eventually brought (*MO'S* at para. 60). It is the obligation of the court when presented with such reasons to assess them '*carefully and critically*' (*SC SYM Fotovoltaic Energy SRL v. Mayo County Council* (at para. 72(7))). It should undertake this exercise conscious of the purpose underlying the rule in its present form: the present version of Order 84 Rule 21 '*is framed in terms which indicate*

a clear intent to reduce delay and to further limit time periods which previously existed for applications for judicial review' (*Heaphy v. Governor of Cork Prison* at para. 99 per Whelan J.).

- (iii) Before it can extend time, the court must be satisfied that the reasons so given explain and objectively justify the delay in bringing the application and are sufficient to justify the court in exercising its discretion in favour of the applicant (*O'Donnell v. Dun Laoghaire Corporation* [1991] ILRM 301, at p. 315 to 316; *MO'S* at para. 60). In this regard the addition of the word '*sufficient*' to the '*good reason*' previously required by the rule will not in most cases add to the pre-existing test (*MO'S* at para. 60), although it may be relevant in situations where the explanation given is in theory a good one, but the evidence adduced in support of it is insufficient to sustain it (*AB v. XY* at para. 44).
- (iv) In conducting that exercise the court must take account of all relevant circumstances, including the decision that is sought to be challenged, the nature of the claim that it is invalid and '*any relevant facts and circumstances pertaining to the parties*' (*MO'S* at para. 60). In applying the factors so found, the essential function of the court is to engage in a '*balancing exercise*' (*AB v. XY* at para. 46).
- (v) In this regard, factors of which account may be taken will include the nature of the order or actions the subject of the application, the conduct of the applicant, the conduct of the respondent, the effect of the decision

it is sought to challenge, any steps taken by the parties subsequent to that decision, and the public policy that proceedings relating to the domain of public law take place promptly except where good reason is furnished (*De Róiste v. Minister for Defence* [2001] 1 IR 190, at p. 208 per Denham J.). The ‘*blameworthiness*’ of the applicant is relevant, albeit as only one such factor to be weighed in the balance (*Kelly v. Leitrim County Council* [2005] IEHC 11, [2005] 2 IR 404 at para. 19(d)).

- (vi) It follows that the court may be required to balance the rights of an applicant with those of a respondent or notice party, taking into account also the prejudice to either consequent upon the failure of the applicant to proceed to make its application within the time fixed by the rules. This, in particular, requires the court to take account of the effect of the extension of time upon a third party affected by the decision in question (see *AB v. XY* at para. 47).
- (vii) It is ‘*probable that in most instances where a court has been satisfied of good and sufficient reason to extend time it will also be in a position to make a positive finding under sub-rule (3)(b) in relation to the circumstances which resulted in the failure to apply within the three month period*’ (*MO’S* at para. 100).
- (viii) That said, the rule clearly positions an inquiry as to whether the applicant had within its ‘*control*’ the effluxion of time: it is clear from the rule that in addition to being satisfied that good and sufficient reasons exist for an extension of time, the court must be satisfied as a matter of fact that

the circumstances which resulted in the delay were outside the control of the applicant (per Baker J. *Irish Skydiving Club Ltd. v. Kilkenny County Council* at para. 9). Where a delay arises from circumstances which were within the control of the applicant, the court may not extend (*id.* at para. 10).

- (ix) The court is also free to take account the interests underlying the proposed proceedings. Commercial cases – in which the requirements of certainty may be particularly pressing and in which it is reasonable to assume that the parties are well resourced and in a position to readily obtain access to legal advice – may justify a stricter approach than in other types of challenge (*MO'S* at para. 62; Hogan and Morgan 'Administrative Law' (5th ed. 2019) at para. 18-179).

Application of provisions governing extension of time

- (a) *The findings of the trial judge as to the application to extension of time.*

88. The High Court judgment records Arthrofarm as relying upon two principal factors as justifying the delay in the institution of the proceedings. The first was its claim that it was necessary and/or appropriate to engage in correspondence with HPRA before having recourse to the courts. The second is that it was necessary to obtain a sample of Osteopen on the open market in order that it be analysed before proceedings were instituted. It follows from the provisions of the rule and the authorities interpreting it that the task of the court in respect of each of these justifications was to determine

whether they presented ‘*good and sufficient*’ reasons for not thereupon seeking leave and in that regard to determine either that the reasons so suggested were outside the control of the applicant or could not have been anticipated by it.

89. Simons J – referring to the judgments of Baker J. in *Irish Skydiving Club Ltd. v. An Bord Pleanála* and of Noonan J. in *McCaffrey v. Central Bank of Ireland* [2017] IEHC 546 – recorded his doubts as to whether engagement in correspondence with a decision maker could ever ground an application for an extension of time. From there, he expressed the view that the only conceivable basis on which correspondence might be seen as necessary in advance of the institution of judicial review proceedings was where the information available in respect of the decision is so sparse that no meaningful steps could be taken towards the preparation of the proceedings. Having regard to the published information in the assessment report, he felt this was not the case here. Then, he noted that for a period of almost two months no attempt was made to pursue HPRA on its promise of a substantive response to the submission of 12 October. From there he commented that none of the correspondence was addressed to Chanelle, the party who would be most immediately affected by judicial review proceedings. Observing that one of the purposes of the tight three-month time limit is to protect the interests of affected third parties by ensuring that they were put on notice of the challenge to a decision, Simons J. expressed the view that the failure to communicate with Chanelle militated against the correspondence being relied upon as justifying an extension of time (at para. 75). Had Chanelle been so advised, the judge said, Chanelle would at least have had an opportunity to consider whether it wished to hold off further investment pending the outcome of the dispute (at para. 76). Responding to Arthroparm’s contention that it was a matter for HPRA to advise

Chanelle of the correspondence, Simons J. said (at para. 77) *'the onus is on the party seeking to challenge a decision to ensure that the affected party is put on notice of the intended proceedings within the three month time limit'*.

90. In rejecting the claim that the asserted need to obtain a sample of the generic product justified the delay in instituting the proceedings, Simons J. emphasised that generally a party is not entitled to delay the bringing of judicial review proceedings in order to assemble all of the materials on which it wants to rely. Instead, he said, the correct approach is to institute the proceedings within time and, if appropriate, to apply to amend the proceedings when the additional awaited materials are to hand. He said that it was *'only in circumstances where it would be impracticable or unreasonable to institute judicial review proceedings in the absence of an expert report that it will be appropriate to defer the institution of proceedings'* (at para. 81). Such cases, he said, would be very rare indeed.

91. Here, the court was heavily influenced by the complaints recorded in Arthroparm's letter of 12 October 2018. It was clear from that correspondence, Simons J. said, that many of the grounds of challenge had already crystallised at that stage without the benefit of a sample of the product. Two of the principal planks of the proceedings stood independently of the need for a sample and any report thereon – the claim that PPS is fundamentally unsuitable for approval as a generic because it did not have uniform composition and the contention that the product is a biological veterinary medicinal product and thus subject to the requirements of Article 13(4) of the Directive. Grounds as to adequacy of reasons could also have been agitated at that time. Simons J. reiterated in this context his concern that Arthroparm had not advised

Chanelle of the proceedings and that, if it had, it could have sought a sample of the product.

(c) Arthropharm's argument

92. Dr. Cullis-Hill's grounding affidavit identified ten factors which, it was contended, were relevant to any application for extension of time. These, as they were developed and refined in submissions before this court, can be reduced to the following:

- (i) Arthropharm had no notice of Chanelle's application prior to the approval date and had no prior involvement or right to participate in the approval process. The trial judge, it is contended, failed to take sufficient account of the fact that Arthropharm was unaware of the application until 23 August 2018.
- (ii) The court failed to take into account or to have sufficient regard to the fact that the information contained in the publicly available information was extremely limited, and that HPRA provided Arthropharm with very little data at every stage.
- (iii) Arthropharm requested a review, and there was no indication from HPRA that there was a time limit of which Arthropharm was about to fall foul.
- (iv) There was no access to the product until it was put on the open market on 8 November 2018 and it was only at the point where the product was

put on the market that it was possible to carry out a scientific examination of it. The case, it is stressed, is in a technical area in regard to which it was appropriate to await the receipt of the relevant scientific information.

- (v) The trial judge failed to take sufficient account of the fact that Arthroparm was operating under the mistaken impression until 14 December that a substantive response had not been received to its letter of 12 October 2018.
- (vi) The judge failed to have sufficient regard to what was described in oral submissions as ‘*the Iris Oifigiúil factor*’, that is that the official publication of the decision to grant the marketing authorisation was not effected until 8 January 2019.

(d) The relevance of the publication on 23 July 2018

93. As I have previously noted, the judgment of CJEU in *Uniplex* requires that the court exercise its discretion to extend time in such a way that Arthroparm has a period equivalent to that which it would have had if the time limit provided for by Order 84 Rule 21(1) had run from the date on which it either (a) knew or (b) ‘*ought to have known*’ of the infringement. In this case that means either 23 August 2018, when Arthroparm learnt of the decision, or 23 July 2018 when HPRA published it on its website. The former absolves Arthroparm of any responsibility to check and see if its products are being used as a reference point for the authorisation of competing generics. Choosing it would also mean that time runs would run from different points

for different litigants. The latter might be said to fix Arthroparm with the consequence of not reviewing a method of publication of which it had no formal notice and, effectively, to conjure from the applicable legal regime an obligation to monitor a method of publication which is not provided for within it.

94. Either way, it should be stressed, Arthroparm is out of time and, for reasons to which I come shortly, I would not extend time irrespective of which of these dates applied. However, in my view – while it is unfortunate that a clear method of publication in accordance with Article 25 of the 2001 Directive was not identified in the 2007 Regulations and that HPRA published the decision in accordance with the method of publication that was so specified many months after the decision was made – it would be contrary to both that Regulatory scheme and the provisions of Order 84 to run time from any point after 23 July 2018. What Arthroparm ought to have *known* is necessarily a by-product of what it ought to have *done*, and what it ought to have done if in fact it was concerned at the potential use of its product as a reference for a competing generic product was to take some basic steps to ensure that it was aware when decisions were made to grant marketing authorisations on that basis.

95. As I explain later, the court must in the exercise of its discretion take account of the fact that the impugned decisions were made in a regulatory context in which any challenge to the legality of the grant of a marketing authorisation will be both driven by commercial objectives and will involve a disruption to the commercial operations of a competing undertaking. That being so, and given that the 2001 Directive envisages public notification to be the mechanism by which undertakings holding marketing authorisations will learn of decisions to grant such permissions for other medicines using their products as a reference, it is proper to expect that Arthroparm

would have taken reasonable steps to ensure that it was aware of those decisions when made and thus of how and where they were to be published. This is the necessary consequence of a legal regime that (a) confers – as I have assumed but not decided - a right of action on a party who will not be aware of the process leading to the grant of the marketing authorisation, (b) envisages that party learning of the resulting decision through publication to the world at large, (c) did not envisage challenges to those decisions being made without some temporal limitation (as must be assumed having regard to the demands of legal certainty and rights of the holder of a marketing authorisation) and (d) places at the centre of an inquiry into whether time should be extended, whether the circumstances resulting in the failure to make the application within time were ‘*outside the control*’ of the applicant.

- 96.** Arthroparm could easily have positioned itself to find out about this decision if not by the very simple expedient of subscribing to the free RSS feed, then by either ascertaining from HPRA how precisely it complied with Article 25 of the 2001 Directive or by consulting the (fully searchable) HPRA website (hardly an unexpected location in which to find a record of a regulator’s activities). Had Arthroparm averred that it understood that publication in *Iris Oifigiúil* was the means by which HPRA complied with its obligations of publication and that it actually monitored the gazette to that end, one might have some sympathy with its protestation that it could not have been expected to know that HPRA would use a different method of publication altogether (although even then issues would arise as to how it could have believed this given that provision was only made for publication of the decision in this way, not of the other materials mandated by Article 25). However, it did not so aver and tendered no evidence of the precautions taken by it to ascertain whether its authorisation had, in fact, been used as a reference for competing generic products. For this same reason, I

should add, Arthroparm's reliance upon the '*Iris Oifigiúil factor*' as a ground for extending time, was misconceived.

97. In these circumstances, the evidence permits only the conclusion that although Arthroparm had enjoyed market exclusivity for twenty-seven years, it took no steps of any kind to ascertain how, or whether, decisions using its product as a reference for a generic authorisation might be made and published in any state in the EU. That being so, to permit it to, effectively, deploy its own failure to take elementary precautions in the protection of its own commercial interests as a basis for extending time beyond three months from the point at which the decision was made publicly available would undermine the regulatory scheme and would defeat the objective of legal certainty underlying both Order 84 itself, and the decisions of the CJEU in *Commission v. Ireland* and *Uniplex*.

98. Indeed, taken to its logical conclusion, to run time from the happenstance of Arthroparm's discovery of the authorisation could afford it three months from a date well after the grant of the marketing authorisation before it was required to proceed to litigation. The conclusion that this could occur would undermine the entitlement of the holder of a marketing authorisation to certainty in the conduct of its commercial operations and would, effectively, reward at its expense a competitor holding the authorisation for a reference product who had failed to take elementary precautions to ensure it was aware of regulatory developments affecting the market for its product. All of these considerations are clearly relevant to the identification of the point at which an undertaking '*ought to have known*' of such a decision, and each points to the conclusion that that date was, at the latest, 23 July 2018.

(e) *Judicial review and commercial cases*

99. This brings me to a broader issue to which I have already made reference. Every application for an extension of time for leave to seek judicial review must be undertaken in the light of the objective served by the time limit. That purpose, as explained by Lord Diplock in *O'Reilly v. Mackman* [1983] 2 AC 237 (at p. 280 to 281) is to implement a public interest of good administration that state authorities and third parties should not be kept in suspense as to the legal validity of a decision the authority has reached in purported exercise of its legal powers for any longer period than is absolutely necessary in fairness to those affected by those decisions. A similar explanation appears in the judgment of Clarke J. in *Shell E&P Ireland Ltd. v. McGrath* [2013] 1 IR 247 at p. 264 and in the judgment of Power J. in *AB v. XY*. Time limits in judicial review proceedings, she explained, fulfil the important function of enabling people to know where they stand on foot of decisions of administrative bodies and to conduct their affairs accordingly: '*if a practice were to develop whereby time limits were set aside lightly, adverse consequences for the judicial system would, inevitably, follow*' (at para. 52).

100. Proceedings seeking judicial review of decisions in the commercial sphere – most notably of regulators, of licencing authorities, of public bodies in awarding contracts, of decisions impacting on projects involving large disbursements of public funds or of decisions of the executive impacting on the conduct of the business of commercial undertakings – are of a kind in which the courts should usually incline to strict enforcement of the applicable time limits and should scrutinise with particular care explanations advanced for the failure to comply with those requirements.

- 101.** This is so for a variety of reasons operating broadly at two levels. First, it is to be expected that both the decision makers and the commercial undertakings affected by such determinations will frequently have adjusted their operations and (in the case of the latter) financial affairs and business operations on the basis of such administrative decisions, and it will often be the case that they can legitimately expect that those decisions will not be upset outside the period prescribed by the law. The recognition that certainty in the law is critical to the proper functioning of commercial undertakings – an assumption exemplified in this jurisdiction by the establishment of the Commercial Court and investment therein of very significant judicial resources - carries an advantage for those engaged in that activity, but also imposes a corresponding burden upon litigants whose cases originate in, and seek to promote their economic interests within, that context.
- 102.** Moreover, and second, it will also usually be the case that the considerations that may cause the courts to sympathetically incline to extend time for some categories of litigant (at least for short periods) – ignorance of legal entitlement, inability to access appropriate professional advice, a reluctance to embark upon litigation because of the exposure to legal costs it may entail, particular circumstances of personal vulnerability that rendered proceeding to court difficult and the absence of any countervailing third party interests impacted by enabling a delayed assertion of their legal rights – will not apply in such cases. It is to be expected that those who seek to challenge decisions of the kind in issue in this case will be well resourced, will have legal advice at their disposal, will be robust in their acceptance of the consequences of the risk attending any legal action and will be in a position to organise their affairs so that litigation can be rapidly brought and pursued. I have earlier noted observations to this effect in

MO'S, and similar statements can be found throughout the case law (see *Noonan Services Ltd. v. Labour Court* [2004] IEHC 42 (the appeal against which was dismissed in an ex tempore judgment of 14 May 2004), *SIAC Construction Ltd v. National Roads Authority* [2004] IEHC 128, *Mulcreavy v. Minister for Environment* [2004] IESC 5, [2004] 1 IR 72 at p. 80, *Cityjet Ltd v. Irish Aviation Authority* [2005] IEHC 206).

- 103.** All of this means that there is a strong public policy in such cases that leans towards the refusal of extensions of time – even those of seemingly modest periods. In public procurement cases, most notably, it is not uncommon to see extensions of a short number of days being refused (see *Dekra Éireann Teo. v. Minister for Environment* [2003] IESC 25, [2003] 2 IR 270 and *Veolia Water UK plc v. Fingal County Council*). Indeed, other situations in which there are similarly strong (but - in some cases - different) policy issues in play (notably in planning cases) result in similar outcomes – nineteen days in *Kelly v. Leitrim County Council* [2005] IEHC 11, [2005] 2 IR 404, five days in *Duffy v. Clare County Council* [2016] IEHC 618, seventeen days in *Irish Skydiving Club Ltd. v. An Bord Pleanála*, two months and four days in *McCaffrey v. Central Bank of Ireland and ors.*, twenty-five days in *Cassidy v. Waterford City and County Council* [2017] IEHC 711, and two weeks in *AB v. XY*.

(f) *Assessment*

- 104.** It follows from the foregoing that the focal point for the purposes of the exercise by the court of its discretion is 23 July 2018 (and at the very most 23 August of that year), that the extension required by Arthroparm is of two months (or at best from its point of view, of one month) but that the application for an extension of that time should be

viewed in the light of the nature of the claim, the commercial context in which it was brought, the steps taken by Arthrofarm to advance its complaints and proceedings and the potential impact upon the respondent and notice party if that time is to be extended.

105. From shortly after the point at which Arthrofarm knew or ought reasonably to have ascertained of the fact of the marketing authorisation for Osteopen, it also knew or could readily have ascertained that PPS was an active ingredient of the newly authorised product. It knew that there were issues around the differences between PPS arising from diverse manufacturing processes, and it must have understood the basis for the claim that PPS was a biological product. These facts, it is to be again stressed, were the central elements of its claim.

106. If it did not know then or shortly thereafter that Irish law imposed temporal conditions on the challenge to regulatory decisions of this kind, it could and should have ascertained this also and it should have equipped itself to understand the legal constraints attending the bringing of any challenge to the HPRA decision. Had it done this it would have been under no misapprehension that Irish law prescribed a strict period of time within which to bring a challenge of the kind in issue here.⁸

107. Armed with that knowledge, a reasonable undertaking that was genuinely concerned at the legality of the grant of a marketing authorisation to Chanelle would have moved with far greater despatch than Arthrofarm did. It would have made contact with

⁸The affidavit evidence did not disclose when Arthrofarm first sought legal advice in this jurisdiction. In the course of oral submissions to this court, and upon his being specifically asked that question, counsel for Arthrofarm said that the first '*point of contact*' it had with '*the firm of solicitors who instruct me*' was in October, and that '*the first formal engagement*' was in November 2018.

HPRA immediately, advised HPRA of its interest in the matter, it would have immediately sought full details of the regulatory decision making process, it would have taken active steps to procure as much information as it could in relation to the chemical composition of Osteopen, and it would have ensured that it had in place the necessary expert assistance to put in place any challenge it ultimately determined to pursue.

- 108.** The letter sent by it to HPRA on 12 October 2018 shows that Arthroparm did take some of these steps. The time that elapsed between 23 August 2018 and that date seems to me, in the circumstances of urgency in which Arthroparm should have been operating, to be very long, yet very little by way of specific information is provided by Arthroparm as to why it took this time to formulate and send that letter. But one paragraph of the affidavit evidence delivered on behalf of Arthroparm explains what happened between its discovery of the fact of the authorisation and the sending of this e-mail. Dr. Cullis-Hill explains what he did between his learning of the grant and the letter of 12 October 2018 in two sentences in his first affidavit:

‘On becoming aware of this, I carried out investigations in relation to Osteopen with a view to identifying the manufacturer and finding out as much information as possible about the product. The Applicant also carried out significant research of the available scientific literature on the potential impact of difference in the manufacturing process on Pentosan Polysulfate Sodium (“PPS”), the active ingredient of Cartrophen and Osteopen.’

- 109.** This is the first difficulty facing Arthroparm in seeking an extension of time. It should have explained why, exactly, it took over six weeks to formulate this position and it

should have detailed what, precisely, it did during that period. The information given as to this period of time is too scant, and that deficiency is not compensated for by the large number of references in the letter to the relevant literature. Arthroparm, it must be recalled, was in a better position than most to elaborate upon the nature and features of PPS.

110. More importantly, by the time it sent that letter it was on risk that the three-month period was going to expire on 23 October 2018 and, at most on 23 November 2018. It was thus on any version at a critical juncture. Having sent its letter on 12 October 2018 setting forth its complaints, it was in those circumstances incumbent on Arthroparm to pursue HPRA for a response and, if it did not obtain one, to proceed with as much of its action as it was then in a position to formulate. Had it pursued HPRA, it would have become apparent that HPRA had provided a substantive response on 30 October 2018. Its failure to ascertain this by actively seeking a response from HPRA was its second significant default. It appears that it was satisfied to rest on the fact that it sent its letter on 12 October without taking any step for two months to pursue a response. Given the time constraints under which it was operating, I find this difficult to understand.

111. It is especially difficult to excuse its inactivity in circumstances in which it was advised by the UK regulator on 26 October 2018 that Arthroparm was to receive a more detailed response from HPRA (suggesting that that authority had either seen or been advised of the contents of an advanced draft of the response) and, more remarkably, given that on 2 November 2018 the German authority advised Arthroparm that it had been in touch with HPRA and that it understood that Arthroparm had actually received a response from it. Yet, notwithstanding being on notice of these matters, it

did nothing until it had obtained the results of the analysis of the sample obtained by it in early November 2018.

112. This leads to a third point of importance. Arthroparm did receive HPRA's response on October 30, it was just that a junior member of staff deleted the relevant email. That was unfortunate, but it was a matter within its control. What is important is that even had it obtained HPRA's response on 30 October (and as I have observed had it taken reasonable steps to pursue that correspondence it would have become aware of this at or shortly after that date) it appears to be Arthroparm's position that it still could not have proceeded to seek leave without first obtaining and then having analysed, a sample of Osteopen. This could not have been obtained on the market until 8 November 2018, and it was not until 9 December 2018 that Arthroparm obtained a comparative analysis of that sample. Thus, the argument is, Arthroparm could not have proceeded with its application for leave to seek judicial review until that point, and it did so within a very short period of it. As it puts the matter in its notice of appeal, the '*central specific scientific evidence to support the particular case being made in these proceedings only crystallised upon receipt of the comparative analysis of the particular products*'.

113. I cannot accept this contention. While Arthroparm says that the objections it was in a position to formulate in its letter of 12 October 2018 were '*procedural*' and that there was no data about the actual scientific assessment of the material made publicly available, it is clear that it had by at the latest 12 October 2018 the essential information it required to advance its basic complaint as eventually articulated in the proceedings.

- 114.** The central point in the case is expressed by Dr. Cullis-Hill in his grounding affidavit, as follows:

‘Osteopen is not a generic of Cartrophen in circumstances where the manufacturing processes for the active substance registrations in both products are not the same, as a result of which the biological activity of the substance registrations varies widely, resulting in varying potency levels, depending on where they are manufactured. The difference in the manufacturing process results in a product that may have similar chemical compounds, but has varying toxicity/potency levels, which are twice that of Cartrophen.’

- 115.** The essential complaint here was known or capable of being known once Arthroparm learnt of the grant of the authorisation. The product assessment report published by HPRA on its website on 23 July 2018 disclosed that HPRA had assessed the application under Article 13(1) of the 2001 Directive and Regulation 6 of the 2007 Regulations, that it had decided that Osteopen and Cartrophen were essentially similar within the meaning of Article 13(1), that it had accepted the omission of the in-vivo bioequivalence data based on the essential similarity between the reference and generic products, that specified tests had not been required as the application was under Article 13(1) and bioequivalence was accepted and that due to the essential similarity of the formulations of the generic and reference products, no difference in terms of safety was anticipated.

- 116.** Shortly after learning of the decision, Arthroparm could have ascertained that the PPS used by Chanelle was produced in a different factory and thus by a different process than that used in the reference product. It made it clear in its letter of 12 October 2018

that it was conscious by then that not all PPS batches were the same, stating in that correspondence that PPS produced by different manufacturing facilities were demonstrably not structurally identical and hence that every batch may have different biological properties. This is a key feature of the claim made in the proceedings. For the same reason, Arthroparm was in a position to contend that the product was a biological veterinary product and thus subject to the requirements of Article 13(4) of the Directive.

117. In his grounding affidavit Dr. Cullis-Hill, I think tellingly, described the tests conducted on the sample as **confirming** that there were major structural differences between the two products. That was a correct characterisation of what the tests revealed, because it was the claim that there were those precise differences that subtended the demand in his letter of 12 October 2018 that the approval of Osteopen be suspended. This description of the effect of the tests was repeated in the Amended Statement of Grounds (at para. 15). To that extent and in these circumstances, I believe that the trial judge was quite correct in concluding that the appropriate course of action for Arthroparm to have adopted was to proceed with the claim it could formulate and to seek leave to obtain judicial review on the basis of the facts it did know within the prescribed period. It was entirely possible for it to flag the fact that it was awaiting the obtaining of a sample in order to confirm the essential claim it believed that it enjoyed. Obtaining the data that would prove what was described in submissions as proof that *'scientifically ... beyond peradventure these are not the same'*, was a counsel of perfection that may well have been required at the final hearing of the case, but was not evidence needed to meet the low threshold fixed for obtaining leave to seek judicial review. At the leave stage, it is to be remembered, the court's concern with the

evidence is limited to satisfying itself that the facts averred to, if proved, would be sufficient to support a stateable ground for the form of relief sought by way of judicial review and that on those facts an arguable case in law can be made that the applicant is entitled to the relief which he seeks (*G. v. Director of Public Prosecutions* [1994] 1 IR 374 at p. 377 to 378). All Arthroparm needed for this purpose was the claim it was already in a position to make – that the PPS in the two products came from different manufacturers, were produced by different processes and were thus liable to have very different biological properties.

118. Even if this is not so, I do not think it acceptable in the circumstances that presented themselves here for Arthroparm to simply assume that the time taken by Chanelle to place the product on the market (whatever that may have been) operated to indefinitely extend the time afforded to Arthroparm to proceed with its challenge. It ought to have at least tried to obtain a sample from Chanelle. The fact that Chanelle might not have co-operated is not relevant to the reasonableness of Arthroparm's actions in simply doing nothing. This is the fourth feature of its conduct of significance to this application.

119. This leads to a fifth point. One of the consequences of Arthroparm's seeking a sample from Chanelle would have been to advise it of the fact that a challenge was being contemplated. Arthroparm did not give Chanelle any indication that a challenge was being considered. It proceeded to place its product on the market unaware of this fact. I believe that the trial judge was correct when he criticised the failure of Arthroparm to advise Chanelle of the possibility of proceedings being brought. While Arthroparm was not under a legal obligation to provide such a notification, had it done so it could have to at least some extent neutralised the prejudice invoked by Chanelle. By not

providing Chanelle with any hint that it was considering a challenge, it left the field open for it to contend - with some force - that once the time fixed for challenging the decision had lapsed, it was entitled to rely upon the prejudice to it arising not simply from what it did in reliance upon the legality of the authorisation after the expiry of the three months, but all the detriment it would incur were it now to face an otherwise timed out case.

120. The evidence Chanelle adduced in this regard was clear and compelling. According to its managing director, Mr. Burke, once the authorisation was granted it applied for licences using a procedure (the ‘repeat use procedure’) to obtain authorisation in seven other jurisdictions (Czech Republic, Denmark, Hungary, Italy, Romania, Slovakia and Slovenia). That entailed a relatively slight cost (€30,864), but the process was obviously an important one commercially, and it was necessary to place these applications on hold once the proceedings commenced (in fact the applications were revived upon the determination of the matter in the High Court).

121. Moreover, he averred that the issue of the proceedings had caused Chanelle to face difficulties with customers who came as a result of the action to understand that its product was unsafe. Various communications from customers to that effect were exhibited by him. One of the two main companies operating veterinary practices in the United Kingdom placed Osteopen on hold pending the determination of the case. As of March 2019 he estimated the consequent loss to Chanelle in the region of €106,000. And of course, the unsettling of the decision could have implications for authorisations in those other jurisdictions which had granted permissions on foot of it. This is corroborated by HPRA. Its first affidavit records as follows:

‘given that Osteopen’s MA was approved during the Decentralised Procedure, following which those Concerned Member States in that procedure also approved MAs, I say and am advised that a substantive review of Osteopen’s MA on the basis of the HPRA’s Decision could also have repercussions for the status of those MAs granted by the Concerned Member States.’

122. These are significant factors weighing against the grant of the extension of time. They arose in a context in which Chanelle prepared for, invested in and conducted the launch of Osteopen on 8 November 2018 without any knowledge that it faced a risk of the decision being challenged. As I have explained, the whole purpose of the time limits in proceedings of this kind is to allow parties affected by an administrative decision to proceed on the basis that it is final and immune from attack. Clearly, much of this prejudice might have been sustained in any event had Arthroparm brought its action within the three month period provided for in Order 84. That, however, is not the point. It is a matter for Arthroparm as the party that has not brought its action timeously to establish that the court should exercise its discretion in its favour, not for Chanelle to establish that prejudice which it will clearly sustain if the action is permitted to proceed would have been avoided by compliance with the time period fixed by the rules. The fact that it will now face such prejudice is what is relevant in the exercise of that discretion and, in my view, it weighs against affording Arthroparm the indulgence of an extension of time.

123. Two final issues arise from Arthroparm’s submissions. First, it claims that its action is convincingly established by the expert evidence it has adduced and, relying upon the decision in *MO’S*, contends that this is a matter of which account should be taken in the exercise by the court of its discretion to extend time. I disagree. In *MO’S* the issue

of an extension of time arose in a most unusual circumstance. The applicant had obtained an unfavourable ruling from the Residential Institutions Redress Board ('the Board'), the effect of which was to preclude him from proceeding before that body with a claim for statutory compensation for injuries sustained consequent upon his detention in a residential institution. The Board determined that it could not extend the time for him to bring such a claim, it not being satisfied that he had, on the basis of the factors identified by him, established exceptional circumstances required by statute before that facility could be granted. At the time High Court decisions confirmed the correctness of this interpretation of the law, and the applicant did not proceed to seek judicial review of the Board's decision. Then, this court rendered a different interpretation of the relevant statutory provisions, and the applicant sought (four years after the decision of the Board) to extend time to seek judicial review of the Board's decision. In the course of her explanation as to why she felt that time should be extended, Finlay Geoghegan J. referenced comments of Hardiman J. in *GK v. Minister for Justice* [2002] 2 IR 418, at p. 423 as follows:

'On the hearing of an application such as this it is, of course, impossible to address the merits in the detail of which they would be addressed at a full hearing, if that takes place. But it is not an excessive burden to require the demonstration of an arguable case.'

124. Based upon these observations, Finlay Geoghegan J. said this (at para. 57):

'one of the factors which a court may consider in the context of determining whether there exists good and sufficient reason to extend the time is the

underlying merits of the application, in the sense at least of requiring demonstration of an arguable case.'

125. I agree with the observations of Simons J. in *DPP v. Samantha Tyndall* [2021] IEHC 283 (at para. 47) that '*there are dangers in embarking upon an elaborate assessment of the underlying merits on an application to extend time*'. In *GK v. Minister for Justice* Hardiman J. was doing no more than confirming that where a case is not shown to be arguable, this is one factor that must be taken into account in determining whether to extend time. In *MO'S*, conversely, the applicant's case was extremely strong to the point that the only extant issue in the proceedings was whether time should be extended because, as a result of the decision of this court which gave rise to the late application for leave, it was accepted that the applicant would prevail in his case if he obtained an extension. Between these two extremes lie the vast majority of applications of this kind, and in those cases the court has no role in determining the merits of the action. Were the position otherwise, an application for an extension of time would be converted into a trial of the merits, defeating at least part of the purpose of the rule giving rise to the necessity to seek an extension of time in the first place.

Article 83 and the correspondence exchanged between the parties

(a) The issues

126. The other point made by Arthroparm is that it sought in its correspondence of 12 October 2018 to pursue an alternative remedy, and that the court should extend time because there was an ongoing exchange taking place between the parties. This, it

seems to me, is closely related to the contention that the failure of HPRA to accede to Arthroparm's request that it suspend or withdraw Osteopen constitutes a distinct decision. It is convenient to address them together.

127. As to the first of these, Arthroparm says that the court ought, in weighing matters relevant to the exercise of its discretion, have had regard to the fact that Arthroparm was seeking to engage with HPRA in the exercise of a specific power conferred upon it by the Directive. Simons J., it is said, failed to take sufficient account of the substantive exchanges taking place between Arthroparm and HPRA as of 20 December 2018. In that regard, Arthroparm referred to the decision of this court in *Murphy v. Garda Síochána Ombudsman Commission and ors.* [2021] IECA 26 where Collins J. suggested, *obiter*, that an applicant who had pursued a review of a decision of a Chief Superintendent of an Garda Síochána before the Garda Síochána Ombudsman should obtain an extension of time to challenge the former decision because – essentially – litigants should be encouraged to pursue alternative statutory remedies (at para. 65).

128. To put the second of these in context, at paragraph D (6) of its Statement of Grounds Arthroparm sought a declaration to the effect that HPRA erred in failing to suspend or withdraw Osteopen '*on becoming aware that the qualitative and quantitative composition of [the] product is not as stated and/or that the risk-benefit analysis of the veterinary product is unfavourable*'. When the application for leave to seek judicial review was moved, leave was not sought in respect of this ground pending the provision by HPRA of a response to correspondence from Arthroparm's solicitors, although the court treated the application for leave as having been made on that date.

Thereafter and on foot of an affidavit sworn by Dr. Cullis-Hill on 10 April 2019, leave was granted to seek this relief, with certain amendments made to reflect the fact that HPRA had, since the leave application, refused to suspend the authorisation.

129. I have referred earlier to the sequence of correspondence as of the date of the leave application. To recap, on 13 December 2018 Arthroparm's solicitors (then unaware that HPRA had on 30 October responded to the letter of 12 October 2018) contended by reference to an analysis obtained of the two products that there were major structural differences between Osteopen and Cartrophen. HPRA re-sent the response of 30 October 2018 on 17 December 2018. On 18 December 2018, Arthroparm's solicitors indicated that they wished to consider the email of 30 October 2018 and to respond to it, and the following day the solicitors for HPRA recorded that HPRA was happy to consider any response from Arthroparm to the email of 30 October 2018, confirming that they would respond to the letter dated 13 December 2018 by 21 December.

130. Then, on 21 December 2018 – leave having been obtained the previous day – a revised timetable was suggested for the exchange of correspondence. Arthroparm's solicitors then responded to the mail of 30 October 2018, on 4 January 2019. There were various other exchanges between the parties, culminating in a letter dated 4 March 2019 in which Arthroparm's solicitors argued that it was incumbent on HPRA to consider and engage substantively with the scientific literature and data furnished by Arthroparm for the purposes of considering whether the authorisation of Osteopen ought to be suspended or revoked in accordance with Article 83 of the 2001 Directive. This was the first reference to Article 83 in Arthroparm's correspondence. On 6 March 2019, HPRA sent two letters to Arthroparm's solicitors. The first responded to the letter of 13 December 2018 and the second to the letter of 4 January 2019. In its response of 6

March 2019, HPRA said that nothing in that correspondence grounded a basis for the withdrawal of the authorisation.

(b) The pleading

131. Article 83 of the Directive mandates the suspension, revocation, withdrawal or variation of a marketing authorisation where one of seven matters are ‘*clear*’. One of these arises where the qualitative and quantitative composition of the veterinary medicinal product is not as stated, and another where the risk-benefit assessment of the veterinary medicinal product is unfavourable. This is expressed as follows:

‘Member States’ competent authorities shall suspend, revoke, withdraw or vary marketing authorisations when it is clear that:

(a) the risk-benefit assessment of the veterinary medicinal product is, under the authorised conditions of use, unfavourable ...

(b) ..

(c) its qualitative and quantitative composition is not as stated’

132. Article 13(1) of the 2007 Regulations provides:

‘Without prejudice to the generality of these Regulations, the Board shall suspend, revoke or vary a veterinary product authorisation if it is of the opinion that a circumstance referred to in Article 83(1) of the Directive applies or if an undertaking given under Regulation 9(3) has not been honoured or fulfilled.’

133. In relief D (6) of its Statement of Grounds, Arthroparm sought a declaration that HPRA erred:

‘in failing to suspend or withdraw the veterinary product authorisation granted to the Notice Party in respect of Osteopen on becoming aware that the qualitative and quantitative composition of a product is not as stated and/or that the risk-benefit assessment of the veterinary medicinal product is unfavourable’

134. Then, paragraph 42 of the Amended Statement of Grounds put this relief (which it will be observed is not grounded in any particular decision of HPRA) in context, as follows:

‘Article 83 provides that, where it becomes clear that the qualitative and quantitative composition of a product is not as stated, or that the risk-benefit assessment of the veterinary medicinal product is unfavourable, the HPRA is required to suspend or revoke the authorisation ...’

135. The grounds on which this relief was sought were, essentially, that the product was not a true generic (42A), that there had been no meaningful risk-benefit assessment (42C), that there had been a failure to explain why Osteopen and Cartrophen are not biological medicinal products (42D), and that there had been a failure to take into account (essentially) the differences in the manufacturing processes of PPS (para. 42F). Paragraph 42E is thus:

‘HPRA erred in concluding that the risk-benefit analysis of Osteopen is favourable. The use of the Article 13(1) procedure was not appropriate and

Osteopen ought not to have been approved as a generic. As a result of the use of the Article 13(1) procedure, the appropriate pre-clinical and clinical trials were not carried out in respect of Osteopen. In addition, bioavailability studies were not required on the basis that the active ingredients in Osteopen and Cartrophen are 'identical'. The PPS in Osteopen and Cartrophen is not identical and bioavailability studies ought to have been required. Further, the HPRA failed to have regard to impact of the differences in the manufacturing processes of the PPS used in the products, as they are required to do in accordance with Article 13(4) in circumstances where Cartrophen is a biological medicinal product. In the premises, there was no basis for the assumption by the HPRA that the safety and efficacy of Osteopen can be assumed to be same as that of Cartrophen and the safety and efficacy of Osteopen are unknown.

Without prejudice to the foregoing HPRA failed in concluding that the qualitative composition of Osteopen was the same as Cartrophen given that they are qualitatively different and the two products are not bioequivalent.'

136. The position of HPRA in response to these pleas as recorded in its Statement of Opposition and replying affidavits included the following:

- (a) That the 6 March 2019 letters were not decisions and/or decisions susceptible to judicial review.

(b) To invoke Article 83(1)(a), it is necessary to demonstrate a lack of benefit or harm to the animal intended for treatment under the authorised conditions of use contained in the summary of product characteristics, and to activate Article 83(1)(c) it must be shown that that summary, product labels, packaging and package leaflet state the correct composition of the product. The correspondence from Arthroparm responded to in the letters of 6 March 2019 did not demonstrate either of these and raised no safety concerns as regards Osteopen.

(c) The latter correspondence from HPRA were not separate, challengeable acts but rather were affirmations of the 20 July 2018 decision to grant the marketing authorisation for Osteopen.

(c) The decision of the trial judge

137. I have referred earlier to the trial judge's reasoning as to the first question arising from these arguments: essentially, he found that an applicant for judicial review must comply with the applicable time limits and cannot rely on their engagement in correspondence as justifying a failure to make the application for leave within time. In this regard, he specifically noted that there was nothing in the correspondence suggesting that Arthroparm was seeking information in order to allow it to prepare judicial review proceedings.

138. As to the issue of Article 83, Simons J. noted that in principle a formal decision made pursuant to Article 83 would be justiciable as a separate decision, instancing the

example of a putative applicant who contended that a veterinary medicinal product does not have any therapeutic effect on the species of animal for which the treatment is intended and thus that the marketing authorisation should be revoked or withdrawn. In that situation, he explained, there would be a distinct decision and it would be no answer to the proceedings to say that they involved a collateral challenge to the earlier decision to grant the marketing authorisation.

139. This, however, was not the case here. In this case, he explained, the letters of 6 March 2019 did no more than reiterate the decision of 20 July 2018 and elaborate upon the reasoning underlying that decision. Referring to the decision in *Sfar v. Revenue Commissioners* he stressed that the reiteration of an earlier decision does not constitute a fresh decision for the purposes of the time limit under Order 84 Rule 21(3). He emphasised that the grounds contained in Arthroparm's pleadings were a repeat of its challenge to the grant of the marketing authorisation, and that Article 83 was not in terms referred to, the focus being upon Article 13. He said: '*the correspondence does not disclose a formal decision pursuant to Article 83 of the Directive*' (at para. 92).

(d) Assessment

140. Three relevant propositions are well established by the case law. First, the existence of a remedy which affords an adequate alternative to judicial review represents a discretionary bar to the grant of that relief. Often where an applicant pursues that alternative remedy he will lose his right to relief by way of judicial review of the original decision, most usually because that decision is rendered moot by outcome of the alternative process. In circumstances where this is not the case and the original decision can be said to still be live and justiciable, the fact that an applicant has pursued

the alternative route may afford an excuse for his failure to seek judicial review within the permitted time period and it is that consideration that underlay the comments of Collins J. in *Murphy v. Garda Síochána Ombudsman Commission* upon which Arthroparm relies here.

141. At the same time, and second, an applicant for judicial review cannot obtain an extension of time by corresponding with the original decision maker, asking them to reconsider their decision and then asserting that there is a new ‘decision’ to review when they respond (or as the case may be, fail to do so): *‘[a] decision which is a reiteration of a previous decision is not a new decision. Time therefore begins to run when the final decision is first made’* (*Finnerty v. Western Health Board* [1998] IEHC 143 per Carroll J., approved in *Sfar v. Revenue Commissioners* at para. 41).

142. The third principle is related to the second but focusses not primarily on the substance of the underlying decision but looks instead at the grounds of challenge that are sought to be made to it. It would make a nonsense of the time limit imposed by Order 84 Rule 21 if an applicant could under the guise of a challenge to a decision made within time, obtain the invalidation of an earlier decision for which time had run and expired. The rule against collateral attack prevents this. It was most recently explained in *Independent Newspapers plc v. IA* [2020] IECA 19 as follows (at para. 56):

‘A ‘collateral attack’ in this sense arises in multi-stage decision making processes within which later decisions inevitably depend on and assume the legality of an earlier determination. In that situation, a challenge to the later decision may directly or indirectly present an issue as to the legality of the earlier one. Such an indirect attack is not permissible where the earlier decision

could and should have been challenged within a fixed period which has passed. The rationale underlying the relevant case law is that a party who has the benefit of an administrative decision which is not challenged within a legally mandated time frame should not be exposed to the risk of having the validity of that decision subsequently challenged in later proceedings which seek to quash the validity of a subsequent decision (Sweetman v. An Bord Pleanala [2018] 2 IR 250, at p. 264).’

143. The high point of Arthroparm’s case insofar as it is based upon the correspondence and the decision of 6 March 2019 is the fact that Article 83 invests HPRA with a distinct jurisdiction to suspend or withdraw a marketing authorisation it has previously granted, and from the consideration that because Arthroparm was not involved in the process leading to the decision of 20 July 2018, it can say that no ‘decision’ was made by HPRA that took account of the factors it sought to raise in its letter of 12 October 2018. Arthroparm, on this thesis, was invoking a self-contained process enabled by Article 83 of the Directive which, had it been successful in its application, would have avoided the need for judicial review proceedings at all (therefore rendering the time spent pursuing this remedy a justification for an extension pursuant to Order 84 Rule 21(3)). A decision having been made by HPRA pursuant to that power, Arthroparm contends that this is independently justiciable and that proceedings challenging that decision were clearly brought within the appropriate period.

144. Obviously, the application of the three principles to which I have just referred to a particular decision depends in any given case on the relevant facts and issues viewed in the light of the proper construction of the relevant regulatory regime. In any given

case, accordingly, the court must ask whether in substance the decision which it is sought to challenge, and the responses issued by the decision maker in reply to subsequent objections to the impugned determination, are the same '*decision*' or a new decision and, if the latter, whether the grounds of challenge are in substance a challenge to a decision the entitlement to review which has expired by effluxion of time.

145. Usually in the '*alternative remedy*' cases it is clear that the body making the second determination has made a new '*decision*'. In this case (insofar as some or all of the correspondence from HPRA can be characterised as '*decisions*') the alleged decisions made by HPRA on 6 March 2019 and the decision of 20 July 2018 were the same essential decisions and (insofar as material here) they were made on the same grounds. As Simons J. suggested in the course of his judgment there will be cases in which it is possible to detach a request to exercise the power under Article 83 and decision consequent upon that request, from the underlying determination to grant the authorisation so that a challenge to the legality of the former is not a challenge to the legality of the latter. This was not, however, such a case.

146. Central to that issue is what HPRA was being told, and what it was being asked to do. On 20 July 2018 it decided to grant the marketing authorisation to Chanelle in respect of Osteopen because it concluded that that product was a generic of Cartrophen within the meaning of Article 13 of the 2001 Directive. On 12 October 2018, Arthroparm delivered what it described as an '*objection*' to the registration of Osteopen. The core point made in the letter was that the active ingredient in the products were produced in different factories and by different processes. The letter concluded by requesting that the generic application approval be suspended pending a review of the facts and a review of the decision to register being taken. Article 83 was not referred to in this

letter, and the grounds identified in Article 83 and now purportedly relied upon in the pleading (*'the qualitative composition of a product is not as stated and/or that the risk-benefit assessment of the ... product is unfavourable'*) were not recited in the letter. HPRA rejected this contention and this request in its letter of 30 October 2018. It explained that based upon the data provided with the original application, HPRA considered that a sufficiently robust data package was provided to permit the conclusion that the generic product could be accepted as being sufficiently similar to the reference product to permit extrapolation of the safety and efficacy characteristics of the reference product to the generic product. So, at this point there was no formal invocation of the procedure under Article 83, merely a request to review the earlier decision. There was no basis on which this could *'toll'* the time provided for in Order 84 Rule 21(1) and, even if Arthroparm had not been at fault in failing to pursue this correspondence, the fact that it was awaiting a response would not have afforded a ground for extending time. For the same reason, there was at this point – clearly – no fresh *'decision'* from HPRA.

- 147.** It is accordingly unsurprising that the letter from Arthroparm's solicitors of 13 December 2018 described the letter of 30 October 2018 as a *'letter of objection'* and not as a request to exercise the powers conferred by Article 83. That letter stated that Arthroparm's analysis of the sample of Osteopen it had by then obtained enabled it to *'confirm'* that there were major structural differences between Osteopen and the reference product. The remainder of the letter elaborated upon that confirmation. The letter was thus, again, directed to the objection to the original decision (*'should not have been registered as a generic', 'the regulator's decision should be reviewed', 'a full review of risk analysis was not conducted'*). While withdrawal of the product was

requested pending further analysis there was, once again, no reference made to Article 83 nor even to the grounds referred to in that provision on which it is claimed that that power ought to have been activated.

148. HPRA's solicitors in their letter of 19 December 2018 reiterated that the Directive did not require that the generic product and the reference product be identical, merely that they have the same qualitative and quantitative composition in active substances as the reference product. By this point Arthroparm's solicitors appear to have been approaching the matter on the basis that because Arthroparm had had neither involvement or notice of the process leading to the decision of 20 July 2018, it now had a right to apply to HPRA to have that decision reopened and, indeed, the grounds on which that review was sought include the grounds on which the decision of 20 July 2018 is now challenged in this action. This was not correct: the procedure for grant of the authorisation is bilateral and upon a grant the decision in *Olainfarm* makes it clear that if Arthroparm had any right of complaint it arose from Article 47 of the Charter and in this jurisdiction that is enabled by judicial review proceedings. So when, as they did in their letter dated 19 December 2018, they described the parties as being, at that point, engaged in an '*ongoing consultation process*' that does not appear to me to be a legally accurate description of where matters stood: HPRA had made a decision, Arthroparm had requested that the decision be reviewed, and HPRA had refused to do so.

149. The letter from Arthroparm's solicitors of 4 January 2019 did not purport to present any new request to HPRA, being instead a response to HPRA's reply of 30 October 2018 to the '*objection*' of 12 October 2018. Thus, it was focussed entirely on Article

13 and made the same essential point, and reiterated the same basic request, albeit with additional information and argument. It said:

‘it is incumbent on your client to carefully consider the analyses furnished under cover of our letter dated 18 December 2018 and the scientific literature identified by our client, which clearly establishes that the requisite pharmaceutical equivalence between Osteopen and Cartrophen to justify the use of the Article 13 procedure is not present’.

150. Referring to material provided under cover of their letter of 13 December 2018 they asserted *‘serious concerns ... in relation to the safety and efficacy of Osteopen ... until this material has been considered by your client and the appropriate scientific analysis carried out, the authorisation of Osteopen as a generic of Cartrophen should be suspended’.*

151. It is important to note that the letters from HPRA of 6 March 2019 were in response to those of 13 December 2018 and 4 January 2019. Given that neither of those letters framed a request to exercise a power under Article 83 in those terms, and more importantly that they were not even framed as engaging the grounds identified in that Article, it is hard to see how it can be said that on 6 March 2019 HPRA issued a formal decision under Article 83. To be clear in this regard I say this not only because neither Article 83 of the 2001 Directive nor Article 13 of the 2007 Regulations were referred to in the correspondence – that is just a matter of form and the correspondence did clearly request suspension of the authorisation – but because the whole tenor of the correspondence is directed to the re-opening of the decision of July 20. In that the letters of 13 December 2018 and 4 January 2019 sought a review of the decision of 20 July 2018, it is proper to characterise the response to that correspondence refusing such

a review as the same decision, not as a new decision. Therefore, it cannot function to extend time, and the challenge to the refusal to withdraw or suspend expressed in those letters is not an independent decision which allows Arthroparm to bring a challenge to the 20 July 2018 determination which is otherwise out of time, under a different guise.

- 152.** In their letter of 4 March 2019 Article 83 was specifically referenced by Arthroparm's solicitors. They said that '*there is no pharmaceutical equivalence between Osteopen and Cartrophen*' and that '*it is highly likely that .. the qualitative and quantitative composition of Osteopen is not as stated*'. They asserted that it was incumbent on HPRA to review the evidence and information furnished with a view to determining whether the authorisation granted in respect of Osteopen '*ought to be revoked in accordance with Article 83 of the Directive*'. Rightly or wrongly, the specific invocation of Article 83 and the making of a request thereunder has not been responded to in correspondence (although it is addressed in very considerable detail in the affidavit evidence); this is perhaps unsurprising given that it was made in the course of correspondence directed primarily to whether the issues between the parties should be addressed within the proceedings or by way of distinct correspondence and that the detailed and lengthy responses of HPRA issued two days later. What is relevant for present purposes is that what was addressed in those letters of 6 March 2019 – and what is challenged in these proceedings – are responses to requests to revisit the 20 July 2018 decision by reference to Article 13 of the Directive. This is why HPRA's reply in those letters was focussed on what happened before the 20 July 2018 decision: one concludes that '*a full review of risk analysis was conducted as is evident from the PAR for Osteopen*', the other that '*HPRA maintains that its Decision was lawful*'. Certainly each referred to events since 20 July 2018 – the first letter to the fact that no

valid safety concerns had been raised in relation to Osteopen, and the second to the fact that it considered that nothing had been raised grounding a claim that there was a basis for withdrawing the authorisation. What is critical, however, was that each of these propositions was based upon a rejection of the very case made by Arthroparm in support of its claim that the decision of 20 July 2018 was invalid. This is why it was the '*same decision*'.

- 153.** But even if this is wrong, the grounds of challenge relied upon by Arthroparm in its Amended Statement of Grounds are *in terms* a challenge to the decision to grant the marketing authorisation. While Arthroparm is correct when it observes that paragraph 42 of the original Statement of Grounds referred to Article 83 of the 2001 Directive, the substantive challenge introduced by the new paragraphs 42A-G were replications of the challenge to the original decision. Each one of the substantive allegations as I have summarised them above replicate or rephrase the basis for the challenge to the decision of 20 July 2018 to the extent that it is hard to envisage any one of them succeeding without it ineluctably following that the decision of 20 July 2018 was in error in concluding that Osteopen was a generic of Cartrophen. The challenge is properly viewed as being out of time under the theory of collateral attack.

Conclusions

- 154.** It follows that I agree with the conclusion reached by Simons J. that Arthroparm has sought to bring these proceedings outside the three-month period specified in Order 84 Rule 21(1) RSC, that it is not appropriate to extend time for the bringing of these

proceedings, and that the letters from HPRA of 6 March 2019 do not change this. Accordingly, this appeal should be dismissed.

155. The reasons I have reached this decision are similar to, but technically different from, those explained by Simons J. They are in summary as follows:

- (I) Time runs for the purposes of Order 84 Rule 21(1) from the point at which a decision results in a formal consequence that is adverse to the interests of the applicant. That may coincide with the date of the publication of the decision if the relevant legal provisions have this effect, expressly or by necessary implication.
- (II) There is nothing in the provisions of the 2001 Directive or in the 2007 Regulations that postpones the legal efficacy of a decision granting a marketing authorisation to the point at which that decision is published in accordance with Article 25(4) of the Directive.
- (III) Therefore, strictly speaking time began to run on 20 July 2018. In particular, time did not begin to run from either 30 October 2018 (being the date of HPRA's response to Arthroparm's letter of objection of 12 October 2018) or 8 January 2019 (being the date of publication of the decision in *Iris Oifigiúil*).
- (IV) I have approached this application on the basis (but without finally so deciding) that Arthroparm enjoyed a right under Article 47 of the Charter to challenge the decision to grant a marketing authorisation in

respect of Osteopen. In those circumstances the court must operate its discretion under Order 84 Rule 21(3) so that Arthroparm is given a three month period to bring such a challenge from the point at which it either knew or '*ought to have known*' of that decision.

- (V) Had Arthroparm taken reasonable steps to acquaint itself with the manner of publication by HPRA of decisions to grant marketing authorisations (whether by subscribing to the free RSS feed advising of products added or changed on the VRMI, or by making basic inquiries of the relevant regulators) it would have learnt of the decision by 23 July 2018. Even if this is not the correct starting point, time began running no later than 23 August 2018 when it did learn of the grant of the authorisation.
- (VI) Whichever of these dates is the correct one, the time for seeking judicial review of the decision of HPRA expired on either 22 October 2018 or 22 November 2018.
- (VII) I would not extend time from (as the case may be) 22 October 2018 or 22 November 2018 having regard to the combined effect of the following:
 - (a) This is a case arising in a commercial context in which the time limits prescribed in Order 84 Rule 21(1) should be applied with particular rigour.

- (b) A reasonable undertaking that was genuinely concerned as to the legality of the market authorisation granted to Chanelle would have moved with far greater despatch than Arthroparm did upon learning of that grant. The papers furnished to the court do not provide an adequate explanation of what it did to progress its objections to the decision between 23 August and 12 October.
- (c) Having sent its letter of 12 October 2018, it was incumbent on Arthroparm to pursue HPRA for a response. This is particularly the case having regard to the information it received from the UK regulator on 26 October 2018 and from the German regulator on 2 November, each of which put Arthroparm on notice that (respectively) a detailed reply to its objection had been formulated and sent. Had it taken this step it would have learnt far earlier than it did of the position adopted by HPRA to its objection to the decision to grant the marketing authorisation in respect of Osteopen.
- (d) Arthroparm was not justified in postponing the bringing of a legal challenge until it obtained a sample of Osteopen on the open market. If it were so justified, this would mean in practical terms that time under Order 84 Rule 21(1) would be pushed back for a potentially significant period limited only by the happenstance of when the product appeared on that market. Arthroparm had sufficient information to formulate the essential challenge it wished to bring by – at the latest - 12 October 2018.

- (e) Arthroparm's actions in not seeking a sample of the product from Chanelle and in failing to advise it that it was proposing a challenge to the decision were not reasonable in the circumstances.
 - (f) Permitting Arthroparm to proceed with a challenge to the decision of 20 July 2018 outside the period of three months prescribed by Order 84 Rule 21(1) would in the circumstances of this case have caused considerable prejudice to Chanelle.
- (VIII) Save in those cases where it appears that a claim is so weak as to be unarguable or is admitted to be so strong as to be incontrovertible, it is not appropriate in an application for an extension of time pursuant to Order 84 Rule 21(1) to embark upon an analysis of the merits of the case.
- (IX) The positions adopted by HPRA in its two letters of 6 March 2019 were in response to objections made to the grant of a marketing authorisation having regard to the provisions of Article 13 of the 2001 Directive and reiterated that decision. The letters did not, accordingly, comprise a 'new' decision capable of distinct challenge and consequent avoidance of the time limit for seeking judicial review of the decision of 20 July 2018.
- (X) In any event, the challenge to that decision is a collateral attack on the decision of 20 July 2018 and is, on that basis, properly viewed as being time barred.

156. Accordingly, this appeal should be dismissed and, on its face, HPRA and Chanelle are entitled to the costs of the proceedings including this appeal. Costello J. and Haughton J. agree with this conclusion and with the reasons I have reached it. If Arthroparm proposes to challenge the preliminary view I have expressed as to the disposition of costs it should advise the Court of Appeal office within fourteen days of the date of this judgment and a hearing will be convened to address those costs.