THE HIGH COURT

[2019] IEHC 629

RECORD NO. 2018/1080JR

BETWEEN

ARTHROPHARM (EUROPE) LIMITED

APPLICANT

AND

THE HEALTH PRODUCTS REGULATORY AUTHORITY

RESPONDENT

AND

CHANELLE PHARMACEUTICALS MANUFACTURING LIMITED

NOTICE PARTY

JUDGMENT of Mr. Justice Noonan delivered on the 30th day of August, 2019

Facts

1. This is an application for discovery brought by the applicant ("Arthropharm") in these judicial review proceedings against the respondent ("HPRA") of five categories of documents.

2. Arthropharm is the manufacturer of a veterinary pharmaceutical product known as Cartrophen which is used for the treatment of arthritis in dogs. In 1991, Arthropharm received a licence known as a marketing authorisation ("MA") for this product from HPRA. This gave Arthropharm the exclusive right to market and sell this product in the European Union for a period of 10 years.

3. In 2017, the notice party ("Chanelle") applied to HPRA for a MA in respect of a similar product known as Osteopen which is claimed to be a generic of Cartrophen. In order to make this application, Chanelle availed of what is known as the decentralised procedure pursuant to the provisions of Directive 2001/82/EC ("the

Directive"). This enables an applicant for a MA to make an application to the relevant regulatory body of a Member State ("the Reference Member State"), in this case HPRA, identifying the Member States in which it is proposed to market the product. Those other Member States are consulted throughout the process which is led by the Reference Member State. In this instance, there were 12 such concerned Member States in addition to Ireland as the Reference Member State.

4. Article 13 (1) provides for an abridged procedure where it can be demonstrated that the medicinal product in respect of which the MA is sought is a generic of a reference medicinal product. The advantage of this procedure is that it exempts the applicant from the necessity to provide the results of safety and residue tests or of preclinical and clinical trials, the underlying premise being that the generic is substantially identical to the reference product in respect of which such information was already provided and which received a MA.

5. Article 13 (2) (b) defines a "generic medicinal product" as:

> "a medicinal product which has 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... 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."

6. The reference veterinary medicinal product for Chanelle's application in respect of Osteopen was Cartrophen. On 20 July 2018, HPRA granted a MA to Chanelle and on the same date published a publicly available assessment report ("the PAR") which identified Article 13 (1) as the legal basis of the application and Cartrophen as the reference product. The report records that HPRA accepted the omission of *in vivo*

bioequivalence data based upon the essential similarity between the generic and reference product formulations. The PAR further records that since the application was a generic application and bioequivalence with the reference product had been accepted, a range of tests and trials, *inter alia*, was not required.

7. Arthropharm alleges that it became aware of the grant of the MA on 23 August 2018 and on 10 October 2018, submitted a detailed objection to HPRA. Arthropharm's fundamental objection is that Osteopen is not in fact a generic of Cartrophen. The basis for this assertion lies in the fact that the active ingredient in both products is Pentosan Polysulfate Sodium ("PPS") but Arthropharm claims that there are differences in the manufacturing process of PPS as between different manufacturers leading to significant differences in the resultant product's toxicity and potency levels. Arthropharm further claims that both Cartrophen and Osteopen are biological veterinary medicinal products and consequently the provisions of article 13 (4) of the Directive apply which require the applicant to provide the results of appropriate preclinical tests or clinical trials. Essentially therefore Arthropharm claims that HPRA ought to have assessed the application under article 13 (4) rather than 13 (1).

8. As noted above, over a month elapsed between the grant of the MA to Chanelle and Arthropharm becoming aware of it. This is because there is no requirement under the Directive for the manufacturer of the reference medical product to be put on notice of an application to licence a generic, presumably on the basis that once the period of exclusivity expires, the original manufacturer is no longer considered to have an interest in the matter. When Osteopen went on sale in November, 2018, it obtained a sample of Osteopen and submitted it for analysis to two companies, respectively Biopharm, the holder of the MA for Cartrophen in Australia, and Bene pharmaChem, the manufacturer of the PPS utilised in Cartrophen. The test results from this analysis

were sent to HPRA on 13 December 2018 in support of Arthropharm's original objection.

9. Further reports were subsequently obtained by Arthropharm from four different academic experts in support of its claim that Osteopen is not a generic of Cartrophen and both are biological medicinal products. This was to counter any suggestion that neither Biopharm or Bene pharmaChem could be regarded as independent of Arthropharm. On the basis of its objection and supporting expert evidence, Arthropharm invited HPRA to revoke the MA to Chanelle and in a letter of 6 March 2019, HPRA declined to do so. It is of some relevance to note that Arthropharm has had market exclusivity for its product for some 27 years until the MA was granted to Chanelle who is now Arthropharm's only competitor in the market place.

The Statement of Grounds

10. At paragraphs (D) (1) to (7) of the statement of grounds, Arthropharm seeks the reliefs that continue to be relevant in these proceedings. At (1) to (4) orders of *certiorari* of the decision of 20 July 2018 are sought with ancillary declarations that the decision that Osteopen is a generic of Cartrophen is *ultra vires*. Paragraph (5) seeks a declaration that HPRA failed to take relevant considerations into account in granting the MA and at (7) failed to give adequate reasons for its decision. Subsequent to the original grant of leave, Arthropharm was permitted to seek relief (6) being a declaration that HPRA was in error in failing to suspend the MA on 6 March 2019.

11. Paragraph (E) sets out the specific grounds on foot of which each relief is sought. In brief summary, reliefs (D) (1) – (4) are sought on the grounds that Osteopen is not a generic of Cartrophen because it does not have the same qualitative and quantitative composition in active substances as Cartrophen. The manufacturing processes of the

active ingredient, PPS, are different in each case so that the finished products are not bioequivalent and have different potency and toxicity. The consequence of this in legal terms is that the article 13 (1) procedure was not permissible and in utilising if, HPRA therefore acted *ultra vires*.

12. The grounds for D (5), (failing to take relevant considerations into account), are that HPRA failed to have regard to differences in the manufacturing processes of PPS. In its response, HPRA pleads that, as a matter of law, it had no obligation to take this into account. The grounds for D (6), (failing to suspend the MA), are that HPRA ought to have done so when the differences in the manufacturing processes of PPS were brought to its attention and it failed to engage in any meaningful risk/benefit analysis in the light of Arthropharm's submissions and again gave no adequate reasons for this decision. It is further pleaded that the matters to which HPRA failed to have regard included the data on the Carthrophen master file. In that latter regard, the director of HPRA, Dr. J. G. Beechinor, in an affidavit sworn in this discovery application clarifies that this data was in fact considered by HPRA.

13. Finally, with regard to relief D (7), (failing to give reasons), Arthropharm pleads that the PAR does not contain sufficient information on the pharmacological qualities of Osteopen which therefore amounts to inadequate reasons.

Categories Sought

14. In its request for voluntary discovery and in the motion now before the court, Arthropharm has sought five categories of documents which may be summarised as follows:

    (a) all documents concerning HPRA's consideration of whether Osteopen is a generic of Cartrophen including the dossier submitted by Chanelle and any documents from the Cartrophen file that were considered;

(b) all documents considered regarding whether Osteopen or Cartrophen are biological products;

(c) all documents considered in deciding to exempt Chanelle from demonstrating bioequivalence – these would appear to be included in the documents sought at category (a);

(d) all documents concerning the specification for the PPS used and comparative analysis of product composition submitted by Chanelle in respect of Osteopen and Cartrophen – again this would appear to be covered by (a);

(e) all documents concerning the benefit/risk assessment carried out by HPRA between 20 July 2018 and 6 March 2019.

Legal Principles

15. The starting point is Order 31 rule 12 which requires the party seeking discovery to establish that the documents sought are both relevant and necessary for the fair disposal of the case or for saving costs. The party seeking discovery is required in the first instance to establish relevance. Once that has been done, prima facie the documents may be considered to be necessary. Thus, Clark C.J. recently noted in *Tobin v. Minister for Defence* [2019] IESC 57 (at p. 18):

> "7.16 Having regard to the importance which discovery can play in at least some cases, it should, in my view, remain the case that the default position should be that a document whose relevance has been established should be considered to be one whose production is necessary. However, that remains only a default position and one which is capable of being displaced for a range of other reasons."

16. While Order 31 rule 12 applies equally to all civil proceedings, including of course judicial review, it has often been said that the necessity for discovery in judicial review proceedings is rare and the exception rather than the rule – see for example

Sheehy v. Ireland (High Court Unreported 30th of July, 2002, Kelly J.). This is for the reason that in judicial review, decisions of public bodies are challenged on purely legal grounds and disputes of fact are uncommon. The merits of the decision are irrelevant to a consideration of whether it has been made lawfully. In *Barbara Flynn v. Charities Regulatory Authority* [2018] IEHC 359, Reynolds J. summarised the principles applicable to discovery in judicial review proceedings, including the following:

> "(e) generally, the only instance in which discovery may be necessary or appropriate is where the court is required to resolve a conflict on the evidence is set out on affidavit;
>
> (f) in considering whether such an unavoidable conflict of evidence must be resolved by way of discovery, such a factual dispute must be based on substance and on evidence provided by the applicant;"

17. It is important to bear in mind that in judicial review proceedings, as in all other proceedings, the concept of relevance relates to the issues as defined in the pleadings rather than being simply relevant to the underlying decision under challenge – see *Bam PPP Pggm Infrastructure Cooperative UA v. NTMA* [2015] IECA 246. Thus Clark J. (as he then was) noted in *MacAodháin v. Ireland and the Attorney General* [2012] 1 IR 430 at paragraph 14:

> "... It seems clear that in judicial review proceedings it is important, when considering relevance, to identify how the document concerned can be relevant to the specific types of issues which will arise in the relevant judicial review application rather than being relevant to the substantive questions which were before the decision-maker."

18. In *R v. Secretary of State for Health ex parte Hackney London Borough* (Unreported Court of Appeal 24 July 1994), Sir Thomas Bingham M.R., delivering the judgment of the Court of Appeal of England and Wales said (at p. 9):

> "The basic approach is that discovery and production will be ordered in judicial review proceedings where they are necessary for disposing fairly of the application but not otherwise... I think it is probably true to say that discovery will be regarded as necessary for disposing fairly of the action, or application, if a party raises a factual issue of sufficient substance to lead the court to conclude that it may, or will, be unable to try the issue fairly, fairly that is to all parties, without discovery of documents bearing on the issue one way or the other... It is not open to a plaintiff in a civil action, or to an applicant for judicial review, to make a series of bare unsubstantiated assertions and then call for discovery of documents by the other side in the hope that there may exist documents which would give colour to the assertions of the applicant, or the plaintiff, which he is otherwise unable to begin to substantiate."

19. This judgment was subsequently approved in this jurisdiction in *Carlow Kilkenny Radio Ltd v. Broadcasting Commission of Ireland* [2003] IR 528 and *Barry v. The Governor of the Midlands Prison* [2018] IEHC 713. Bingham M.R. went on to note that the courts are averse to granting orders designed to find out whether mere assertions have any basis in fact. For example, it is not open to an applicant to make an assertion, unsupported by any evidence, that certain matters were or were not taken into account by the decision-maker and then seek discovery to find out what was in fact taken into account.

20. In the course of argument, counsel for Arthropharm relied on the provisions of Regulation (EC) No. 1049/2001, more commonly known as the Transparency Regulation, as it applies to the European Medicines Agency (EMA) and a number of

European decisions considering its application to the EMA. The Transparency Regulation is most closely analogous in domestic law to the freedom of information legislation and accordingly the European decisions considering it do not seem to me to be of great assistance in the context of a discovery application before a national court. Insofar as the applicant suggests that the Transparency Regulation somehow modifies the legal principles applicable to a discovery application, I cannot accept that proposition, being as it is one for which there is no authority.

Discussion

21. The first issue therefore to be considered is whether Arthropharm has established that the documents sought in each of the categories are relevant to the issues defined by the pleadings. The fundamental case advanced by Arthropharm is that Osteopen is not a generic of Cartrophen. If it is right about this, then HPRA concedes that the application should not have been considered under article 13 (1) but rather 13 (4). Arthropharm says that its many experts have from their analysis of the actual product reached the conclusion that Osteopen is not in fact a generic of Cartrophen. This is a matter of scientific opinion and of law. It is not a dispute of fact. The applicant's experts do not require discovery of any documents to reach a conclusion that they have already arrived at.

22. In reality, it seems to me that there are no facts in dispute in this matter which require discovery to enable them to be resolved. Certainly Arthropharm has not pointed to any. Rather it is said that it requires discovery because without it, it cannot determine the manner in which the decision under challenge was made. As the authorities to which I have already referred make clear, that is not a permissible use of discovery but rather is a classic fishing expedition. In any event, this complaint has been

overtaken by the subsequent affidavit of Dr. Beechinor which makes clear the matters to which HPRA had regard in arriving at its decision. The complaint about failing to take relevant matters into account relates to an alleged failure by HPRA to take differences in the manufacturing processes of PPS by different manufacturers into account. But HPRA says it had no legal obligation to take that into account and did not do so. There is thus no dispute of fact arising which requires discovery, merely an issue of law.

23. In arguing for discovery in this case, Arthropharm contends that the standard of review to be applied by the court in challenges to decisions of national competent authorities implementing European directives is that of "manifest error" and that the court will not be in a position to determine whether such error was made without the benefit of discovery. Whether that is the relevant standard or not, and in that regard I do not find it appropriate or necessary in this discovery application to determine that issue, it is clearly not part of the case pleaded by Arthropharm. As such, it cannot therefore form a basis for ordering discovery. However, even if manifest error had been pleaded, I would still reach the same conclusion by analogy with the authorities on unreasonableness or irrationality. Thus in *Carlow Kilkenny Radio Ltd*, Geoghegan J. said (at p. 533):

> "Therefore, in so far as any case is being put forward on the basis of unreasonableness or irrationality, it would be wrong to make an order for discovery as discovery would be nothing more than a fishing exercise. That has always been forbidden by the courts irrespective of whether the discovery is sought in plenary proceedings or in judicial review proceedings. On the other hand, insofar as procedural misconduct is alleged, that issue can be litigated without discovery of documents. In the written submissions, counsel for the

respondent cited in this connection the passage from the judgment of Carswell J. in *Re Glor na Gael's Application* [1991] N.I. 117 which made clear that an order for discovery of documents concerning the issue of unreasonableness in relation to the manner in which a decision had been reached would not be made unless there was material which indicated that the evidence put before the court was inaccurate or false."

24. Similarly, in *McEvoy v. An Garda Siochana Ombudsman Commission* [2015] IEHC 203, McDermott J. expressed the view (at para 25):

> "If a decision is challenged as unreasonable or irrational, discovery will not be necessary because, if the decision is clearly wrong, it is not necessary to ascertain how it was reached."

25. It therefore seems to me that Arthropharm has failed to demonstrate the relevance of the documents sought in any category. In addition to that overarching consideration, with regard to category 1, Arthropharm advances the reason that discovery of documents in this category is required because no adequate reasons were given by HPRA for concluding that Chanelle demonstrated essential similarity as between Osteopen and Cartrophen. A failure to give reasons is purely a matter of law and accordingly, discovery cannot be relevant or necessary. As regards category 2, Arthropharm's case is that its experts have concluded that both Osteopen and Cartrophen are biological products and if that is correct, HPRA accepts that the article 13 (1) procedure is not appropriate. There is thus no necessity for discovery.

26. As I have noted, category 3 is in effect covered by category 1. Here again, Arthropharm's experts have concluded that the two products are not bioequivalent and discovery is therefore not necessary. The same considerations apply to category

4. The request for category 5 equally fails on relevance grounds but in any event, Dr. Beechinor has sworn on affidavit that HPRA has no documents in this category.

27. Even if Arthropharm's discovery application did not fail on grounds of relevance, it is clear from the voluminous expert evidence adduced by it on the central issues in the case that the documents sought are not necessary for it to be in a position to fairly present its case. This is an important point of distinction between this and the public procurement cases relied upon by Arthropharm. These concerned the circumstances in which documents which are confidential and commercially sensitive should be the subject of an order for discovery. In the instant case, this arose in the context of the argument by HPRA that even if the documents sought were considered to be relevant and necessary, their disclosure should not be ordered because they contain confidential and commercially sensitive information concerning not only Osteopen but also the PPS manufacturer whose identity is protected.

28. In *Word Perfect Translation Services Ltd v. the Minister for Public Expenditure and Reform* (No. 2) [2018] IECA 87, the applicant was the unsuccessful tenderer for a public service contract and sought discovery of the successful tender which was resisted on the grounds of commercial confidentiality. Hogan J. delivered the judgment of the Court of Appeal and noted that where documents are relevant, confidentiality in itself does not preclude discovery. An obvious tension arose between the need to protect the confidentiality of the commercial tender on the one hand and the ability of a disappointed tenderer to meaningfully challenge the process on the other. Hogan J. noted (at p. 9):

> "Rather, the critical point is that without access to the tender documentation a disappointed tenderer might in some instances never be in a position to

advance a case of manifest error or to contend that there was some other significant flaw in the assessment process. One might equally say that in such circumstances the right to challenge the tender award on these grounds – itself a key aspect of the rule of law and the fair operation of the procurement process – would remain illusory.

All of this means is that access to a rival's tender documentation via the discovery process is not just governed simply by the standard requirements of relevance and necessity. Rather, the case for discovery of this documentation must be convincingly established as indispensable for the fair disposal of the procurement challenge."

29. These views were echoed by the Supreme Court on appeal (at [2019] IESC 38) at p. 11:

> "It is apparent that there are real difficulties here. An unsuccessful party cannot be permitted to gain access to the full tender of the successful party simply by alleging that the marks awarded to the latter are too high and constituted a manifest error. But as long as that is a viable ground for challenge, it is difficult to see how it can be advanced without sight of the tender, particularly where the reasons given are limited. It may be that if more detail is given in the reasons letter, that would mean that discovery would not require to be ordered unless the challenger could make a convincing case from the reasons that a manifest error could be in principle identified from the existing material."

30. This stands very much in contrast to the situation here, where the applicant has had unfettered access to the product itself which it has subjected to extensive scientific analysis and assessment and was not, and had no right to be, a participant in the process that led to the grant of the MA. Both the Court of Appeal and Supreme Court

identified the requirement for the applicant for discovery to establish a convincing case for the necessity for discovery of commercially sensitive documents. The evidence as a whole in this application satisfies me that the documents of which discovery is sought are commercially sensitive. As such, even if the applicant had established that they are relevant and necessary, the court would be required to consider the proportionality of an order for discovery. Thus in *Independent Newspapers (Ireland) limited v. Murphy* [2006] 3 IR 566 Clarke J. (as he then was) observed (at p. 572):

> "I am satisfied that the court should only order discovery of confidential documents (particularly where the documents involve the confidence of a person or body who is not a party to the proceedings) in circumstances where it becomes clear that the interests of justice in bringing about a fair result of the proceedings require such an order to be made…"

31. In my view, apart from any issues of relevance, Arthropharm has not established a convincing case that the discovery sought is necessary for the fair disposal of the case.

Conclusion

32. For the reasons I have explained, Arthropharm has not discharged the burden of establishing either the relevance or necessity of the documents in respect of which discovery is sought but even if that were not so, the application of the requirement for proportionality in orders for discovery militates against the making of an order in this case. I will therefore refuse this application.