THE COURT OF APPEAL

Neutral Citation Number: [2018] IECA 239

Record No. 2016/430

Peart J.
Hogan J.
Whelan J.

IN THE MATTER OF IRISH PATENT NUMBER 65528 FILED ON THE 14TH DAY OF SEPTEMBER 1990 AND REGISTERED IN THE NAME OF BOEHRINGER INGELHEIM INTERNATIONAL GMBH IN RESPECT OF AN ALLEGED INVENTION FOR "NOVEL THIENYLCARBOXYLATES OF AMINO ALCOHOLS, THEIR QUATERNARY PRODUCTS AND THE PREPARATION AND USE OF THESE COMPOUNDS" AND

IN THE MATTER OF SUPPLEMENTARY CERTIFICATE NUMBER 2002/021 FOR THE SAID PATENT FILED ON THE 14TH DAY OF AUGUST 2002 AND DUE TO EXPIRE ON THE 13TH DAY OF MARCH 2016 FOR A PRODUCT IDENTIFIED AS "QUARTERNARY SALT FORMS OF SCORPINE DI-(2-THIENYL) GLYCOLATE, ESPECIALLY SALTS OF TIOTROPIUM – PREFERRED TO TIOTROPIUMBROMIDE AND TIOTROPIUMBROMIDE MONOHYDRATE" AND

IN THE MATTER OF THE PATENTS ACT 1992 AND THE PATENTS (AMENDMENT) ACT 2006 AND

IN THE MATTER OF REGULATION (EC) NUMBER 469/2009 OF 6 MAY 2009

JUDGMENT OF MR. JUSTICE MICHAEL PEART DELIVERED ON THE 24TH DAY OF JULY 2018

1. These proceedings were commenced in the High Court on the 23rd October 2014 by the presentation of a petition by Norton (Waterford) Limited trading as Teva Pharmaceuticals Ireland ("Teva") in which the respondent was identified as Boehringer Ingelheim International GmbH ("Boehringer"). In its petition Teva sought an order revoking a Supplementary Protection Certificate ("SPC") granted to Boehringer in reliance upon Irish Patent No. 65528, on the basis that it was invalid having regard to Article 3 of Regulation (EC) No. 469/2009. Patent 65528 expired on the 13th September 2010.

2. As of the date of the commencement of the proceedings, the SPC was due to expire some 17 months later on the 13th March 2016 which was therefore *the latest date* by which Teva's proceedings seeking its revocation would become moot.

3. However, by its notice of motion issued on the 28th October 2015, Boehringer sought a stay of the proceedings on the basis that they were already moot, and seeking to have the date provisionally fixed for the hearing, namely 16th February 2016, vacated. The hearing was expected to take some four weeks. This stay application was granted by order of the High Court (Hedigan J.) dated the 10th November 2015 for reasons stated in a written judgment of that date ([2015] IEHC 687). There is no appeal against that order.

4. However, the question of what costs order should be made following the Court's finding that the proceedings were moot was adjourned for the filing of affidavits, and preparation of submissions. The costs hearing took place on the 25th and 26th July 2016. On the 27th July 2016 the trial judge delivered a written judgment explaining his reasons for concluding that in all the circumstances the appropriate order in relation to the costs was that Boehringer should get its costs of the *stay motion* itself, but that otherwise there would be no order as to costs in relation to the proceedings. In other words, each party bears its own costs of the proceedings.

5. Boehringer have appealed to this Court against that order, essentially on the basis that Teva should have to bear responsibility for the proceedings becoming moot due to the timing of their commencement by Teva, and also its conduct of the proceedings especially by its having unnecessarily sought very extensive discovery which it knew would always be strongly resisted by Boehringer, and that, in those circumstances, Boehringer ought not to have to bear their own costs of defending the proceedings.

6. In his written judgment on *the stay application*, Hedigan J. found that the proceedings should be stayed because even if the hearing commenced on the 26th February 2016, the hearing would not conclude until around the 11th March 2016, which was just two days before the SPC would expire. n that judgment he did not consider which party, if any, was responsible for the proceedings becoming moot, or whether it was caused by some external party or event. His conclusions as to mootness are stated as follows:

> "To allow a case to proceed on a hypothetical or academic basis can only be permitted where some important public interest may be served thereby. This might occur where the same point is going to arise in some further cases and it might as well be resolved in the proceedings that are already extant all the SPC proceedings herein moot question? They certainly were not moot when the petitioner decided to move in courts across a range of countries to revoke the patent and the SPC. The value of the market for a generic version of the respondent's Spiriva product is so high that a quick decision might well have been of substantial value to the petitioner. That situation however has now changed. The hearing of the case involving the SPC will occur over a four-week period commencing on 16th of February next. It will conclude in all probability therefore on or around 11th of March. Yet the SPC will expire two days later. Thus the judge commencing to write a judgment will know that the validity of the SPC which is questioned in proceedings has then become irrelevant because the SPC will have expired. It seems the very epitome of futility that a court expend four weeks of court time determining the issue of the validity of SPC that will expire before the judge can adjudicate on the issue. Moreover to any judge, absent some exceptional and clear public interest, the concept of embarking upon the complex and onerous task of drafting a judgment in such circumstance, must border on the absurd. In my judgement the issue of the validity of the SPC must be treated now as though it were a moot because when the time comes to resolve this question it will have already expired."

7. The question of who should be held responsible for the proceedings being moot, and in what degree, arose on the later costs hearing for which affidavits were filed by the parties. Boehringer submitted that even at the date when Teva presented its revocation petition at the end of October 2014, which was they must have known that there was little chance of getting the proceedings

determined ahead of the expiry of the SPC on the 13th March 2016. Boehringer submitted that Teva chose to delay the commencement of these proceedings, and could instead have commenced its challenge to the SPC at any time after it was granted on the 20th September 2004. Boehringer draws attention to the fact that an identical petition was issued by Teva in the United Kingdom in June 2014 and that in those proceedings no discovery was sought. It submits also that in delaying the presentation of the petition until the 23rd October 2014 they did so in the full knowledge that they were going to be seeking extensive discovery from Boehringer in this jurisdiction, and that their application in that regard would be strenuously resisted by Boehringer, as indeed it was. Boehringer's view is that Teva at all times knew that it was going to seek extensive discovery, and therefore that it was inevitable that the proceedings would be moot by the time they would be determined where they delayed until late October 2014, since there was then never any realistic possibility that the proceedings could be finally determined before the SPC expired. Boehringer accepts that if no discovery was sought here - as was the position in the UK proceedings - there may have been some prospect of the proceedings being determined by the 13th March 2016.

8. Teva first sought voluntary discovery of some 12 categories of documents by letter dated the 15th January 2015. By letter of the same date Boehringer also sought discovery from Teva, though its request was confined to a part of a single document. An order for discovery by Boehringer was ultimately made on the 19th May 2015, but a stay was granted pending an appeal to this Court. Teva's appeal against that stay was dismissed by this Court on the 29th June 2015.

9. I should add that before the discovery application had been determined in the High Court, Teva, without notice to Boehringer, made an application to the Commercial Court on the 23rd March 2015 for a hearing date for the petition. A date in November 2015 was provisionally fixed even though the discovery applications had not been determined. Boehringer relies on the fact that Teva saw fit to seek a date on an urgent basis as far back as March 2015, and submits that they did so because even by that date they knew that there was serious risk that the proceedings would become moot.

10. On the 20th July 2015 Teva made a further application to the High Court, without notice to Boehringer other than telling them on the day of the application, to vacate the November hearing date, since Boehringer's appeal against the discovery order dated the 19th May 2015 was not yet determined by this Court. On that occasion the 16th February 2016 was fixed provisionally for the hearing to commence.

11. By letter dated 14th October 2015 Boehringer's solicitors wrote to Teva's solicitors requesting that they indicate whether there was any reason why the SPC proceedings should not be considered to be moot given the approaching expiry date of the SPC. This letter stated, *inter alia*, the following:

> "Whether the SPC proceedings are moot is of central relevance to the appeal of the discovery motion due to be heard by the Court of Appeal next Monday. If the proceedings are moot, there could be no justification to press for discovery; the appeal on discovery should fall away with the discovery itself. This question becomes acute in the circumstances of this case where discovery of extremely sensitive documents is in issue.
>
> In view of these matters, you might please inform us, and the Court, if there is any reason why these proceedings along with any provision for discovery made within them, are not redundant.
>
> If they are not and if there is still some justification in continuing with these proceedings, please explain in broad terms what that justification is, purely so that it can be clear that it is not simply a question of a deferral of a decision to discontinue the proceedings while maintaining the request for discovery in the meantime.
>
> If it is not intended to discontinue these proceedings on the basis of any such continued justification for them, and if your client intends to maintain the position frequently asserted on its behalf, but never substantiated, that its commercial interests require special expedition in the discovery (and other) phases of the proceedings, we should be grateful if you would specifically identify the commercial interest that your client will rely on for that position. In particular could you please identify to our client and to the Court whether your client is, or when your client expects to be, authorised, or otherwise in a position to actually launch the product for which these sets of proceedings represent a clearing of the path to market."

12. This letter evoked a response by letter dated the 16th October 2016 which Boehringer characterise as not addressing the question asked, and as an obfuscation. I will set out a substantial portion of this response:

> "We are surprised at the timing of this letter and the point made. We can only speculate that this issue has been raised only now because your client does not wish to go ahead with its appeal on Monday.
>
> No application has previously been made by your client on foot of this issue before the numerous hearings before Mr Justice McGovern or Mr Justice Hedigan (the latter of whom has heard a recent interlocutory motion on confidentiality and has indicated to the parties that he will be the judge hearing the case at trial). During the recent confidentiality motion hearing before Hedigan J. on 7 and 8 October 2015 your client indicated when questioned by the judge that the motion should proceed because your client will be discovering its marketing authorisation and other documents that it will be relying on at trial in these proceedings regardless of the outcome of the appeal hearing. That was mere days ago and this issue was not raised.
>
> Absent any such application previously by your client, the issue which your client now raises on the eve of its appeal is misconceived and unstateable.
>
> Further, for your letter to state that the trial date in February was fixed with "no advance notice" to your client is incorrect. The original trial date in November 2015 was vacated because your client has sought to delay the proceedings by bringing these very appeals and had to be re-fixed for February 2016 at a directions hearing on 20 July 2015. Previously, Mr Justice McGovern at a directions hearing two weeks earlier on 6 July 2015 adjourned the matter for two weeks so that the trial date could be considered by the parties. We wrote to you on 17 July 2015 prior to that directions hearing and indicated that the November trial date would need to be vacated in view of your client's appeal delaying matters and that a new trial date would be sought. This latest issue was never raised at the time. In fact, it was your client that indicated to Mr Justice McGovern when fixing the new trial date in February 2015 that the original three week provision should be increased to four weeks. There could be no misunderstanding on the purpose of the directions hearing on 20 July 2015, the *raison d'etre* of which was to fix a new trial date. We simply do not accept this attempt by your client to resile from its participation in the fixing of the trial date of which you now complain."

13. The discovery appeals went ahead before this Court on the 19th October 2015. The transcript from that hearing clearly shows this Court's concerns about the use of scarce court time in dealing with a discovery appeal in relation to the SPC proceedings where there was a real risk that these proceedings would not conclude prior to the expiry of the SPC. The above correspondence was brought to the attention of the Court, and it would be fair to say that the Court expressed some unhappiness that this question of whether the proceedings were moot or not was being raised by Boehringer at a rather late stage. In fact counsel for Boehringer was asked by a member of the Court if he had instructions to bring an application to stay the SPC proceedings on the ground of mootness, but he confirmed that no such instructions had been obtained as of that date. However, it appears that such instructions were obtained rapidly thereafter, as Boehringer informed this Court on the 22nd October 2015 that it intended to bring such an application, and issued its motion seeking to have the proceedings stayed on the 28th October 2015.

14. As noted earlier, it was on the costs application that the trial judge had to consider which party, if any, should bear the responsibility for the proceedings becoming moot. In that regard, he expressed his conclusions as follows:

> November, 2015, the proceedings when issued by Teva were not moot. I would add that it is improbable that any party would issue court proceedings in the full knowledge that they were or would become moot. On the evidence before the court, I was on the 10th November, 2015, and still am, satisfied that Teva had reason to believe on the 23rd October, 2014, when they issued the petition herein that they might be able to launch their generic product Braltus prior to the expiry of the SPC on 13th March, 2016. I am satisfied that, as the following twelve months unfolded, as the petitioner and the respondent fought many courtroom battles to protect their respective commercial interests, it became clear that the SPC proceedings could not be concluded before the expiry date. I am satisfied that this was primarily due to delays that emerged in the process of TEVA seeking market authorisation for their Braltus product.
>
> 3. To decide to move to strike out proceedings on the basis that they will become moot before the court has the opportunity to adjudicate on them, is a very serious decision indeed. To decide to concede in such circumstances that proceedings had become moot is, at least, as serious. I appreciate how hard a decision that must be for either party. Nonetheless, it is essential that when it becomes necessary to do so, an application should be made at the earliest time. This obligation rests on both parties because any waste of invaluable court time is to be avoided. It may be possible to criticise both parties for not moving sooner but I would not wish to be overly harsh in this regard. Until immediately following their face to face meeting with the MHRA on 9th September, 2015, I am satisfied that it would have been premature for TEVA to have conceded their proceedings herein would become moot by March 2016.
>
> 4. It is not easy to determine just when precisely they should have been ready to make this concession. As things transpired, it was Boehringer who took the initiative in this regard. On 14th October, 2015, they wrote to Teva asking if there was any reason why the proceedings should not be considered moot. Teva did not respond on that particular question. On 19th October, 2015, the Court of Appeal raised the issue, questioning Boehringer as to why they had not brought a motion to vacate the trial date and stay the proceedings for being moot. On 22nd October, Boehringer notified the Court of Appeal of their intention to bring such emotion. On 28th October, 2015, Boehringer issued a motion to stay. This motion came on for hearing on 6th November 2015. It was opposed by Teva. On 10th November, 2015 this court delivered judgement on the motion. The court stayed the proceedings and vacated the trial date.
>
> 5. It is a weighty decision for any party to concede that its proceedings are moot. This is even more so when the decision is that they will become moot, as was the case here, at some future time. Allowing a certain reasonable measure of time to consider their position since their meeting with MHRA on 9th of September 2015, I conclude that Teva should have made the decision to concede when the motion was brought. It may be possible to criticise both parties for failing to move prior to that time but, as I find above, that might be overly harsh in the circumstances. In my judgment, these proceedings became moot as time passed, and the external event of the MHRA's consideration of the market authorisation was delayed through no fault of the petitioner Teva. It thus fits into McGovern J's category (b). However, because in my judgment, Teva should have conceded when the motion to stay was brought, they should be liable for the costs of that motion. There will be no order as to costs in respect of the rest of the proceedings."

Boehringer's submissions

15. Boehringer makes a number of complaints about the reasoning of the trial judge. But essentially it submits that there was no evidential basis established by the affidavits filed for the purposes of the costs hearing for the trial judge's conclusion that it was the delays in TEVA's marketing authorisation that ensured that these proceedings could not be determined before the expiration of the SPC in March 2016, and that insufficient weight was given by the trial judge to the conduct by Teva in seeking very substantial discovery of sensitive material which they knew would be strenuously opposed, rather than proceeding expeditiously without discovery as it did in the UK proceedings.

16. Boehringer also submits that the question of the marketing authorisation is entirely separate from the prosecution of these proceedings, and that for this reason also the trial judge was incorrect to determine that it was the delay in the issue of the marketing authorisation, described by him as an external event, that resulted in these proceedings becoming moot.

17. It is submitted also that the delay in the marketing authorisation process could only be properly considered to be causative of mootness if there was sufficient evidence before the trial judge of TEVA's ability to market its rival Braltus product ahead of the expiry of the SPC, and that this would have saved the proceedings from being moot. Boehringer makes the point that a marketing authorisation is but one of several steps that TEVA would need to take or have in place before launching its product, and that there was no evidence before the trial judge, for example, of its manufacturing capacity, its distribution capacity, or its pricing and reimbursement arrangements prior to March 2016, or even an expressed intention by TEVA that it wished to launch the Braltus product onto the Irish market prior to the expiry of the SPC.

18. In that regard, counsel has referred to a short passage from the judgment of the trial judge dated the 10th November 2015 (on the stay application) where he referred to the element of speculation by TEVA as to its launching the product in advance of March 2016:

> "6. Are there any public interests identified that might justify continuing the court's consideration of the SPC's validity notwithstanding that it is a moot? I cannot find any. There do not appear present anything so concrete as the 20 other cases before the Revenue Commissioners involving the same issue as in *Irwin v. Deasy* cited above. It has been hinted that the petitioner might consider risking bringing to market an infringing product during the time between now and March 13, 2016 and either proceeding to do so, or obtaining an undertaking as to damages if an injunction were granted – all

this creating an interest of value during these four months. But no details whatever have been furnished of such a plan. *This remains highly speculative* and cannot meet the requirement of a real, identifiable public interest that is required to be present before the court can proceed to try a moot." [Emphasis provided]

19. At the commencement of the hearing of the discovery appeal in this Court on the 19th October 2015 the possibility of TEVA's launch of the Braltus product prior to expiry of the SPC was canvassed as one reason why the proceedings might not be considered moot, and was the subject of some discussion between counsel and the members of the Court. The President of the Court (Ryan P.) is noted in the transcript as suggesting that inevitably such a launch would be met with an unanswerable injunction application by Boehringer, to which counsel's response was that while that may be so, Boehringer would be required to provide a valuable undertaking as to damages which would be called upon in the event that TEVA's challenge was ultimately successful. Immediately prior to that exchange there had been discussion about the possibility of a launch in advance of March 2016 in the context of the unlikelihood of a decision on the SPC proceedings being available prior to the expiry date. At that point counsel for TEVA indicated that he was not committing himself to whether or not there would be such a launch before March 2016. Any intention on the part of TEVA in this regard was not revealed one way or the other.

20. Boehringer submits that it was in the light of this lack of any assurance by TEVA that there was any good reason why the proceedings were not moot, and the lack of any assurance in response to its letter to Teva's solicitors dated the14th October 2014, that it issued its stay motion on the 28th October 2016.

21. Boehringer have relied upon the judgments of the Supreme Court in *Telefonica O2 Ireland Ltd v. Commission for Communications Regulation & ors* [2011] IEHC 380 and *Cunningham v. The President of the Circuit court and the DPP* [2012] IESC 39 for its submission that costs should be awarded to a party where the mootness is attributable to the other party, and where that other party asserts that external factors intervened to render the proceedings moot so that it should not have to pay the costs, the onus was on the party so asserting to provide sufficient evidence to the Court to permit a determination of the issue. Boehringer submits that TEVA has failed to adduce sufficient evidence that it was the delay by the MHRA in relation to the marketing authorisation that rendered the proceedings moot, as found by the trial judge

22. In any event, it was submitted that TEVA itself should have to bear responsibility for any delay in the marketing authorisation process, since it was their application, and that they ought to have anticipated that there might be such delays when deciding not to commence its challenge to the validity of the SPC, until October 2014, and that certainly Boehringer should not be penalised by having to bear its own costs by the order of the trial judge where it played no part in the marketing authorisation process, or any decisions made by Teva in relation to its commencement and conduct of the SPC proceedings.

23. Boehringer have drawn attention to the affidavit of Ms. Fry which was filed on behalf of TEVA for the purpose of the costs hearing. In particular they draw attention to the fact that it is clear from her affidavit that by the 9th September 2015 TEVA knew for certain that there was no possibility that a marketing authorisation would issue prior to expiry of the SPC in March 2016, and did not inform Boehringer of that fact, and even persisted in its defence of the discovery appeal by Boehringer, refused to confirm to either the High Court or the Court of Appeal that the proceedings were moot resulting in this Court having to hear the SPC discovery appeal, and defended fully the mootness application before the High Court in November 2015, while at the same time hinting at least that a launch of their Braltus product at risk was still a possibility prior to expiry of the SPC.

Teva's submissions

24. Teva's position on the question of costs in the High Court was that there should be no order as to costs in all the circumstances of the case. Boehringer on the other hand sought its costs of the proceedings, and blamed Teva for the fact that the proceedings had become moot given the date of commencement and the extensive nature of discovery sought. Teva considers that this application for costs by Boehringer is simply opportunistic, particularly given its own delay in bringing any application for a stay of the proceedings at a much earlier stage of the proceedings if it truly considered that once discovery was sought in such extensive terms it was inevitable that the proceedings could not be determined before the expiry of the SPC in March 2016.

25. Teva submits that if Boehringer believed that the proceedings never had any chance of being determined prior to expiry of the SPC once such extensive discovery was sought by letter dated the12th January 2015 which they knew they were gong to vigorously contest, then the question of mootness could and should have been raised by them on any of several opportunities that presented between January 2015 and October 2015. Teva refers for example to the fact that on the 20th July 2015 it made application to move the hearing date from November back to the February 2016 because the discovery appeals to this Court were listed for hearing on the 19th October 2015. Teva refers to the fact that on that date it had indicated to the High Court that the hearing of the substantive proceedings (including the challenge to what is referred to as the 220 Patent) might last three weeks, and that it was counsel for Boehringer who considered that in fact four weeks would be required, yet made no complaint that this would mean (a) that the hearing would not be concluded until almost the expiry date of the SPC, and (b) that inevitably any reserved judgment could not be delivered until well after the SPC had expired.

26. Teva refers to the fact that it was not until its letter dated the 14th October 2015, just days before the hearing of the discovery appeal that Boehringer first raised the question of mootness, and that it has not explained why it waited so long if it was a serious concern for it since January 2015. It is submitted that another opportunity to bring up the question of mootness which was missed by Boehringer, was at any time during the hearing of the discovery motions in the High Court before Mr Justice Cregan on the 18th and 19th March 2015.

27. Teva also refers to the fact that Boehringer had itself sought voluntary discovery from Teva by its letter dated the 12th January 2015, and that it also had lodged an appeal against the order of Cregan J. made on the 19th May 2015 refusing discovery by Teva of category 1 documents. It submits that Teva alone should not therefore be blamed for the fact that the discovery process delayed the progress of this litigation.

28. Boehringer explained that the reason why it did not move to seek a stay prior to the end of October 2015 was that over the previous months it was focussed on the various interlocutory matters which were being dealt with, and not on the question of mootness. Teva submits that this is not a credible explanation.

29. In particular it is submitted that once the trial date was moved back from November 2015 to February 2016 on the 20th July 2015 Boehringer had ample reason to move for a stay if they had been minded to do so. Teva submits that if, as was quite possible, such an application was granted, then most of their costs which Boehringer now wish Teva to pay would not have been incurred, and that it would be unfair to now visit those unnecessary costs upon Teva, and reward Boehringer for its own delay.

30. Teva does not accept that the question of the delay in the issue of the marketing authorisation for its Braltus product by the

MHRA was irrelevant and entirely separate from why these SPC proceedings became moot, as submitted by Boehringer. It is submitted that when addressing the cause of the proceedings becoming moot and who should be found responsible for that situation, the trial judge was correct to conclude that it was only when it became clear that this market authorisation would not issue prior to the 13th March 2016 that Teva ought to have conceded that the proceedings were moot, and also that he was correct to characterise the delay in the issue of same as an external event in the context of the three categories of mootness referred to in the judgment of McGovern J. in *Viridian Power Limited v. Commission for Energy Regulation* [2014] IEHC 614 and therefore a case where it was appropriate to make no order as to costs.

31. Much of the evidence upon which Teva relies in relation to the delay in the marketing authorisation process is contained in the affidavit of Lucy Fry sworn on the 15th July 2016 for the purpose of the costs application. Much of that affidavit is subject to a strict confidentiality regime (see order of Hedigan J. made on 14th July 2016), and for that reason I do not propose to refer to the details of that evidence as it is unnecessary to do so, other than by general references, so that confidentiality is observed.

32. That affidavit is relevant in the context of Teva's submission that as long as there was the possibility that it could launch its rival generic Braltus product at any time during the life of the SPC, albeit at risk of an application by Boehringer to restrain such a launch, the SPC proceedings were not moot because on any such injunction application the issue of invalidity of the SPC would arise for determination, and Boehringer would be required to give an undertaking as to damages. Accordingly, Teva submits that the delay in the progress of the proceedings by reason of the discovery process, is not actually the central question as far as mootness is concerned. Rather, as they submit was found by the trial judge in his costs judgment, it was the delay in the issue of the market authorisation for which they cannot be held responsible, since any at risk launch was held up until such time as it became available.

33. Teva filed an affidavit sworn by Gerard Kelly in response to the affidavit of Laura Scott filed in support of Boehringher's application for costs. Ms. Scott's affidavit dealt in detail firstly with the delays caused by discovery, and thereafter with the question of whether there was any intention on the part of Teva that it might launch its product ahead of the SPC expiry date. In relation to the latter, she stated at para. 26 of her affidavit that it was her belief that Teva knew when it commenced its SPC proceedings or shortly thereafter that "they would not be in a position to launch their product prior to the expiration of the SPC and for that additional reason these proceedings are moot". She referred to the absence of any indication to either this Court on the discovery appeal or in answer to Boehringer's letter dated 14th October 2015 as to its intentions to launch its product which might give some comfort that the proceedings were not in fact moot by this time. She stated at para. 59 in relation to the judgment of Hedigan J:

> "59. The Court also noted that it had been 'hinted' that Teva might carry out infringing activity at risk prior to 13 March 2016 and that this might confer an interest in continuing the proceedings but that no details had been furnished of such a plan and that is "remains highly speculative and cannot meet the requirement of a real identifiable public interest that is required to be present before the court can proceed to try a moot".

34. That is the context in which those remarks were made – *i.e.* in the context of whether there was a public interest would justify the court in determining what was otherwise a moot issue. That in my view is a different context to the present one, where the court is determining whether Teva was justified continuing procedurally towards a hearing in February 2016 in circumstances where there was no real prospect of the case being fully heard and judgment delivered prior to the expiry of the SPC, on the basis that the issue of validity would arise on any injunction application brought against it in the event that it launched its product at risk at any date prior to the 13th March 2016.

35. Mr Kelly's affidavit dealt in the main with the complaints made by Boehringer in relation to the delay in commencement and discovery, though he also referred to the market authorisation as well, *inter alia* by rejecting what Ms. Scott had said at para. 26 of her grounding affidavit. At para. 61 of his affidavit he stated:

> "61. For the avoidance of any doubt, [Teva] entirely rejects the assertion by Ms Scott at paragraph 26 of her affidavit that [Teva] knew at the time the Irish proceedings issued or shortly thereafter that they would not be in a position to launch a product prior to the expiration of the SPC. I find it hard to believe that Ms. Scott or her client do not understand that there is no reality to a competitor indicating 'state of readiness to manufacture, the extent to which they had developed a marketable product and the date of their application for a marketing authorisation and their progress in securing a grant of a marketing authorisation'. This simply would never occur, nor indeed would Ms Scott's client ever entertain such a request."

36. Mr Kelly went on in his affidavit to update the situation regarding a potential launch of its rival Braltus product, and in particular to a press release by the Teva group of which the petitioner is part on the 30th May 2016 which post-dated Ms. Scott's affidavit. That press release indicated that that there had been a positive conclusion to the decentralised procedure for a tiotropium bromide inhaler product in favour of the Teva group, and that national marketing authorisations for the competing product in the EU named Braltus would then take place in selected markets "over the coming months as assessed by national Teva companies. Mr Kelly went on to state that it should be apparent to [Boehringer] that such an application would have been made some time ago and indeed well in advance of the expiry of the SPC in March 2016.

37. Mr Kelly then referred to the extreme commercial sensitivity and confidentiality attaching to the progression of Teva's marketing authorisation application, and that it was not in a position to disclose the progress of such an application until it was obtained and a matter of public record. That commercial sensitivity relates to the need of the first mover to protect knowledge from any potential competitor generic company which might have ambitions to launch a similar generic product.

38. Ms. Fry's affidavit was sworn and provided on the basis of confidentiality protected by the order of Hedigan J. dated 14th July 2016. As indicated earlier I do not propose to disclose any of the confidential information set forth. I will make only general reference to its contents in the knowledge that both parties are aware of the confidential facts disclosed.

39. Ms. Fry's affidavit relates to the progress of the marketing authorisation application made to MHRA. She outlines the procedures to be adopted, and the various timelines involved, under Directive 2004/27/EC (amending Directive 2001/83/EC) in respect of such applications. It is unnecessary to set out that procedure in detail here. She gives details of the timetable presented to Teva in respect of its application for market authorisation. She states that by reference to the date of Teva'a application and the timetable provided it was envisaged that the authorisation would issue well in advance of the expiry of the SPC. She avers that this was in the contemplation of Teva at the time it issued its proceedings on the 23rd October 2014. She then refers to a procedure whereby the clock is stopped on the timetable when issues or queries are raised in relation to the application, and time is given to respond. She outlines how this occurred in the present case, but how that despite these stops it was still envisaged well into 2015 that an authorisation would issue in good time before March 2016 to facilitate a launch at risk. However there remained some outstanding issues to be addressed, as she describes, and a meeting was held with the MHRA on the 9th September 2016 which made it clear at

that point that there was no longer any prospect of the authorisation issuing prior to the expiry of the SPC. I have deliberately omitted the detail provided by Ms. Fry as to the issues raised and the reasons for the clock stops being applied. But she explains this in some detail. As of the date she swore her affidavit (15th July 2016) she expected that the marketing authorisation for Ireland would issue "imminently". Ms. Fry concluded her affidavit by stating the following:

> 30. In the circumstances, I respectfully disagree with [Boehringer]'s suggestion that these proceedings were moot when they issued and served no commercial purpose for the Teva Group. In addition, [Boehringer] could not have known about Teva's marketing authorisation plans or commercial launch plans and are, with respect, not in a position to make such observations in the evidence. To divulge this information prior to grant of a marketing authorisation does not reflect the commercial reality of the pharmaceutical industry as such matters are confidential and highly commercially sensitive.
>
> 31. I believe the above demonstrates that it was always anticipated that Teva would be in a position to launch prior to SPC expiry until the relevant regulatory authority intervened … and the process was delayed as a result as set out above. I do not believe that Teva can be criticised for the above developments in the application process, which were not anticipated at the start of the process."

Conclusions

40. The trial judge's judgment on the stay application is certainly brief, and succinct. He was satisfied that the SPC proceedings were moot simply on the basis that there was no prospect of the issue of invalidity being determined prior to the expiry of the SPC, and therefore it would be a waste of scarce judicial resources for a judge to have to hear a four week case and deliver a written judgment on a question that would by then no longer be of relevance to the parties. There was no appeal against that decision.

41. As part of its resistance to Boehringer's stay application Teva raised the argument that the issue of invalidity was not moot despite the impossibility of the issues being determined before the SPC expired, since Teva could launch its rival generic product at its own risk at any time prior to the expiry date and, perhaps inevitably, face an injunction application for which the question of invalidity would have to be determined even after the SPC expired, if for no other reason than to decide whether the undertaking as to damages which Boehringer would have to give as the price for any injunction should be enforced in the event that Teva was successful in its invalidity claim. The transcript for the hearing on the 6th November 2015 indicates quite an amount of discussion of the question whether the invalidity of the SPC could have any relevance after the 13th March 2016. Teva made its position very clear. Its submission was that it intended to launch its product at risk before the expiry date, and that the issue of invalidity would be live in the context of any injunction that Boehringer would bring, and any finding of invalidity, even one after the 13th March 2016, would have retrospective effect so that the SPC would be found to have been invalid *ab initio*, and not just prospectively. Counsel also argued that a trial date had already been fixed, meaning presumably that were Boehringer to have to issue its own plenary proceedings in order to seek an injunction against Teva, the hearing date would be far beyond February 2016.

42. It is clear also from the transcript that Boehringer did not accept the bona fides of that submission against mootness. Counsel drew attention to a part of Mr Kelly's affidavit sworn on the 3rd November 2015 for the purpose of opposing the stay application, where at para. 56 he stated:

> "It cannot be credibly argued that the petitioner has initiated these proceedings in this jurisdiction and expended considerable resources in pursuing these proceedings to trial, including the multiplicity of interlocutory applications in the hope that an interlocutory injunction application would issue. If the petitioner truly wanted to obtain a cross-undertaking as to damages in the context of an injunction application it would have saved a lot of time, effort and money by simply writing a letter indicating that it intended to infringe the SPC without further notice to the respondent."

43. I have already indicated my view that when the trial judge concluded that the idea of a plan to launch the Teva product at risk onto the Irish market prior to the expiry of the SPC was "highly speculative" he did so in the context of whether there was some public interest in having the SPC invalidity issue determined. Be that as it may, it is clear that he did not consider that the stay should be refused because of a possibility that the issue might have to be determined at some stage in the context of any injunction application, as otherwise he would have said so. That submission had been clearly made to him by Teva. The ratio of his decision is that there was no public interest in play, and that since there was no prospect of a determination of the invalidity claim in the time available prior to the expiry of the SPC the scarce court resources should not be expended pointlessly by determining something which by then would be academic or hypothetical. There is no appeal against his decision in that regard.

44. On one level, it could be said that what Teva are attempting to do on this costs appeal is to re-run the argument against mootness based on the failure to obtain marketing authorisation, and the utility for Teva of continuing with the proceedings because it might have launched the product at any time prior to the expiry of the SPC, and faced an injunction application, not so much for the purpose this time of saying that the proceedings were not a moot (since that has already been determined against Teva), but rather that they were justified in persisting with the proceedings because of the possibility that some useful purpose might be served in the event that they launched their product at risk, and faced an injunction application.

45. That, it seems to me, amounts to an impermissible collateral purpose, and particularly so when no doubt for understandable commercial reasons, and perhaps for tactical reasons, that purpose was not made known to Boehringer.

46. In my view the delay in the marketing authorisation application, and the reasons detailed by Ms. Fry in her first affidavit are not matters that should influence the Court in determining where responsibility for mootness should lie. It seems to me that whenever these proceedings were stayed as being moot, and a launch at risk took place, Boehringher as plaintiff would simply have issued a plenary summons seeking injunctive relief, and would have sought an interlocutory injunction. It should be stressed that these petition proceedings were not necessary for that to occur. An interlocutory injunction may or may not have been granted according to the usual legal principles. In the event that one was granted, Boehringer would have given an undertaking as to damages. The issue of the invalidity of the SPC would no doubt have been raised by Teva by way of defence and counterclaim in the main proceedings. In due course that issue would be determined, probably long after the 13th March 2016, but in the context *only of whether the undertaking as to damages should be enforced and if so in what amount*.

47. While I understand the submission by Teva to the High Court that it would be advantageous to avail of the trial date already in place, and for that reason keep the proceedings alive rather than stay them on the ground of mootness, there was nothing imperative as far as an early trial is concerned once the SPC expired. The enforcement of the undertaking as to damages by Teva was never going to be critical to its survival. Whether there was some additional delay in that matter was in a sense unimportant.

48. The question then is whether the manner in which these proceedings were conducted by Teva, and taking account also of Boehringer's conduct of its side of the proceedings, merits interference with the broad discretion in the matter of costs enjoyed by the trial judge. He heard all the arguments and submissions and came to his conclusion that a fair exercise of discretion was that each side should bear its own costs, save that the costs of the stay motion itself should be awarded to Boehringer.

49. Were the proceedings doomed to mootness from their very commencement? I think not. Of course they could have been commenced even sooner, but that could be said in the case of many proceedings. It would be harsh, in my view, to conclude that with 17 months to go before the SPC expired, there was no possibility that the proceedings could be determined within that period, even where it would be presumed by Teva that its application for discovery would be opposed.

50. The question then is at what point should Teva be considered to have unreasonably persisted in progressing these proceedings when they ought instead to have formed the view that since a result could not be achieved within that period, the proceedings should be brought to an end.

51. Given the basis for the finding of mootness made by the trial judge in his November 2015 judgment, I consider that he fell into error if on a proper construction of his judgment at para. 5 he has concluded that the proceedings became moot as a result of the delay in the issue of the marketing authorisation. As stated earlier his conclusion was stated thus:

> "In my judgment, these proceedings became moot as time passed, and the external event of the MHRA's consideration of the market authorisation was delayed through no fault of the petitioner Teva. It thus fits into McGovern J's category (b)."

52. It is by no means clear that this was intended by him to revisit his earlier conclusion in which he stated that the question of a launch at risk was highly speculative. There seems to be a disjunction between the statement that the proceedings became moot as time passed, and then stating that the delay in the market authorisation was through no fault on the part of Teva. It may be that this should be read as meaning that it was the failure to get the authorisation before the expiry date that rendered the proceedings moot. But if so, that runs contrary to his un-appealed finding in the earlier judgment. Yet by placing the case in category (b) (*Veridian*) he does appear to conclude that mootness arose due to an external event beyond the control of the parties.

53. But whatever way one reads the judgment, the question for this Court is whether the making of no order as to costs was in all the circumstances an exercise of his discretion with which this Court should interfere.

54. In my view the proceedings did not become moot on the 9th September 2015 on account of Teva knowing on that date that they would never be able to launch their product at risk ahead of the expiry date of the SPC. The proceedings may have become redundant or cease to serve any useful purpose *for Teva* at that point, but that in my view is a different consideration, and if I may say so a somewhat self-serving one which ignores the interests of the Court in not wasting resources on matters which cannot be determined in time to have any real relevance for the parties, and the interests of Boehringer in not having to defend proceedings which do not need to be determined.

55. Teva kept these proceedings alive during the summer months of 2015 for its own purposes – in case they might launch at risk and face an injunction application. In these circumstances, I consider that Boehringer should not have to discharge their own costs from the 20th July 2015. That is the date when Teva knew that the hearing in the High Court would not conclude until a few days prior to expiry date of the SPC. Thereafter they kept them alive for their own advantage only, namely to see if the marketing authorisation might issue before March 2016 so that they might be in a position to launch at risk onto the market in order to gain the most valuable first mover advantage.

56. It was, of course, open to Boehringer itself to move sooner in relation to mootness, but I do not believe that they should be penalised for not having done so. Indeed, when they attempted to do so by letter dated the 12th October 2015, the response received was not encouraging.

57. It can also be borne in mind that the earlier Boehringer might bring such an application the less chance they would have of succeeding. One cannot overlook also the simple fact that within a very short time of the 20th July 2015 the long vacation intervened, and it was shortly after the commencement of the Michaelmas term that the question of mootness was raised by that letter dated 12th October 2015.

58. Boehringer were defending proceedings commenced against them. Teva had carriage of the proceedings. They were in the driving seat, so to speak. Boehringer was entitled to continue to defend them, including the discovery application, and to appeal the discovery order of Cregan J. In my view Teva should bear responsibility for costs from the date on which they knew the proceedings would not be determined before the expiry date, and a reasonable date to fix in that regard is the date on which the application was made to put back the trial date from November 2015 to February 2016. The pursuit of the proceedings thereafter by Teva was for its own purpose, which purpose was not disclosed to Boehringer, and, in my view, it should pay the costs incurred by Boehringer thereafter.

59. I consider that the trial judge erred in placing this case in category (b) of McGovern J's categories of mootness cases. In fact it does not fit neatly into any of these categories. But those categories are not exhaustive. Each case and the circumstances in which mootness arises must be considered on its own particular facts and circumstances in order to see where the justice of the situation lies in relation to costs. For the reasons given I believe that the justice of this case lies in requiring Teva to pay to Boehringer the costs of the proceedings from the 20th July 2015, including the costs of the motion to stay the proceedings. I would accordingly allow this appeal, and vary the order for costs as I have indicated.