THE HIGH COURT

[2023] IEHC 159

[2021 No.4758 P]

BETWEEN

BRISTOL-MYERS SQUIBB HOLDINGS IRELAND ('BMS')

PLAINTIFF

– AND –

NORTON (WATERFORD) LIMITED
t/a TEVA PHARMACEUTICALS IRELAND ('Teva')

DEFENDANT

JUDGMENT of Mr Justice Max Barrett delivered on 17th February 2023.

SUMMARY

This is a successful application by BMS for an interlocutory injunction restraining Teva from infringing Supplemental Protection Certificate No. 2011/032 (the 'SPC') and in particular by making, offering, putting on the market and/or using and/or importing or stocking for the aforesaid purposes, a generic version of BMS's medicinal products Eliquis (active ingredient: apixaban).

A. Introduction

1. By notice of motion of 2nd December 2022, BMS has come seeking an interlocutory injunction restraining Teva from infringing the SPC and in particular by making, offering, putting on the market and/or using, and/or importing or stocking for the aforesaid purposes, a generic version of BMS's medicinal products Eliquis (active ingredient: apixaban). (Apixaban is, I understand, an anti-coagulant that is effective in the treatment of conditions that give rise to a risk of thromboembolism.)

B. Matters as Perceived by Parties

2. A fulsome account of how the parties perceive matters to sit between them at this time is outlined in the affidavit of Mr O'Brien, as sworn on 2nd December 2022, the affidavit of Ms Reynolds, as sworn on 20th December 2022, and the further affidavit of Mr O'Brien, as sworn on 16th January 2023, extracts from each of which I quote below.

3. Mr O'Brien avers, amongst other matters, as follows:

"*5. The proceedings are patent/SPC infringement proceedings that were taken, initially on a* quia timet *basis, in circumstances where Teva had applied for a marketing authorisation for an infringing generic apixaban, indicated that it intended to 'clear the path' of the relevant rights by taking an invalidity action seeking revocation of the relevant patent and SPC and that it intended to launch its generic product by mid 2022 and refused to give any undertaking not to launch….*

6. The SPC extends the exclusive rights BMS enjoys under European Patent (IE) 1 427 415 entitled 'Lactam-containing compounds and derivatives thereof as factor Xa inhibitors' (the 'Patent') in respect of apixaban and pharmaceutically acceptable salts thereof. The Patent expired on 17 September 2022 and the SPC is due to expire on 19 May 2026, though that date may be extended by a possible paediatric extension.

7. BMS seeks an interlocutory injunction in circumstances where: (a) Teva accepts that the product that it proposes to launch in the State infringes the SPC and the Patent before it expired (in related invalidity proceedings…(the 'Revocation Action'). Teva asserts that the Patent and consequently the SPC, was invalid); (b) launch of Teva's product would cause irreparable damage to BMS…(c) an order restraining launch of Teva's product

pending trial, if reversed on determination of substantive case however, would merely cause a delay to Teva's plans which would be more readily compensable in damages than the loss that BMS would suffer in the event of an unlawful launch.

8. *It is clear from the terms of Teva's notice of its intention to launch that Teva places its hope of resisting interlocutory relief in the accusation that it has been thwarted in its attempts to prosecute the Revocation Action and 'clear the path' of the SPC by BMS such that the balance of convenience favours the denial of the relief sought….*
9. *There are two fundamental problems with Teva's narrative in this regard.*
10. *First, it presupposes that Teva will be successful in the Revocation Action in circumstances where I respectfully believe the indications are to the contrary and where BMS is confident in its right in and to the SPC and in its defence of it in the Revocation Action.*
11. *Second, the fact that the Revocation Action has not been completed in advance of Teva's desired launch date is a matter that is entirely down to Teva. As I outline in more detail below:*

    (a) *Teva chose, apparently arbitrarily, a proposed launch date for its product – the date initially flagged in its pre-action correspondence was mid-2022 – this has clearly shifted since that initial indication, but crucially neither mid-2022 nor any time before the trial of this action in June 2023 is a significant date in terms of imminent expiry of the right, or any other matter that would make time of the essence.*

    (b) *Teva then appeared to decree the amount of time that it would allow this Honourable Court to hear and determine the Revocation Action. Working back from mid-2022, by initiating the action in March of 2021, Teva allowed one year and a quarter – by any reckoning, a very tight timeline for the determination of a complex invalidity action.*

    (c) *Significantly and from the inception of the dispute in the State, Teva clearly never conceived of its launch proposals as being contingent on the Court's determination of the validity of the Patent/SPC. On the contrary it consistently privileged its commercial plans over the Court's determination of the issues and repeatedly refused to give any undertaking not to launch before the hearing and determination of the matter – even on its own extremely ambitious timeline.*

(d) Within an already extremely constrained timeline, and 8 months into the action, Teva decided to double the size and complexity of the trial by amending its proceedings to seek the invalidation of the Patent (and consequently the SPC) on an entirely separate, non-technical patent ground, i.e., on the basis that the BMS company that applied for the Patent on which the SPC is based was not the BMS company that was entitled to claim an earlier priority date for it; this has implications for validity because the later priority date affects the prior art available to challenge the novelty of the Patent and Teva asserts the publication of one of BMS's own patents between the priority date and the filing date of the Patent in this regard.

(e) Teva then proceeded to seek to telescope the time for discovery and witness statements regarding this entirely new case and demand exacting attention to them.

(f) Teva then raised extensive interrogatories – most of which were irrelevant and/or unnecessary and/or resulted from Teva's refusal to engage with normal accommodations on admissibility of documents.

(g) Teva refused to agree to the delivery of one additional witness statement on behalf of BMS which addressed the very subject matter which Teva was assiduously probing in interrogatories and in discovery. This meant that BMS had to bring a motion seeking leave to deliver the witness statement.

(h) Despite rehearsing its complaints for months on discovery and interrogatories, Teva chose not to issue motions on these matters until August 2022 in circumstances where the bringing of them at that stage could only be expected to have the effect of delaying the trial.

(i) In so far as Teva claims that the outcome of these motions vindicates its narrative of default on the part of BMS, BMS prevailed on its motion to adduce additional evidence; prevailed on two sets out of three of the interrogatories pursued. BMS was ordered by the Court to make further discovery but in circumstances where the Court adjourned the remainder of the discovery motion to trial and indicated that costs of anything other than the hearing of the motion could not yet be determined and that – in circumstances where the outcomes of the

motions had been split - no decision be made as to any wasted costs in terms of the delay of trial.

(j) Perhaps most tellingly, on each occasion when the opportunity arose to have the case heard, Teva passed on it. It opted for the hearing of the case in September/October 2022 by a judge with experience of patent invalidity actions rather than the originally scheduled hearing in June 2022. Despite the fact that the motions heard by the Court in September this year all related to the priority case, as opposed to the technical patent case, Teva never pressed, or even suggested, proceeding with the patent invalidity portion of the proceedings (which if successful would 'clear the path' for their product)….

13. In the sections immediately below I address the substantive issue that is between the parties and the basis upon which BMS is confident of defending the validity of the SPC first and then turn to address the comparative damage that would be caused to the parties by the grant or withholding, respectively of the relief requested in this application.

Fair issue to be tried

14. Not only is there a fair issue on infringement of the SPC, there is admitted infringement. At paragraphs 13 and 14 of its Defence of 1 October 2021…Teva admitted that its generic apixaban products would infringe the Patent. This is equivalent to an admission of infringement of the SPC. Teva relies on its assertion that the Patent is invalid to escape liability for infringement. At paragraphs 13 and 14 of the Defence, it pleads: 'it is admitted that carrying out the acts referred to in paragraphs 6 and 7 of the Particulars of Breaches…would infringe claims 1-12, 15-18, 21 and 22 of the Patent. However, as and for the reasons set out in the Particulars of Objection delivered in the Revocation Proceedings, the 415 Patent and the SPC are and have at all material times been invalid.'

15. As regards its assertion of invalidity, Teva's case is set out in its pleadings in the Revocation Action, to which I beg to refer when produced.

16. As will appear to the Court, there are two distinct and independent parts to Teva's bid to revoke the Patent and the SPC: a technical patent challenge as to patentability (the 'technical patent challenge'); and, a challenge on the basis of whether the Patent can claim priority from an earlier BMS company group filing, which if it cannot, will render

it vulnerable to a novelty attack on the basis of yet a third patent publication of the BMS group which will rank as prior art if the earlier priority date cannot be claimed (the 'priority challenge')

17. *Teva has pleaded various grounds of challenge in the technical patent challenge, but the only ones actually in issue are: Teva's allegation that the discovery of apixaban did not make a technical contribution over the prior art (the 'inventive step/technical contribution' challenge); and, Teva's allegation that the Patent was not sufficient, as of the priority date, to enable the skilled person to perform the invention (the 'sufficiency challenge').*

18. *Teva has not mounted any traditional inventive step/technical contribution and/or sufficiency challenge. It has not sought to contradict the indisputable fact that the Patent disclosed and enabled the skilled person to make apixaban as of the priority date, and that, as of the priority date, apixaban was a new (and very effective) factor Xa inhibitor that not only made a technical contribution, but a ground-breaking one. Its effectiveness and ground-breaking nature supplies Teva's motive for mounting the Revocation Action to try to bring its own generic product to the market.*

19. *What Teva relies on for its attack is a relatively new and evolving concept, as utilised in patent invalidity actions, which is referred to as 'plausibility'. It asks whether it would have been 'plausible' to the skilled person at the priority date that the invention of the patent made the technical contribution at issue. This concept has its origin in examination procedures at the European Patent Office ('EPO') as a means of excluding speculative patents. The policy is to prevent the making of speculative patent applications purely on the off-chance the invention works. The reason is that speculative claiming, if it were permitted, could have the effect of prematurely and perhaps unjustifiably where the speculation is not borne out, putting areas of research out of bounds for other innovators. As a ground of patent attack it has perhaps reached its apotheosis in the UK under the UK Supreme Court decision in* Warner-Lambert v Generics *[2018] UKSC 56 where the Court appears to have been interpreted as deciding, at least for the type of patent claims at issue in that case (i.e. second medical use claims), that the specification of the patent must either contain experimental data supporting the invention and/or an explanation of the inventive concept. While the formulation of the concept has been inconsistent, for much of the jurisprudence of the EPO to date, for most types of claims and consistent with the objective of excluding only speculative claims, the question is whether the invention would have been implausible from the specification of the patent*

in light of the common general knowledge of the skilled person. The standard set by the Irish Court of Appeal in Norton *(*Waterford Ltd t/a Teva Pharmaceuticals Ireland v Boehringer Ingelheim Pharma GmbH & Company KG *[2022] IECA 58 refers to* Warner Lambert *but is not as exacting in terms of what must be in the specification as opposed to the common general knowledge and what must be shown by way of support for plausibility.*

20. *The significance of these matters is that Teva prevailed in its plausibility challenge to the UK counterpart of the Patent, and the related SPC, at first instance in the High Court of Justice of England and Wales and places great reliance on that fact in its submissions in the Revocation Action and in its assessment of its chances of success.*

21. *However, in finding for Teva in the UK, Mr Justice Meade strictly applied the legal test laid down in Warner Lambert, which BMS believes does not represent Irish law on the point even as it currently stands.*

22. *Moreover, the UK decision also predates the anticipated decision of the EPO Enlarged Board of Appeal in* Sumitomo Chemical Company, Limited - *G 2/21. In giving his judgment, Mr Justice Meade acknowledged that the result of that referral 'will be extremely important for the EPO and for all EPC member states'. As described in the affidavit of Edouard Kling made in support of this application, the Enlarged Board of Appeal of the EPO has expressed views in its non-binding preliminary opinion of 13 October 2022 which, if they are confirmed will standardise the approach to plausibility under the EPC as one where, for most claims, a patent will only be ruled out on the grounds of plausibility if the invention would have been implausible to the skilled person at the relevant date i.e., there will be no requirement for positive proofs of the invention (as long as it is in fact inventive and enabled in the patent) in the patent specification….*

23. *Not only does the legal test that currently falls to be applied as regards plausibility in this jurisdiction differ from that applied by Mr Justice Meade in the UK therefore, the more liberal approach that is apparent from much of the EPO case law stands to be rationalised and formalised. If it is, I respectfully cannot see how Teva will be left with a stateable case on plausibility in the Revocation Action.*

24. *Furthermore, the evidence to be given in this jurisdiction will anyway address gaps left in the evidence given in the UK on the issue of plausibility.*

25. *As also indicated by Mr Kling, the Court of Appeal of England and Wales has given leave to appeal the decision of Mr Justice Meade on the UK counterpart patent on the basis*

that the necessary standard for appeal has been reached, namely that the grounds of appeal have real prospects for success.

26. *More recently, on 2 November 2022, the Patent and Market Court of the Stockholm District Court in Sweden dismissed Teva's claim that the Swedish counterpart of the Patent and the SPC should be declared invalid….*
27. *Unlike the UK, Teva's attack in Sweden was based on grounds corresponding to both the plausibility attack and the priority attack.*
28. *The UK and Swedish judgments are to date the only decisions on the merits in respect of the allegation that the national designations of EP 1 427 415 are invalid and the Swedish judgment is the only decision in respect of the priority attack.*

Adequacy of damages

29. *For all the reasons set out in the affidavit of Scott Cooke grounding this application, to which I beg to refer when produced, damages would not be an adequate remedy for BMS if the relief sought in this application were refused and BMS was ultimately successful at trial. As Mr Cooke explains, the damage caused would be likely to be permanent and ongoing and present very significant difficulty in assessment with the likelihood that BMS would not be fully compensated.*
30. *This stands in stark contrast to Teva's position. As touched on above, there is no imperative for Teva to get onto the market now as opposed to the date when the Court can determine the substantive action. The SPC is not approaching expiry and considerations of trying to obtain first-mover advantage among generics suppliers as apixaban goes off patent/SPC do not apply. The only damage that Teva will sustain if it is restrained from infringing pending trial, and if it is ultimately successful at trial, is a later launch date. How it fares on the market at that point will be directly indicative of how it would have fared at the earlier date, assuming it would have had adequate supply at that date and, if appropriate, a calculation of lost sales can readily be made.*

Balance of justice

31. *Turning to the intention evident in Teva's letters 29 November 2022 and 1 December 2022…to assert that some kind of blame accrues to BMS in terms of the progress of the Revocation Action. The implication is that Teva has been obstructed in 'clearing the*

path' in such a way that that would justify refusal of the relief requested in this application. In that regard, Teva is the untrammelled author of its own timings in this matter – both as to the proceedings and as to the proposed commercialisation of its generic product – and BMS has in fact tried to accommodate Teva to the greatest extent reasonably possible in marshalling the proceedings to hearing.

32. *First, Teva chose its proposed launch date for its product apparently arbitrarily. The date initially flagged in its pre-action correspondence was mid-2022…. As I mention above, there was no rights-based imperative attaching to this date – in terms of any imminent expiry of rights for instance and a related desire to launch before other generics suppliers on expiration of the rights. The fact that it was arbitrarily chosen seems abundantly clear from the fact that it has shifted. The key point is that neither mid-2022, nor indeed any date before the trial of the Revocation Action will take place, is anything other than arbitrary, apart from the fact that it seems that Teva is determined to launch before this Court has an opportunity to determine the substantive issues in these proceedings.*

33. *By initiating the proceedings in. March 2021 in light of its stated countdown to launch, Teva imposed an entirely artificial urgency to which it expected all Court procedures to be subservient. The one and a quarter years Teva deemed should be allocated for the hearing and determination of the proceedings would be insufficient for most patent invalidity proceedings, particularly those where discovery was intended to be requested, as it was by Teva (even though it was not requested in the UK proceedings).*

34. *It is clear from the pre-action correspondence that Teva never tied its plans for launch to the prior hearing and determination by the Court. While it was content to use its intended launch date as a pressure to impose stringent, and sometimes impossible time limits for procedural steps in the proceedings, it was careful to avoid any indication that the successful determination of the action was the precondition for its commercial plans.*

35. *As already outlined, within the extremely constrained timeline that it had already imposed, and 8 months into the action, Teva decided to double the size and complexity of the trial by amending its proceedings to seek the invalidation of the Patent (and consequently the SPC) on the priority ground.*

36. *Teva then proceeded to seek to telescope the time for discovery, witness statements and submissions, regarding this entirely new case from what might usually be expected into extremely short timeframes. BMS tried to facilitate Teva. It consented to the addition of the new basis for challenge and even agreed to consider the request for discovery made*

in respect of it before it was formally part of the case. A number of matters made this phase of the case very demanding for BMS…. In summary the challenges that arose included the following:

(a) *Discovery on the priority issue had not been requested in any of the challenges undertaken by Teva against foreign counterparts of the Patent and SPC and accordingly it had to be undertaken for the first time for the Irish proceedings. That was demanding in itself. When that was added to the fact that what was insisted on by Teva was discovery spanning more than 20 years, BMS concentrated on identifying those sources that would hold documents of any materiality. Despite the extremely constrained timeline to the trial date that it had desired, however Teva insisted on an exacting discovery process, repeatedly wrote seeking iterative additions to the discovery and ultimately issued a motion in August 2022 for further and better discovery….*

(b) *Teva began to demand the delivery of BMS's witness statements as to fact on the priority issue on 16 December 2021 before the Order of discovery was made and in advance of even suggesting the timeline by which it would provide its own witness statements (as challenger)…. In the course of the dispute as to Teva's right to demand witness statements before it deigned to say when it would deliver its own witness statements, moreover in an addition to the case that BMS found itself having to freshly defend, Mr Justice McDonald queried whether the trial date was too early to permit the necessary pre-trial steps to be taken….*

(c) *BMS encountered difficulties in preparing and delivering witness statements in circumstances where one proposed witness on the priority issue tragically died and an issue arose as to the availability of the main intended fact witness such that alternate witnesses had to be found very quickly. The ensuing delays in delivering witness statements were aggressively pointed to by Teva in the course of its motions for discovery and interrogatories as evidence of unacceptable 'default' by BMS…*

(d) *Teva delivered a Notice for Interrogatories seeking 115 interrogatories, most of which were not relevant and not necessary in light of the arrangements for admissibility of documents normally agreed between parties to commercial litigation. Teva delayed or refused to agree similar arrangements. BMS answered even those unnecessary interrogatories that were not objectionable and was put to the trouble of explaining a second time why those that had been objected to were still objectionable. Ultimately Teva issued amotion in August 2022 seeking responses to 12 interrogatories and succeeded in having 2 directed….*

37. *Teva refused to agree to the delivery of one additional witness statement on behalf of BMS which addressed the very subject matter which Teva was assiduously interrogating in interrogatories and in discovery. This meant that BMS had to bring a motion seeking leave to deliver the witness statement, which was granted.*
38. *Despite rehearsing its complaints for months on discovery and interrogatories, Teva chose not to issue motions on these matters until August 2022 and in circumstances where the bringing of them at that stage could only be expected to have the effect of delaying trial.*
39. *In so far as Teva claims that the outcome of these motions vindicates its narrative of default on the part of BMS, BMS prevailed on its motion to adduce additional evidence; prevailed on two sets out of three of the interrogatories pursued (12 out of an initial 115 were pursued). BMS was ordered by the Court to make further discovery but in circumstances where the Court adjourned the remainder of the discovery motion to trial and indicated that the costs of anything other than the hearing of the motion could not yet be determined and that no decision could be made as to any wasted costs in terms of the delay of trial….*
40. *Significantly, Teva eschewed the opportunities that presented themselves for an early determination of the Revocation Action. First Teva opted for the hearing of the case in September/October 2022 by a judge with experience of patent invalidity actions rather than the originally scheduled hearing in June 2022. I beg to refer to a copy of the Court transcript of 2 June 2022….Teva is keen to point to the motions, and allocate to BMS the blame for having to bring them and apparently, the timing of them, but never adverts to the fact that these motions affect the priority issue only. The Patent/SPC stands to be*

revoked if either Teva's technical patent case or its priority case succeeds. Teva never once suggested to the Court that it keep the September/October date for the hearing of its invalidity case – the only case that it started out with, that it expresses so much confidence in and that, if successful, would 'clear the path' for its generic product.

41. *Teva even resisted determination of these infringement proceedings after full hearing of the only issue encompassed in them, namely invalidity; they proposed that the infringement proceedings be 'adjourned' pending determination of the invalidity proceedings and 'put in for mention' following the invalidity trial. The only conclusion that can be reached, in circumstances where the determination of the invalidity action, is that Teva hoped to play for time in the event that the invalidity action went against them such that no order could issue in respect of the infringement portion automatically on the upholding of the patent and time would be taken in waiting for the 'for mention' and engaging in a separate application for orders on infringement. Only at the hearing of the motion did Teva relent and consent to the listing of the infringement action in the last day of the scheduled invalidity trial.*

42. *In summary, the idea that BMS has been guilty of some kind of obstruction of Teva in having its challenge determined so as to load the balance of justice in favour of allowing Teva to launch infringing product in the State is simply wrong in my respectful belief. BMS tried to facilitate Teva on its timings and simply could not do so in certain circumstances despite devoting considerable resource in the effort. However it is clear that Teva did not prioritise early trial in its actions. In so far as its former or new proposed launch date is anything other than an arbitrary date selected by Teva, it was clearly in Teva's power to initiate proceedings in good time to allow for the kind of exacting pre-trial process that it sought in this case.*

43. *I believe the matters of primary importance however to be the fact that BMS is confident in its defence of its right and does not expect Teva to prevail in its challenge and that launch by Teva of its generic product pending trial will result in damage to BMS that will be irrevocable and very difficult, if not impossible, to fully compensate for, whereas the damage to Teva for imposing a temporary restraint that is later lifted will amount to no more than a delay in the commercialisation that it will go on to make*."

4. Ms Reynolds avers, amongst other matters, as follows:

"*5. By Notice of Motion dated 2 December 2022 BMS seeks an interlocutory injunction restraining Teva from infringing Supplemental Protection Certificate no 2011/032 (the 'SPC'). The relevant 20 year patent on foot of which the SPC was granted expired on 16 September 2022 - Irish Patent Number EP (IE) 1 427 415 entitled 'Lactam Containing Compounds and Derivatives Thereof as Factor Xa Inhibitors,' (the 'Patent'). Both the Patent and SPC are registered in the name of BMS.*

6. The claims of the Patent relate to a compound, apixaban, which is sold by BMS under the trademark ELIQUIS and is authorised to treat certain thromboembolic disorders.

7. It is Teva's case that the Patent and, by extension, the SPC, are and have always been invalid. Teva launched revocation proceedings in Ireland on 19 March 2021, bearing record number 2021 / PAP1 (the 'Revocation Action').

8. The purpose of the Revocation Action was to enable Teva to launch a generic version of apixaban ('Apixaban Teva'). It was stated at an early stage in the Revocation Action that the proceedings were what are termed 'path clearing' proceedings and that Teva 'has indicated in open correspondence that it's planning to launch a rival product during the course of next year and it has summarised why it believes there's going to be a public interest benefit to that in terms of a generic coming out, if it clears the path successfully in the High Court, with a rival product and there is clearly a big commercial significance attaching to that.'…As explained in greater detail below, owing entirely to BMS' conduct in the Revocation Action, those proceedings will not now be heard until July of 2023.

9. If the interlocutory injunction is granted Teva will not be able to launch Apixaban Teva. I say and believe there is no legal basis to justify the grant of an interlocutory injunction and that the clear balance of convenience lies in the refusal of same….As set out in greater detail below, it is Teva's position that: (a) The Patent is and always has been invalid and thus the SPC is also invalid; (b) Any damage caused to BMS, if Apixaban Teva is launched and the validity of the Patent is later upheld, is quantifiable and Teva will be in a position to meet any award of damages; (c) Conversely, if Teva is restrained from launching Apixaban Teva, it will suffer irreparable harm as described in detail in the Affidavit of Paul Neill and supported in the Affidavits of two independent experts Alan Long and William Potter….

PRELIMINARY POINTS ON INTERLOCUTORY INJUNCTION APPLICATION

Key Facts on Apixaban

12. *I outline below some key facts on apixaban for this Honourable Court to be aware of in considering the arguments made by the parties in this application and I set them out below:*

a) Apixaban is a direct oral anticoagulant ('DOAC') produced by BMS under the brand name Eliquis;

b) In Ireland, apixaban is licensed and reimbursed by the Health Service Executive ('HSE') for three main conditions in adult patients. It is indicated for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, the treatment of deep vein thrombosis ('DVT') and pulmonary embolism ('PE') and the prevention of recurrent DVT and PE in adults. The 2.5 mg tablet is also indicated for the prevention of venous thromboembolic events ('VTE') in adult patients who have undergone elective hip or knee replacement surgery;

c) Apixaban is the DOAC of choice by the HSE-Medicines Management Programme. This is confirmed by a circular from the HSE dated 6 September 2019 and an extract from the Irish College of General Practitioner guide entitled 'Practical use of Direct Oral Anticoagulants (DOACs) in Atrial Fibrillation in General Practice'….

d) The market for apixaban in Ireland is growing all the time. As noted in an article in the British Journal of Clinical Pharmacology co-authored by Irish physicians, in Ireland, 'The number of patient prescribed OACs increased by 94% from 2010–2018 with a significant change from 2013 ...associated with a large increase in the number of patients on DOACs. There was a 3.3-fold increase in the expenditure on OACs nationally from 2013 to 2018, of which 94% was DOAC related'. An extract from the British Journal of Clinical Pharmacology, entitled 'The association between increasing oral anticoagulant prescribing and atrial fibrillation related stroke in Ireland' Br J Clin Pharmacol 2022; 88:178….

e) Apixaban is one of the largest selling medicinal products in the world. In an Irish context, according to the HSE, apixaban is the second most costly product prescribed on the General Medical Scheme. In that regard I beg to refer to a HSE list entitled 'The Top 100 Products by Ingredient Cost'….

Teva's Commercial motivation

13. *As outlined in paragraph 39 of the Affidavit of my colleague Paul Neill, IQVIA data for the full year 2021 demonstrates the list price value of Eliquis® is €47,521,689 for the full year in both community and hospital pharmacy.*
14. *Another key consideration for Teva in the timing of its launch is the first mover advantage that might be achieved. The concept of first mover advantage is well known and is addressed at paragraph 55 of Mr Alan Long's Affidavit and also paragraphs 85 to 95 of Mr Neill's Affidavit. Mr Long describes the advantage as follows:*

> *'Generally, the first generic to launch on the market will obtain and retain the largest share of the switching market. This is known as first mover advantage and there is a significant advantage to a generic product that launches first in a market. If Teva was allowed on to the market, it would be able to secure an initial share of the market in competition only with BMS. That share would, in my view, be far bigger than the share it could secure in competition with multiple generics. When multiple generics eventually do come onto the market, Teva would already have established relationships with wholesalers, hospitals, prescribers and patients in relation to the supply of its product. As a result of those relationships, I would expect it to retain a larger market share following the entry of the other generics than it would be able to secure if it launched at the same time as them.'*

15. *Mr Long goes on to provide some practical examples of first mover advantage. If Teva does not secure first mover advantage, it is not possible to quantify the losses that it will suffer, either in the short or long term. I also refer to Section 5 of the Affidavit of William Potter in that regard.*

Public Interest considerations

16. *In this case, I say and believe there is a clear public interest in launching Apixaban Teva. In that regard I wish to refer to a letter dated 24 November 2022 in respect of a launch of a generic brand of apixaban from Professor Michael Barry, Head of National Centre for Pharmacoeconomics ('NCPE') and Head of the HSE Medicines Management*

Programme which evidences that there will be substantial multi-million euro savings to the State to the benefit of patients once a generic apixaban is launched. In this letter, Professor Barry concludes: 'Therefore, in view of the current very high expenditure on apixaban and the associated opportunity cost, the introduction of a generic alternative would have profound implications for our healthcare system benefitting many patients across a range of therapeutic areas. In my opinion it would be one of the most important developments in the area of medicines in 2023'….

17 *By way of background, HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds on the advice of the NCPE. As the name suggests the HSE Medicines Management Programme aims to promote safe, effective and costs effective prescribing. Therefore, those agencies are the two bodies charged with the public interest when it comes to the potential launch of new medicines and I believe their views ought to be given due consideration in assessing where the balance of convenience lies in assessing the merits of this injunction application.*

No injunction sought in the United Kingdom – damages were an adequate remedy

18. *On 7 April 2022, Teva Pharmaceuticals Industries Limited successfully prevailed in revocation proceedings before the High Court of England and Wales in relation to the Patent. ([2022] EWHC 822 (Pat), per Meade J.; the 'UK Judgment'.) BMS has recently been granted leave to appeal to the Court of Appeal. (For the reasons set out in paragraph 77 below, Teva Pharmaceuticals Industries Limited is confident that the UK Judgment will be upheld on appeal.). I am informed that the appeal is listed for hearing on 18 to 20 April 2023.*
19. *Following the UK Judgment, BMS was given notice of the intention of Teva Pharmaceuticals Industries Limited to launch Apixaban Teva in the UK on 24/25 May 2022. Critically, BMS did not seek an interlocutory injunction in the UK and Apixaban Teva was launched in the UK on 25 May 2022. In addition, l say and am advised that another generic brand of apixaban was launched by Sandoz Limited ('Apixaban Sandoz') and was likewise not injuncted.*
20. *I say and am advised that whether or not damages are an adequate remedy remains a key (albeit not the key) consideration in assessing the balance of convenience. In that regard, it is striking that BMS specifically did not seek an interlocutory injunction in the*

UK despite prior notice of the launch of Apixaban Teva. Tellingly, nowhere in the Affidavits of Mr Shane O'Brien or Mr Scott Cooke is this contradiction addressed. It is difficult to reconcile BMS' claims of seemingly 'irreparable'…and immeasurable harm in Ireland in the absence of an injunction, with its deliberate inaction prior to the launch of Apixaban Teva or Apixaban Sandoz in the UK.

BACKGROUND TO INTERLOCUTORY INJUNCTION APPLICATION

21. *BMS' application for a preliminary injunction against Teva forms part of a wider suite of four sets of proceedings between the parties, namely:*
22. *The Revocation Action issued by Teva on 19 March 2021, seeking revocation of the Patent and the SPC, on the grounds of invalidity and lack of priority;*
23. *Teva issued a further set of revocation proceedings (the 'Formulation Revocation Proceedings') bearing record number 2021/3PAP on 13 April 2021 against BMS and Pfizer Inc. The Formulation Revocation Proceedings sought the revocation of [certain recited patents]….*
24. *BMS then issued these infringement proceedings on a* quia timet *basis against Teva bearing record numbers 2021/4758P (the 'Infringement Proceedings') and also 2021/4759P (the 'Formulation Infringement Proceedings'). These Infringement Proceedings were listed on the final day of the trial of Revocation Action. The within application forms part of the Infringement Proceedings.*

STATUS OF THE IRISH PROCEEDINGS

25. *The Revocation Action has always been treated as urgent by Teva and has been accorded significant priority by this Honourable Court. Regrettably, owing to delays and serious defaults on the part of BMS, the trial of the Revocation Action has been significantly frustrated and delayed. The proceedings are now scheduled to be heard on 4 July 2023.*
26. *The goal of the Revocation Action was to 'clear the path' i.e. to allow the launch of Apixaban Teva in 2022. Teva has always been clear about its intended launch plans. In its initial correspondence of 9 April 2021, Teva explicitly confirmed that the proceedings were clear the path proceedings and the Application for Entry to the Commercial Court made expressly clear that an expeditious hearing was being sought. BMS consented to the entry into the Commercial Court on that basis. On 2 July 2021 Teva wrote to BMS to*

seek agreement on directions for the expeditious hearing of the case and notified BMS of its then intention to launch Apixaban Teva in 'mid -2022 or as close to that date as possible'.....The intended purpose of the Revocation Action has been frustrated by BMS such that Teva has been unable to clear the path and can only launch at risk.

27. *Tellingly Mr O'Brien devotes…significant parts of his affidavit…to arguing that, in weighing the balance of justice, BMS ought not to be blamed for obstructing the hearing of the Revocation Action. It is simply extraordinary that Mr O'Brien avers that this state of affairs is 'entirely down to Teva.' (paragraph 11). On the contrary, the obstruction by BMS of the Revocation Action has been egregious.*
28. *For ease of the Court however I summarise the persistent manner in which BMS has obstructed the hearing of Revocation Action with the consequence of preventing the launch of Apixaban Teva….*

Persistent default of Court Orders and Directions

29. *The Revocation Action has been marred by a consistent pattern of disregard by BMS of the Orders, rules and running of the Commercial Court. In summary, the conduct of BMS can only be described as evidencing persistent and habitual default.*
30. *Apart from the persistent default by BMS in complying with Court Orders, there has been a pattern of BMS delaying to the last minute with its replies to, and engagement with, Teva, often in breach of the Court rules, causing prejudice to Teva and hindering the effective use of Court time and resources. In that regard, I refer to a series of detailed chronologies that have been prepared for me by Pinsent Masons exemplifying the repeated defaults by BMS to comply with Court orders and directions throughout these proceedings….*
31. *Teva has sought to ensure that the trial would proceed with the expedition and efficiency that the Commercial Court has sought to provide. However, the conduct of BMS has thwarted those efforts by Teva and the Court.*

Brief chronology of the Revocation Action

32. *I say and believe it would be helpful to set out a brief chronology of these Proceedings and the Revocation Action to date to illustrate the emphasis Teva has placed from the start on obtaining an expeditious hearing.*

33. *As far back as 9 April 2021, Teva confirmed to BMS that it did not seek to or intend to carry out restricted acts while the Patent and /or SPC remained in force in Ireland. Instead, it sought to clear the way by initiating the Revocation Action. However, this was with the clear caveat that the proceedings would be prosecuted expeditiously to trial.*

34 *Again, on 2 July 2021, Teva made it clear to BMS that it was seeking a hearing on an expedited basis. This letter also clarified Teva's intention to launch a generic brand of apixaban on the Irish market by mid-2022 or as close to that date as possible.*

35. *Consequently, it was made clear to BMS from the outset that the Revocation Action was urgent. There has never been any dispute but that these proceedings are urgent concerning, as they do, the challenge to the Patent which is asserted to protect against competition one of the largest selling drugs in the world annually.*

36. *The Revocation Action has accordingly been recognised, and treated, by three successive judges of the Commercial Court as being highly urgent.*

37. *BMS did not object to Teva's application to put in place an expedited set of directions from the outset.*

38. *On 26 July 2021, in recognition of this urgency…[the case was] assigned a provisional hearing date of 21 June 2022 for 12 days for the Revocation Action despite the fact that discovery had not yet been sought.*

39. *On 17 December 2021, McDonald J affirmed the view of the Commercial Court as to the urgency of the proceedings, allocating additional days and moving the hearing date….*

40. *The Court continued to recognise the urgency and importance of these proceedings when the Court took the exceptional step of offering the parties to list the case for hearing during the Long Vacation on 19 September 2022 before Mr Justice O'Moore. Again, this offer was accepted with the express consent of both parties. Neither the parties nor this Honourable Court considered there to be any 'artificial urgency' as is latterly alleged by Mr O'Brien at paragraph 33.*

41. *Clearly, this Honourable Court has gone to considerable lengths and dedicated valuable resources to ensuring these proceedings – which are one of a multiplicity of related cases Europe-wide – would be determined with exemplary efficiency.*

42. *Regrettably, however, these efforts were in vain. The 19 September 2022 hearing date was vacated on 27 July 2022, because of the existence of unresolved pre-trial issues, particularly BMS' failures to make proper discovery and its last-minute attempt to introduce new evidence and a new factual case on priority.*

43. *To accommodate the pre-trial issues the case was re-listed for hearing on a provisional basis on 11 October 2022. However, it became clear that this date was also unrealistic given the extent and serious nature of the pre-trial issues and their potential impact upon the hearing date. The 11 October 2022 was vacated as a result.*

44. *Consequently, the earliest possible provisional hearing date for the Revocation Action, subject to BMS having finally complied with all its pretrial obligations, is now 4 July 2023, such date being a year after the trial was fixed originally for hearing on an expedited basis.*

45. …[Confidential annex]…

46. *By letter from McCann FitzGerald solicitors dated 28 November 2022, BMS confirmed that it would be seeking injunctive relief against Teva.*

47. …[Confidential annex]…

48. …[Confidential annex]…

49. *The trial of the Revocation Action was scheduled for 4 weeks on 19 September 2022 and then subsequently on 11 October 2022. Both trial dates were vacated due to (a) the failure of BMS to make proper discovery and (b) the late introduction of a witness statement by BMS. These issues are considered in turn below.*

Category 9 Discovery Default – Loss of provisional and fixed Trials

50. *By consent, this Honourable Court (McDonald J.), made an Order on 17 December 2021 requiring BMS to make discovery of documents relating to inter alia the priority issue in the proceedings ('Category 9') on or before 21 February 2022 (the 'Discovery Order').*

51. *BMS failed to comply with the Discovery Order. Arising from the significant issues with BMS' discovery under Category 9, Teva brought a motion seeking further and better discovery and/or to strike out the BMS' defence for failure to make proper discovery (the 'Discovery Motion').*

52. *The Discovery Motion was heard in September 2022 and determined by this Honourable Court (O'Moore J.) on 12 October 2022, on which date the Court made an Order for further and better discovery (the 'Order for Further and Better Discovery').*

53. *In an* ex tempore *ruling on 12 October 2022, the Court found that it was 'plain that there has been a failure, a continuing failure to make proper discovery in respect of Category 9.' BMS was ordered to undertake a full discovery exercise. Unusually, BMS was directed to write to Teva's solicitors identifying the approach to be taken towards all of*

the requirements of discovery as set out in the Commercial Litigation Association of Ireland Good Practice Guide on discovery obligations. The Judge also directed that 'There is to be a maximum level of transparency in respect of things like search terms, things like custodians and so on.' This reflected the deficient approach that had been taken by BMS to its discovery obligations, despite the vast resources available to it. On 20 October 2022, the Court directed that discovery 'be re-done in accordance with best practice...'. BMS were ordered to make further and better discovery to Teva on 12 January 2023, with liberty to apply….

54. *It is another unusual feature of the Order for Further and Better Discovery, again reflecting the degree of BMS' default, that the balance of Teva's motion was adjourned to the trial of the action.*

55. *Against that backdrop, it is very surprising that BMS now continues to make various arguments justifying its failure to make discovery in paragraph 36 of the Affidavit of Mr O'Brien. These arguments were made to – and rejected by – Mr Justice O'Moore.*

56. *BMS seek to make a virtue in paragraph 39 of the fact that a wasted costs order has not been made against them to date, but this issue (as with other reliefs Teva have sought in that Discovery Motion) have been adjourned to the Trial Judge. Teva will for the avoidance of doubt be seeking a wasted costs Order.*

57 *On 7 November 2022 Judge McDonald provisionally set a new hearing date for the Revocation Action in June/July 2023 (which has now been confirmed for 4 weeks from Tuesday 4 July 2023).*

58. *On 2 December 2022, BMS' solicitors wrote inter alia indicating that it would yet again, not be in a position to deliver the further and better discovery on 12 January 2023 as directed by Mr Justice O'Moore, but without providing any indication as to when it would do so, stating 'However, in light of our investigations, it has become apparent that the initially estimated deadline of 12 January 2023 is not realistic. We cannot yet say with confidence how much additional time we will require...'. It has to be borne in mind that BMS was originally ordered to make this discovery 1 year ago on 17 December 2021. Teva is naturally concerned that <u>yet again</u> BMS appears to be jeopardising the hearing of the Revocation Action in July 2023 by failing to comply with another Court Order on discovery, this time to make further and better discovery of Category 9 by 12 January 2023….*

59. *On 9 December 2022, Teva's solicitors requested confirmation from BMS as to when they intended to apply to the Court for a variation of the Order for Further and Better*

Discovery, in circumstances where BMS was not going to be in a position to comply with it…..As at the time of the final draft of this affidavit, no response has been received to this letter.

60. *Category 9 discovery is critical to the priority claim made in these proceedings. BMS notably makes the express admission in paragraph 40 of Mr O'Brien's Affidavit that 'The Patent/SPC stands to be revoked if either Teva's technical patent case or its priority case succeeds.' Yet despite the Discovery Order on 17 December 2021 and Order for Further and Better Discovery on 12 October 2022, it remains unclear when this discovery will be produced in compliance with the CLAI Guide. What is clear from McCann FitzGerald's letter of 2 December 2022, is that BMS will not be complying with the Order for Further and Better Discovery. Although, BMS has liberty to apply, it is noteworthy that no application has been made to Mr Justice O'Moore by BMS to vary Order for Further and Better Discovery.*

Adducing witness statements on eve of trial

61. *In response to paragraph 37 of Mr O'Brien's Affidavit, BMS first raised the proposal to adduce the evidence of Ms Sandra Leung General Counsel of BMS on 27 July 2022. No prior warning was provided to Teva's solicitors despite there being just two days of Court term remaining before the start of the Long Vacation and with the (then) impending trial date of 19 September 2022 set to commence.*

62. *Teva objected to the admission of the Ms Leung's statement on reasonable grounds: First, BMS did not provide the witness statement on 15 March 2022 in accordance with that relevant Court Order. Second, Ms Leung was now being hailed as the most authoritative, best qualified, most experienced, most relevant witness – as well as being a recipient of the key email on which BMS' case rests. Third, there was no discovery of Ms Leung's documents. Fourth, there was no explanation for the attempted delivery of a witness statement at the eleventh hour.*

63. *Ultimately, Mr Justice O'Moore allowed Ms Leung's witness statement. However, by that time, the September and October trial dates had already been vacated. Further, the statement was admitted on the basis that Teva was permitted to adduce any witness statements (either factual or expert and either supplementary or new) in response to the proposed evidence of Ms. Leung on 26 January 2023. The key fact is that the introduction*

of this witness – even apart from the serious issues with BMS' discovery, would have halted the trial date.

AFFIDAVIT OF SHANE O'BRIEN

64. *A consistent motif throughout Mr O'Brien's Affidavit is that BMS can be forgiven for its procedural defaults because, semble, Teva insisted on 'a very tight timeline' (paragraph 11(b)) an 'extremely ambitious timeline' (paragraph 11(c)) an 'extremely constrained timeline' (paragraph 11(d)), Teva is the 'untrammelled author of its own timings,' (paragraph 31), Teva 'imposed an entirely artificial urgency' (paragraph 33), used its launch date 'as a pressure to impose stringent, and sometimes impossible time limited for procedural steps in the proceedings,' (paragraph 34), resulting in 'extremely constrained timeline' (paragraphs 35 and 36(a)), 'extremely short timeframes' (paragraph 36) an 'exacting discovery process' (paragraph 36(a)) and an 'exacting pre-trial process' (paragraph 42). This is a very partisan characterisation.*

65. *The directions which BMS habitually missed and now decries, are not Teva's directions: they are a series of directions made Orders of this Honourable Court, generally by consent. Likewise, the discovery rules are not Teva's 'exacting discovery process' (paragraph 36(a)) but the normal discovery rules, well known to BMS. All parties give a best endeavours undertaking to this Honourable Court to comply with the Orders and Directions of the Commercial Court upon acceptance into the Commercial list.*

66. *For those reasons, it's deeply regrettable that Mr O'Brien belatedly seeks to suggest that the Commercial Court's directions to which Teva adhered diligently (not to mention the resources made available by the Commercial Court in the process) were never considered by BMS as being realistic. It is telling that BMS' apparently persistent concerns over a near two year period were never revealed that to this Honourable Court (save for some similar complaints made — and rejected – when it was attempting to defend the failure to make proper discovery before O'Moore J).*

67. *Only when BMS was attempting to justify its historical defaults to resist an order for further and better discovery and again in an attempt to support this application, does BMS seek to argue that the Court's directions were unrealistic. These attempts to explain and justify BMS' failures have already been rejected by O'Moore J. Insofar as those contentions are sought to be relied upon again, it bears emphasis (as it was emphasised before O'Moore J) that the inescapable fact is that BMS never raised these apparent*

concerns until after the trial of the proceedings should have commenced in June 2022 – and not until long after BMS had defaulted on a large portion of the Court's directions. On three occasions (June 2022, September 2022 and October 2022) Teva has made intricate preparations on the presumption that the trial was proceeding as planned. The multiple cancelled flights from all over the world arranged for Teva's seven expert witnesses, together with the repeated arrangements and cancellation of hotel accommodation pay truth to the fact that Teva genuinely expected the Revocation Action to have reached trial by this point.

68. *Mr O'Brien seeks in a number of paragraphs to argue (paragraphs 11 (j), 40, 41) about the mode of trial seemingly seeking to suggest that the invalidity case could or ought to have proceeded before the priority case is heard. This is a very recent theme from BMS and it bears emphasis that no application for a modular trial of the Revocation Action has ever been brought or even mooted by BMS.*

69. *The mode of trial as between these proceedings and the Revocation Action was the subject of motion, upon which the parties made submissions and on foot of which Judge Twomey made his order of 18 February 2022….However, for the avoidance of doubt, no application has ever been brought to separate the priority and invalidity issues.*

70. *In summary, the defaults, procedural failures and delays of BMS in the Revocation Action are serious and have thwarted Teva's reasonable attempt to clear the path (and the Court's efforts to accommodate same). The chronologies, transcripts and Orders speak for themselves. In the context of the balance of justice, BMS' attempt to place a retrospective slant on those objective facts, repeating contentions that did not find favour with O'Moore J, and to now blame Teva for those failures is self-serving and untenable.*

FAIR ISSUE TO BE TRIED: PLAUSIBILITY

71. *I wish to respond to paragraphs 14–28 of Mr O'Brien's Affidavit, 'Fair Issue to be Tried', although I am advised that this is predominantly a matter for legal submission.*

72. *In paragraph 19 of Mr O'Brien's Affidavit he states that the issue of plausibility is a 'relatively new and evolving concept'. Mr O'Brien goes on to give a potted history of the law of plausibility in the UK and in Ireland that both mischaracterises the point, and omits considerable important information.*

73. *A fuller summary of the law of plausibility in the UK is set out in the Opening Written Submissions of Teva (and Sandoz) in the UK proceedings. This explains the basis for the*

point and how it has developed by at the European Patent Office and in the UK. The original decision in AgrEvo was in 1995, and the point was considered by the UK Supreme Court in Warner-Lambert LLC *v* Generics (UK) Limited *and others in 2018. Plausibility has been applied in numerous UK cases over the years, including in particular in* Generics (UK) *v* Yeda Research and Development *(Court of Appeal, 2013),* Regeneron Pharmaceuticals *v*. Genentech *(Court of Appeal, 2013),* Eli Lilly & Co *v* Janssen Alzheimer Immunotherapy *(Patents Court, 2013),* Merck *v* Ono *(Patents Court, 2015),* Merck *v.* Shionogi *(Patents Court, 2016),* Idenix *v.* Gilead *(Court of Appeal, 2016),* Eli Lilly *v*. Genentech *(Court of Appeal, 2019),* FibroGen *v.* Akebia Therapeutics *(Court of Appeal, 2021), and* Neurim Pharmaceuticals *v.* Generics (UK) *(Court of Appeal, 2022). Plainly it is not right to consider plausibility to be a 'relatively new and evolving concept' in the UK.*

74. *Furthermore, I am advised that plausibility has been applied in Ireland by the Court of Appeal in* Norton (Waterford Ltd t/a Teva Pharmaceuticals Ireland *v.* Boehringer Ingelheim Pharma GmbH & Company*). Mr Justice Maurice Collins reviewed in considerable detail decisions of both the European Patent Office and the UK, finding in that case that Boehringer's patent was invalid for lack of plausibility. Mr O'Brien seems to suggest that the Court of Appeal's judgment was lacking in precision in some way, but I respectfully disagree….*

75. *Finally, as I discuss below, plausibility also has been applied in the Netherlands as a means of assessing inventive step and sufficiency.*

76. *In paragraphs 22 and 23 Mr O'Brien refers to the pending decision of the Enlarged Board of Appeal in G2/21. This was referred to by BMS in the UK trial and Mr Justice Meade made the comment at paragraph 72 of his judgment which is quoted in the Affidavit of Mr O'Brien, which notably included additional wording: 'The result of the reference to the Enlarged Board of Appeal in this case will be extremely important for the EPO and for all EPC member states, but (other than as an example of reformulating the technical contribution) the TBA's decision in itself does not affect my analysis in this case because I am bound by* Warner-Lambert*.'...*

77. *Importantly, in his account Mr O'Brien has failed to explain to the Court that BMS sought permission to appeal from Mr Justice Meade following his decision at trial. That permission was refused by a very experienced patents judge, following both written submissions and oral argument. However, as Mr O'Brien has noted recently the Court of Appeal has given permission to appeal. The threshold for permission to appeal in the*

*UK is whether there is a real prospect of success or some other compelling reason why the appeal should be heard. 'Real prospect' has been held to mean a realistic prospect as opposed to fanciful prospect of success (*Swain *v.* Hillman *[2001] 1 All ER 91, CA, as applied by* R (A Child) *[2019] EWCA Civ 895). The bar is therefore relatively low, and many appeals that are given permission are unsuccessful at the full appeal hearing. In any event, Teva believes that it has strong factual findings and arguments for maintaining the revocation decision in the UK, notwithstanding any potential outcome from the Enlarged Board of Appeal in G2/21*

78. *Mr O'Brien refers to 'gaps left in the evidence given in the UK on the issue of plausibility'. I do not know what this oblique reference is supposed to relate to. Presumably BMS put their best case forward in the UK and the expert evidence exchanged in Ireland so far does not seem to differ in any material respect from that deployed in the UK. If BMS are suggesting that they are running a different technical case in Ireland than in the UK then it would be useful for them to confirm that, and provide more detail to the Court.*

79. *Mr O'Brien refers to the recent decision in Sweden. Whilst the Patent and Market Court of the Stockholm District Court has dismissed Teva's claim, Teva has initiated an appeal of the decision. Teva considers that the decision of the Swedish court is flawed and that the court has not properly engaged in the evidence that was before it.*

80. *Finally, it is notable that Mr O'Brien has omitted to refer the Court to the decision of the District Court of the Hague in* Bristol-Myers Squibb Holdings Ireland Unlimited Company *v.* Sandoz BV *(C/09/627925). In this case (in which Teva is not involved) BMS sought a preliminary injunction against another generic company, Sandoz. As is usual in Dutch injunction proceedings, the court considered invalidity arguments, and in particular whether there would be a good chance that the Dutch designation of the patent would be found null and void in proceedings on the merits (See paragraph 6.3 of the translation of the decision). The court considered the pending referral in G2/21, and came to the following conclusion:*

> *'The question whether a plausibility requirement in the sense referred to by Sandoz can be imposed on the application and, if so, how that requirement is to be implemented, has – as the parties have acknowledged – been submitted to the Grand Board of Appeal of the EPO (EBA) in case G2/21. However, that ruling will take some time. Incidentally, the question is whether that*

statement is the last word. It is not inconceivable that, for example because BMS itself points out that in England with Warner Lambert there would be a plausibility requirement but no plausibility requirement in Germany, the EBA will therefore choose the path that no plausibility requirement is set. For example, the EBA could prevent applicants from being denied protection across Europe when in some countries such protection could have been granted under national law. In the context of these interlocutory proceedings, the judge hearing the application for interim measures therefore sees no other way than to take as a starting point the case-law already given in the Netherlands on this point.'

81. *After considering both EPO law (AgrEvo) and considerable national Dutch law, the Dutch court decided that there was a good chance that the patent would be found null and void in main proceedings. The passage at 6.16 of the decision is important and summarises why the Dutch court reached this position:*

'For that reason, too, it is certainly uncertain whether the court hearing the merits will consider any beneficial or surprising effect plausible after reading the application. If he finds no effect plausible in the application, he may not be able to take post-published evidence from BMS into account as considered above. Thus, it is equally uncertain that the court heating the merits will count any advantageous or surprising effect in the context of the inventiveness test. In the current state of jurisprudence in the Netherlands as discussed above, the preliminary relief judge considers this rather unlikely. In fact, BMS's most appealing argument is that its patent is not a speculative invention, so that no plausibility requirement should be imposed. That is certainly not an unsympathetic argument. However, it can be immediately countered that there was no reason not to include the advantageous results of Ki measurements in the application. After all, they had been available for quite some time. BMS was also unable to give any reason for it when asked at the hearing, other than that this would not have been customary at the time. However, the preliminary relief judge has certainly not become convinced that describing advantageous effects in the application for a patent, certainly in the case of a selection invention, was not yet sufficiently on the radar of the

patent attorneys in this field at the time. Least taken, in the preliminary opinion, something could and should have been included in the application about the fact that favorable Ki's (in the nanomolar range) had been found in the selected compounds so that an average professional would also have been triggered to test those compounds. This is all the more true because at present the application really only writes down a wish for nanomolar Ki's and, furthermore, that Ki's were found up to the micromolar range, far from interesting. It now has everything to do with the fact that that information has been omitted for another reason, for example, to essentially (for as long as possible) not open up about the invention made. Although the patent that was eventually granted only relates to apixaban, it still does not state in so many words why that compound is so interesting. This violates the so-called quid pro quo or patent bargain in patent law (the applicant obtains his monopoly in exchange for disclosure of the invention).'

82. *Finally, I wish to respond to certain averments in the Affidavit of Edouard Kling. Mr Kling refers to the Preliminary Opinion of the Enlarged Board of Appeal in paragraph 29 of his statement. It is worth recalling that this was a preliminary opinion, and was rendered before the hearing that took place on 24 November 2022.*

83. *It is also worth adding that the President of the EPO made written (and oral) submissions to the Enlarged Board of Appeal….In these submissions the President outlined that plausibility was not a distinct and separate ground of patentability, and considered the options of ab initio plausibility and ab initio implausibility, looking at the EPO case law. The President concluded in his submissions (which were filed before the Preliminary Opinion):*

'65. There is an implicit requirement in Articles 56 and 83 EPC for applicants to provide sufficient information in their patent application on the date of filing to allow the EPO to conclude that their invention plausibly/credibly/obviously solves the technical problem. This ensures that the patent bargain is a fair one for all parties involved. For the EPO, it provides the basis to conduct its tasks as the patent granting authority for Europe, to grant patents with high expectation of validity given that the

applications filed provide the basis for thorough examination of the relevant patentability requirements.'

84. *Finally, it is also interesting to consider the preliminary opinion and what it doesn't say — there is no mention of the word 'plausibility' in the opinion at all. It is entirely possible that the final decision of the Enlarged Board of Appeal does not address plausibility in a manner that is relevant to the current proceedings.*

IMPACT ON TEVA IF INJUNCTED

85. *In Section 5, Mr Potter addresses the quantifiability of the losses incurred by Teva where Teva is injuncted from launching Apixaban Teva and at the final determination of the Revocation Action, the patent, and therefore the SPC, is found to be invalid and revoked. This is described as 'Scenario 2'.*
86. *Mr Potter avers that in Scenario 2, losses incurred by Teva (and any other injuncted generic companies) will be extremely difficult to estimate with any level of confidence. He notes that the estimation of market shares achieved by each company, the volumes that would have been sold and the price secured would need to be based on market comparisons and the assertions of the parties in any damages enquiry and this is unlikely to lead to consensus or accurate outcomes. Therefore, the determination of the quantum of the total loss incurred by Teva and other generic companies will be very difficult and the allocation of that loss between such companies would be equally uncertain. Further, arguments placed for the enduring nature of this loss would make this a more complicated and subjective exercise.*
87 *In addition, Mr Potter notes that in Scenario 2, there may be some other generic companies who expect to have a claim, for example if they had given a cross undertaking not to launch, who argue that they would have launched during the period when they would have been at risk of being liable to BMS for damages. It is impossible to say which companies would have, in fact, launched during this time.*

IMPACT ON BMS IF NO INJUNCTION GRANTED

88. *Section 4 of Mr Potter's Affidavit addresses the quantifiability of loss for BMS in the event that Apixaban Teva is placed on the market following the determination of this*

preliminary injunction application and then following the determination of the Revocation Action (wherein the patent and SPC are found to be valid) Apixaban Teva is removed from the market. This is described as 'Scenario 1'. In his view this is a mathematical calculation and the losses incurred by BMS in Scenario 1 can be readily estimated with reasonable accuracy.

89. Mr Potter makes it clear that in Scenario 1, BMS's loss is calculated in Scenario 1 as the difference between the actual profits BMS earned and the amount that it would have earned in a counterfactual scenario where no directly competing generic products (including Apixaban Teva) had been launched into the Irish market. Profits in the factual scenario are known, and the counterfactual can be calculated with a good level of accuracy based on assumptions that would be made with a high degree of confidence based on facts and data from the factual. Having made the assumptions, it is essentially a mathematical exercise to calculate BMS's loss that arises in this well-defined period between launch of Apixaban Teva and the restoration of BMS's position.

ABILITY TO MEET DAMAGES

90. Based on Teva's accounts for 2021, I do not believe that Teva would have any difficulty meeting a claim by BMS for damages if it was decided, following a final decision on the merits, that the interim injunction was wrongly refused….

5. In a further affidavit sworn by Mr O'Brien he avers, amongst other matters, as follows:

"*3. In my first affidavit, and that of Scott Cooke of 2 December 2022, facts demonstrating the following matters were set out: the product that Teva intends to launch undoubtedly (and admittedly) infringes the SPC; the damage to BMS of such a launch if BMS ultimately prevailed in the action would not be compensable in damages as it would necessarily entail the supply of a generic product within the lifespan of a valid SPC with all of the consequences explained by Mr Cooke in his affidavit of 2 December 2022; the damage to Teva if an interlocutory injunction was granted and Teva ultimately prevailed in the proceedings can only ever result in a delayed launch of Teva's product - still within the anticipated lifespan of the SPC - in circumstances where trial is scheduled a number of years in advance of expiration of the SPC so that any differences in the market for Teva's product before the trial of the action and after will be marginal; and that the*

primary reason behind Teva's revocation proceedings not having been determined prior to its desired launch is the timing of Teva's initiation of those proceedings and the timing of its proposed launch - neither date having any significance in terms of the lifespan of the SPC and having been selected, apparently arbitrarily, by Teva. I respectfully believe that nothing said by Ms Reynolds in her affidavit alters any of these facts.

4. *The essence of Teva's purported justification in seeking to secure unconstrained launch of its product during the lifetime of the SPC, and pending determination of the action is summed up in Ms Reynolds assertion (at paragraph 8) that Teva's application to revoke the Patent and therefore the SPC has been delayed "owing entirely to BMS' conduct in the Revocation Action, these proceedings -will not now be heard until July of 2023".*

5. *As I sought to illustrate by the chronology attached to my first affidavit, and as will be outlined in more detail below in response to Ms Reynolds' detailed, and inaccurate, assertions, the facts are that: Teva initiated an entirely new substantive attack on the SPC, unrelated to the existing grounds in the Revocation Action, approximately eight months before the original scheduled trial date of June 2022; Teva proceeded to insist on exhaustive discovery going back 20 years, respectfully of doubtful relevance, in respect of that new attack, early delivery of witness statements from BMS (the respondent to the action) -in respect of that new ground, and 112 interrogatories the vast majority of which were irrelevant or objectionable; BMS accommodated Teva's desire to keep its trial date and tried to comply with the time limits for the pre-trial steps of particulars, witness statements, discovery, and interrogatories in respect of the new basis of challenge, but could not do so, at least to the exacting standard, of discovery in particular, that Teva required; Teva did not initiate motions in respect of what it alleged was default in these pre-trial steps at a date that could have accommodated the initial trial date in June 2022 (having stated in its communication to the Court on 2 June of its decision to opt for a September hearing that all pretrial directions had been completed apart from written legal submissions), or the adjourned date in September and only did so at a date when such motions were bound to cause further delay to proceedings; Teva itself caused unnecessary pre-trial work and/or delay by refusing to agree customary accommodations in relation to the admission of documents and refusing to consent to the delivery of a clearly relevant additional witness statement; and Teva did not take up the clear option to retain its initial, or the adjourned, trial date for its original invalidity attack on technical patent grounds which were entirely unaffected by the matters the subject of the motions belatedly brought.*

6. *In short, I respectfully believe that Teva set up an unrealistic trial schedule in the circumstances of the addition of what was effectively a second action halfway through the directions laid out for the first, then engaged in the kind of prosecution of that second action that did not lend itself to accommodation of an early trial but would require a much greater allowance of time and now seeks to get its infringing product onto the market before any trial has taken place on the basis of allocating blame to BMS for the fact that the initial trial date turned out to be an impossibility in these circumstances.*

7. *Apart from all of those matters, Teva never made its launch contingent on the determination of the proceedings, whenever scheduled, in its favour. In fact Teva made it clear that it was reserving its right to launch before the proceedings were heard and determined. It is therefore unclear how the delay to trial - which is otherwise of no significance in terms of the lifespan of the SPC - is alleged to impact Teva's interests.*

8. *Finally, the notion that delay in the Revocation Action should justify its launch before its validity attack is heard assumes that it will be successful in its attack. For the reasons referred to in my first affidavit, I respectfully believe that the likelihood is that it will not.*

9. *In paragraphs 13 to 15 of her affidavit, Ms Reynolds refers to Teva's commercial motivation, presumably for its threatened infringing pre-trial launch of its product, as being to obtain 'first-mover advantage'. She relies on Mr Alan Long's affidavit to explain that this is the advantage that the first generic supplier of a leading product can get over other generics suppliers by being first on the market.*

10. *Ms Reynolds appears to argue that Teva is acting in the public interest in threatening to launch in view of the importance of apixaban and the impact of such a launch on the price paid from the public purse to pharmacists who supply the drug. This argument takes no account of Teva's clear self-interest - evident in its chief argument in resisting this application that unless it can launch first, it will not be able to gamer the lion's share of the market over other (cheaper) generics. Neither does it take account of the fact that the incentive to innovate provided by the period of patent, and SPC, exclusivity is the carefully balanced product of the cost of innovation and the exclusivity needed to recoup that cost and fund further innovation. This balance has been worked out in the public interest. The patent exclusivity accorded is only accorded to medicines where there has been valuable innovation that has been made public; SPC exclusivity is only accorded where a resulting innovative medicine has been developed and extensively tested to ensure safety and efficacy to treat disease and has obtained a marketing authorisation on that basis, and only to compensate for some of the shortened period of effective*

protection that the product enjoys as a consequence of having to meet those regulatory requirements. It is an exclusivity that may be challenged and removed if not deserved - a process that Teva purports to commence but not to accept as a precondition to its own freedom to market. I respectfully believe that the impacts on price consequent upon entry of generic apixaban to the market, mentioned by Ms Reynolds by reference to Professor Barry's letter in paragraphs 16 and 17, serve only to substantiate Mr Cooke's evidence on behalf of BMS as to the damage that will be done if Teva's product goes onto the market pending trial.

11. *At paragraphs 18 to 20, Ms Reynolds points out that BMS, following the decision of the High Court of England and Wales to revoke the corresponding UK patent, did not seek to obtain an interlocutory injunction in the UK, and alleges that it is difficult to reconcile this with the irreparable harm that BMS will suffer in this jurisdiction if Teva's launch is not restrained. The irreparable harm that BMS will suffer has been set out in the other affidavits filed on behalf of BMS. Respectfully, the approach adopted by BMS in another jurisdiction, which is subject to its own regulatory regime and market dynamics, in a different legal and factual context, and after a decision on the validity of the corresponding UK patent and SPC, does not have any bearing on that or what the impact of a launch at risk would be in this jurisdiction.*

12. *From paragraph 24 to 63, Ms Reynolds engages in a mischaracterised account of the progress of the Revocation Action with the apparent aim of persuading the Court that BMS has engaged in deliberate delaying tactics regarding the Revocation Action. This is simply not the case as I outline in the paragraphs below. The Revocation Proceedings are not 'frustrated', as Ms Reynolds puts it at paragraph 25. They are scheduled to take place in July of this year which, having regard to the kind and scope of discovery procedure insisted upon by Teva, may always have been the more realistic trial date. There has certainly been no culpable default by BMS for which an appropriate punishment would be effective nullification of a property right. I deal with each of Ms Reynolds averments in the following paragraphs.*

13. *Ms Reynolds recites (paragraph 24) that this Infringement Action was listed on the final day of the Revocation Action. The linked hearing of the actions was in fact strongly resisted by Teva, despite the fact that the only issue in the Infringement Action is the validity of the Patent/SPC. Teva made every effort to separate the Infringement Action from the Revocation Action, seemingly so that it could have time to evade an immediate injunction if the determination of validity issue went against it. It attempted to appear*

not to do so by reluctantly offering to put in the Infringement action after the Revocation Action 'for mention'. In order to secure the linked hearing of the infringement actions with their related revocation actions, motions had to be brought by BMS both in these proceedings and in the infringement proceedings in respect of the related formulations patents….It was only after hearing of these motions commenced that Teva acceded to the linked hearing of the two sets of proceedings.

14. *I take issue with Ms Reynolds' characterisation of the Revocation Action as being to 'clear the path' (paragraph 26) in circumstances where Teva, from the outset, made sure* ***not*** *to give any undertaking making the determination of proceedings a precondition to the launch of its product…As will appear to the Court Teva's resistance to giving the necessary undertaking was the reason why these infringement proceedings were issued on a* quia timet *basis and why this application for interlocutory relief can be now taken under cover of those proceedings.*

15. *Teva used its stated intended launch to secure a very expedited schedule to trial, but never agreed that determination of the action in its favour governed its commercial options for launch.*

16. *Second, the expeditious trial date sought, and agreed to by BMS as recited by Ms Reynolds, was agreed to, and achievable, on the basis of the original challenge brought - namely that brought on the technical patent grounds which had been the subject of trial before the High Court of Justice of England and Wales. Notably no discovery was sought in the UK proceedings in respect of the technical patent grounds, but was sought in this jurisdiction. Even so, I respectfully believe that the original schedule to trial was achievable in respect of the case Teva originally brought.*

17. *Ms Reynolds sets up a straw man to knock down at paragraph 27 of her affidavit. I did not say in my affidavit that the need to adjourn the trial date (wrongly characterised by Ms Reynolds as 'obstruction …of the hearing of the Revocation Action') was entirely down to Teva. I said that the fact that Teva had not achieved determination of the Revocation Action before its intended launch was entirely down to Teva as a result of the free choices Teva made as regards the dates it alone chose for initiation of the Revocation Action and its intended product launch. Teva was not compelled by any external factor to choose either date - or indeed to seek to avail of multiple, exhaustive pre-trial procedures available under the Rules as it did - and could easily have afforded sufficient time for the case that it intended bringing - and all of those procedures if it wished to seek them- and still have secured a trial date years before expiry of the period of*

exclusivity of the SPC. Both dates were arbitrary and Teva's manner of proceeding was chosen by it.

18. *Teva confirmed, in a letter dated 9 April 2021, that it did not intend to carry out restricted acts while the Patent and/or the SPC remained in force in Ireland, as indicated by Ms Reynolds in paragraph 33, but crucially and as outlined in paragraph 15 above, refused to give an undertaking in those terms and maintained a contradictory intention to launch in mid-2022 or as close to that date as possible, indicating that they would give four weeks' notice of any launch.*

19. *When Ms Reynolds says in paragraph 35 that 'it was made clear to BMS from the outset that the Revocation Action was urgent' and that 'There has never been any dispute but that these proceedings are urgent...' the only thing that is clear is that the urgency is subjective commercial urgency in Teva which is keen to capture and ring-fence a market for itself; no objective or external urgency exists. In that regard: the right is not due to expire; the economics of other generics entering on expiry is not in issue; even if Teva were motivated by public spiritedness in terms of breaking down exclusive rights that it believes to be invalid, it could have initiated these proceedings at any time since the grant of the patent on 12 August 2009. Teva did not oppose the patent on grant. It refused to undertake not to launch pending determination of the proceedings in its favour - no matter how expeditious. It initiated revocation proceedings when it suited it.*

20. *I am not sure what Ms Reynolds means when she says at paragraph 36 that the 'Revocation Action has accordingly been recognised and treated by three successive judges of the Commercial Court as being highly urgent'. The Commercial Court facilitates expedition. In this case BMS also did its best to do so, adopted a facilitative approach and agreed, certainly at the outset of the case when the case was comprised entirely of the technical patent issues, with the expedited directions made. There has been no substantive finding of any particular urgency affecting Teva. No grounds for such a finding have been offered by Teva.*

21. *I am surprised at Ms Reynolds' averment that Mr Justice Barniville assigned a provisional hearing date of 21 June 2022 for the Revocation Action* 'in recognition of the urgency'. *In fact, BMS* consented *to a provisional trial date in recognition of Teva's wishes in the matter, but only on the basis that that date would stay provisional pending the outcome on discovery. Barniville J. was receptive to the concern expressed on behalf of BMS that the date should remain provisional pending discovery and emphasised the provisional nature of the date for that reason….As described in more detail below, it is*

very clear that the time originally allowed for discovery could never have been sufficient to complete the discovery exercise that has since unfolded and the originally scheduled trial date was never realistic if an exercise of that magnitude was to be carried out. As mentioned in my first affidavit (at paragraph 36(b)), referring to the comments of McDonald J on 17 December 2021, when dealing with a disagreement between the parties as to the scheduling of witness statements, I believe the Court itself had the first insight in relation to a potential lack of feasibility of the original trial date.

22. *Those comments post-dated those referred to by Ms Reynolds at paragraph 39 of her affidavit. I do not know what is intended to be referred to in terms of an 'affirmation' of urgency by Mr Justice McDonald in according additional days to hear the priority challenge - added after the provisional trial date was sought and obtained and ostensibly simply acceding to what was requested by Teva (and acceded to by BMS). As is evident from the suggestion made on behalf of BMS at that time, it was not clear to BMS at that point that the additional challenge introduced late into the proceedings by Teva would comprise more than legal argument on the subsistence of beneficial interests in patent and patent applications as a matter of Delaware law, or as a matter of US Federal law as had been contended by expert reports filed by Teva in other jurisdictions, and the effectiveness of holding such an interest in a priority document to claim priority. BMS did not anticipate the full scale attempt that would be launched by Teva to undermine BMS's evidence as to its internal company organisation and its use of very extensive discovery and interrogatories to seek a basis for such a challenge.*

23. *I do not know what Ms Reynolds finds in Teva's agreement to adjourn the hearing to September/October 2022 to support the notion of urgency.*

24. *Ms Reynolds goes on to cast slippages in the directions, which admittedly were on BMS's side - the demands being solely made against BMS - as egregious defaults obstructing the determination of Teva's challenge. As indicated it is difficult to see any irreparable consequence of this, but even in its own terms, Ms Reynolds gives an inaccurate and unfortunately misleading picture. The obvious point is however that these matters all related to the new challenge Teva launched mid-way through -that relating to BMS's right to claim priority for the Patent - and that it was open to Teva to proceed with the original portion of its challenge, which it will anyway have to do, according to the original scheduling. At paragraph 68 Ms Reynolds objects that this was not suggested by BMS before. It is however an obvious point and it is Teva that is insisting that it wanted to get its action on and was prevented (the implication is deliberately) from doing so by*

BMS. I am not sure how BMS is to be blamed for Teva not pursuing such an obvious course. There would have been no objection from BMS.

25. *I deal with Ms Reynolds' specific allegations about alleged culpable default on the pretrial steps for the priority case in the following paragraphs.*

26. *In paragraphs 50 to 60 of her affidavit, Ms Reynolds focusses on the issues encountered by BMS regarding discovery of the category relating to the priority issue (and only that issue).*

27. *Ms Reynolds refers to an order of discovery against BMS but does not make it clear that the category was agreed by BMS. The category, and very tight timing to make discovery, were agreed in circumstances where the requirement was to make discovery before witness statements which, apparently owing to the tight scheduling to trial were required by Teva to be exchanged as opposed to sequential - apart from BMS's fact evidence on the priority issue which Teva required in advance.*

28. *The category in question, category 9, sought 'All documents concerning or relating to the assignment of rights, legal and or equitable, in, and/or the formal chain of title flowing from ...' the priority document to the patent. This category was puzzling to BMS since it was clear that BMS's case was that the equitable title arose from control within the company group as opposed to assignments of equitable interests and accordingly BMS had offered a more relevant discovery, namely of documents relevant to its legal and equitable title; this offer was rejected by Teva.*

29. *In seeking to comply with the order in the permitted timeframe, BMS took the approach of identifying custodians and sources that were most relevant to the initial acquisition of rights and subsequent dealings with them and in retrieving documents from those custodians and sources.*

30. *There was a delay completing discovery, which was not unusual or exorbitant in terms of Commercial Court cases. BMS sought to alleviate the effects of delay by providing discovery to Teva in tranches as it was completed. Category 9 was due on 21 February 2022; Teva agreed to that being moved to 1 March 2022; a first tranche of documents was delivered on 3 March 2022; the Court directed that a second tranche be delivered by 11 March and that was ultimately done on 12 March 2022. Subsequently, arising from a search of additional sources that had previously been believed to not exist, supplemental affidavits of discovery were sworn on 7 September 2022 and 16 September 2022 producing a near duplicate of an already produced document and scheduling four additional privileged documents. From early on, Teva queried the extent of the search*

that had been made - which admittedly had focussed on custodians most centrally involved in dealings with the priority document and the patent, as opposed to all possible custodians and which had done so in light of the timing constraints. Efforts were made to address issues as they were raised by Teva and to explain BMS's process. On 2 June when Teva was indicating its decision to opt for a trial commencing in September as opposed to the original 15 June start date, it was indicated to the Court on behalf of Teva that the only outstanding direction was the delivery of BMS's written submissions. With the additional time to trial afforded by the adjournment however Teva commenced an iterative process of querying and challenging discovery. It also then raised interrogatories. Ultimately it issued motions for further and better discovery and interrogatories. However it did so late, having regard to the fact that its first post 2 June letter on discovery in this regard was sent on 7 June 2022 and that detailed correspondence continued from that time to its issuing of its motion on 19 August 2022….

31. *Ms Reynolds is incorrect to say (at paragraph 55) that 'BMS now continues to make various arguments justifying its failure to make discovery.... These arguments were made to - and rejected by - Mr Justice O 'Moore'. BMS did not in fact try to assert that it had conducted a perfect discovery effort or to say that it should be considered to comply with requirements on the basis of the timing constraints it was operating under. Rather BMS admitted gaps and some mistakes and referred the Court hearing the discovery motion to the logic of its approach and the constraints that it was operating under as an explanation of its approach. While the Court found the approach lacking under the discovery rules and ordered further and better discovery, it did not 'reject' the explanation of why it was lacking. On the contrary, it acknowledged that things were happening very quickly in an effort to hold trial dates….*

32. *I respectfully believe that the fact that O'Moore J refused to make a wasted costs order as Teva had sought, but rather left that over to the Trial Judge, is indicative of the fact that he was not at that point satisfied to apportion blame for any timing consequences of the three motions (BMS having had to issue a motion seeking leave to adduce relevant evidence in the absence of Teva's consent) that had been issued.*

33. *Teva succeeded in obtaining an order for further and better discovery which entails a fresh comprehensive approach to include all possible custodians over a very extended period of time. This involves an extremely extensive and unavoidably time consuming collection process. It has unfortunately turned out to be a slower process than initially hoped and accordingly BMS has had to seek additional time as indicated by Ms Reynolds.*

That was done on 11 January 2023 and Mr Justice O'Moore extended the time for providing discovery by a period of 8 weeks, to 9 March 2023. The extent of the task involved is apparent from the affidavit of Scott Brown sworn on 11 January 2023 supporting BMS's application to extend the time, to which I beg to refer to when produced.

34. *As will appear to the Court, that process has involved an exhaustive, and continuing, task of identifying persons (internal and external to BMS) who might have had any involvement in dealings with the priority document and patent over many years. This has resulted so far in the collection of some 57,930,523 documents and a process of de-duplication, threading and filtering by reference to keyword searches to leave 72,847 documents for review. Even at that, what is likely to be a very large number of documents still remain to be collected.*

35. *In my experience of discovery exercises involving scoping and searching electronic and hard copy documents ranging over time periods of many years held by large corporate entities and with numerous, multiple changes in systems and internal and external custodians over the years, it is generally impossible to predict at the outset how long a particular exercise will take, or even to make a prediction in advance of all documents being collected. The experience of colleagues in my firm is the same and indeed it is recognised in the Commercial Litigation Association of Ireland Good Practice Discovery Guide.*

36. *Furthermore, discovery reviews are often labour intensive exercises and this one is no exception. In that regard, a team of more than 20 document reviewers has been put in place to conduct the review. This is by way of addition to the various solicitors and external advisors involved, both from McCann FitzGerald LLP and other firms who advise BMS and the BMS in-house resources and external service providers who have been engaged to maintain the database and provide support services including technical quality control and analytics.*

37. *The point that I wish to make to the Court for the purposes of the application now before the Court is that the time needed is needed as a result of the difficulty encountered by BMS in conducting the kind of exhaustive search in respect of which Teva has stood on its strict legal rights - to a questionable end in terms of relevance - and not as a result of any deliberate delay on BMS's part.*

38. *Respectfully, Ms Reynolds' assertions (at paragraphs 61 to 63) in respect of the witness statement of Ms Sandra Leung are remarkable.*

39. *Ms Reynolds indicates that Ms Leung's statement was proffered late in the day (the issue of leave to deliver it was raised with Teva and before the Court on 27 July 2022). Ms Leung's evidence deals with BMS's internal organisation which underlies BMS's position that the priority document was beneficially owned by the correct entity at the time of the application for the patent. It was offered late owing to BMS's growing realisation - through certain evidence Teva maintains as expert evidence and through Teva's increasingly intensive focus on the issue in interrogatories and discovery -that Teva intended to seek to undermine not only BMS's legal argument that a beneficial interest in a priority document could provide a basis for a right to claim priority, but the fact evidence of BMS's internal operations by which BMS maintains the beneficial interest was conferred.*

40. *This realisation could have come sooner, and perhaps it should have, but it was certainly not foreseen at the time when the original evidence in this regard was filed and accounts for a late introduction of Ms Leung's evidence.*

41. *Remarkably Ms Reynolds states (at paragraph 62) that 'there was no discovery of Ms Leung's documents'. First, Ms Leung is simply giving evidence of the internal control applied to BMS companies - the pleaded basis for the equitable interest - for which no discovery was sought. In the course of the hearing of the motions in September and October, Teva tried to assert that a new case was being made in this respect, no doubt to provide the basis for a new request for discovery. This was not accepted by O'Moore J.. In so far as Ms Leung may have documents falling within the category actually sought by Teva, a search was made for documents in her possession in August 2022 and she is included in the scope of the further discovery process currently under way.*

42. *Ms Reynolds also asserts at paragraph 62 that there was no explanation for the late introduction of Ms Leung's evidence. That there was is clear from the motion papers and in particular paragraph 41 of the grounding affidavit in the motion to deliver Ms Leung's statement.*

43. *It is not clear to me how the delivery of a statement further substantiating, from an alternative perspective, the kernel of evidence (by Mr Golian) already filed, two months in advance of trial could have halted the trial date, even if it were to be accepted that no work should be done in Commercial List cases in the Long Vacation, which I believe has never been the position in the Commercial List.*

44. *I entirely accept that the directions to trial were not Teva's directions but the directions of the Court.*

45. *As I have set out below there were also directions that were agreed by BMS in an attempt to facilitate the time to trial requested by Teva. They were realistic as a timeline for the original case. As I have explained, they were thought to still be possible on the basis of an understanding that what was sought in the category 9 discovery was everything relevant on the chain of title. It was not however a realistic timeline for the exhaustive search, retrieval and review exercise enforced by Teva in its motion for discovery, namely for all custodians over a 20-year period of all documents relating to the chain of title where that chain involved complex commercial transactions.*

46. *It was matter for Teva whether it prioritised the latter approach over the former. It chose the latter and succeeded in its motion in achieving an order to that effect. I am not sure what Teva believes is to be found of value to it in the massive discovery operation that it has enforced, in particular where the case made by BMS does not rely on documents in the chain of title, however that is the approach it has decided to take.*

47. *One thing is not clear to me in Ms Reynolds' averments and that is Teva's reference to a presumption that trial would proceed and to multiple cancelled flights. No detail is given on this for any witness and/or whether any consideration was given to proceeding with some witnesses in respect of the clear-standing technical patent case. It is not clear to me either why, even if Teva for some reason felt it should not progress the case it originally brought - the part of the case that it could have progressed (and on the basis of which it maintains it could have cleared the path), it thought that it could engage in complex motions, including involving discovery, to be issued in August without the expectation that such motions would impact trial in September or October.*

48. *In summary, and contrary to what Ms Reynolds asserts as to a 'retrospective slant' being put on matters, the timing difficulties experienced, in terms particularly of the discovery that Teva sought to enforce were unrealistic and this was a developing realisation. It was up to Teva to consider its priority - timing or a very involved discovery process - and it opted for the latter.*

49. *As to Ms Reynolds' comments on the substance of the case, I am unsure of the point that she wishes to make in some of her references. I will respond specifically to two points. First, and contrary to what Ms Reynolds states, the application of the concept of 'plausibility' to invalidate patents many years after grant in national courts is, as I said in my first affidavit, relatively new and evolving. It was not dealt with in* Terrell on Patents *- the key text for UK patent law until the 18th edition 2016, was not the subject of any authority in the State before the High Court judgment in* Re Boehringer Ingelheim

Pharma GmbH & Co. KG & Patents Acts, Ireland *[2017] IEHC 495* [a decision of my own] *and has not been dealt with in any other Irish case.*

50. *Second, I did not assert that the Court of Appeal decision in the Boehringer case lacks precision as regards plausibility. It is relied on in some detail by BMS in the legal submission in the substantive case as marking a distinction between the law of plausibility in this jurisdiction and the law as it currently stands in the UK.*

51. *In general terms, I also respectfully believe that the law in both jurisdictions and indeed in other EPC contracting states will have to be reviewed in light of the impending decision of the Enlarged Board of Appeal of the EPO in G 2/21* - Sumitomo. *This arises in both jurisdictions in light of, inter alia, rules of construction applicable to statutes specifically passed to implement the State's international obligations, such as the Patents Act, 1992 was. I am unsure if Ms Reynolds is suggesting that the approach in the Netherlands - where the District Court of the Hague has in fact stayed the proceedings pending that decision, as mentioned in the affidavit of Edouard Kling sworn on 1 December 2022 - or other EPC-member states might differ, but I would be surprised if that were the case.*

52. *I simply do not follow Ms Reynolds averments to the effect that the impact on the price of Eliquis® of launch before the expiration of a valid SPC (if it is successfully defended) and attested to earlier in her affidavit by reference to comments of Professor Michael Barry of the HSE, would somehow be compensable in damages but a delay to Teva in launching its product in circumstances where the delayed launch would still be within the original lifespan of the SPC (such that the economics of general generics launch would not apply) would not be. These matters are responded to in the other replying affidavits delivered on behalf of BMS.*"

C. The Expert Evidence

6. I have been provided with and considered all the extensive affidavit evidence from a number of experts. Some of that evidence has already been touched upon in the quoted extracts above from the affidavit evidence of Mr O'Brien and Ms Reynolds. It is not possible to recite exhaustively what has been put before me. Instead, I touch on various points that seem to me to be of particular interest in the affidavit evidence when it comes to deciding whether or not to grant the injunctive relief sought. (Although I do not quote from the affidavit evidence of Mr Kling and Mr Long, that evidence, as with all the affidavit evidence has been considered.)

a. Cooke #1

7. Mr Cooke is the General Manager of BMS Group in the UK and Ireland. He avers, among other matters as follows:

"*24. Parallel imported versions of some of the above products are also available in Ireland. These are original medicines originally purchased in other EU Member States at lower prices and then repackaged and imported by various parallel importers for the Irish market. For example, Eliquis (Originalis B.V.), just one such parallel imported product, is included on the HSE's Reimbursement List. These parallel imported ELIQUIS products are not supplied by BMS in Ireland, but by the parallel importers such as Originalis B.V. Such parallel trade accounts for a significant amount of ELIQUIS sales in Ireland (on average about 40% of all of ELIQUIS products sold in Ireland). There are often large fluctuations in the volume of parallel trade from month to month and the graph below [not shown in my judgment] demonstrates that in some months, parallel trade would account for around 25% of ELIQUIS sales in Ireland, while in other months it can account for up to 47%....*

47. Under the Generic Medicines Framework Agreement…the reimbursement price for new generic medicines must be no greater than 40% of the 1 October 2021 price of the equivalent branded original medicines (Clause 7.2.1). This means that the cost to the HSE is significantly reduced, such that - quite apart from incentives that generics would like [to?] be able to offer pharmacies - the HSE would also be incentivised to introduce measures to encourage uptake of the generic product.

48. While in theory, I accept that BMS could seek to maintain its price for ELIQUIS in the face of generic launch, in reality BMS would have to engage in vigorous price competition by reducing price and offering substantial rebates/discounts to wholesalers and pharmacies, if it wanted to try and retain its market share on generic market entry. In practical terms, once they had done this it would be impossible for BMS to reverse these and reinstate its current price….

55. The import of the various factors outlined above is ultimately that, on premature generic entry, BMS will be faced with a most unattractive choice - which will involve very significant harm to it either way - between seeking to maintain its price pending trial of the action or competing with the generic, which it would in reality likely have to do.

Assuming BMS chose to compete in an effort to maintain market share, any attempt later to restore the pre-generic launch price following the trial of this action would be severely damaging to its reputation, commercial relationships and wider commercial interests and I believe would be practically impossible. Even assuming BMS lowers its price to compete, it would, be unpredictable to what extent it could maintain its market share in any event given the very deep discounts likely to be offered by generics….

59. *If the reimbursement price has been reduced, it would not be possible to raise this again, without agreement from the HSE, which I believe would be unprecedented. However, even assuming the reimbursement price is not reduced, and BMS instead reduced its price by way of discounts and rebates to wholesalers and pharmacists, it would be impossible in practice for BMS to reverse these either.*

60. *If BMS tried to raise the price subsequently, this may be unacceptable to its buyers, with obvious damage to BMS's reputation, goodwill and its relationship with the HSE. This would have long-lasting effects on BMS, who will need to co-operate with the HSE not only in relation to ELIQUIS, but also reimbursement approval and pricing for other existing and future treatments it brings to market.*

61. *I am not aware of a company ever having restored the price of a product in Ireland following price depression caused by generic activity. The effect of generic sales prior to expiry of the intellectual property rights would therefore be to prematurely shorten BMS's exclusive rights in ELIQUIS and it would never effectively be possible to restore the benefit of those rights.*

62. *The damage to BMS will therefore continue even after the removal of all generic apixaban from the market and BMS may never actually fully recover its market for ELIQUIS. The market would have been permanently altered and it would be very difficult, if not impossible, to calculate the effect that the presence of generic apixaban on the market in Ireland would have on BMS's sales and market share of ELIQUIS in Ireland or quantify the impact on BMS.*

Impossibility of predicting and assessing the impacts on the anticoagulant market

Growing, not-static anticoagulant market

63. *I have described the current state of the anticoagulant market…above. As as described, parallel trade accounts for a significant and unpredictable share of the market and BMS*

does not have control over parallel imports of ELIQUIS. As it is not a static market, this adds another layer of complexity to calculating any damages.

64. *The DOAC market in Ireland is currently also growing at a faster rate than was anticipated and sales of apixaban have also been increasing. Apixaban's market share as compared to rivaroxaban, for example, has been increasing.*

65. *There will always be a proportion of new patients who will be prescribed apixaban. It is impossible however to predict the number of new patients, what proportion of the new patients will be prescribed apixaban and how apixaban's market share will change going forward. This is especially significant because new patients account for a large percentage of the dynamic DOAC market, as set out in paragraph 22….*

Competition from other DOACs and generics and the possibility that generic apixaban could impact the market for other DOACs and not just ELIQUIS

71. *As explained above, ELIQUIS is not the only product on the oral anticoagulant market. It is a fluid market with patients switching between products and new patients being prescribed one of a number of different anticoagulant treatments and market shares changing between the different products. It is not possible to predict with any certainty what a product's market share might be for the next six months let alone during the remaining period of protection conferred by the SPC. For example, if one of the other innovators decided to offer a rebate like Daiichi Sanyko did with its LIXIANA product in other countries, including the UK, market shares could quickly change. BMS has no control over any such events and is obviously not privy to competitors' future plans. All of this makes estimating future damages very difficult.*

72. *The impact of market entry of generic apixaban on other DOACs and warfarin and the resultant re-shaping of the market would also be difficult (if not impossible) to unpick. Cheap, generic apixaban is likely to take market share not only from ELIQUIS but also from the other DOACs currently prescribed for existing patients. Clinicians may choose to switch patients from their existing DOAC to generic apixaban, thus increasing the overall market share of apixaban. It is not possible to predict in advance what arty such shifts in market share may be.*

73. *More significantly, it is likely that the availability of low-priced apixaban would prompt new prescriptions for DOACs to favour apixaban over other DOACs (which will probably remain more expensive than a generic apixaban whilst they remain 'on patent'*

even if prices are reduced). It is not possible to predict what the impact of this might be and whether new patients would be switched back to the other branded DOACs if generic apixaban was later removed from the market, another factor which makes calculating any damages wholly speculative.

74. *It is possible that the other DOACs may introduce some type of rebate (whilst maintaining list price) in order to compete with the newly introduced generic apixaban There is a risk that generic apixaban entry may trigger some form of HSE intervention such as a preferred medicine procurement process/MMP, which I discuss further below.*

75. *If there was an unexpected and early launch of generic versions of other DOACs, that would also complicate the market dynamics even further. As described above, generic versions of dabigatran and rivaroxaban have obtained MAs.*

76. *Given that the market share for dabigatran is relatively low at approximately 4% volume market share (see paragraph 18), BMS do not anticipate that market entry of generic dabigatran will have a significant impact on the market for ELIQUIS. However, it is possible that clinicians may switch to the lower priced generic dabigatran and that the market share for ELIQUIS will be impacted more than BMS anticipate. It is simply not possible to predict with any certainty at this stage what will happen in Q3 2023 when the patent protecting dabigatran is due to expire.*

77. *The market share of rivaroxaban is significant…and BMS currently anticipates that generic rivaroxaban may have a significant impact on ELIQUIS's market share. Again, however, it is impossible to predict what will happen with any certainty and this is made even more complicated by the current uncertainty surrounding the rivaroxaban patent expiry dates, as mentioned above. Obviously, there will be a significant impact on the DOAC market if it transpires that rivaroxaban is going to remain a branded product-until 2026 rather than 2024 which was the previous assumption….*

Other non-quantifiable losses and damage to BMS's intellectual property rights

85. *A launch at risk by Teva would also cause additional non-quantifiable losses and would damage the rights granted by and value of BMS's SPC.*

86. *BMS plans its budget, including for innovation, by reference to the full length of its intellectual property rights; in order to run its business, it has to engage in forward planning of this sort. One example is the manner in which it prepares for competition at the end of the period of exclusivity. Premature launch of competitor products before*

expiry of intellectual property right fundamentally interferes with this forward planning and budgetary management.

87. *These are matters that cannot be calculated or fully compensated by damages. Even if Teva's generic product were removed from the market after the conclusion of the trial, changes to the market and pricing structures would mean that future plans may already be disrupted….*

Impact on Operations and Potential Loss of jobs

90. *In 2021, BMS invested $11 billion in R&D. If the Defendant is permitted to launch its generic product while the SPC remains in force, and BMS were to lose the greater part of its sales of ELIQUIS within a few months as a result, as outlined above, the whole company would be affected by the budget cuts necessitated by the resultant decrease in profitability. Reinvestment of profits from profitable drugs such as ELIQUIS is essential to fund research for new and innovative medicines, including less profitable drugs which promotes patient welfare. Such investment helps to address the unmet medical needs of patients with serious diseases.*

91. *In Ireland a significant proportion of BMS employees work exclusively on ELIQUIS but the whole company would be affected as ELIQUIS is the largest brand by revenue. Such losses of sales and revenue could obviously lead to budget cuts and potentially to job losses and consequential loss of valuable experience and expertise.*

92. *BMS sales representatives also perform important support services by distributing patient support information totalling thousands of booklets annually. BMS also provides significant training for the entire class of DOACs in the form of education of GPs by expert cardiologists in particular. Such services would likely have to be cut back / stopped as a result of Teva's premature launch. This would have significant impacts on the relationships BMS has with health care professionals and would also ultimately be damaging to the well-being of patients, including patients being treated with other DOACs.*"

b. Cooke #2

8. In a second affidavit, Mr Cooke avers, amongst other matters, as follows:

"*Other Losses*

39. Mr Neill discounts the possibility that BMS would have to lay-off staff and that Teva's launch at risk could cause job losses at BMS by merely stating that BMS is a large and well-resourced organisation….However, as BMS informed the UK government, BMS had to cut 100 members of staff, mainly in the Eliquis® commercial team, as a direct result of the entry of generic apixaban onto the market."

c. Stomberg

9. Mr Stomberg is an economist and a director at NERA Economic Consulting. He has been engaged by BMS to provide an independent opinion on (i) the likelihood of entry to the market of other suppliers of generic apixaban pre-trial/pre-determination of the action if Teva is not restrained from doing so; (ii) the calculability of damage caused to BMS by Teva's proposed supply of generic apixaban before determination of the action; (iii) the impact of such premature supply on BMS as rights-holder. Mr Stromberg has averred, amongst other matters as follows:

"*THE CONSEQUENCES OF TEVA'S ENTRY AT RISK FOR DAMAGES CALCULATIONS*

22. The foregoing discussion illustrates the many complexities and the potentially very long horizon over which damages may accrue to BMS should Teva launch at risk prior to trial. Suppose Teva launches at risk, and also obtains a favorable decision at trial. Presumably other companies would enter along with Teva either before or after the trial. These launches are all at risk in the sense that a subsequent appeal by BMS could reverse this outcome. If that were to happen, BMS has suffered harm not only from Teva, but from several competitors that have piled into the market as a result of Teva's actions.

23. This scenario raises serious apportionment concerns since these added competitors may either 1) affect prices by bidding them downward, or 2) further erode BMS sales of apixaban. It is my understanding that those other companies are not party to this litigation, and it is therefore unclear how Teva would intend to parse which units are its responsibility, and at what price for the purposes of compensating BMS. Suppose, for

example, that BMS continued to sell its product at discounted prices to remain relevant in the Irish market. If those prices are adversely affected by the added competition, does Teva intend to compensate BMS for the incremental impact of its generic competitors? Similarly, if BMS maintains its prices, but suffers added erosion of sales as a result of the non-party competition, would Teva compensate BMS for the incremental sales of its competitors? In either case, what recourse would BMS have within the scope of this litigation to recoup what had been lost from non-parties?

OTHER AVENUES OF IRREPARABILITY

25. *There are other avenues by which Teva's launch of apixaban at risk causes irreparable harm to BMS.*
26. *First, parallel imports have a substantial and unpredictable impact on BMS sales of apixaban in Ireland. Parallel imports of apixaban into Ireland from other countries are not under BMS control, and according to Mr. Cooke's figures, these imports account for as much as 50% of apixaban sales in Ireland but also vary quite a bit over time. It would be highly speculative to reconstruct the volume of these parallel imports as part of a damages exercise.*
27. *Moreover, there remain serious issues even if one were to credit Mr. Long's argument, as stated in paragraph 41 of his affidavit, that parallel imports are nevertheless BMS sales even though they are sold by non-parties at different prices and are coming from other countries. The problem with that argument from a damages perspective is that it would require a highly speculative exercise in predicting the changing fraction of apixaban sales accounted for by parallel imports, the countries of their origin, and the prices and volumes of apixaban bought by the importers in those countries at the time stock was purchased. The 2013 ESRI report indicates that price variation across EU source countries for parallel imports could be in the order of 30%. It is improbable that any of this could be done reliably.*

INTELLECTUAL PROPERTY RIGHTS PROVIDE INCENTIVES TO INNOVATE

34. *The enormous cost, risk, and difficulty of bringing forth an innovation like apixaban is precisely what exclusivity periods are designed to reward. Without the promise of that reward, there would be no innovative product for generic companies to subsequently*

copy and sell. Pharmaceutical companies spend considerable efforts on researching and developing novel therapies. These investments are risky and often made years before the potential returns may be realized. Very few of these see the light of day. For example, a research study by DiMasi et al. (2016) finds that fewer than 12 percent of investigational compounds that initiate human trials achieve clinical approval in the U.S., and that it costs an average $2.6 billion in fully capitalized costs for each approved new therapy….Capitalized costs matter because of the very long time that it takes to bring a pharmaceutical to market; they account for the cost of tying investment capital up for lengthy periods of time.

35. *A launch at risk by Teva diminishes the value of the exclusivity granted through the SPC to the extent that it renders uncertain whether the exclusivity period can be fully defended or restored without irreparable losses. The harm to BMS therefore goes beyond just its lost profit on apixaban. Raising the risk that patent exclusivity may not be what was initially understood creates a spillover effect to all future investment endeavors. This shift in the balance of future benefits would have a cooling effect on the system that could bring the next apixaban to the table. Those spillover effects are not felt just by BMS, but by all innovator companies who must re-evaluate their investments in this light. The risk introduced by Teva's launch is potentially systemic*."

d. Potter #1

10. Mr Potter is the founder and director of Charlwood Pharma Ltd and has provided an expert opinion on the quantifiability of damages resulting from two scenarios that he identifies, averring, amongst other matters, as follows:

"*3.10 I have been asked to provide my expert opinion on the quantifiability of damages resulting from the following scenarios:*

3.10.1 [Scenario 1:] *No injunction is granted and Apixaban Teva is placed on the market. At the final determination of the Revocation Action judgment is handed down finding the Patent is valid and infringed and accordingly, generic apixaban including Apixaban Teva is removed from the Irish market. BMS seeks damages from Teva and any other generics companies which have marketed apixaban for losses it has incurred as a result of generic apixaban wrongly being allowed to be available on the Irish market*

during the period from the determination of the preliminary injunction application to the judgment from the final determination of the Revocation Action….

3.10.2 [Scenario 2:] *An injunction is granted and Teva is restrained from placing Apixaban Teva onto the market until the final determination in the Revocation Action. The final determination of the Revocation Action results in the revocation of the Patent and SPC. Teva seeks damages from BMS for losses they have incurred for wrongly being kept off the Irish market in the intervening period…For the purposes Scenario 2 I make the assumption that BMS will also seek and be granted interim injunctions against all other companies attempting to launch a generic apixaban….*

4. QUANTIFIABILITY OF LOSSES IN SCENARIO 1

4.1 *BMS's loss is calculated in Scenario 1 as the difference between the actual profits BMS earned (the factual scenario) and the amount that it would have earned in a counterfactual scenario where no directly competing generic products (including Apixaban Teva) had been launched into the Irish market (the counterfactual scenario). Profits in the factual scenario are known, and profits in the counterfactual scenario can be calculated with a good level of accuracy based on assumptions that can be made with a high degree of confidence based on facts and data available from the factual scenario. Having made the assumptions, it is essentially a mathematical exercise to calculate BMS's loss that arises in this well-defined period between launch of Apixaban Teva and the restoration of BMS's position. In order to calculate this sum, the following information would be required….*

4.5 *As noted…above, the necessary data and assumptions to estimate the counterfactual can be all obtained, calculated or estimated with reasonable accuracy by reference to well-known, reliable and accessible data from the factual without the need to refer to comparable markets. I consider that these assumptions would be a reliable base for the calculation which would then essentially be a mathematical exercise. Further, as* [previously] *noted…I consider that the losses are restricted to a defined and relatively short period between the launch of Apixaban Teva and the date on which the final determination of the Revocation Action judgment is handed down finding the Patent is valid and infringed. Taking this into account, it is my opinion that the losses incurred by BMS in Scenario 1 can be readily estimated with reasonable accuracy….*

5. QUANTIFIABILITY OF LOSSES IN SCENARIO 2

5.1.4 Having determined the size of the market in Scenario 2 the Court will have to determine an estimate of the extent to which Teva (and any other generic companies that would have launched at risk of being liable to BMS for damages) would secure market share from BMS, as well as the price at which that share is likely to have been secured. In my experience these are highly variable and difficult predictions to make that are significantly influenced by the number and identity of companies competing against BMS and each other for that business. Even if the number of competitors were known (which is not necessarily a given as not all generic companies injuncted might have chosen to launch between the determination of the preliminary injunction and the determination of the Revocation Action), the outcome is hard to predict as the actions of each competitor are different, both between companies and even within companies depending on the circumstances.

5.1.5 One potential source of evidence for the counterfactual market share and pricing assumptions in Scenario 2 may be from the data that can be gathered from the factual situation after the launch of generic apixaban that will have occurred in this scenario shortly after the judgment is given in the Revocation Action. However, in my opinion the competitive environment is expected to be materially different in the factual to the counterfactual (specifically in my opinion the factual scenario is expected to be more competitive than the counterfactual given the passage of time, and in particular the removal of any damages risk to the generic companies in the interim period), it is therefore not appropriate simply to apply the outcomes of the market shares and prices achieved in the factual as recorded to a counterfactual."

e. Potter #2

11. In a later affidavit, Mr Potter avers, amongst other matters, as follows:

"*The number of generic companies launching in the pre-determination phase*

8. *Mr Cooke makes a number of assertions that my first affidavit assumes or implies with certainty that there will be other companies launching generic apixaban into the Irish market prior to the determination of the Revocation Action (for example,* inter alia, *Cooke 2 paragraphs 12, 13, 21, 47). This is not a correct portrayal. The consideration of the possibility of additional generic entrants is a feature that would clearly be remiss to ignore. My inclusion of this as a feature is to show that the quantifiability in Scenario 1 is not rendered significantly harder than in Scenario 2 simply because of additional generic companies. This inclusion makes no statement of certainty as to how many (if any) additional generic companies enter the market, but merely indicates that their presence can be managed in the calculation of damages in Scenario 1*

9. *It is this uncertainty about whether other generic companies would enter the market prior to the determination of the Revocation Action, and if they were to do so, the uncertainty as to the number of entrants and the timing of their launches along with the aggressiveness of their pricing strategy, the response of BMS, the resultant market shares and sales of any claimant in Scenario 2 that are the key reasons why Scenario 2 is harder to quantify. A post hoc counterfactual analysis of these factors that would be required would need to rely on extensive disclosure and supposition along with analysis of comparable market situations that are unlikely to be readily available as described at 5.1.5, 5.1.6, 5.3 and 5.4 in my first affidavit. It is these uncertainties which cause Scenario 2 to be very difficult to quantify that is the cornerstone of my evidence, not the certainty that other generics will launch in Scenario 1 as asserted by Mr Cooke (paragraph 12 of Cooke 2).*

10. *Dr Stomberg presents a number of points relating to this. For example, at Stomberg 1 paragraph 10 he states that additional generic manufacturers will likely launch adding complexity to the scenarios. It is exactly for this reason that I included the presence of additional entrants in my assessment of quantifiability, and Dr Stomberg is wrong to say that this complexity is additional to the analysis I have conducted.*

First mover advantage

11. *These uncertainties as to how many (if any) other generic companies would launch in the pre-determination phase, and the timing of those launches is also what lies behind the apparent qualification I make of the first mover advantage that Mr Cooke highlights*

in paragraphs 12 and 48 of Cooke 2 My use of the terms 'may' and 'potentially' refer to the uncertainty as to how strong the first mover advantage is, and not a reflection of any doubt that Teva would have a first mover advantage. It is the case that in Scenario 1 the extent of Teva's first mover advantage will be clear and calculable from the actual post hoc data, whereas in Scenario 2 there would only be a series of difficult to prove claims and counterclaims in any damages enquiry.

12. *At Stomberg 1 paragraph 12 he states that other registrants may appear over time, particularly as the end date for BMS's apixaban SPC draws near. This supports the fact that these timings are variable, and that the longer the time progresses towards the SPC expiry the lower the advantage. This paragraph refers to registrations and layered on top of that is the uncertainty of the commercial intention to launch as Dr Stomberg describes as unpredictable at paragraph 19. Dr Stomberg also confirms in paragraphs 14 to 15 that the key to profits is the timing of entry for generic companies, and at paragraph 18 he notes that a favourable decision against the SPC would create a situation where all generics get the information simultaneously. Taken together these statements underline the fact that first mover advantage exists in favour of Teva if it were permitted to launch, and that little or none of this remains if a preliminary injunction is granted*."

f. Dodd #1

12. Mr Dodd is a director of Epic Pharma Ltd. He has been engaged by BMS to review the affidavits of Messrs Neill, Long, and Potter and to give his views on the likely harm, that would not be captured by any mathematical exercise to arrive at an award of damages, in the event Teva is not prevented from launching its generic apixaban product on the market but is later taken off the market if it is unsuccessful in the proceedings. In the course of his report he observes, amongst other matters, under the heading "*Potential Damage to Relationships*" that:

"[R]*elationships with prescribing physicians and commercial relationships with pharmacy groups and wholesalers are also very important. The importance of such relationships to BMS and potential impacts have already been noted by Mr Cooke in his first affidavit at 59-60. I would agree that these kind of relationships are very significant and I can readily see that it could potentially be negative and damaging for such relationships and for BMS's reputation amongst these important stakeholders if BMS were to introduce discounted prices in order to*

compete with Teva and other generics entering the market and then seek to withdraw those discounts when it succeeded at trial and Teva had to leave the market, which could effectively be viewed by payors as a price increase."

g. Neill

13. Mr Neill is the Director of Generic Medicines for Teva. He has averred, amongst other matters as follows:

"*DOACs & APIXABAN….*

26. I do not agree with paragraph 31 of Mr Cooke's Affidavit wherein he states that if 'Teva is not prevented from launching it is difficult to [sic] not to conclude that some of the other generics suppliers would also seek to enter the market'. Furthermore, no other generic has sought to clear the way and if they were to launch, they would do so at risk. It cannot be said with any level of certainty that another generic apixaban would be launched pending the determination of the trial. In any event, the launch of any other generic is more likely to take market share from Teva than BMS. In the event that Teva does not secure the position of first mover, it will as outlined below, permanently lose significant market share. Therefore, the risk of other generics launching should be of little significance to BMS but is crucial to Teva.

27. Currently, Accord Healthcare S.L.U., Clonmel Healthcare Limited, Krka d.d., Novo mesto, McDermott Laboratories Limited and Rowex Limited have marketing authorisations for apixaban generic products in Ireland….

28. None of these has been added to the Reimbursement List as at the date of swearing this affidavit….

DAMAGE TO TEVA….

87. Mr O'Brien makes an assumption that generic entry to the market now pending trial while the patent is under challenge and generic entry to the market once the patent has been invalidated will be identical. This is not the case for a number of reasons: (a) Teva is the only generic to have sought to clear the way by issuing revocation proceedings;

(b) As far as Teva is aware, no other generic has indicated to BMS its intention to launch; (c) No other generic has been given a Reimbursement Price; (d) The risk appetite varies from generic company to generic company. There are companies who may be in a position to launch in Ireland pending the trial but will not do so due to the risk of having to pay damages to BMS in the event the patent was upheld. The same company may instantly launch in the event the patent was revoked; (e) There are likely to be companies who for commercial and practical reasons are not yet ready to launch but once the Revocation Action is determined may be.**"**

D. The Decision in *Merck*

14. The parties are agreed that in terms of the law to be brought to bear in deciding whether or not to grant the injunction the critical case in Irish law is the relatively recent decision of the Supreme Court in *Merck Sharp & Dohme Corporation* v. *Clonmel Healthcare Ltd* [2019] IESC 65, [2020] 2 I.R. 1.

15. In *Merck,* the plaintiff sought an interlocutory injunction restraining the defendant from launching its generic product on the basis that the product infringed the plaintiff's rights under its supplementary protection certificate. The lower courts refused the injunction. The issue had ceased to be live by the time the Supreme Court issued its judgment; however, it indicated that if the matter had still been live it would have granted the interlocutory injunction.

16. It is useful to consider the judgment in *Merck* in a little detail as it identifies at some length the key issues to which I will have to have regard in the pages that follow. The judgment of the Supreme Court was given by O'Donnell J. I consider key passages of that judgment below and after each passage have sought to distil what I consider to be the key element of what O'Donnell J. has observed:

(1) "*Patent law and patent extension by SPC provide a monopoly as a reward and incentive for innovation and for the disclosure of the teaching involved, leading in this case to the development of beneficial products. However, once a monopoly comes to an end, whether by natural expiration or by determination of invalidity, there is a strong competing public interest in encouraging entry to the market by generic alternatives,*

particularly since in Ireland, as in many European countries, the bulk of the cost of the drugs is met from the public purse" (p11).

Distilled Observation 1: Patent law rewards incentive and innovation by awarding monopoly; however, in the pharmaceutical context, once a monopoly ends (by timing out or invalidation) there is a strong competing public interest in encouraging generic entries.

(2) "*The grant of an injunction is an equitable remedy. While statutory authority for the grant of an injunction when a court considers it just and convenient to do so can be traced to the provision of the Judicature Acts, the injunction nevertheless retains its origins in the law of equity administered in the Courts of Chancery. It has always been a flexible remedy and is one of the most important ways in which equity tempered the rigidity of the common law*" (p.17).

Distilled Observation 2: Injunctive relief is an equitable and flexible remedy.

(3) "*The logic of an interlocutory application is that it is heard and determined in advance of the trial. It would make little sense for valuable and expensive court time to be used in an attempt to predict, on the balance of probabilities, the outcome of a case which is yet to be heard, where the evidence had not been ascertained and, more relevantly, had only been adduced on affidavit, and where the arguments were not fully developed. Accordingly, Lord Diplock concluded that there was no rule that a prima facie case should be established before an injunction could be granted. Instead, the court should consider whether a fair issue was to be tried, which means no more than the case not being frivolous or vexatious. If so, the court should then proceed to consider how the matters should best be regulated pending the trial which involved a consideration of the balance of convenience*" (p.18).

Distilled Observation 3: In *American Cyanamid* Lord Diplock concluded that there was no rule that a prima facie case should be established before an injunction could be granted. Instead, the court should consider whether a fair issue was to be tried, which means no more than the case not being frivolous or vexatious. If so, the court should then proceed to consider how the matters should best be regulated pending the trial which involved a consideration of the balance of convenience.

(4) "[T]*he decision in American Cyanamid…,* [as] *adopted in* Campus Oil *v.* Minister for Industry (No 2) [1983] IR 88*… was* [essentially] *negative: it rejected the prima facie case test. Second, the underlying theme of the decision was to reassert the flexibility of the remedy and the essential function of an interlocutory injunction in finding a just solution pending the hearing of the action….*[I]*t should not, in my view, be approached as though it were the laying down of strict mechanical rules for the control of future cases.*" (pp.19-20).

Distilled Observation 4: Whether or not to grant an injunction is not a matter of applying strict mechanical rules.

(5) "*In my view, the preferable approach is to consider adequacy of damages as part of the balance of convenience, or the balance of justice, as it is sometimes called. That approach tends to reinforce the essential flexibility of the remedy. It is not simply a question of asking whether damages are an adequate remedy. As observed by Lord Diplock, in other than the simplest cases, it may always be the case that there is some element of unquantifiable damage. It is not an absolute matter: it is relative. There may be cases where both parties can be said to be likely to suffer some irreparable harm, but in one case it may be much more significant than the other. On the other hand, it is conceivable that while it can be said that one party may suffer some irreparable harm if an injunction is granted or refused, as the case may be, there are nevertheless a number of other factors to apply that may tip the balance in favour of the opposing party.*

This, in my view, reflects the reality of the approach taken by most judges when weighing up all the factors involved." (p.21).

Distilled Observation 5: It is preferable to consider adequacy of damages as part of the balance of convenience (balance of justice): this tends to reinforce the essential flexibility of the remedy. It is not simply a question of asking whether damages are an adequate remedy.

(6) "[I]*t is important to keep in mind that, while the end point of most civil cases is the award of damages, the interests that the law exists to protect often extend beyond the purely financial. In the aftermath of the decision in* American Cyanamid *v.* Ethicon Ltd [1975] A.C. 39*, it was, however, recognised (though more slowly in Ireland) that the judgment could not be treated as a single test for the grant of interlocutory injunctions applicable in all circumstances, and instead required sometimes substantial qualifications and exceptions….The observation of this court in* Okunade *v.* Minister for Justice *[2012] IESC 49…that a court should, in an appropriate case, give weight to the public interest in the orderly implementation of measures which were prima facie valid is an example in this jurisdiction of a similar approach*" (pp.21-22).

Distilled Observation 6: While the end point of most civil cases is the award of damages, the interests that the law exists to protect often extend beyond the purely financial. A court should, in appropriate cases, give weight to the public interest in the orderly implementation of measures which are prima facie valid.

(7) "[T]*he approach in* American Cyanamid *v.* Ethicon Ltd *[1975] A.C. 396 and* Campus Oil *v.* Minister for Industry (No. 2) *[1983] I.R. 88 is predicated on the basis that a trial will occur. It should be recognised, however, that…trials do not occur in all cases where interlocutory injunctions are sought….*[C]*ommercial and practical reality means it may be sensible to compromise the claim. Parties who have been restrained by an injunction are often understandably unwilling to devote time and*

resources to a further hearing at some time in the future simply to establish that the plaintiff was wrong and that an injunction ought not to have been granted. The existence of an interlocutory injunction in such circumstances may therefore have a significant impact upon the party's position in such negotiations. Courts should be aware of this possibility on an application for interlocutory injunction which is a further reason why the test must be, and normally is, applied with a degree of flexibility and sensitivity" (pp.22-23).

Distilled Observation 7: In practice, a decision on interlocutory injunctive relief may impact on whether a matter proceeds to trial. This enhances the need for a court to show flexibility and sensitivity in approaching whether or not to grant interlocutory injunctive relief.

(8) "*Finlay CJ in* Curust Financial Services Ltd *v.* Loewe-Lack-Werk *[1994] 1 IR 450 at pp. 468–469 …*[did not establish] *a rule of general application that if damages may be awarded, an injunction must be refused*" (p.24).

Distilled Observation 8: There is no general rule that if damages may be awarded an injunction must be refused.

(9) "[As to Finlay CJ's observation that] '*Difficulty, as distinct from complete impossibility, in the assessment of such damages should not … be a ground for characterising the award of damages as an inadequate remedy'*….[t]*here may be circumstances where it can be said that the calculation of damages involves a complicated formula with a number of component parts but that there is no dispute about the correct formula or the figure it would produce in a particular case. In that sense, I would agree that the difficulty of the calculation does not itself mean that damages are not an adequate remedy. However, the sentence has also been relied on as suggesting that it must be completely impossible to assess damages before such damages can be said to be an inadequate remedy for a plaintiff, so that an injunction could be granted. I doubt that this was what was intended, or indeed that it is regularly applied in this way, but if*

it is so capable of being so understood, then, and with respect, I consider it requires some qualification" (pp.24-25).

Distilled Observation 9: Difficulty in the calculation of damages does not mean that damages are an inadequate remedy. However, this does not mean that that it must be completely impossible to assess damages before such damages can be said to be an inadequate remedy.

(10) "*There is a conundrum in any case in which an interlocutory injunction is sought. The parties at the interlocutory hearing vie with each other in arguing that they will suffer a loss or damages which cannot be compensated for by the award of monetary damages if they succeed at trial. Nevertheless, if the trial of the action proceeds, then the plaintiff will put forward a claim for damages, and the defendant would be in a position to make a claim for damages under the plaintiff's undertaking, if the defendant succeeded in defeating the plaintiff's claim. In either case, a court will award damages and it cannot be suggested that the outcome is not to do justice to both parties. It is rarely, if ever, asserted by a successful plaintiff that it is simply impossible to award damages to compensate it for its loss, and rarer for any plaintiff to maintain that position at trial. On the other hand, the fact that it is possible to award damages does not preclude the grant of a permanent injunction, and should not be understood as an absolute bar to the grant of an interlocutory order*" (p.25).

Distilled Observation 10: The fact that it is possible to award damages does not preclude the grant of a permanent injunction, and should not be understood as an absolute bar to the grant of an interlocutory order.

(11) "[D]*amages are not a perfect remedy, and cannot be a complete answer to an application for an injunction whether permanent or interlocutory. It should be recalled that the basic role for the intervention of equity in any case is that the common law remedy is inadequate. I consider that the correct test is that set out at p 58 of Spry,* Equitable Remedies *(4th ed., Sweet & Maxwell, 1990): "The precise question that has been asked is*

whether the relegation of the plaintiff to such remedies as he has in damages or other legal remedies would leave him in as favourable position in all relevant respects as would exist if the obligation in question was performed in specie (p.26)."

Distilled Observation 11: As to damages, the correct test is whether the relegation of the plaintiff to such remedies as he has in damages or other legal remedies would leave him in as favourable position in all relevant respects as would exist if the obligation in question was performed *in specie*.

(12) "*There is still substance in the test advanced by Lord Redesdale in* Harnett *v*. Yielding *(1805) 2 Sch & Lef. 549 at pp. 553–554:*

> *'Unquestionably the original foundation of these decrees was simply this: that damages at law would not give the party the compensation to which he was entitled, that is, would not put him in a situation as beneficial to him as if the agreement were specifically performed. On this ground, the court, in a variety of cases, has refused to interfere where, from the nature of the case, the damages must necessarily be commensurate to the injuries sustained.'*

This does not mean that an equitable remedy, whether specific performance or injunction, must be granted, but simply that, in the exercise of the court's discretion, it may decide to award damages rather than relief in specie*, and other discretionary considerations may mean that it is just to leave a party to his or her remedy in damages. The sole question at this stage, however, is whether the remedy in damages can be said to be necessarily commensurate with any possible injury so as to preclude the possibility of the grant of an injunction*" (p.26).

Distilled Observation 12: The "*sole question*" at the interlocutory stage (presumably as regards the issue of damages) is whether the remedy in

damages can be said to be necessarily commensurate with any possible injury so as to preclude the possibility of the grant of an injunction

(13) "[I]*t is noteworthy that in* American Cyanamid*…at pp 408–409, Lord Diplock observed that….'Difficulty of calculation of damages may be relevant at the interlocutory stage because the more complex the calculation and the greater the number of variables involved, the more likely it is that a court at trial would be forced to make an estimate or indeed to compound one hypothesis with another to arrive at its best assessment of damages to do justice in the case. But that necessarily increases the risk that the award of damages, although the best the court can do, may be something less than the doing of justice to either the plaintiff or indeed the defendant. In such a case, it may be more convenient not to leave one or other party to the possibility of an assessment of damages which is theoretically possible, but highly imprecise, speculative and therefore inconvenient*'" (pp.26-27).

Distilled Observation 13: Where the risk presents that the award of damages, although the best the court can do, may be something less than the doing of justice, it may be more convenient not to leave one or other party to the possibility of an assessment of damages which is theoretically possible, but highly imprecise, speculative and therefore inconvenient.

(14) "*The fact that it is not completely impossible to assess damages should not preclude the grant of an injunction to the plaintiff in an appropriate case. Accordingly, I cannot agree that it is possible to resolve this case merely by determining that it is not completely impossible to assess the damages which the plaintiff might obtain, and therefore that it is not necessary to consider further any other aspects of the case. An injunction should not be granted merely because an applicant can tick the relevant boxes of arguable case, inadequacy of damages, and ability to provide an undertaking as to damages, and by the same token should not be refused merely because damages may be awarded at trial*" (p.27).

Distilled Observation 14a: The fact that it is not completely impossible to assess damages should not preclude the grant of an injunction.

Distilled Observation 14b: An injunction should not be granted merely because an applicant can tick the relevant boxes of arguable case, inadequacy of damages, and ability to provide an undertaking as to damages.

(15) "[It has been claimed that there is] *a general principle that damages are an adequate remedy for a claim of breach of infringement of a patent or SPC [sic – presumably what is meant is a claim of breach 'or' infringement]…. Both* SmithKline Beecham PLC *v.* Genthon B.V. *(Unreported, High Court, Kelly J., 28 February 2003) and* Teva Pharmaceutical Industries Limited *v.* Mylan Teoranta *[2018] IEHC 324 were, in my view, correctly decided and are, when analysed, examples of careful and nuanced applications of the test relating to the grant of interlocutory injunction. It is true that both cases are examples of a court refusing an application for an interlocutory injunction with the effect that a plaintiff was left to the remedy in damages in the event that they should succeed, and in that regard, it is understandable that reliance is placed upon* Curust Financial Services Ltd *v.* Loewe-Lack-Werk *[1994] 1 I.R. 450. However, the decisions cannot be understood, in my view, as extending the application of that case, or still less establishing some general principle that interlocutory injunctions are inappropriate in the field of patents, SPCs, or intellectual property more generally*" (pp.27 and 30).

Distilled Observation 15: There is no general principle that interlocutory injunctions are inappropriate in the field of patents, SPCs, or intellectual property more generally.

(16) "[I]*t is perhaps not necessary to go to the lengths of placing a constitutional right in the balance to agree with Hogan J. in the Court of Appeal that the majority judgments do not give appropriate weight to the*

right involved from the SPC holder's point of view. It is, in my view, incorrect both to depreciate the 001 SPC as being no more than a right to an income stream, and at the same time elevate Clonmel's interest in becoming the incumbent generic to the key status of an interest which, if damaged, cannot be compensated by the award of monetary damages. The interests of the SPC holder and the interests of the generic challenger are both interests in acquiring a position in the market. The difference between them is that the SPC holder has a right conferred by a process of law which is presumptively valid: something which, if anything, ought perhaps to favour Merck" (p.30).

Distilled Observation 16: It is incorrect both (i) to depreciate an SPC as being no more than a right to an income stream, and simultaneously (ii) to elevate a party's interest in becoming the incumbent generic to the status of an interest which, if damaged, cannot be compensated by monetary damages. The interests of the SPC holder and the interests of the generic challenger are both interests in acquiring a position in the market. The difference is that the SPC holder has a right conferred by a process of law which is presumptively valid: something which, if anything, ought perhaps to favour the SPC holder.

(17) "*I recognise that the interest of Clonmel in exploiting a first-mover advantage is something of value which is to be considered and given weight in the application for an interlocutory injunction, since it will necessarily be lost if an injunction is granted. If Clonmel is correct, therefore, in its belief that the SPC is invalid, then it should be entitled to reap the commercial reward for its acumen in identifying the frailty in the SPC and being willing to back its judgement by investing in the product to the point of making both the regulatory application for approval and the practical preparations to launch a product in April 2018 rather than await the expiry of the 001 SPC a year later. That, however, is the high point of Clonmel's case. If it is wrong in its contention that the 001 SPC is invalid, then its conduct constitutes an actionable wrong. However, I cannot see how that interest can be said to outweigh the right of Merck (if it in turn is*

correct) to exploit its monopoly, granted, on this hypothesis, in accordance with law" (p.31).

Distilled Observation 17a: [T]he interest of the generic producer in exploiting a first-mover advantage is something of value to be considered and given weight in the application for an interlocutory injunction, since it will "*necessarily be lost*" (*sic*) if an injunction is granted.

Distilled Observation 17b: If a generic producer is correct in its belief that an SPC is invalid, it should be entitled to reap the commercial reward for its acumen in identifying the frailty in the SPC and being willing to back its judgement by investing heavily in the product.

Distilled Observation 17c: If a generic producer is wrong in its contention that an SPC is invalid, then its conduct constitutes an actionable wrong. However, that interest does not outweigh the right of the SPC holder (if it is correct) to exploit a monopoly granted in accordance with law.

(18) "*The interest of Clonmel in exploiting the possible frailty of the 001 SPC depends, indeed, on two things – the existence of the SPC (and a prior patent granting monopoly to Merck and therefore excluding all others from the field) and the observation of that monopoly by other market contenders. It is only if both these features are present that Clonmel can hope to exploit what it describes as its first-mover advantage and achieve a position of practical (if not legal) monopoly as the only generic in the field, and at one and the same time capturing the bulk of the market previously held by Merck by a deep price discount, while deterring entry by generic competitors. In a way, therefore, Clonmel's interest is dependent on and derivative of the assumption of validity of the 001 SPC. I do not see, therefore, that the case can be resolved by preferring that interest (which may or may not be valid) to the legal right to monopoly of Merck (which itself may or may not be invalid)*" (p.31).

Distilled Observation 18a: The interest of a generic producer in exploiting the possible frailty of an SPC depends on (i) the existence of the SPC (and a prior patent) and (ii) the observation of that monopoly by other market contenders. It is only if both these features are present that a generic producer can hope to exploit its first-mover advantage.

Distilled Observation 18b: In a way, therefore, the generic producer's interest is dependent on and derivative of the assumption of validity of the SPC. The case cannot therefore be resolved by preferring that interest (which may or may not be valid) to the legal right to monopoly of the SPC holder (which itself may or may not be invalid).

(19) "*The fact, indeed, that Merck's right is one which arises pursuant to a lawful procedure for the grant of a patent and SPC, and which is valid until otherwise declared invalid by a court, is also relevant to the balance of convenience*" (p.31).

Distilled Observation 19: The fact that an SPC holder's right arises pursuant to a lawful procedure for the grant of a patent and SPC, and which is valid until otherwise declared invalid by a court, is relevant to the balance of convenience.

(20) "*Merck, for its part, relies heavily, in this court at least, on authorities from the UK courts dealing with claims for injunctions by SPC holders seeking to restrain entry by generic competitors. This current of authority favours the grant of an injunction restraining generic entry….An early case in* [the relevant]*…line of authority appears to be the decision of Jacob J. in* SmithKline Beecham Plc *v.* Apotex Europe Ltd *[2002] EWHC 2556 (Pat)….He considered that there would be formidable difficulties in the plaintiff's way if it tried to get back to his present position after a major collapse of prices. At para 63, he was firmly convinced that* 'the damage caused by entry into the market on a substantial scale will be both very, very substantial and not adequately quantifiable'. *Jacob J. was also influenced by the fact that the defendant had not moved to determine either*

that their product did not infringe the patent or that the patent in question was invalid. In an earlier case, SmithKline Beecham PLC v Generics U.K. Ltd (Unreported, High Court of England and Wales, Jacob J., 23 October 2001), he had said it was 'purely commercial common sense. If there may be an obstacle in your way, clear it out. To my mind this is a case where the retention of the status quo was a rational thing to do. It was something that could have been avoided by the defendants; they chose not to do it'. *…That was what the procedures for revocation and declaration for non-infringement were for. Accordingly, he granted the injunction….The same analysis has been applied in a series of subsequent cases….*
[W]*hile I consider that weight should be given to the 'clearing the path' argument, it cannot be accepted without qualification as dispositive of the issue. Lawyers tend to value order and process, but if full weight is to be given to Clonmel's interest in capturing a first-mover advantage, then it must be recognised that clearing the way poses some problems for Clonmel and any other generic, since, of necessity, any such proceedings would clear the way not just for Clonmel itself, but for any other generic who would be to that extent a free ride on Clonmel's action. I also doubt that it can be said that, in every case, the damage to an SPC holder is necessarily more unquantifiable than the damage which may be suffered by a prospective generic entrant.*" (pp.12-13 and 31-32).

Distilled Observation 20a: Weight should be given to the 'clearing the path' argument; however, it cannot be accepted without qualification as dispositive of the issue (of whether or not to grant an injunction).

Distilled Observation 20b: If full weight is to be given to a generic producer's interest in capturing first-mover advantage, then it must be recognised that clearing the way poses some problems for any generic producer, since, of necessity, any such proceedings would clear the way for any generic producer (who would to that extent get a free ride on the first mover's proceedings).

Distilled Observation 20c: It is doubtful that it can be said that, in every case, the damage to an SPC holder is necessarily more unquantifiable than the damage which may be suffered by a prospective generic entrant.

(21) "*Part of the difficulty in this case is that each party asserts an interest which, if valid, is something encouraged by the law. The resolution of the same issue – the validity of the 001 SPC – will determine which interest is to prevail. If the 001 SPC is valid, then it is a monopoly which the law accords for good reason to an inventor. If the 001 SPC is invalid, then a generic entry into the market with consequent competition is to be positively encouraged. There is, therefore, a symmetry of interests which turns on the question of which interest is to prevail, and this case depends on the resolution of the same question. That, in itself, is a reason to approach this case by seeking the earliest possible trial of that single issue, rather than protracted debate that must necessarily depend on a number of hypotheses and which does not advance the determination of that fundamental issue*" (p.32).

Distilled Observation 21: Where each party asserts an interest which, if valid, is something encouraged by the law, that is a reason to approach a case by seeking the earliest possible trial of that single issue, rather than protracted debate that must necessarily depend on a number of hypotheses and which does not advance the determination of that fundamental issue.

(22) "*Given the essential symmetry of the parties' interests, I consider it appropriate to conclude that in neither case will damages be a fully adequate remedy, and, furthermore, the likelihood of some irreparable harm being occasioned to the successful party is also equally balanced between the parties*" (p.32).

Distilled Observation 22: This is really a conclusion, rather than a principle. In the case before him, where each party asserted an interest which, if valid, was something encouraged by the law (yielding a symmetry of interests) O'Donnell J. concluded that (i) in neither case

would damages be a fully adequate remedy, and (ii) the likelihood of some irreparable harm being occasioned to the successful party was also equally balanced between the parties.

(23) "*Merck's right was not simply to recover income and profit pending the expiry of the 001 SPC. The rights of a valid SPC holder are to exclude all competitors with products covered by the SPC until the last day of the SPC. It follows that the SPC holder will know the precise date on which its rights will expire, and one of those rights, therefore, is to be able to plan for that eventuality so that it may maximise its position in the market both until that period and the period immediately after expiry. If Clonmel is held to have wrongfully launched its product and yet was not restrained by injunction, then Merck would lose that significant benefit. The expiry of the SPC, as a matter of fact, if not law, would be determined by the fact of entry by Clonmel: a circumstance for which Merck would not be able to plan or take defensive steps in advance. In the event that no injunction was granted, but the validity of the SPC was upheld, it would be necessary, therefore, to carry out essentially the same speculative calculation in reverse, and attempt to assess how Merck might have exploited its monopoly position pending expiry and defended its position in the market post-expiry, if it had not been deprived of the ability to control the date of expiry of the 001 SPC. In other words, it would be necessary to take the information in relation to the development of the market between April 2018 and 2019 and thereafter, and then hypothesise as to what would have occurred had Clonmel been restricted from entering until April 2019 when other generics might also have entered the market*" (p.33).

Distilled Observation 23: The rights of a valid SPC holder are to exclude all competitors with products covered by the SPC until the last day of the SPC. It therefore knows the date on which its rights will expire, one of those rights being to be able to plan for that eventuality so that it may maximise its position in the market pre- and post-expiry of the SPC. If a generic producer is held to have wrongfully launched its product and yet was not restrained by injunction, the SPC holder would lose that

significant benefit. The expiry of the SPC would be determined by the fact of entry by the generic producer: a circumstance for which the right-holder would not be able to plan or take defensive steps. In the event that no injunction was granted, but the validity of the SPC was upheld, it would be necessary, therefore, to carry out essentially the same speculative calculation (as considered in Distilled Principle 22) in reverse.

(24) "*Both parties must accept that this is not a case, as* Curust Financial Services Ltd *v.* Loewe-Lack-Werk *[1994] 1 I.R. 450 was, where a market for a single product was shared between two parties. Instead the calculation is complicated further by the possibility of entry by up to four other generic producers*" (p.33).

Distilled Observation 24: Of relevance to the Supreme Court's considerations in *Merck* was the possibility of entry of up to four other generic producers.

(25) "*I consider that this is a case where damages, while available, cannot be considered to be said to be a full or adequate remedy for Merck so as to exclude the necessity to seek an injunction. I also consider that damages will not be an adequate or full remedy for Clonmel if an interlocutory injunction is granted and it is then determined that the SPC was invalid. Furthermore, it is plain that both parties have sufficient resources to pay any damages awarded. I do not consider, therefore, that the balance of potential irreparable harm favours either party decisively. While the question of the adequacy of damages to either party and the capacity of the parties to pay them is often the largest single element in the balance of convenience, and will often be decisive in most cases, there are other factors which are relevant and which, in a closely balanced case, may tip the balance*" (p.34).

Distilled Observation 25: The Supreme Court did not consider that damages were a full or adequate remedy for either party in Merck. Additionally, it noted that both parties had sufficient resources to pay any

damages awarded. So it did not consider that the balance of potential irreparable harm favoured either party decisively. In this context it observed that while the question of the adequacy of damages to either party and the capacity of the parties to pay them was often the largest single element in the balance of convenience, and would often be decisive, it noted that there are other factors which can be relevant and which, in a closely balanced case, may tip the balance.

(26) "*One feature of this case, to which, in my view, weight should be given, can be viewed in three different, though related, ways. That is the fact that Merck is the holder of an SPC granted pursuant to an authorisation process provided for by law and which involves the consideration both of the application for the 599 patent by the Controller of Patents, and the subsequent application for the SPC. As a matter of law, the SPC is valid and effective until declared invalid by a court of competent jurisdiction. Just as in* Okunade *v.* Minister for Justice *[2012] IESC 49…it was recognised that it was appropriate to take into account the fact that an order had been made in accordance with law, by a body established and authorised by law to do so, and which must be treated as valid unless and until determined otherwise by a court or body, it is, in my view, not unreasonable to give this greater weight in the balance than the interests of Clonmel, which only arise after it is determined that the SPC is invalid. Another way of valuing this factor is that it represents the status quo ante. In this case, there was no unreasonable delay in the commencement of the proceedings, and the status quo must therefore be taken to be the position which existed prior to Clonmel's launch. Finally, the same factor comes into play if consideration is given to the question of clearing the way. For the reasons discussed above, this cannot be treated as a single dispositive argument and, for example, in cases where the defendant might plausibly contend that his product did not infringe a patent, it might be of lesser weight. Here, however, the only issue is validity and, moreover, that issue itself is to be determined within the limited confines of article 3 of the 2009 Regulation. Since, by definition, any generic challenger will have to have taken preparatory steps both of a practical and regulatory nature, it is, in*

my view, a legitimate factor to which weight should be given to consider that no steps have been taken to clarify the essential matters upon which Clonmel's right to launch the product depends: those concerning the question of the validity of the SPC" (pp.34-35).

Distilled Observation 26: When it comes to the rights of the SPC holder, as established by the authorisation, etc. process, three possibilities present. First, it is appropriate to take into account the ostensible validity of the rights of the SPC holder and to give them greater weight in the balance than the interests of the generic producer, which only arise after it is determined that the SPC is invalid. Second, the position in which the SPC holder possesses its ostensible rights represent the status quo ante (in a case where there had been no unreasonable delay in the commencement of the proceedings). Third, where the only issue was validity it was a legitimate factor to which weight should be given to consider that no steps had been taken to clarify the essential matters upon which the generic producer's right to launch the product depended, i.e. those concerning the question of the validity of the SPC.

(27) "*In cases where the balance of convenience may be finely balanced, it may be appropriate to have regard, even on a preliminary basis, to the strength of the rival arguments as they may appear to the court. Certainly, if it was apparent that Clonmel's case for invalidity was strong, and/or if there had been successive determinations in Clonmel's favour of a similar challenge in other jurisdictions, then that might weigh against the grant of an injunction. In intellectual property matters where the same issue may have been addressed in other European countries, or the same issues adjudicated on in other comparable jurisdictions, it may be appropriate to take into account the outcome of such litigation*" (p.35).

Distilled Observation 27: In cases where the balance of convenience may be finely balanced, it may be appropriate (i) to have regard, even on a preliminary basis, to the strength of the rival arguments as they may appear to the court, (ii) in intellectual property matters, where the same issue may

have been addressed in other European countries, or the same issues adjudicated on in other comparable jurisdictions, to take into account the outcome of such litigation.

(28) "*It is recognised in the decision in* American Cyanamid*…that if the question of adequacy of damages is evenly balanced, it may not be inappropriate to consider the relative strengths and merits of each party's case as it may appear at the interlocutory stage….For this reason, I consider that Hogan J., taking the view he did of the balance of convenience, was quite correct to form some tentative view of the merits. However, it is, in this case, sufficient to say that Clonmel's case has not been shown to have that degree of strength which would outweigh the factors in favour of the grant of injunction*" (p.35).

Distilled Observation 28: If the question of adequacy of damages is evenly balanced, it may not be inappropriate to consider the relative strengths and merits of each party's case as it may appear at the interlocutory stage.

17. One further aspect of the judgment in *Merck* is worth touching upon. In terms of the steps to be taken by a court in an interlocutory injunction such as that now presenting, O'Donnell J. observes as follows, at 36-37:

"*At the risk of perhaps creating a further rule that will require subsequent qualification and correction, it may be useful to outline the steps which might be followed in a case such this:*

(1) *…*[T]*he court should consider whether, if the plaintiff succeeded at the trial, a permanent injunction might be granted. If not, then it is extremely unlikely that an interlocutory injunction seeking the same relief pending the trial could be granted.*

(2) *The court should then consider if it has been established that there is a fair question to be tried, which may also involve a consideration of whether the case will probably go to trial. In*

many cases, the straightforward application of the approach in American Cyanamid*…and* Campus Oil *v.* Minister for Industry (No 2) *[1983] I.R. 88 will yield the correct outcome. However, the qualification of that approach should be kept in mind. Even then, if the claim is of a nature that could be tried, the court, in considering the balance of convenience or balance of justice, should do so with an awareness that cases may not go to trial, and that the presence or absence of an injunction may be a significant tactical benefit.*

(3) *If there is a fair issue to be tried (and it probably will be tried), the court should consider how best the matter should be arranged pending the trial, which involves a consideration of the balance of convenience and the balance of justice.*

(4) *The most important element in that balance is, in most cases, the question of adequacy of damages.*

(5) *In commercial cases where breach of contract is claimed, courts should be robustly sceptical of a claim that damages are not an adequate remedy.*

(6) *Nevertheless, difficulty in assessing damages may be a factor which can be taken account of and lead to the grant of an interlocutory injunction, particularly where the difficulty in calculation and assessment makes it more likely that any damages awarded will not be a precise and perfect remedy. In such cases, it* may *be just and convenient to grant an interlocutory injunction, even though damages are an available remedy at trial.*

(7) *While the adequacy of damages is the most important component of any assessment of the balance of convenience or balance of justice, a number of other factors may come into play and may properly be considered and weighed in the balance in considering how matters are to be held most fairly pending a trial, and recognising the possibility that there may be no trial.*

(8) While a structured approach facilitates analysis and, if necessary, review, any application should be approached with a recognition of the essential flexibility of the remedy and the fundamental objective in seeking to minimise injustice, in circumstances where the legal rights of the parties have yet to be determined."

E. Analysis

18. A number of the steps identified by O'Donnell J. in *Merck,* at 36-37, as required to be taken by me can be despatched fairly quickly. First, if BMS is successful at the trial an injunction might well be granted. Second, in a rare note of agreement, I do not understand it to be disputed between the parties (and I do not myself see how it could seriously be disputed) that there is a fair question to be tried between them at the trial of these proceedings. One need merely read the pleadings in the substantive proceedings to see that a fair issue has been raised.

19. The next thing to decide is how best to arrange matters pending the trial. That involves bringing the balance of convenience (balance of justice) into play. So I turn now to consider the balance of convenience. I look first to the adequacy of damages. When it comes to this aspect of matters, essentially two questions present:

(i) would BMS be adequately compensated by damages if the interlocutory injunction *is not* now granted and it later triumphs in the revocation proceedings?
(ii) would Teva be adequately compensated by damages if the interlocutory injunction *is* now granted and it later triumphs in the revocation proceedings?

20. On balance, when it comes to the adequacy of damages, for the reasons that follow I conclude that the scales of convenience are equally weighed on both sides, *i.e.* that neither side has shown that it would be more or less difficult to compute damages for it than it would be for the other. By coincidence a similar 'draw' was found to have presented in *Merck* (§60), *Biogen MA Inc* v. *Laboratorios Lesvi SL* [2022] IEHC 592, and *Merck, Sharpe & Dohme LLC* v. *Mylan Ire Healthcare Ltd* [2023] IEHC 24 (§90). However, I do not read anything into this

coincidence: each case turns on its own facts and it may be that in the next pharmaceuticals/patent injunction case something other than a draw will be found to present.

21. Would BMS be adequately compensated by damages if the interlocutory injunction *is not* now granted and it later triumphs in the revocation proceedings? BMS maintains that there are essentially three ways in which it would suffer damage were Teva now to be allowed to bring its generic drug to the market in the manner in which it now proposes: (1) BMS maintains that there would be a challenge in calculating the loss suffered;[1] (2) BMS maintains that it would suffer permanent damage through a collapse in process/market share were Teva now allowed to enter the market with a generic that costs a fraction of the BMS's product;[2] (3) there would be damage that is not compensable at all, in particular the loss of exclusivity that goes with being an SPC holder.[3]

22. As to points (1) and (2) it seems to me that these are near-classic circumstances in which a court would assess damages. The evidence before me suggests that it is essentially a mathematical exercise that could be approached and completed logically. Thus, (i) Mr Potter in his evidence indicates that the difference between BMS's actual profits and what it would have earned had no generic entered the market could be "*calculated with a good degree of accuracy based on assumptions that would be made with a high degree of confidence*".[4] And he later moves on to observe that "[T]*he necessary data and assumptions to estimate the counterfactual can be all obtained, calculated or estimated with reasonable accuracy by reference to well-known, reliable and accessible data*".[5]

23. As to the notion that BMS would suffer permanent damage through a collapse in product/market share I would have found this proposition more convincing if someone within BMS had sworn that it would drop its price to meet the generic price. Even its own expert seems a little reticent on the point referring to "*if BMS were to introduce discounted prices*".[6] BMS, its own evidence suggests, has a choice in this regard and its own evidence is that it could elect to maintain its price.[7] But even if BMS did drop its own prices this again seems to me to be

[1] See Cooke #1, §§63-65 and §§71-77 and Stomberg, §23 and §§26-27.
[2] See Cooke #1, §48, §55 and §§59-62.
[3] See Cooke #1, §§86-87 and §§90-92. See also Cooke #2, §39. See also Stomberg, §35.
[4] See Potter #1, §4.1.
[5] See Potter #1, §4.5.
[6] See Dodd #1, §23.
[7] See Cooke #1, §48.

classic calculation of damages territory with damages calculable as indicated in the previous paragraph above. As McGovern J. observed in not altogether dissimilar circumstances in *Gilead Sciences Inc* v. *Mylan S.A.S.* [2017] IEHC 666, while the plaintiffs there (as here) did "*not go so far as to say that they would voluntary reduce their price, it seems unlikely they would do so. But even if they did, (or for that matter, were forced to do so) it would not be difficult to work out any damages to which they might be entitled in respect of a market that is very mature with only a short time left to run as a monopoly*" (para. 38).

24. The same applies as regards the contention that BMS would never be able to reverse price reductions (a quite remarkable proposition the more one thinks about it). There is suggestion in BMS's evidence that the implications for goodwill and reputation would preclude a price raise.[8] But it does not seem to me that BMS ever gets beyond the realm of assertion in this regard.[9] And in any event one remains very much in the realm of pecuniary loss, eminently calculable and recoverable as damages (see *Neurim Pharamceuticals (1991) Ltd* v. *Generics UK Ltd* [2020] EWCA Civ 793, §12).

25. I accept the contention made by BMS that its losses would become more challenging to quantify if other generic producers were to enter the market. However, in this regard I note the uncontroverted evidence that to date no other generic has sought to clear the path (or launch without doing so), no other generic has indicated that it intends to launch, and no other generic has been added to the reimbursement list.[10] While the launch of a second or further generic is a possibility, the evidence before me falls a long way short of indicating that this is likely. But even if it were to occur, the height of BMS's case in this regard seems to be that a challenge would present in calculating damages, not that it would be impossible.

26. As to the risk of job losses, while I accept (as was found in *Powerteam Electric Services Ltd* v. *ESB* [2016] IEHC 87) that redundancy costs are quantifiable, I accept also the point that I understood BMS to make in its submissions, namely that there is a tough-to-quantify loss in terms, *e.g.*, of the loss of in-house knowledge that goes when redundant staff leave.

[8] See Cooke #1, §§59-60. See also Dodd #1, §23.
[9] See Cooke #1, §47 and §55.
[10] See Neill, §§26-28 and §87.

27. Where Teva has struggled in this case is with point (3) and understandably so: it is an undeniable fact that if the injunction is not granted BMS will lose the exclusivity that goes with being an SPC holder, despite the presumptive validity of an SPC.[11]

28. Would BMS be adequately compensated by damages if the interlocutory injunction *is not* now granted and it later triumphs in the revocation proceedings? When it comes to (3), the answer must be 'no'.

29. Would Teva be adequately compensated by damages if the interlocutory injunction *is* now granted and it later triumphs in the revocation proceedings? I admit that I find Teva's evidence in this regard slightly perplexing in one respect. Its case for non-compensable damage rests greatly on the proposition, canvassed by one of its experts, that if Teva proceeds to the market before the revocation proceedings are decided then other generic producers will follow suit.[12] But another of Teva's experts appears later to dispute that other generics will in fact follow Teva's lead.[13] (And if this were not to occur, then any damages suffered by Teva would seem readily calculable). However, (i) Mr Potter has averred as he has averred (that if Teva proceeds to the market before the revocation proceedings are decided then other generic producers will follow suit), (ii) even BMS (in its submissions) acknowledges the cogency of Teva's evidence that the perception of risk on the part of other generic producers will evolve if the injunction is not now granted; and (iii) BMS seems also (in its written submissions) to accept the position advanced by Mr Potter that the evolving competitive position will make the calculation of damages deeply challenging.

30. Would Teva be adequately compensated by damages if the interlocutory injunction *is* now granted and it later triumphs in the revocation proceedings? For the reasons identified above, the answer must be 'no'.

31. Other factors of relevance to the balance of convenience/justice that have not previously been considered include the following five points (in no particular order) as well as other points considered hereafter: (1) BMS has spent a lot of time, effort, and money to get its presumptively

[11] See Cooke #1, §§86-87 and §§90-92. See also Cooke #2, §39. See also Stomberg, §35.
[12] See Potter #1, §§5.1.4-5.1.5 and Potter #2, §§8-12.
[13] See Neill, §26.

valid patent and presumptively valid SPC;[14] (2) that presumptive validity has real meaning and value, as do the patent and SPC to which that presumptive validity attaches; (3) there are sound public policy reasons (and a real public interest) in the monopoly/exclusionary rights that attach to patents and SPCs. The temporary monopoly is seen both as a reward for invention and as an incentive for inventors (especially, when it comes to SPCs in the pharmaceutical sector, a sector which offers particular benefits to humanity); (4) there is a public interest that the process whereby an extant patent/SPC may be challenged proceeds in an orderly manner and not in a way that lightly sets the rights of a patent-holder/SPC-holder at nought; and (5) Teva contends that it should be free to enter a market with an infringing product because its infringement would, among other matters, yield lower drug costs for the public. That is certainly a factor to be borne (and that I have borne) in mind; however, it falls to be viewed in the context of the preceding points. And I cannot but note that it wishes to enter the market at this time with what would be a product that assuredly infringes a presumptively valid SPC.

32. As can be seen from the facts already described, this injunctive application is concerned with a situation in which Teva seeks not so much to 'clear the path' but to arrive at the end of the path before it has been cleared, *i.e.* it wants to bring a generic to market without duly clearing away the boulder that sits in the path at this time in the form of an ostensibly valid SPC. I recall in this regard: the remarks by O'Donnell J. in *Merck*, at paras.19-23; the observations of Floyd L.J. in *Novartis AG* v. *Hospira UK Ltd* [2013] EWCA Civ. 583, §54 – where he squarely (and, if I might respectfully observe, rightly) lays at the door of generic manufacturers the blame for any ill-timing on their part that sees a trial date coincide with an intended launch date, and the simple and sensible exhortation by Jacob J. in *Smithkline Beecham plc* v. *Generics Ltd* (High Court, 23rd October 2001) that "*If there may be an obstacle in your way clear it out*", not 'vault over the obstacle so that you get to your desired end, leaving the path uncleared in your trail'. I do not consider that it greatly advances Teva's opposition for it to point (and it has pointed) to the fact that it has a marketing authorisation for its generic drug when a presumptively valid SPC remains sitting elephant-like in the room.

33. The trial of the revocation action will take place during the lifetime of the SPC. So the gravamen of Teva's complaint is that it would like to launch its generic for some commercial reason/s best known to itself at a time when the SPC remains extant. But that, with respect, is a

[14] See Cooke #1, §24 and Stomberg §34.

problem of Teva's own making – which in essence is what Floyd L.J. and Jacob J. were each getting at in the passages referred to above (in the context of the different cases before them). The point in time when Teva came to commence Teva's revocation proceedings was a matter within Teva's control. That said, Teva regrettably does have *some* cause for complaint as to how BMS has conducted itself in these proceedings. There was 'to-ing and fro-ing' between the parties at the hearing as to how the proceedings have been conducted to this point (and that finds echo in the affidavit evidence considered previously above). However, it seems to me that certain points cannot be disputed as a matter of historical fact when one has regard to that evidence: BMS defaulted on the delivery of witness statements; it failed to make discovery on time; it failed to reply to interrogatories on time; it failed to comply with its discovery obligations; it was ordered to make further and better discovery; it had to be ordered to deliver further responses to interrogatories; and only a couple of days before the trial was due to commence last year it announced that it had a new witness of fact.

34. It is important, however (if I might use a metaphor) not to 'over-egg the custard' in this regard. I do not see that BMS has at any point acted in a malign or improper manner or with any intention to defy the court or to ignore court orders. How it has acted has not always been optimal and that may yet fall to be reflected in costs. But at worst it is guilty of more procedural 'misdemeanours' than one would wish for (and one has to remember that even the best-run cases have undesirable episodes/delays in the run-up to trial and sometimes even during the trial).

35. As to the suggestion that BMS's behaviour is somehow analogous with that of the defendant in *Board of Management of Wilson's Hospital School* v. *Burke* [2023] IEHC 22, that is, with respect, fanciful. There, the defendant declined to comply with an *ex parte* injunction, was arrested and later brought to court, indicated to the judge who decided the interlocutory injunction application that he would not comply with any injunction the court would grant, was imprisoned until he purged his contempt, refused to purge his contempt and, upon release, quickly set about breaching the interlocutory injunction that had been granted despite having a financial penalty imposed upon him each time he committed a breach. Nothing similar presents here. (In passing, I should note for the avoidance of doubt that it has not been asserted that any member of BMS's legal team has at any point acted other than with the utmost propriety. Both legal teams, I note for the sake of good form, have always acted with complete propriety).

36. Although the point was not raised at the hearing it is not entirely clear to me how, in circumstances where the lawyers in proceedings (the people tasked with the carriage of proceedings) are not even alleged to be guilty of (and in point of fact are not guilty of) any impropriety, their clients/principals (who have entrusted the due carriage of proceedings to their lawyers) could nonetheless be found by me, when it comes to the carriage of the proceedings, to be guilty of impropriety so egregious as to merit the refusal of an injunction. However, this point was not raised and I have not brought it to bear in my considerations.

37. Three additional points might be made in this context. First, if BMS's actions were aimed at 'stringing out' the revocation proceedings, and I see nothing to suggest that this is what it has been doing, it would have done a pretty poor job, for the revocation action is due to be heard well within the lifespan of the SPC. Second, I do not see it as an inexorable consequence of any (if any – and here I see no) egregious behaviour that the necessary price to be paid by BMS for any (if any – and here I see no) egregiousness would be, in effect, to forfeit the benefits of its SPC through the refusal of the injunction it now seeks. Third, if it was always Teva's intention to proceed to market come what may (and I do not know if it was or is) I do not see what possible impact a delay in the trial date would have on it, for if it were now to choose to launch before its proceedings had been heard it would simply be doing what it always intended to do.

38. Teva complains in its submissions that it did not contemplate that the revocation trial would not be held until next July. I struggle to believe that a litigator as experienced as Teva did not contemplate in its planning that a trial could come on sooner or later than expected (or indeed precisely when expected) and plan accordingly. But I do not see that BMS has acted egregiously in this regard. The fact that the revocation trial is taking place next July, during the lifespan of the SPC, and without egregious behaviour on the part of BMS aimed at 'stringing out' the timespan of the revocation proceedings is really neither here nor there: Teva continues to get to bring its revocation application and (should it be successful) to clear the path well within the lifetime of the SPC.

39. A far more convincing point to me than Teva's complaints about the fact that it has taken time for the revocation proceedings to come on, and one that has given me very considerable cause to pause, is the fact that the equivalent patent to the Patent has been declared invalid in England (in *Sandoz Ltd* v. *Bristol-Myers Squibb Holdings Ireland Unlimited Company* [2022] EWHC 822). There are, I understand, no material differences, at least factually, between that

case and this. (There may or may not prove to be differences between English and Irish law when it comes to the law on plausibility; this will be tested at the pending trial in July). I am mindful in this regard of the duty incumbent upon me (as recently noted in *Norton (Waterford) Ltd t/a Teva Pharmaceuticals Ireland* v. *Boehringer Ingelheim Pharma GmbH & co KG* [2022] IECA 58) to give weight to the decision of the English High Court in *Sandoz*. I am mindful too that the priority date/filing date argument touched upon above was not raised in the English proceedings and that this may yet offer an additional ground for the revocation proceedings to succeed. However, by way of counter-consideration, (additional to the possible difference in the law as to plausibility) (i) the decision of the English High Court in *Sandoz* has been appealed (so the judicial involvement in the matter is still incomplete even if, pending a decision on appeal, the decision of the English High Court remains good and may be upheld), (ii) the SPC in this jurisdiction remains presumptively valid, and (iii) (a) there is surely a public interest in good order, *i.e.* in the observation of a process whereby the path is cleared and products then come to market, rather than (b) products coming to market when 'path-clearing' is still underway and where (c) they are allowed to come to market on the basis of largely uninformed speculation by an Irish court as to whether an English High Court decision will be upheld on appeal to the English Court of Appeal. On balance, these counter-considerations have prevailed in my considerations.

40. In passing, (i) I accept that the fact that an injunction was not sought in the United Kingdom is due ultimately to calculation as to how best to proceed in the context of the laws of that jurisdiction, that different laws pertain here, and that (regardless of similarities in law) it is perfectly feasible that the calculations in one jurisdiction might lead to a decision not to seek an injunction there, as opposed to seeking an injunction here, (ii) I notice that thus far in the proceedings that have unfolded between the parties in Europe (including in the European Union) there has essentially been a 'draw' between the parties to this time, so those cases do not really assist from a comity perspective.

41. Coming now to my concluding observations it will be recalled that O'Donnell J. identified in the following terms, at 36-37, the steps to be taken by a court in an interlocutory injunction such as that now presenting:

42. **"*(1) …*[T]*he court should consider whether, if the plaintiff succeeded at the trial, a permanent injunction might be granted. If not, then it is extremely unlikely that an interlocutory injunction seeking the same relief pending the trial could be granted."***

43. Clearly if BMS succeeds at trial a permanent injunction might be granted.

44. **"*(2) The court should then consider if it has been established that there is a fair question to be tried, which may also involve a consideration of whether the case will probably go to trial. In many cases, the straightforward application of the approach in* American Cyanamid*…and* Campus Oil *v.* Minister for Industry (No 2) *[1983] I.R. 88 will yield the correct outcome. However, the qualification of that approach should be kept in mind. Even then, if the claim is of a nature that could be tried, the court, in considering the balance of convenience or balance of justice, should do so with an awareness that cases may not go to trial, and that the presence or absence of an injunction may be a significant tactical benefit.*"**

45. It is not disputed here that a fair question arises to be tried (and if it were disputed it is perfectly clear from the pleadings in the revocation application that there is a fair question arising to be tried).

46. **"*(3) If there is a fair issue to be tried (and it probably will be tried), the court should consider how best the matter should be arranged pending the trial, which involves a consideration of the balance of convenience and the balance of justice.*"**

47. I have undertaken my analysis of the balance of convenience and the balance of justice previously above. All in all, I consider that the balance of convenience favours the granting of the injunction sought by BMS. I have had regard to all of the factors I have considered above. However, nine key factors stand out:

(1) Teva intends to engage in intentional infringement of BMS's SPC.
(2) Such infringement will cause loss to BMS that to some extent is not compensable in damages.
(3) The SPC enjoys a presumptive validity.
(4) The 'first mover advantage' that Teva wishes for at this time is an advantage that would see it infringe BMS's presumptively valid SPC.

(5) BMS is not seeking to injunct Teva from doing anything that Teva has a *prima facie* legal right to do.

(6) If Teva succeeds in the revocation proceedings, the calculation of Teva's damages will be complex; however, calculating BMS's damages will likewise be complex should BMS succeed.

(7) Insofar as I may have regard to the likely outcome of the proceedings, there are strengths and weaknesses in the cases that both sides seek to make. Neither side has an 'open and shut' case – but what BMS has is an SPC that is presumptively valid. I have explained my position regarding the decision of the English High Court in *Sandoz Ltd* v. *Bristol-Myers Squibb Holdings Ireland Unlimited Company* [2022] EWHC 822 (which decision is now under appeal). So far as the 'macro' picture in the UK and the European Union is concerned, the two parties have essentially scored a 'draw' thus far in their various proceedings and no advantage derives therefore from considering same further).

(8) I do not see that BMS's procedural 'misdemeanours' in the conduct of these proceedings should render it ineligible, in all the circumstances presenting, for the interlocutory injunctive relief sought.

(9) I do not see that the delay in the trial to next July has had an irremediable impact on the position of Teva.

48. "*(4) The most important element in that balance is, in most cases, the question of adequacy of damages.*"

49. Here there is effectively a draw when it comes to the adequacy of damages. So the other factors considered above have an especial resonance in the within application in terms of determining whether or not to grant the injunction sought.

50. "*(5) In commercial cases where breach of contract is claimed, courts should be robustly sceptical of a claim that damages are not an adequate remedy.*"

51. No breach of contract is claimed here.

52. "*(6) Nevertheless, difficulty in assessing damages may be a factor which can be taken account of and lead to the grant of an interlocutory injunction, particularly where the difficulty in calculation and assessment makes it more likely that any damages awarded will*

***not be a precise and perfect remedy. In such cases, it <u>may</u> be just and convenient to grant an interlocutory injunction, even though damages are an available remedy at trial.*"**

53. Here, as considered when damages were addressed above (in the context of the balance of convenience) the problem is really that there would be an element of loss that would not be compensable in damages. So damages would not be a precise and perfect remedy for BMS. I respectfully do not see how it could be just not to grant the injunction sought in such circumstances – especially when one has regard to the other factors presenting, including those touched upon under O'Donnell J.'s point (3) above.

54. "*(7) While the adequacy of damages is the most important component of any assessment of the balance of convenience or balance of justice, a number of other factors may come into play and may properly be considered and weighed in the balance in considering how matters are to be held most fairly pending a trial, and recognising the possibility that there may be no trial.*"

55. Please see my observations following O'Donnell J.'s point (6) above.

56. "*(8) While a structured approach facilitates analysis and, if necessary, review, any application should be approached with a recognition of the essential flexibility of the remedy and the fundamental objective in seeking to minimise injustice, in circumstances where the legal rights of the parties have yet to be determined.*"

57. I have taken the required approach.

F. Conclusion

58. Having regard to all of the foregoing, I will grant, on the terms sought, the injunction that BMS has come seeking.