THE HIGH COURT

[2024] IEHC 91

[2021 No. 1 PAP]

IN THE MATTER OF IRISH PATENT NUMBER EUROPEAN PATENT (IE) 1 427 415 "LACTAMCONTAINING COMPOUNDS AND DERIVATIVES THEREOF AS FACTOR XA INHIBITORS" AND REGISTERED IN THE NAME OF BRISTOL-MYERS SQUIBB HOLDINGS IRELAND UNLIMITED COMPANY

AND

IN THE MATTER OF THE PATENTS ACT 1992 TO 2019

AND

[2021 No. 4758 P]

BRISTOL MYERS SQUIBB HOLDINGS IRELAND UNLIMITED

PLAINTIFF

– AND –

NORTON (WATERFORD) LTD T/A TEVA PHARMACEUTICALS IRELAND

DEFENDANT

JUDGMENT of Mr Justice Max Barrett delivered on 2nd February 2024

SUMMARY

In my judgment of 8th December 2023, I held (among other matters) that Irish Patent Number EP (IE) 1 427 415 (the Patent) is invalid. By virtue of Art.15(1)(c) of Regulation (EC) No.469/2009 that invalidity triggers the invalidity of the related SPC. By notice of motion of 15th December, BMS has come seeking (i) a stay pending an appeal to the Court of Appeal from so much of my judgment of 8th December as held the Patent to be invalid, and (ii) (a) a continuation of the interlocutory injunction that I ordered on 23rd March 2023 (following on my judgment of 17th February 2023) pending the outcome of the appeal against my judgment of 8th December, or (b) 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 a generic version of Eliquis (active ingredient apixaban) pending the outcome of the appeal. In this judgment I explain why I will grant a stay on the revocation of the Patent and its removal from the register, and why, respectfully, I will not grant the injunctive relief sought.

A. Introduction

1. The facts underpinning these proceedings have been described in my judgment of 8th December 2023. In that judgment I held, among other matters, that the Patent is invalid. By virtue of Art.15(1)(c) of Regulation (EC) No.469/2009 that invalidity triggers the invalidity of the related SPC.[1]

2. By notice of motion of 15th December, BMS has come seeking (i) a stay pending an appeal to the Court of Appeal from so much of my judgment of 8th December as held the Patent to be invalid, and (ii) (a) a continuation of the interlocutory injunction that I ordered on 23rd March 2023 following on my judgment of 17th February 2023 pending the outcome of the appeal, or (b) 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 a generic version of Eliquis (active ingredient apixaban) pending the outcome of the appeal.

3. I note that:

[1] *I.e.* Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6th May 2009 concerning the supplementary protection certificate for medicinal products (OJ L152, 16.6.2009, 1-10). Article 15(1) provides, among other matters, as follows:

> "*The certificate* [the SPC] *shall be invalid if...(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation*."

(i) what must be sought by BMS at this time is a fresh injunction, not a continuation of the injunction that I granted following on my judgment of 17th February last. That injunction was an injunction "*pending the determination of the proceedings by the High Court*". Those proceedings were determined in Teva's favour (so far as the validity of the Patent is concerned) in my judgment of 8th December last. With that determination, the previous injunction expired. So what is being sought now is a fresh injunction against Teva (and, I note, Teva alone). I am buttressed in my view that the injunction now being sought is a fresh injunction when I have regard to the judgment in *MP v. Teaching Council of Ireland* [2019] IEHC 148, §24.

(ii) just because the previous injunction was granted does not of itself entitle BMS to another injunction at this time (per Clarke J., as he then was, in *Harding v. Cork County Council* [2007] IEHC 31, §3.7).

(iii) for what it is worth, there appears to be no reported case in this jurisdiction in which a generic company succeeded in revocation proceedings but was then injuncted from launching its generic product pending appeal. (I say 'for what it is worth' because this may simply indicate that no such injunction was previously sought.)

(iv) there has been indication at Supreme Court level in the past that the jurisdiction to grant an injunction pending appeal should be exercised sparingly (*Cosma v. MJELR* [2006] IESC 44, 3.)

4. I note also that:

– O'Donnell J., as he then was, in *Krikke and ors v. Barranafaddock Sustainability Electricity Ltd* [2020] IESC 42, §16, held that a court in considering a stay (but the same surely holds true in the context of an application for injunctive relief)

can "*properly have regard*" to the first instance decision of a trial court reached "*by a trial judge after a lengthy hearing and...an opportunity to assess the facts and law, and the attitude of the parties, in much greater detail than is inevitably available to a court hearing a preliminary stay application*",

– "*significant deference*" (see *Re Boehringer Ingelheim Pharma GmbH & Co KG* [2022] IECA 58, §105) will be afforded by any appellate court to my judgment of 8th December, particularly given what I described in §1181 of that judgment as the "*abundant evidence*" on which it is based, and

– in *Donegal Investment Group Plc v. Danbywiske, Wilson* [2017] IESC 14 Clarke J., as he then was, observed at §5.7 , that "[A]*n appellate court should show significant deference to the views of a trial judge on the question of findings based on expert evidence*".

5. The observations quoted in the preceding paragraph are (obviously) observations made by appellate court judges, not by me. Clearly any appellate court called to adjudicate upon any appeal from my judgment of 8th December last will do what it considers to be required by law. However, what the just-quoted references do mean is that some weight can be attached by me in the present application to my judgment of 8th December last, being a considered judgment given by a trial court following a lengthy and complex case and abundant oral evidence.

6. As mentioned, in the within application BMS seeks both a stay and injunctive relief. The reader might wonder why one would need both a stay and an injunction. I cannot better the explanation that was provided to me in this regard by counsel for BMS (whose submission I respectfully accept as correct):

> "*Our submission is that the difference between the stay and the injunction is as follows: If the stay is refused, then the right disappears* [from the register of patents] *as against all. In respect of the injunction, the parties are at least bound within these proceedings. So, insofar as BMS is suing Teva, if an injunction is granted, Teva is restrained from the market. If an injunction is not granted and we come to the end and*

the right is reinstated, then obviously BMS would be seeking damages from Teva in relation to that. BMS does not have an existing action with all the world in which it can potentially seek that kind of relief. Now, depending on the circumstances, Judge, obviously people can be written to and so on. But the real danger of a stay is, the right disappears from the register; as a matter of law, there is no obstacle to anybody using the technology, and people who do use the technology can simply say 'I have accrued rights in the meantime'. In this particular case, there is the extant action which at least binds the parties into some kind of relationship....And I think…[the lead counsel for BMS] *also mentioned this morning that there may be issues in relation to reinstating a right that is removed, in circumstances where there's no process for that set out in the Patents Act. So it is a very radical step, and it is a step that we believe is unprecedented, would be unprecedented, the refusal of a stay, in circumstances where it was requested and where there was an appeal pending.* [The lead counsel for BMS] *reminds me, of course our case is, though, that if the injunction was refused, it would also destroy our exclusivity temporarily. But in that instance, I think the difference between the stay and the injunction is if the right is reinstated on appeal, it would be much more difficult to say we've accrued rights and we can continue to use. The stay is, if I could put it this way, Judge, a sort of turbocharged removal of exclusivity that may never be reclaimed. The injunction threatens the same thing, in fact, but is not quite so devastating in terms of removing a right that, at the moment, is there on the register and that informs people that there is a registered right over this technology.*"

B. The Stay

7. The stay element of this matter can be swiftly dealt with. In *Re Lobar Ltd* [2018] IECA 129, Irvine J., as she then was, summarised the existing authorities on the principles to be applied by a court on an application for a stay in the following terms:

> "*15. The aforementioned authorities make clear that the court is bound to engage in what is often described as a two-stage test. First, the applicant must demonstrate that they have an arguable ground of appeal and is one which is* bona fide *rather than tactical.*
>
> *16. ...Assuming...the appellant demonstrates a* bona fide *and arguable ground of appeal, then the court must consider where the balance of justice is to be found.*"

8. The parties to the within proceedings are agreed that BMS has shown that it has one or more arguable grounds of appeal. (Teva believes that BMS will not succeed in any of its grounds of appeal but is satisfied that they are arguable, which is, in any event, a notably low threshold.) When I read the draft grounds of appeal appended to BMS's written submissions, I respectfully agree with the parties that BMS has shown that it has one or more arguable grounds of appeal. I am not even sure that it is contended by Teva (and, if it is contended, how strenuously it is contended) that BMS's grounds of appeal are tactical rather than bona fide. However, in what have been long and hard-fought proceedings in which BMS clearly and genuinely believes that the Patent (and hence the SPC) are valid and in which BMS has kindly furnished me with the draft, arguable grounds of appeal, I entertain no doubt whatsoever but that BMS's intended appeal is bona fide rather than tactical. I will, therefore, grant a stay on the revocation of the Patent and its removal from the register. My judgment as to validity remains extant and un-stayed. The stay will endure to the conclusion of the first directions hearing before the Court of Appeal. At that point it will be over to the Court of Appeal to proceed as it wishes.

9. I note in passing the arguable ground pertaining to the decision of the Enlarged Board of Appeal of the EPO in Case G2/21 and of the Technical Board of Appeal in Case T/116/18, a point which, having regard to the submissions of BMS at the hearing of the present application, seems likely to me to result in an eventual appeal to the Supreme Court. Were such an appeal to occur the SPC would effectively have expired before Teva had any opportunity of getting on the market. That is surely a factor to be borne in mind when deciding whether or not to grant the injunction now sought.

C. The Injunction Now Sought

10. The application for the stay addressed, that leaves me to deal with the injunction application. It will take a little longer to explain my reasoning in this regard. I will begin, if I may, by describing BMS's case as to why it *should* now get the injunction that it has come seeking. In doing so, I am effectively describing BMS's case at its height. Later below, I will explain why I consider that BMS's application for an injunction, as advanced by BMS before me, *i.e.* even at its height, should not now succeed.

D. The Case Advanced by BMS

11. In this section D, headed 'The Case Advanced by BMS', I deal with the adequacy of damages and balance of convenience arguments *as made by BMS*. Unless I expressly indicate otherwise, (i) I merely recount in this section what has been submitted to me by BMS, and (ii) I do not in this section express any view on what I make of BMS's submissions in this regard. In effect, what I am doing is setting out BMS's case at its height.

12. For anyone reading this judgment who is not familiar with these proceedings, it may assist for me to note that my judgment of 17th February 2023 in which I indicated why I would grant an injunction at that time was subsequently appealed unsuccessfully to the Court of Appeal; Teva then sought leave to bring a further appeal to the Supreme Court but its application for leave was refused, leaving the judgment of the Court of Appeal as the 'last word' on the initial bout between the parties regarding interlocutory relief.

13. As counsel for BMS noted, the Court of Appeal and myself have already made findings, as between the parties to these proceedings, in respect of adequacy of damages if an injunction goes against one or other of them and the party against whom it goes is ultimately vindicated (and BMS submits that, for the most part, it does not much matter whether the ultimate vindication comes in the first instance or on appeal). In this regard, counsel for BMS referred me to the judgment of Clarke J. in *CC v. Minister for Justice* [2016] 2 IR 680, where he observed, at 696-697, that:

> "*In principle, the risk of injustice is just the same if one grants or rejects an application for a stay or injunction pending trial or if one grants or rejects an*

application for a stay or injunction post-trial and pending appeal. The risk is that the case will ultimately turn out in such a way that, with the benefit of hindsight, a party will have had its rights interfered with by the presence or absence of an order. In one case, what may confer that hindsight may be the result of a trial. In the other case, hindsight may be conferred by the result of an appeal."

14. BMS rightly accepts that changes in fact may affect the findings that the Court of Appeal and myself have already made. However, its submission is that such changes as have occurred in this case, since the interlocutory injunction of last year was granted, overwhelmingly support the grant of the injunction now sought.

15. At §21 of my judgment of 17th February last, I identified the three types of damages that BMS asserted it would not be able to be compensated for in damages: (i) damage that could not be compensated because of difficulty of calculation; (ii) damage that could not be compensated because it would be permanent (this was the price-drop, that BMS said it would not be able to raise); (iii) damage that is not compensable in money terms (the loss of exclusivity).

16. Turning to (iii) (loss of exclusivity) first, there was a submission in the written submissions received from Teva regarding this application that BMS had abandoned this head of damage as a head of incalculable damage and that it was right to do so. However, it was confirmed to me at the hearing that BMS has not abandoned this head of damage.[2] Counsel brought me in this

[2] I have been provided by BMS with evidence in this regard. Thus:

(1) Mr Cooke (Aff.1, §38) observes as follows, under the heading "*Loss of Exclusivity*":

> "*In my earlier affidavits, I gave evidence as to the impact of loss of exclusivity for apixaban under the SPC that generic entry on the market would entail. As I already stated in that regard, he chief impact would be the rendering redundant of business plans for Eliquis made on the basis of the full statutory period of the SPC, and the loss of the ability to make further plans. I respectfully say that this would be a very significant business impact and a systemic blow if it contributed to an inability to engage securely in such business planning for other products in the future.*"

(2) Mr. Stomberg (Aff.1, §§ 45, 47 and 48) observes as follows, under the heading "*IP Rights Provide Incentives to Innovate*":

> "*45. The risk of irreparable harm introduced by Teca or other competitors being (possibly temporarily) allowed to launch at risk is potentially systemic. Public interest arguments raised in favour of allowing Teva to enter before the full appellate process resolves necessarily focus on benefits in the here and now – known in economics as static short-run gains. The money that the HSE can save today by paying less for apixaban is no doubt considerable. Once an invention has been created, there will always be a short-run benefit to consumers if the fruit of that IP is passed along for a bargain price. However, the losses here are felt not only by BMS, but by an entire industry deeply reliant on a different bargain that was struck long ago to stimulate a stream of innovative medicines that all will eventually face future generic drug competition.*
>
> *...*
>
> *47. 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 Joseph di Masi et all finds that fewer than 12 per cent of investigational compounds that initiate human trials achieve clinical approval in the US and that it costs an average of $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.*
> *48. 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 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 endeavours. Effectively the*

regard to my judgment of 17th February last, in particular my observations at §§27 and 28, where I state as follows:

> "*27. Where Teva has struggled in this case is with point (3)...*[I]*t 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.*
>
> [I then footnote certain evidence of Mr Cooke[3] and Dr Stomberg,[4] who gave evidence as to the impact of loss of exclusivity on an ability to plan on the basis of the full statutory exclusivity period. The point (3) to which reference is made, is a point that features in §21 of the judgment where I state as follows:]
>
> "*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...(3) there would be damage that is not compensable at all, in particular the loss of exclusivity that goes with being an SPC holder.*

> *cost of capital may rise in response to this increased risk. This shift in the balance of expected future benefits would have a cooling effect on the system that could bring the next apixaban to the table. Those spillover effects are not just felt 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*".

In effect, Mr Stomberg canvasses what, in legal parlance, is something of a 'floodgates' argument, *i.e.* if the court proceeds as Teva seeks then (on Mr Stomberg's view of the world) adverse systemic consequences could ensue.

[3] Mr Cooke is Senior VP, Worldwide Commercial Cardiovascular and Established Brands of BMS. Formerly he was the general manager of the business of the BMS group in the UK and Ireland.

[4] Dr Stomberg is an economist and the managing director of NERA Economic Consulting. He has been engaged to give evidence on behalf of BMS.

> [I indicated previously above that unless expressly indicated otherwise, I do not generally in this section express any view on what I make of BMS's submissions in this regard. In effect, what I am doing is setting out BMS's case at its height. Here, the view I express is as follows. It is necessary when reading my earlier judgment to recall that the position which now presents is that in my judgment of 8th December last I held the Patent not to be valid (and so the SPC likewise falls). That is by no means a determinative factor when it comes to the present application but it is a relevant factor which presents now that did not present in February of last year and which falls to be taken into consideration when determining whether the present injunction application should succeed.]

17. In her judgment (on Teva's appeal from my judgment of 17th February), Costello J., for the Court of Appeal, observes as follows:

> "*61. Mr. Potter's evidence*[5] *was accepted by the judge by and large, but it did not address the entirety of BMS's case in relation to the inadequacy of damages as a remedy for the wrongful infringement of its SPC. As was pointed out by O'Donnell J. in* Clonmel *at para. 60:-*
>
> > *'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*

[5] Mr Potter is the founder and a director of Charlwood Pharma Ltd. He has been engaged to give evidence on behalf of Teva.

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.'

62. *The same consideration applies in this case and there was no evidence on behalf of Teva which would have enabled the High Court or this Court to distinguish this case from the decision in* Clonmel*. Indeed, the conclusion of O'Donnell J. that damages could not be said to be a full or adequate remedy for Merck so as to exclude the necessity to seek an injunction is further analogous to the situation in these proceedings as, in each case 'the calculation is complicated further by the possibility of entry up to* [in the case of Clonmel] *four other generic producers' while in this case it is up to five.* [It has since risen to eight].

63. *I am satisfied that there was ample, credible evidence before the High Court to conclude that damages would not adequately compensate BMS in the event that the injunction was refused and it ultimately succeeded in the revocation action. There was no countervailing evidence from Teva in*

relation to the third category of damages which would warrant the High Court reaching a different conclusion."

18. What Teva appears to now wish to do – per counsel for BMS – is to say that BMS is not relying on that head of damage, but BMS *is* relying upon it. Loss of exclusivity is the first head of damage that BMS is relying upon here. BMS submitted in this regard that findings have already been made by the Court of Appeal and myself and no fact has intervened to change that finding and no fact has been suggested by Teva to change that finding.

19. The second category of damage that BMS contends cannot be compensated for arises from complexity. Last February, I did not accept BMS's case in this regard, that case being that the underlying market before generic entry, is complex: Eliquis competes with other direct oral anticoagulants and Warfarin and there is also parallel importation, so it is a moving system, which, if no fresh injunction is granted, will see generic competition enter into that system. In this regard, I recall para.25 of my judgment of last February in which I stated as follows:

"*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. 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.*"

20. I was making two key points in that paragraph. First, I had not seen enough evidence that other generics would enter, but I accepted that the calculation would be more challenging if they did. Second, my sense was that even if other generics entered, it seemed to me that the height of BMS's case in this regard was that a challenge would present in calculating damages, not that it would be impossible.

21. It was on the 'not that it would be impossible' dimension that counsel for BMS focused during oral submissions at the present injunction hearing. She submitted that on the basis of the facts that I address immediately hereafter, there is a danger that large elements of BMS's loss would not be compensated in damages, *i.e.* that there will be extreme complexity which heightens the risk that it would leave portions of damage uncompensated if I do not grant the injunction now sought. BMS maintains that this is the situation that presents.

22. The particular complexity that now presents, per BMS, is that there are now eight generics with marketing authorisations. Two of them have published reimbursement prices. (The word 'published' here has a particular resonance as, during last year's interlocutory injunction, Teva indicated that it had a reimbursement price that was not published. So the possibility cannot be excluded that there are now other generic producers with reimbursement prices or on their way to getting them, but that is not evident from the published material). One of those generic suppliers with a reimbursement price, Mylan, has had to be restrained and I have separately granted an interim injunction in relation to its actions. Additionally, the HPRA has indicated that Eliquis and other generic apixaban are interchangeable: this is an occurrence with very specific consequences under statute. There has been a change in the underlying market, even without generic competition, in that, one product, dabigatran has gone off patent and it seems that generic suppliers are getting ready to supply. And rivaroxaban, another direct-acting oral anticoagulant, is due to go off patent in April and it appears that generic supply is 'ramping up' in relation to that.

23. So, the facts now are that, to borrow from the wording of counsel for BMS at the hearing before me "[T]*here is a gathering at the gate of generics*". There is no dispute that other generic companies are likely to come in now. Neither is there a dispute that this situation will create a real impact on price. The dispute is as to calculability of damages. The changes in the market have been summarised in Mr. Cooke's first affidavit. His averments are helpful and informative, though I trust he will forgive me if, in the interests of brevity, I include BMS's summary at §6.5 of its written submissions, where it describes the key points presenting in this regard in the following succinct terms:

> "*(a) Developments in the structure and operation of the market for oral anticoagulants in the State and specifically (i) Dabigatran went off patent in August 2023, two generics obtained*

marketing authorisation for generic dabigatran etexilate... and of those Accord has now received reimbursement pricing approval....(ii) Rivaroxaban is due to go off-patent in April 2024 (albeit with the potential for continuing exclusivity for certain dosing regimens) and seven marketing authorisations for generic rivaroxaban are listed on the HPRA's website.

(b) The increased potential for generic suppliers of apixaban to enter the market, with a further two such suppliers...obtaining marketing authorisation since the grant of the interlocutory injunction, thereby bringing the total to eight....

(c) Teva and Mylan are now in a position to launch immediately as each has obtained reimbursement prices from the HSE (effective 1 October 2023 and 1 June 2023 respectively) so that their products can be supplied under the State-funded supply schemes which account for the vast majority of the market for anti-coagulants in the State....

(d) The HPRA has determined that ELIQUIS®... and each of the currently licensed generic apixaban products (apart from that of [one company]...) are 'interchangeable' within the meaning of sections4 and 5 of the Health (Pricing and Supply of Medical Goods) Act 2013 and the products have been listed as such on the List of Interchangeable Medicinal Products, as published on 8 November 2023.... Pharmacies are required to offer the cheapest (to the State) available interchangeable product (where an interchangeable group has been established by the HPRA), regardless of whether the prescription specifies the product in the common name or the brand name. Accordingly, if Teva is permitted onto the market, pharmacists will have to offer Teva's generic apixaban to patients first, even if the prescription specifies ELIQUIS®, unless a clinical exemption as specified by the prescriber applies. This will leave BMS with the choice of dropping its price to try to preserve some element of its market against the possibility that Teva will be able to remain on the market, or watch its market

share reduce drastically in a very short time.... If BMS reduced the price of ELIQUIS® it is unlikely that it could subsequently restore it to its original level....

(e) The HSE has redoubled its efforts to encourage savings to the State via generic supply."

24. As to the implications of the foregoing, Dr Stomberg deals with these in Stomberg, Aff. 1 20th December 2023, §§20 and 21, where he avers as follows:

"*20. Apixaban is likely to face vigorous competition from other generics if the interlocutory injunction against Teva is not continued. As it currently stands, there are at least eight registrants that have applied to have generic copies of apixaban sold in Ireland.... Academic studies confirm that drugs with higher sales (especially blockbuster drugs with total sales greater than $1bn p.a.) attract more generic entrants than drugs with lower sales.... The high value of these markets raises the stakes for generic entrants, which is what entices entry. Apixaban is just such a drug since it appears in the number 2 position on the 'Top 100 Products by Ingredient Cost' list produced by the HSE. This is due both to its widespread use...and relatively high per-unit cost.... It is thus a high stakes product for generic manufacturers, and it should be expected that many registrants would be waiting in the wings to sell apixaban,*

21. It is also realistic to expect that other generic registrants may appear as well. Some generic manufacturers, like Sandoz, already produce and sell apixaban products in other countries, such as Canada and the UK.... In addition, their incremental costs of launching in Ireland may be relatively modest since some of the groundwork needed for approvals in other countries has already been done (e.g., completion of bioequivalence studies, validating facilities, securing and validating API supply). In light of the court's

recent ruling against BMS [- this is a reference to my judgment of 8th December -]*, and potential registrants' assessments of the likelihood that BMS's appeal succeeds, as well as other factors like the likelihood of other generic entry...there may be further generic entry.*"

25. I should mention at this juncture that a confidential exhibit was placed before me by BMS during these proceedings which indicates that it has been in correspondence with certain generic suppliers from whom there either has been (i) no response in terms of a request for an undertaking not to market or (ii) an assurance that can be reversed on quite short notice. In other words, that correspondence shows that there is no solid assurance from those generic suppliers that they will not seek to come onto the market if the situation with Teva changes. Mr. Stomberg does not have access to that material, so in the above quoted text, where I have inserted the first set of ellipses, he lists the eight generic suppliers who have marketing authorisations [though I note that receipt of a marketing authorisation is not a guarantee of a subsequent launch].

26. Moving on in his affidavit, Mr Stomberg avers as follows (addressing, in effect, why generic suppliers would want to supply now under the heading "*Entry timing is key to profits for generic manufacturers*"):

"*23. The number and entry timing of registrants that ultimately compete will have a significant impact on market outcomes, such as prices and the total number of generic prescriptions sold. Many academic studies confirm that generic drug prices tend to decline as more manufacturers compete; this can adversely affect the profitability of later generic entrants.... As I discussed in my previous affidavit, generic manufacturers are advantaged if they face fewer competitors. Thus, generic manufacturers have a strong incentive to enter earlier than their competitors.*

24. Apart from those incentives, there is also a greater and separate incentive for generic companies to launch competing products when pre-generic brand prices are higher. A 2013

report by the...ESRI...noted that this occurs in Ireland because the HSE sets generic reimbursement relative to the pre-generic price of the branded product.... I note...that this logic remains applicable today for apixaban, with maximum prices of both branded and generic products being linked, post-expiry, to the reimbursement price of the branded product on the 1st of October 2021.... The authors of the ESRI Report...noted that competition among the generic manufacturers for 'shelf space' at the pharmacy would shift those margins to the pharmacy – presumably due to the 'substantial discounting' of generic products referred to elsewhere in the report and described by Mr Cooke in his affidavit. While the opportunity to enjoy higher market shares and profits may bolster Teva's desire to enter early, it is not unique in this regard. The other registrants will also be looking for an opportunity to enjoy the same benefits of early entry."

27. Mr Stomberg then moves on to address the issue of interchangeability, observing, amongst other matters, as follows:

"*25. The recent designation that Eliquis (apixaban) 2.5 mg and 5 mg and apixaban generics are each interchangeable would further exacerbate the incentives of generic manufacturers to launch early. Interchangeability would heighten price competition between competitors because of the increased ease of switching between products and the increased importance of price in determining which products are offered to patients (as I discuss in more detail later). As such, the interchangeability designation would provide further incentives for generic manufacturers to launch ahead of their competitors.*

26. It is also my understanding that Teva gains no special period of market exclusivity as a result of launching its revocation proceedings against BMS.... With the data exclusivity period

for apixaban expired, any of the other generic manufacturers may enter as and when their registration is complete, and with similar risk considerations as Teva. There is nothing blocking them, other than their own assessment of the risks and benefits of those actions."

28. In the next section of his affidavit, under the heading "*The Role of Information generated by Teva's SPC Litigation*", Mr Stomberg moves on to discuss the significance for other generics of what happens with Teva in the present proceedings, averring among other matters as follows:

> "*27. Teva's potential generic competitors have not invested in challenging BMS' SPC for apixaban; they nevertheless benefit from Teva's efforts to remove entry barriers and 'clear the way' for apixaban generics in general. Teva's favourable decision in the proceedings against BMS' SPC for apixaban will become known to all registrants.*
>
> *28. ...The actions of the court also communicate information to not just Teva but also other generic competitors. If the court issues a stay of the order pending appeal and a continuation of the injunction against Teva, that decision will also communicate information that may reduce the likelihood of other generic competitors entering at risk, which would reduce the likelihood of irreparable harm as I discuss elsewhere in this affidavit.*"

29. Counsel for BMS pointed in this regard to the position that pertains as regards Mylan (against whom I have issued an interim injunction), observing that Mylan has essentially hitched its fortunes, thus far, to what happens to Teva and has threatened to launch if, in the first instance, the interlocutory injunction appeal in the Court of Appeal did not go BMS's way (as it happens BMS won), and so on. So Mylan seems, per counsel for BMS, to be a solid example of the ability to assess risk according to what happens in this litigation with Teva. This is why BMS says that if the injunction is not given, not only would it mean that BMS's exclusivity vis-à-vis Teva would be removed, at the very least pending appeal, but that it is also very likely to encourage other generic entry.

30. Mr Neill, one of Teva's expert witnesses,[6] points to the market changes likely to occur following on the entry of generic companies, opining as follows under the heading "*If the Injunction is not extended*" in his affidavit of 21st December 2023:

> "*22. Based on internal modelling and previous experience, if Teva were to launch on its own and exercise its first mover advantage, it is expected that over the course of the first 2-3 months, roughly 70%-80% of the apixaban market would move to generic apixaban and Teva would obtain and hold this percentage of market share for at least several months. In the months that follow as other generics enter the market, Teva expects to maintain roughly a 40% market share of the generic portion of the market.*
>
> *23. In the event that Teva enters the market at exactly the same time as Mylan (i.e. if BMS's injunctive applications against both parties are refused). Teva expects the same portion of the market to move to generic apixaban (i.e. 70%-80%). In circumstances where two generics enter the market at the same time it is much more difficult to predict an outcome, however it is not unreasonable to expect that this would result in a relatively even split in the generic market between Teva and Mylan.*"

31. The real issue between the parties in this regard, as I see matters, is how damages can be calculated and whether that calculation will give BMS compensation for the full amount of its loss in these new circumstances. In this context, Mr. Neill and Mr Potter deal, in the following terms, with the difficulty of calculating damages in this new scenario where you have multiple generics coming into the market. Thus:

– Mr Neill indicates as he indicates in §§22 and 23 of his first affidavit (as quoted above), continuing as follows into §24:

[6] Mr O'Neill is the director of generic medicines for Teva.

"*24. In these scenarios, BMS' loss of market share would be easily measurable, if necessary, using IQVIA data. Likewise, in calculating any loss, its price would be calculable, being the stable price prior to the competition by Teva (and Mylan, as the case may be).*"

– Mr Potter indicates as follows at §§24-26 (under the heading "*Quantifiability of Losses in Scenario 1B*"):

"*24. BMS's losses are calculated in the same way as Scenario 1A, calculating the loss in total. The number of participants does not change the process of the calculation described above and in my Previous Affidavits. Once the total loss is calculated the proportion attributable to each of the generic companies entering the market must be decided.*

25. This apportionment can be made based on the quantity of product supplied into the market by each generics company on a pro rata basis.

26. Therefore, as with Scenario 1A, the losses can be calculated with a good level of accuracy and the attribution of these to each of the generics companies can be made based on volume as a suitable basis for allocation."

[Scenario 1B is where "[t]*he interlocutory injunction is not granted and Teva's apixaban is placed on the market, and other generics are also permitted to do so. At the final determination of the Appeal, judgment is handed down finding the patent is valid and infringed and, accordingly, generic apixaban including Teva's, is removed from the Irish market. BMS seeks damages from Teva and any other generics companies which have marketed apixaban for the losses it has incurred as a result of generic apixaban wrongly being available on the Irish market in the interim*"].

32. So essentially as can be seen from what both of the just-quoted expert witnesses state is that it would be relatively easy to apportion damage to BMS as between the various generic companies. They also say that changes in the underlying market would not have any real impact and would not add any further element of complexity. Dr Stomberg (in his replying affidavit, 5th January 2024) gave alternative evidence in relation to complexity, opining as follows:

> "*Calculability of BMS Damages*
>
> *20. Each of the Teva Deponents claims that BMS Damages are easily calculable. There are three main points of dispute on this (see, e.g., Second Neill Affidavit...). First, they claim that parallel imports are not a hindrance to the reliable calculation of damages (they can be assessed based on historical data that BMS has access to). Second, they claim that the presence of multiple generic competitors is readily captured in actual world transactions and thus easily identified. And third, it is claimed that entry of generics in related therapeutic categories (DOACS) is unlikely to affect prescribing of apixaban in either the actual or but-for world. I address each of these points in turn.*
>
> *Parallel Imports*
>
> *21. Mr Neill and Mr Potter assert that the volume and price of parallel-traded apixaban are knowable. While this may be true, it misses the point. In a damage calculation but-for parallel-traded apixaban would have to be predicted. As I discuss in my January 2023 Affidavit, the issue with parallel imports...is their inherent unpredictability. The two components of parallel trade - price and volume - vary considerably from time period to time period. According* [to] *the 2013 ESRI report, parallel imports come from countries*

where prices could vary by as much as 30%. Similarly, parallel imports have historically ranged up to 50% of apixaban sales.

22. *Neither the source country (and therefore price and margin), nor the volume of parallel imports available in Ireland are under BMS control. As a result, it is difficult or impossible to forecast ahead of time what the prices and volumes of parallel imports are likely to be at any one time. By the same token, it would be difficult or impossible to reliably predict what prices and volumes of parallel imports would have been in a but-for world that did not happen. So, while BMS may have the ability to look back at past apixaban sales in Ireland to assess what parallel trade was, and what average prices were, it cannot reliably infer what average prices will be from these data.*

Multiple Generic Entrants and Damages

23. *With respect to the entry of multiple generics, the Teva Deponents argue that, because their role is reflected actual-world volume and price data; there is no prediction to be done. One can, they assert, simply collect the IQVIA data for these products and tot up the figures.*

24. *The issue here is, however, more subtle than that and has to* [do] *with the effect of entry on prices which causes spillover effects and greatly complicates who may actually be responsible for damages.* [The point here seems to be that in a scenario where a price is depressed, it is very difficult to attribute the proportions of the depression on price to various generics. It is not just generic A sold X units, generic Y sold Y units and essentially attribute the loss of BMS in proportion.] *This is in addition to the complications introduced by confounding factors unrelated to at-risk entry that may affect prices.*

25. *Consider the following hypothetical. A first manufacturer enters at risk and drives a generic drug's prices down relative*

to the brand's price. If a second manufacturer enters, it likely causes a further lowering of generic prices. This creates a spillover effect that lowers prices received by all generic sellers, including the first manufacturer and all subsequent entrants. This spiral continues as more companies enter and further bid generic prices down. This dynamic greatly complicates the analysis of which party caused what quantum of damages supposing these manufacturers were subsequently found to be violating a valid patent. These cross-effects are largely driven by changing prices due to competitive conditions. Adding further real-world complexities of the competitive environment, such as differentiated prices to different pharmacy customers and changes in supply and demand conditions unrelated to the entry dynamic further complicates this already tangled puzzle.

Entry of Generic Therapeutic Alternatives

26. *Teva's Deponents do not argue that changing competition from other products in the same therapeutic category as apixaban are irrelevant. Instead, Mr. Potter argues that these would either have negligible effects (e.g., dabigatran), or that the effects are readily measured from trend analysis or the planning documents of the brand....*

27. *It is simply supposition to assert that an event such as loss of exclusivity for a product in a related category is likely to be negligible. Data such as internal forecasts can also be misleading. Pharmaceutical companies frequently make forecasting mistakes, and their forecasts are not always 'best estimates.' Sometimes they reflect a goal rather than a forecast. Knowing one from another is not always easy. Potential impacts can also be missed because the unexpected happens - such as a product withdrawal or the publication of a new study.*

...

29. Ultimately the issue here is that the brand faces competition not only from generics, but also potentially from a variety of branded products. If generics are allowed to compete with the brand, then information would be completely lost on how, in a but-for world, sales would have responded to changes in the competitive environment. Sales of the generics are unlikely to respond similarly and are not necessarily a good proxy for the response of the brand."

33. Mr Potter's response to this evidence, in his replying affidavit, was as follows:

"*19. Dr Stomberg also makes the assertion that this price spiral and the companies responsible for driving it have an impact on the allocation of damages.... The price spiral and the degree of its progression will have an impact on the quantum of damage (by eroding BMS volume and ability to compete) but does not add any difficulty to the allocation of those damages which is not further complicated by additional price competition.*

[I do not fully understand this last sentence. I suspect that what Mr Potter means is that the price spiral and the degree of its progression does not add any difficulty to the allocation of damages which is not already generated by the fact of additional price competition. However, I accept that this is not what Mr Potter expressly states and that what he does state is regrettably unclear.]

BMS losses are driven by the volume of the market in any one month, valued at appropriate historical pricing, less costs, compared to the factual position. This loss may be

appropriately allocated to the generic companies on the basis of those companies' respective sales volumes.

20. *Dr Stomberg comments on the wider DOAC market and how this may vary between the factual and counterfactual in Scenario 1A or 1B, suggesting that historical trends and BMS' own forecasts may not be a reliable basis for the estimation of a counterfactual market in these Scenarios.... I however respectfully consider that such trends and forecasts are likely to be reliable, to an appropriate level of accuracy –*

[Counsel for BMS drew my especial attention in this regard to Mr Potter's use of words such as "*trends*", "*forecasts*", "*likely*" and "*appropriate*", adding "*I'm not sure...what level of error Mr Potter considers would be appropriate, but it's clearly not exact, Judge, is the point I want to make.*"]

– as there is to my knowledge no suggestion that BMS' internal forecasts would be a goal, rather than a forecast. My experience of large multinational pharmaceutical companies is that a forecast is carefully constructed with considerable input to represent the expected outcome. In situations where there is considerable uncertainty, it is usual to create a forecast with a base case, an upside case and a downside case, establishing boundaries within which the result is expected to fall. Further, such internal forecasts are frequently relied upon as a part of the process of establishing a counterfactual in any damages enquiry.

[Counsel for BMS observed in this regard, "[A]*gain, the question must be asked: What is the degree of error that is considered to be appropriate? And what we submit is that that process could never guarantee, or even reliably predict, that all elements of loss are going to be captured in that process.*"]

21. *The dabigatran example described by Dr Stomberg in detail at paragraph 28 may cause a small deviation in the market trend should BMS remain in a position with no generic apixaban competition. This is because, as described above, over the relatively short period in question changes in prescribing practice are generally slow to take place.*

[BMS contends that in fact any calcification in the supply and pricing of medicines that may previously have applied "*seems to be going out of fashion*", an aspect of matters to which I will return later below.]

…. However should generic apixaban be available the MMP may even drive additional apixaban use at the expense of dabigatran and the other DOACs. In all of Scenarios 1A, 1B and 2 such market impacts require assessing and estimating as described above (7a, 9a), and each may be made based on the market trends and forecasts as described with a similar level of accuracy."

[What are these scenarios to which Mr Potter refers? They are defined in his first affidavit of the 22nd December 2023, in which he avers, amongst other matters, as follows:

> "*15. I have been asked to provide my expert opinion on the likely market impacts and the quantifiability of damages resulting from the following scenarios:*
>
> *a. The interlocutory injunction is not granted and Teva's apixaban*

is placed on the market, but no other generic is permitted to do so. At the final determination of the Appeal, judgment is handed down finding the patent is valid and infringed and accordingly Teva's apixaban is removed from the Irish market. BMS seeks damages from Teva which has marketed apixaban in the interim, for losses it has incurred as a result of generic apixaban wrongly being allowed to be available on the Irish market ('Scenario 1A').

b. The interlocutory injunction is not granted and Teva's apixaban is placed on the market, and other generics are also permitted to do so. At the final determination of the Appeal, judgment is handed down finding the patent is valid and infringed and, accordingly, generic apixaban including Teva's, is removed from the Irish market. BMS seeks damages from Teva and any other generics companies which have marketed apixaban for the losses it has incurred as a result of generic apixaban wrongly being available on the Irish market in the interim ('Scenario 1B').

c. The interlocutory injunction is granted and Teva is restrained from placing Teva's apixaban onto the market until the final determination of the Appeal. The final determination of the Appeal results in the revocation of the Patent and SPC. Teva seeks damages from BMS for the losses it has incurred for wrongly being kept off the Irish market in the intervening period ('Scenario 2'). For the purposes of Scenario 2 I make the assumption that BMS will also seek and be granted injunctions against all other companies attempting or threatening to launch a generic apixaban. This is based on the fact that BMS is seeking an injunction against Mylan and that I am instructed that BMS' counsel confirmed during the hearing of the injunction application in February 2023, and that BMS' solicitors have confirmed since in correspondence, that such injunctions would be sought."]

22. *Dr Stomberg...highlights that in Scenario 1A or 1B the counterfactual level of parallel importation requires estimating. This is the case, but it is my assessment and conclusion that this can be estimated with considerably*

greater accuracy than the various estimations required in the counterfactual of Scenario 2 as described above in paragraph 11.

[I indicated previously above that unless expressly indicated otherwise, I do not generally in this section express any view on what I make of BMS's submissions in this regard. In effect, what I am doing is setting out BMS's case at its height. Here, the view I express is as follows. I note that Costello J., at §59 of her judgment [[2023] IECA 173] in the appeal against my judgment of 17th February last, criticised Mr. Potter's evidence first time around for treating the weighing up of complexity of calculation as if it was a comparative exercise, saying that that is not the question; the question is whether the level of complexity would mean that damages are unlikely to be an adequate remedy. It seems, with respect, that Mr. Potter is similarly minded in this exercise, and that in discussing trends, estimations, boundaries, he is essentially accepting that all of these things are matters for estimation.]"

34. I have taken some time to quote the relevant affidavit evidence above. In essence, however, I understand BMS's contention in this regard to be as follows:

(1) when I was looking at this aspect of matters in last year's interlocutory injunction application, I considered that I did not have sufficient evidence to convince me that other generics might come in, and I made a finding that matters would be more challenging if they came in, but probably not impossible.

(2) in the scenario now presenting the generic competition, if Teva gets onto the market, is likely to be very febrile (because of, essentially, the business structure of generics companies).

(3) the fact situation has changed, with even Mr Potter using language which suggests there to be a substantial risk that all elements of damage that BMS could sustain if Teva gets onto

the market and other generics follow, would not be compensable in damages.

35. The foregoing addresses the second head of damage that BMS originally relied upon. I turn next to the issue of permanent damage, *i.e.* the circumstance where (per BMS) if there was generic competition, it is very likely that BMS would have to compete on price and that it would not be able to raise a dropped price even in the event that it eventually triumphs before the Court of Appeal and in any onward appeal. In my judgment of 17th February last, I addressed this aspect of matters in the following terms:

> "*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'. BMS, its own evidence suggests, has a choice in this regard and its own evidence is that it could elect to maintain its price. But even if BMS did drop its own prices this again seems to me to be classic calculation of damages territory with damages calculable as indicated in the previous paragraph above....*
>
> *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. But it does not seem to me that BMS ever gets beyond the realm of assertion in this regard. And in any event one remains very much in the realm of pecuniary loss, eminently calculable and recoverable as damages...*"

36. This was the one aspect of my judgment of 17th February with which the Court of Appeal did not agree. The essence of the Court of Appeal's opinion in relation to this aspect of matters, as expressed by Costello J., was that Mr. Potter, who was the main respondent to the question

of whether BMS could raise its prices again had simply said, in effect, 'I think it can'. The Court of Appeal was not satisfied that Mr Potter, in this regard, had taken on board what Mr. Cooke had said in relation to how the entire market (and market expectations), would change with generic entry. BMS's present contention in the within application on the facts now presenting is that (i) the facts that have occurred, or the events that have occurred since the interlocutory injunction have ratcheted up the price pressure enormously, (ii) Mr. Potter does not do much more in terms of saying 'I think you could raise prices' than he did the first time around. It is useful, given the tenor of these submissions, to consider the relevant evidence in a little more detail.

37. In his affidavit evidence, Mr Cooke (a BMS witness) avers, amongst other matters, as follows:

> "*25. As the Court is aware, generics suppliers are in a position to offer much lower prices and greater discounts –*
>
> [I am given to understand by counsel for BMS that the level of discount in the UK, following on the invalidation of its patent in that jurisdiction, has now reached 97%].
>
> *– than research-based companies as a result of the fact that they do not have to try to recoup the extremely high cost of innovation, development and testing of medicinal products. This gives them a significant pricing advantage – even taking account of the fact that the reimbursement price accorded to pharmacies for supply of generics products is lower than that accorded to patent-protected products.*
>
> [It might be useful for me to note in this regard that 'reimbursement price' is the price that a pharmacy gets paid by the State for supplying a drug, and the 'price to the pharmacy' is the price that the pharmaceutical company charges the pharmacy. So, the pharmacy's margins are between those two prices. The pharmacy buys the drug at a particular price from

the pharmaceutical company and the pharmacy receives a reimbursement price. So the pharmacy gets its profit in the middle. The price drop that BMS is fearful of is a reimbursement price drop: if that comes down, the margin is 'squeezed' in terms of the price to the pharmacy.]

26. I outlined in my first affidavit the power of the HSE to set, and review, reimbursement prices accorded under the 2013 Act. If prices affecting research-based products are adjusted downwards, this obviously puts increased pressure on pharmacies' margins and therefore on the suppliers to pharmacies who wish to compete with generic supply.

[This is the point that I have treated with just above]."

38. Mr. Cooke refers next to the various sections in the Act of 2013 that impact on price, then continues as follows:

"*28. As indicated, Mylan's generic apixaban was included on the Reimbursement List on 1 June 2023. On 3 July 2023, the HPRA wrote to BMS with notification of a proposal to add ELIQUIS and generic apixaban products to the Interchangeable List. BMS submitted that that should not happen on the basis that ELIQUIS was still protected by the SPC and that an interlocutory injunction had been obtained against Teva preventing it from launching its generic apixaban product. The HPRA, however, responded that the criteria for interchangeability were met and that the HPRA had no responsibility for matters concerning infringement of intellectual property.*

Accordingly, Eliquis... and the licensed generic apixaban products identified above (with the exception of Renata...which has only very recently obtained authorisations) have been

determined to be interchangeable and the products have been listed in a group on the List of Interchangeable Medicinal Products.

[When addressing this affidavit in her oral submissions, counsel for BMS noted in this regard that "*That, Judge, is an unprecedented thing. That has never happened before, where products were put on the interchangeable list before the generics were actually on the market.*"]

30. *On the same day, 3 July 2023, the HSE sought to impose a cut to the reimbursement price for ELIQUIS under certain provisions of the framework agreement.... The HSE purported to do so with effect from 1 August 2023 under the clause dealing with reduction of reimbursement price on expiry of the relevant patent. The HSE, however, accepted submissions made by BMS that it is not in a position to unilaterally reduce the* [reimbursement] *price of ELIQUIS under the relevant provision until such a time that BMS accepts that it is a patent expired medicine....*

31. *As matters stand therefore, if Teva is permitted onto the market, pharmacists will offer Teva's generic apixaban to patients first, even if the prescription specifies ELIQUIS, unless the clinical exemption applies. Taken together with the fact that pharmacies do not tend to carry more than 5 days' worth of ELIQUIS and the very low prices at which pharmacies will be in a position to acquire Teva's generic product, a very substantial substitution of the Teva's generic apixaban for ELIQUIS can be anticipated in a matter of days if it is permitted onto the market.*

[I indicated previously above that unless expressly indicated otherwise, I do <u>not</u> generally in this section express any view on what I make of BMS's submissions in this regard. In effect,

what I am doing is setting out BMS's case at its height. Here, the view I express is as follows. This stands in contrast to Mr Neill's estimation that it will take a few months for this to happen.]

32. *BMS will therefore be faced with the choice of dropping its price to try to preserve some element of its market against the possibility that Teva will be able to remain on the market, or watch its market share reduce drastically in a very short time.*

[In my previous judgment (at §23), I noted that:

> "*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*".

Counsel for BMS, in her oral submissions in the present proceedings, observed in this regard that:

> "[O]*ur respectful submission, Judge, is that that would have to be judged in the market conditions at the time and that, for understandable reasons, Mr Cooke probably does not want to swear as to a future market choice in that regard*."

I indicated previously above that unless expressly indicated otherwise, I do not generally in this section express any view on what I make of BMS's submissions in this regard. In effect,

what I am doing is setting out BMS's case at its height. Here, the view I express is as follows. The point as to "*understandable reasons*" is not on affidavit. Moreover, with the very greatest of respect, I cannot but observe that I would find the said reasons more understandable if somebody had taken the time to iterate them in affidavit evidence. I do not find "*understandable*" what I have never been told. And I do not know what the "*understandable reasons*" are. What I am presented with is a senior VP within BMS, doubtless a most distinguished individual, who is willing to aver at length as to the difficulties that he anticipates would present in terms of calculating any damage caused to BMS, but for reasons unstated and not at all understandable to me (not least because they *are* unstated) seems strangely unwilling to state that there would be a price drop. Counsel for BMS, rightly doing her very best for her client in this regard, submitted in the present proceedings that "*I don't discern...any real dispute that there's going to be a huge commercial imperative to drop the price*", but there is no averment to this effect by Mr Cooke and I believe I can take judicial notice of the fact that commercial imperative is not merely a matter of price. (To give but one abstract example, which does not refer to any past or intended action/s, known to me, of the parties to these proceedings, a company might decide that for ethical/PR reasons it would not pursue a particular course of action even though that course of action would bring an immediate financial profit.) As a judge, I can only proceed on the evidence that is placed before me. Fundamentally, what seems most notable in this regard is *not* that the reasons for Mr Cooke's hesitation are unknown but rather that neither he nor anyone else on the BMS side has ever sworn (and thus never placed evidence before me), in the previous application or in this one, that BMS would drop its price to meet the generic price.]

33. *No reference price has been set for ELIQUIS and the products for which it is now deemed interchangeable...*

34. *The concern as to this possibility, or a review of ELIQUIS's reimbursement price to a point where BMS would struggle to compete with generics suppliers even with a price drop, is heightened by the Government's statement as part of its announcement of the 2021 IPHA Framework Agreement that '[t]hese agreements represent one element of the suite of measures available to curb the growth in the medicines bill and will not preclude the HSE from applying other saving measures under the relevant legislation'....*

35. *It is clear that the HSE is highly incentivised to obtain savings in the medicines bill in particular in light of the 2024 budget shortfall....*

36. *I respectfully repeat the view I expressed in my earlier affidavits that BMS would not be able to recover its original pricing if the price was forced down by regulatory action or even just by price competition from generics operators all else remaining equal. If the reimbursement price was reduced it would not be possible to raise this again, without agreement from the HSE, which I believe would be unprecedented. If the reimbursement price was 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 without doing severe damage to commercial relationships*.

37. *As I mentioned in my earlier affidavits, I am not aware of any company* [presumably an originator 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 the benefit to BMS of BMS's exclusive rights in ELIQUIS and it would never effectively be possible to restore the benefit of those rights*."

39. Turning next to the relevant evidence of Mr Potter, in his second affidavit he avers, among other matters, as follows, under the heading "*BMS Pricing*":

> "*Mr Cooke asserts that the impact of generic apixaban in scenario 1A or 1B would cause a permanent damage to price.... I maintain that should BMS be successful in the appeal prior to the expiry of the SPC, BMS will be able to reinstate its price in a Scenario 1A or 1B to the price levels achieved prior to the launch of generic apixaban. To suggest that BMS' customers and the HSE would not accept that BMS should be entitled to reinstate its price after defending its patent rights and the SPC at appeal lacks credibility as it would be apparent to customers what the reason for the discount was and that they would understand… that they had essentially benefited from lower prices during the relevant period, and this was a benefit to which they were not entitled because those lower prices resulted from the wrongful entry by generics on the market. As described at §38 in my First Affidavit BMS, would reduce price by offering discounts, leaving the list price unchanged, and such discounts are reversible being at the sole discretion of BMS. It is my experience in the UK that such discounts can be varied and amended*."

40. When it came to the just-quoted averments, counsel for BMS made two points: (i) that it ignores the evidence of Mr Cooke in relation to the statements from the HSE that prices have to come down and presumes a degree of acquiescence on the part of the HSE (to price rises, following price drops) that would not be forthcoming in practice; and (ii) that it is not clear what exactly Mr Potter means when he says "*It is my experience in the UK that such discounts can be varied and amended*", counsel positing in this regard, "[W]*hat does that actually mean and is he talking about different discounts to different pharmacies, is he talking about generic suppliers doing that?*"

41. On a more general note, a point that counsel for BMS made in this context is that the business model of generic companies is entirely different to originator companies. With generic companies, it is all about price. The value proposition for originator companies is different.

They build relationships with pharmacies and prescribers and they invest in the product because their product has to compete with other products, just as here Eliquis has to compete with the other DOACs. The originator invests in that, invests to increase the proportion of the market that Eliquis has, and invests in education, seeking to treat untreated populations. In this regard, I was referred to the evidence of Dr Stomberg (Aff.1, §33), where he avers as follows, under the heading "*Other Avenues of Irreparability*":

> "*33.* ...[T]*here are other avenues by which Teva's or other generic manufacturers' launch of apixaban at risk causes irreparable harm to BMS. First, parallel imports of apixaban into Ireland, which are highly volatile in volume, introduce considerable uncertainty into the calculation of damages. Second, the period of damage could stretch for an unknown amount of time during the appeals process, and other competitive events in this therapeutic category may occur during this time. These factors would also make calculating damages highly speculative. Third, BMS expends effort to compete with other products in the anti-coagulant category and to further extend the reach of apixaban to treat under or untreated populations, for example in their efforts to seek paediatric indications for the use of apixaban. When the economic benefits of those efforts are suddenly spread across competitors, they may cease to be economically viable activities. This type of outcome could permanently and unpredictably alter the trend of growth for apixaban during a potentially temporary generic entry event*."

42. Bringing all of that evidence back to the key point that BMS wishes to make, BMS submits that there does not seem to be, from Mr. Potter at least, any evidence that it is unlikely that price would come down in the face of generic competition, he merely says the price can come back up. And in this regard BMS submits that Mr Potter's evidence does not really get beyond the level criticised by the Court of Appeal in the appeal from my judgment of 17th February last, where the Court of Appeal said that Teva's evidence did not adequately address the factors

put forward by BMS. BMS submits that the factual scenario at play has worsened since last February and strengthened BMS's application for an interlocutory injunction.

43. I turn now to the issue of the adequacy of damages for Teva. In the interlocutory injunction application of last year, Teva argued that its damages would not be able to be calculated, because if they were kept off the market, it was imponderable as to what generics would have followed them on the market pending the determination of the action. And it is, per BMS, essentially the same argument now, or the same evidence from Mr. Potter now. Where BMS take issue in this regard is concerning the same issue that I highlighted in my judgment in the previous application for injunctive relief, which is that that ground of difficulty of calculation was entirely inconsistent with a simultaneous assertion that if the injunction was granted, Teva would lose the first mover advantage, *i.e.* one cannot simultaneously contend 'We cannot calculate our damages because we do not know who will get on' and at the same time contend that 'We are losing a big value here because only we [or only we and Mylan] will get on'. Thus at §29 of my judgment of 17th February last, I observed as follows:

> "*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. But another of Teva's experts appears later to dispute that other generics will in fact follow Teva's lead. (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."

44. So the facts here, BMS maintains, do not support the idea that there is a kind of very valuable first mover advantage to be had. Additionally, and BMS considered this to be an important point, whatever advantage one gets as a generic by being an early mover, and BMS accepts such an advantage to present, that comes down as more generics enter the market, *i.e.* it is a temporary advantage as to market share and price that comes down as other generics enter the market. This, BMS contends, is inconsistent with the evidence given by Mr Neill and Ms Reynolds, who talk about an enduring benefit. The notion of such an enduring benefit, BMS maintains, is completely inconsistent with the way in which generic competition operates. In this regard, counsel for BMS brought me to Dr Stomberg's affidavit (Aff.2, §§13-15) where he states as follows:

"*13. The second sub-scenario is the more likely one based on Mr. Neill's assessment of Mylan's launch readiness. There can also be no first-mover advantage for Teva if Mylan simultaneously enters. Although Mr. Neill does not discuss this, shares for both Mylan and Teva would presumably further erode as other generics would also be expected to enter (as he posits in the 'first mover' scenario). This is an important omission. Mylan and Teva are not likely to simply remain at an 'even split' of the market for long – competition from added generics will erode shares and prices.*

14. Mr. Neill then opines that 'If injuncted again, Teva will have permanently lost its first mover advantage and the consequent ability to grow market share'.... However, the most likely outcome if Teva is not injuncted again is not a first-mover advantage situation. Mylan would likely enter simultaneously with Teva and there is little to stop other competitors from entering soon thereafter. At best, Mr. Neill's argument appears to be that with the added time to prepare during an extended injunction, other competitors will be able to speed to market

more quickly. But even this may not be the case. I note, for example, that it is not known at the moment how many of the six other generics may have already applied for reimbursement approval. Given the incentives discussed above, enough may have already done this so as to largely moot the difference in speed between entry now and entry after further injunction."

45. If the situation posited by Dr Stomberg presents (and BMS contends that it is) that would mean that the first mover advantage being referenced by Dr Stomberg merges seamlessly with the first head of incalculable damage that Teva asserts, which is 'We don't know exactly how many will come on, so we don't know what our price would have been'. That, BMS maintains, is one and the same point as long as first mover advantage is not a permanent advantage (and BMS's strong submission is that first mover advantage just could not be a permanent advantage). It follows, BMS maintains, that the damage that BMS will sustain if Teva is permitted onto the market will not be calculable in damages, it will sustain more serious damage, a greater variety of damage, a loss of exclusivity, and an irrecoverable price drop, all of which will not be compensated in damages because it will be too complex. As against that level and type of damage on the BMS side of the balance sheet, there is (BMS maintains) Teva's one head of incalculable damages if injuncted, which is that it would not be known who would have marketed. In that situation, BMS contends, one has moved from the draw that I pointed to at §49 of my judgment of 17th February last,[7] into a zone where, as between BMS and Teva there would be a much heavier impact on BMS.

46. In *Merck*, the Supreme Court said that the adequacy of damages is very important, often the most important part of the assessment. Counsel for BMS made two submissions in this regard: (1) the path is not cleared until it is cleared finally to appeal, if relevant, and (ii) the value of the registered process in getting a patent and an SPC remains until the path is

[7] There, I stated:

> "*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.*"

definitively cleared. Both of these, counsel submitted, weigh in the balance of convenience in favour of BMS.

47. Counsel for BMS also drew my attention to §61 of the judgment of O'Donnell J. (as he then was) in *Merck*, where he states as follows:

> "*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 S.P.C. 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 S.P.C. As a matter of law, the S.P.C. is valid and effective until declared invalid by a court of competent jurisdiction. Just as in* Okunade v. Minister for Justice *[2012] IESC 49, [2012] 3 I.R. 152 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 S.P.C. 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 S.P.C."

48. So, one aspect of the registered right is the process of registration that it has gone through, which – BMS maintains – lasts until "*definitively adjudicated*" upon. [I indicated previously above that unless expressly indicated otherwise, I do not generally in this section express any view on what I make of BMS's submissions in this regard. In effect, what I am doing is setting out BMS's case at its height. Here, the view I express is as follows. The just-quoted words were used by counsel for BMS in her oral submissions; however, I cannot but respectfully note that there is no mention of 'definitive adjudication' in the just-quoted extract from O'Donnell J.'s judgment. Nor indeed does it appear anywhere in his judgment. What O'Donnell J. states in the above-quoted text is that "*As a matter of law, the SPC is valid and effective until declared invalid by a court of competent jurisdiction*". And this, as it happens, has occurred in the present case.] Counsel for BMS also drew my attention to the issue of the status quo, a factor of relevance since the time of *American Cyanamid* and confirmed in *Merck* to be an important factor. "[A]*s matters stand*", counsel for BMS submitted in her oral submissions, "*the exclusive right has been in place, this Court has given an interlocutory injunction, which has been upheld by the Court of Appeal pending the final determination and that currently is the status quo*." [I indicated previously above that unless expressly indicated otherwise, I do not generally in this section express any view on what I make of BMS's submissions in this regard. In effect, what I am doing is setting out BMS's case at its height. Here, the view I express is as follows. There is also, I would have thought, the matter of my judgment of 8th December holding that the Patent is not valid (and hence the SPC falls also)].

E. Some Aspects of the Application for Injunctive Relief

i. Some Introductory Points

49. I deal first with a trio of points that might usefully be addressed at this juncture.

a. A Refusal For One is a Refusal For All?

50. One of the themes of the evidence placed before me by BMS is that if I refuse an injunction against Teva, that automatically means that an injunction would be refused against everybody else. There is no basis for making such an assumption and it would be inappropriate for me to do so. I am dealing in this application with the position pertaining between BMS and Teva. Of course, in approaching this application I do not place myself in some isolated box with no regard to wider possibilities. Nonetheless it seems to me to be important to note that what I have been asked to adjudicate upon is the rights of BMS *vis-à-vis* those of Teva. What may or may not happen in other litigation in other applications cannot be assumed in terms of outcome, *i.e.* I cannot assume that the consequence will be that if I refuse an injunction against Teva everybody else will come onto the market. In any other application for an injunction that may be brought by BMS, there will be an assessment of the balance of convenience which embraces not only the adequacy of damages, but the broader factors identified in *Merck Sharp & Dohme Corporation v. Clonmel Healthcare Ltd* [2020] 2 IR 1.

b. The Fact of My Judgment of 8th December

51. Following on my judgment of 8th December there is a significant difference in the circumstances in which the parties now find themselves versus those in which they were before I issued that judgment, including the fact that BMS has been the beneficiary of the interlocutory injunction that I granted following on my judgment of 17th February 2023. Specifically, the Patent has been declared by me to be invalid. That cannot be ignored. It does not mean that the injunction which BMS has come seeking cannot be granted. However, the fact of that declaration of invalidity is important in the context of the considerations that I must take into account when determining the balance of convenience in the present application. I am not in this case dealing with a situation where there is a challenge to validity, no judgment, and a presumption of validity in favour of an ostensibly valid patent. Rather I am dealing with a situation in which I have said that the Patent is invalid. That is an important factor.

52. Later below, I will consider various UK authorities that recognise that just because there may (or may not) have been an injunction prior to the trial at first instance does not determine the issue one way or the other in the context now presenting, when a further application for injunctive relief has been made. Also, the significance of a challenger (here Teva) having obtained a judgment in its favour is recognised in a number of cases.

c. ‘Clearing the Path’

53. BMS is correct to say that the path has not yet been cleared in the sense of all appeal hurdles having been jumped over and a conclusion reached by an appellate court at the very end of the litigation. In other words, what is said about clearing the path is that the path is not cleared until *all* appeals are disposed of. That is a line of logic with an ostensible attraction. However, when one pauses to consider it more closely it is, with respect, a deficient proposition. It is, of course, literally true. However, no question could ever arise as to an injunction if the path was fully cleared. Why so? Because if the path were fully cleared, that would mean that the patent in issue had been finally held by some appellate court to be invalid, and in that situation no-one could ever bring an application for an injunction. So, while clearing the path is a factor, its limitations and its context need to be borne in mind, which is clear from *Merck.* If I, as the deciding judge in this application were to say to Teva, ‘Because you have not cleared the path, you cannot resist the granting of the injunction now sought’ that would be a contradiction in terms. Why so? Because by the time Teva had cleared the path, the issue of an injunction just would not arise. So the fact that the path has not been cleared in the sense of all the appeal hurdles having been jumped over and a conclusion reached at the very end of the litigation is a relevant factor but it is not a decisive factor.

ii. *Merck*

54. I have already touched to some extent on the decision of the Supreme Court in *Merck*. I also dealt with that judgment at some length in my judgment of 17th February last. So it seems to me to be reasonable that I would confine myself in this judgment to considering a number of aspects of *Merck* that might usefully be highlighted in the context of the present application.

55. I note in passing that there are notable similarities between *Merck* and the case now before me. I note in particular the system of pricing and alternatives that O’Donnell J., as he then was, makes in respect of pricing and alternatives (at 10), the interchangeability of Inegy in that case with generic alternatives (see §13), and the issue of discounts (see §14). And of course there was the issue of first mover advantage (see §17). So there is a lot of commonality between that case and this.

56. In the course of his judgment, O'Donnell J. (at p.14) refers, in the following terms, to the decision of the English Court of Appeal in *AG v. Hospira Ltd* [2013] EWCA Civ. 583:

> "*[20] ....In* Novartis A.G. *v.* Hospira U.K. Ltd. *[2013] EWCA Civ 583, [2014] 1 W.L.R. 1264, the Court of Appeal of England and Wales (Lewison, Kitchin, and Floyd L.JJ.) granted an injunction pending appeal in circumstances where the High Court had found the patent in question to be invalid. At paras. 52–54, p. 1274, of the judgment, Floyd L.J. cited with approval the* SmithKline Beecham PLC v. Generics U.K. Ltd. *(Unreported, High Court of England and Wales, Jacob J., 23 October 2001) approach:*
>
> > *"52. ...In [SmithKline Beecham plc v. Generics UK Ltd.], Jacob J articulated the need in the pharmaceutical industry for a generic manufacturer who makes plans to launch a generic medicine, to take steps to clear the obstacles facing its manufacture out of the way before it is launched. He said 'You would have to be very naïve in the pharmaceutical industry to think that the patentee, with a product as important as this, would not, if it had anything other than a frivolous chance of success, take action'.*""

57. At p.15 *et seq.*, O'Donnell J. moves on to address, in the following terms, the judgment of Arnold J., as he then was, in *Warner-Lambert Co LLC v. Sandoz GmbH* [2015] EWHC 3153 (Pat):

> "*Arnold J. granted an injunction restraining the defendants from infringing a European patent by dealing [in] a generic pregabalin product. At para.103 of the judgment he concluded:*
>
> > *'In my judgment, granting the relief sought by Warner-Lambert would create a lesser risk of irremediable harm than refusing it. This is for two main reasons. First, I consider that there is a greater risk of Warner-Lambert suffering unquantifiable and irremediable loss if an injunction is refused than there is of Sandoz suffering unquantifiable and irremediable loss if an injunction is granted. Secondly, I consider that there is a strong case for preservation of the status quo pending trial... If no injunction is granted, the arrival of full label generic pregabalin on the market will make it significantly more difficult for the Court to ensure appropriate compensation for those parties which it is finally determined merit compensation'.*"

58. Of note in the just-quoted text is the examination of where the greater risk lies in terms of unquantifiability and irremediable loss. In such an instance the first issue to be examined is whether damages are unquantifiable for the plaintiff and unquantifiable for the defendant. Having done that exercise, one does a comparison, examining whether it is going to be more difficult to quantify for one rather than the other? And that assessment is a factor in the balance of convenience. So, it is a two-stage task. When it comes to the evidence before me, Mr Potter has done this analysis in respect of both parties (and indeed did it in last year's injunction application also).

59. What subtends *Merck* is the previous misapplication (or, more particularly, the almost automatic or rigid application) of the principles in *American Cyanamid v. Ethicon Ltd.* [1975] A.C. 396 (adopted with approval in this jurisdiction in *Campus Oil v. Minister for Industry (No. 2)* [1983] I.R. 88). O'Donnell J. makes clear in *Merck* that *American Cyanamid* does not mandate the application of an inflexible rule. In this regard, *Merck* moved away from what was the previous orthodoxy, being that if damages were an inadequate remedy for the plaintiff, you went on then to see how damages might be calculated and whether they were inadequate for the defendant. But if they were *adequate* for the plaintiff, that was an end of the matter. In *Merck*, O'Donnell J. makes the point that it is very difficult to say as a matter of principle that damages are absolutely unquantifiable. This may be true in certain circumstances. However, where a court awards damages, particularly where there are well-established rules with regard to causation and foreseeability, that court proceeds professionally and in accordance with those rules. The whole purpose of awarding damages is to compensate and to do justice between the parties. So one does not always have the 'tripwire' as a plaintiff that if damages are unquantifiable an injunction is refused. And likewise if, in theory, damages are quantifiable for both sides one looks at the relative difficulties in assessing damages on the different scenarios. This more nuanced type of assessment, it seems to me, is fundamental to Mr Potter's approach in his evidence.

60. Returning for a time to the judgment of O'Donnell J. in *Merck*, he observes as follows:

> "*27. Before addressing the legal issues, it may be useful to observe that there are some distinct features which will nearly always arise when a competitor seeks to enter a market with the product contending that an SPC granted in respect of the incumbent product is invalid....The whole object of a generic manufacturer is to produce a copycat product which can accordingly benefit from the market authorisation, and which can be entered in the register of substitutable products. Accordingly, it seems that in most cases the only argument that could be made will relate to the validity of the SPC, which normally would involve a consideration of whether article 3 of the Regulation had been satisfied. While that can be a difficult*

task, it does not have the range of complexity that is involved in disputes where it is contended" – as it is here – *"that there has been no infringement, or where there has been a challenge to the validity, and perhaps where there are claims for amendment of the patent. More importantly, for present purposes, the features of (1) a successful product enjoying a monopoly, (2) that success attracting generic competitors, (3) the knowledge that such competitors will likely enter the market on the expiration of the SPC, and (4) the fact that entry before the date of expiry can only be achieved if it can be successfully contended that the SPC is invalid, are all features which arise in any such case . To that extent, a presumptive approach is perhaps unavoidable.*

[O'Donnell J. later goes on to say that one must be careful, notwithstanding those factors, to carry out the evaluation and then to make the judgment, having regard to the factors that he finally identifies at the end of his judgment and based on the analysis that is contained in the intervening pages.]

...

33. If there is doubt as to the outcome of the analysis of the respective decision to the parties, then other factors may come into play. For example, where other matters appeared balanced, it was a counsel of prudence to take such measures as were calculated to preserve the status quo. If the defendant was restrained from doing something which he or she had previously not done, the only effect of the interlocutory injunction would be to postpone the date on which he or she was able to embark on that course. Other than in 'the simplest cases', there would be some disadvantages to either party which would not be compensated fully by an award of

damages. If the uncompensatable damage to each party did not differ widely, it might not be improper to take into account in tipping the balance the relative strength of each party's case as revealed by the affidavit evidence.

[So O'Donnell J. intimates that one measures, with respect to both parties, the extent to which damage is unquantifiable. Only where there is no material difference in terms of the unquantifiable nature of the damage does the possibility arise of taking into account factors, such as the strength of the case].

...

36. *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 is an important part of O'Donnell J.'s judgment and reinforces the relative analysis that falls to be undertaken.]

37. *A further noteworthy feature of the judgment for present purposes, is Lord Diplock's acknowledgement that, save in the simplest cases, both parties will be able to show that they would suffer some damage that cannot be adequately compensated for in damages. Even if a very structured and sequential approach is taken, therefore, it 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.*

[Of significance in the foregoing is the fact that just because there may be some element that is unquantifiable is not decisive, *i.e.* there may be some element of estimate involved (*e.g.*, some element of calculation by reference to trends). It is not, with respect, the case, that because Mr Potter acknowledged that in assessing damages one might take into account trends and make a calculation, that some insuperable deficiency presents in that calculation process. The courts regularly take such factors into account in disputes between businesses, with the courts being trained to apply and assess – and experienced in applying and assessing – various factors that might be relevant in determining damage so as to come to what the deciding court considers is probable, just compensation.]

...

If the approach in American Cyanamid... is not applied with some degree of flexibility, it can have a distorting effect on the application itself. A party seeking an interlocutory injunction will normally be concerned with its contention that the defendant is acting wrongfully and unlawfully, and, furthermore, the substantial damage that will be done and might be avoided by an injunction. However, affidavits drafted

with one eye on the criteria in American Cyanamid … will tend to downplay these aspects of the case and emphasise sometimes peripheral features with a view to establishing the much sought after irreparable harm which may trigger the grant of the interlocutory injunction.

[In assessing affidavit evidence, where there has been no cross-examination, I cannot reject the evidence of what somebody says but I can analyse it. And in the judgments of McGovern J. and Barniville J., as he then was – considered later below – both scrutinise various averments with regard to price spirals, *etc*. and form conclusions on the basis of the evidence. So I am not required to accept mere assertion. And I use the word 'assertion' deliberately. This is because, as I have highlighted previously above, it has never been averred to by BMS (either in February of last year or in the within application) that BMS will reduce price in the event of generic entry. From an evidential perspective – and courts proceed on evidence – BMS¸ to use a colloquialism, 'dances around' this issue. It engages in evidence that discusses a future in which an injunction is refused. It submits that there are (unstated) "*understandable reasons*" why it cannot state that it will reduce price (as stated above I do not know what these "*understandable reasons*" are, not least because they are unstated). Its counsel refers in oral submissions to "*commercial imperative*", but commercial imperative is not always a purely bottom line matter of pounds, shillings, and pence. In all the abundant evidence which BMS has placed before me as to the shape of the world in which an injunction has been refused, no-one has ever sworn that BMS will reduce price following generic entry. In this regard I am presented with mere assertion, mention in submissions of unstated "*understandable reasons*" and "*commercial imperative*" but I

am not confronted with evidence – and courts proceed on evidence.]

...

48. *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. The fact that it is in theory possible to gather every feather does not mean that it is not more convenient to stop the pillow being punctured in the first place.*

[Here, when it comes to a proposed entry on the market, I am presented with a vacuum of historical evidence as to trading, even though BMS – operating on the relevant market for about a dozen years – must have relevant material in this regard, which it has elected (as is its right) not to disclose to me. In any event, as O'Donnell J. makes clear, I assess quantifiability. Then, having done this, I make a relative assessment as to who, in a sense, is going to be hurt more, and – as will become clear later below – it is this to which Mr Potter's evidence is (helpfully) directed].

...

62. *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… 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*...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....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".

[In what is, if I might respectfully observe, a notably helpful judgment, there are a number of important principles identified in the just-quoted text. Administrative decisions/processes that are in accordance with law on their face, carry with them a presumptive validity. They can be challenged and they may be declared invalid, but somebody has gone through a legal process and presumptive validity arises. But here, in my judgment of 8th December last, I declared the Patent invalid (with the result that the SPC likewise falls). So the presumptive validity of the Patent is gone. BMS has arguable grounds of appeal, but those arguable grounds do not revive the presumption of validity of the Patent. The presumption now is that my judgment of 8th December last is valid. That is the way our legal system works and it is an important part of the rule of law. It completely changes the position from what it was previously (and the situation that I have just described pertains irrespective of my granting a stay; the stay prevents revocation with the consequence of taking the Patent off the register. But so far as Teva is concerned, my judgment of 8th December last has now established that the Patent is invalid).

In this regard it is also worth mentioning again the issue of clearing a path. As mentioned above, taken literally, if one means by saying that 'you must clear the path', the appeal path must be fully and completely exhausted, then in every case where there has been no eventual appeal to the Supreme Court (or there has been a decision of the Court of Appeal followed by a Supreme Court refusal of leave to appeal) a patent holder will get the injunction it comes seeking almost as of right where the challenger has not cleared the path by going through the whole process to one of the end-events aforesaid and having the patent declared invalid. So yes, clearing the path

may be a factor as O'Donnell J. states, and a factor to which *some* weight would be given if a challenger had taken no steps to clarify the essential matters upon which the right to launch was grounded. But here Teva has taken those steps and has succeeded in having the Patent declared invalid: that is a complete alteration of the balance of convenience.

Turning then to the balance of justice, BMS contends that the balance of justice favours granting the injunction because of the consequences that would follow for it if the injunction is refused. However, in the balance of justice, that is just one part of the balance. I have also to weigh into the balance the fact that (in the face of an invalid Patent and SPC) Teva should be entitled to launch. Given the pending appeal, Teva would launch at risk, and if matters were to go in BMS's favour then there would be an order for damages. Of that order, I respectfully accept as entirely correct the contention made by counsel for Teva in this regard during his oral submissions:

> "*It is said that it* [the order] *won't be perfect. Perhaps in theory no award of damages is perfect, but there are well-established rules, and I'll deal with the various discrete issues that they raise. But those can be comprehended and compensated in an award of damages*."]

63. 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.

[Here, we are well beyond the pre-trial stage. Teva has surely shown that its case for invalidity is strong, having just won its case as to invalidity in the High Court. The fact that there are arguable grounds for appeal (and 'arguability' is not exactly a demanding threshold) does not mean that Teva's case for invalidity is not strong. It simply means that there is a basis for challenging my judgment of 8th December last.]

It is recognised in the decision in American Cyanimid...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.

[Here, I have considered those relative strengths and weaknesses fully and reached the conclusion that I have reached in this judgment].

However, it would be absurd if this rule of abstention were to result in a court conducting an agonised and necessarily imperfect assessment of a number of variable factors in a field with which it has little familiarity and where the evidence is indirect, written, and untested, all the while averting its attention from the area (perhaps of pure law) in which it can justifiably claim expertise [*i.e.* the area of damages].

[Again, this does not arise in the present case, because the variable factors have been assessed.]

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....

[This observation surely applies *a fortiori* in the circumstances now presenting in this case following on my judgment of 8th December.]

I consider that if the case was considered as of April 2018, then an interlocutory injunction ought to have been granted, subject to the Merck's undertaking in respect of damages....

64. *I am conscious that, although expressed in perhaps a nuanced way emphasising the flexibility of the remedy, this decision is nevertheless capable of being read as suggesting that in every case in which an SPC holder seeks an injunction against a threatened challenge by a generic competitor, then an interlocutory injunction ought to normally be granted. Given the fact that a number of the features are common to any such claim, this is inevitable. I would, however, emphasise that the balance is a fine one, and is capable of being affected by the circumstances of particular cases and by a range of factors, such as the outcome of similar litigation in other jurisdictions* [and obviously more particularly the outcome of the trial in this case] *which may lead to a different outcome*.

65. *Finally, 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* [as] *this:-*

(1) First, the 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 upon ending 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....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* [clearly, this does not apply here].

(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 into account 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.*

...

(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".

iii. *Gilead*

61. I turn now to consider a useful case on how a court will approach a consideration of assertions with regard to damages: *Gilead Sciences Inc v. Mylan* [2017] IEHC 666. The background to the application is usefully summarised by McGovern J. at §2:

"*2. The first named plaintiff is a US based company and is the parent of a group of companies (hereinafter referred to as "Gilead") of which the second named plaintiff is a member. Gilead engages in research, innovation and the creation of drugs for the treatment of conditions such as the Human Immunodeficiency Virus....The injunctive relief sought in this application is in respect of an alleged infringement of the plaintiffs' rights in Supplementary Protection Certificate No. 2005/021...which rights derive from Irish registered patent no. EP(IE)0 915 894...The product to which the SPC relates is Tenofovir Disoproxil ('T.D.') and its salts in combination with Emtricitabine ('FTC'). These are the active ingredients in the plaintiffs' medicinal product, marketed as Truvada®, which is used in the treatment of HIV.*"

62. Under the heading "*Are Damages an Adequate Remedy for the Plaintiff*?", McGovern J. observes as follows:

"*31. The plaintiffs concede in their written submissions that the market for T.D. + FTC is an established market but argue that there will be difficult and insuperable obstacles to quantifying*

the loss inflicted by new entrants. The plaintiffs argue that the entry into the market of several generic companies (including the defendants) together with the existing instability in the market would make it exceedingly difficult to ascertain how the market would theoretically have developed in their absence. Therefore, it will be impossible to calculate the loss suffered by the plaintiffs, were an injunction to be refused. The defendants argue that Truvada~® is not a mainstream drug which is widely distributed. It is dispensed to a small cohort of patients. The market is settled and consistent. They argue that all that is protected by the SPC is Truvada® and the plaintiffs are not entitled to claim losses in respect of any other products.

[It is not disputed that this would not be the correct legal test, *i.e.* that what presents is more than a right to claim losses.]

...

33. [Ms Sandra Gannon, a Teva employee] *avers that in order to calculate the plaintiffs' losses (assuming they succeed in defending the SPC), it would simply be a matter of taking the IMS unit sales of the plaintiffs' product and multiplying that quantity by the loss in profit per unit. The plaintiffs and the defendants both contribute to IMS data which will give the relevant volume for the plaintiffs and the defendants' products on a monthly basis for the whole market....*

...

38. The plaintiffs assert that if the generics were permitted to enter the market, they would suffer irreversible price reductions for which they could not be compensated. Ms. Sandra Gannon in

her affidavit offers detailed evidence of a number of cases where the HSE has not enforced price reductions for a considerable period after the generic entry into the Irish market and there are no examples of the HSE imposing price reductions where patent litigation is ongoing between pharmaceutical companies. As pharmaceutical prices in Ireland are part of the data used to set prices in eleven other EU markets and as many as 37 worldwide markets, voluntary price reductions by the plaintiffs would seem unlikely and would not make commercial sense. While the plaintiffs do 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....

39. *The final element in the plaintiffs' claim of impossibility to ascertain damages arises out of the fact that infringing products by several different generic companies would arise posing issues of attribution of liability. I do not accept that as valid argument in the context of a pharmaceutical industry which is so well regulated in terms of traceability. The IMS has a sophisticated tracking system of both pharmaceutical sales and prescription data covering over one million pharmaceutical products from over three thousand companies including the plaintiffs and the defendants. In any event, the market for Truvada® and other… products is, at best, likely to remain static and will, in time diminish as new patients are put on TAF based STR treatments and there is only a small cohort of patients involved who are being treated through seven centres.*

40. *In reaching a conclusion on the issue of adequacy of damages, it is relevant to consider the purpose of a SPC which is to ensure that the holder of a patent has sufficient opportunity to*

recoup the expenses incurred in developing and bringing the product to market and the delay in getting the product to market after the grant of the patent. In an affidavit sworn on behalf of the plaintiffs… the deponent stated that the cost of bringing a product to market in 2016 was estimated to be in the region of US$2.87 bn. Truvada® was launched in 2004 and it is reasonable to assume that the costs were probably lower at that time although this is not particularised. Ms. Sandra Gannon in her affidavit deposes to the fact that the global revenue created by the plaintiffs from the sale of Truvada® in the past four years totalled over US$13.8bn....The SPC Regulation...is intended to strike a balance between the interests of the patent holder and the generic manufacturer. The figures deposed to by Ms Gannon have not been disputed; however, even allowing a wide degree of latitude in respect of those figures, it appears that without the SPC (whether it be valid or not), the plaintiffs had obtained an ample reward for the cost of developing and distributing Truvada®."

63. What is important about *Gilead* is not the factual background (albeit given that the facts relate to the global HIV epidemic it is a very interesting case, even from a factual perspective). What makes the case of particular interest for present purposes is that it offers an example of a judge analysing whether mere assertion satisfies the requirement of being able to establish that damages are unquantifiable. A court, at the interlocutory stage, is entitled to say 'They assert that. Does what they assert make sense? Is it substantiated?'

iv. *Teva v. Mylan*

64. In *Teva Pharmaceutical Industries Ltd v. Mylan Institutional* [2018] IEHC 324, Barniville J., as he then was, gave judgment on the plaintiff's application for an interlocutory injunction restraining the first named defendant, its servant or agents, from directly or indirectly infringing Irish Patent No. EP (IE) 2 949 235 entitled "*Low Frequency glatiramer acetate therapy"*. Without prejudice to the generality of that relief, the plaintiff also sought an injunction

restraining the first named defendant, its servants or agents, from making, offering, putting on the market and/or using any articles, products or other matter which directly or indirectly infringe the Patent and/or from importing or stocking any such articles, products or other matter, together with various ancillary orders.

65. I take up the judgment from §75, by which point Barniville J. has commenced his assessment of the adequacy of damages. There, Teva, then as plaintiff, had advanced various aspects of loss that it contended would be unquantifiable, including suffering diminution in the market share in the US where this drug was sold, along with diminution in price. In his judgment, Barniville J. analyses in some detail the evidence of Mr Hassler, a senior employee of Teva, stating, amongst other matters, as follows:

> "*75. In explaining the effect of a launch of a generic product, such as Mylan's 40mg GA product, to compete with Copaxone 40mg, Mr Hassler outlines the complex system by which patients in the US are supplied with drugs such as Copaxone 40mg (and the competing Mylan product) through what are called Third Party Payors ('TPPs'). He says that the vast majority of patients taking Copaxone 40mg in the US rely on a TPP, such as an insurance company, to pay the bulk of the price of their prescriptions and that the impact of a generic product onto the market leads TPPs to reconsider the price which they charge patients for Copaxone 40mg, as well as whether they will continue to offer patients reimbursement for that product. He states that decisions of TPPs could play a significant role in restricting demand for Copaxone 40mg by placing restrictions on the coverage for patients. Mr Hassler gives a detailed account of how TPP's in the US compile lists of drugs known as 'formularies' which are divided into tiers based on factors such as the quality of the drug....Mr Hassler also explains that many US jurisdictions require TPPs to automatically substitute generic GA 340mg in place of Copaxone 40mg for existing and new Copaxone 40mg prescriptions and that TTPs may also attempt to demand*

'burdensomely high' co-payments for Copaxone 40mg or place other restrictions or conditions on physicians' ability to prescribe Teva's product. He states that if Teva does seek to compete on price that will result in a significant price erosion which is irreversible. [That has a resonance in terms of the present case.] *Further, even if Teva had a contractual right to return to the prices it charged for Copaxone 40mg prior to Mylan's entry on the market, he states that the practical aspects of doing so would be 'complicated' and the success of doing so is 'less than certain'.*

...

77. *Mr. Hassler further asserts that in the event that there is a significant loss of market share for Copaxone 40mg, Teva will be required to reduce the time and effort put into marketing, medical education and outreach efforts for Copaxone 40mg. He further asserts that Teva 'may also be required' to reduce patient support services through its "Shared Solutions" services. This in turn could lead to further losses in market share for Copaxone 40mg and loss of reputation for Teva. He states that such loss of market share "may not be reversible" in that it is difficult to rebuild the prescribing habits of physicians once they are lost and it is also unlikely that patients who chose other branded products would return to Copaxone 40mg should the generic 40mg GA product be withdrawn later from the market. He also states that because of the shelf life of the generic competing product, wholesalers may build up a large supply of stock of Mylan's 40mg GA product (to match the two year shelf life of Copaxone 40mg). He relies on the experience of Teva and its affiliates of irreversible impacts of even temporary loss of exclusivity in the past and gives the example of Cephalon's product Amrix (Cephalon is a Teva affiliate). He states that Teva was unable*

to recover its market share even after the generic product was withdrawn shortly after its launch.

78. *Mr. Hassler also contends that the launch of a generic 40mg GA product will lead to significant price erosion for Copaxone 40mg which will be irreversible. He says that many TTPs will demand significant discounts, rebates and other economic incentives to ensure continued coverage for Copaxone 40mg. He understands that Mylan's 40mg GA product is priced well below that of Copaxone 40mg and if additional generics enter the market, the price of Copaxone 40mg is likely to fall even further. He also states that if it is necessary for Teva to offer rebates to compete with the Mylan product, it is unlikely that rebates could be subsequently withdrawn even if Mylan were restrained from selling its generic product. This is due to the involvement of TTPs. Even if Teva were able to negotiate increased prices after the withdrawal of the Mylan product, he states that Teva would suffer a loss of goodwill with those TTPs. Therefore, he says that it is highly unlikely that Teva could ever restore the price of Copaxone to the pre-Mylan entry price.*

79. *Mr. Hassler expands on the alleged inevitable reduction in Teva's patient support services through the 'Shared Solutions' programme which he asserts will lead to patients not adhering to their therapies and cause damage to the reputation of Teva and the Copaxone brand which will be irreparable and not quantifiable in damages. He further expands on the contention that if Teva loses a significant percentage of its revenues from Copaxone 40mg (a substantial portion of which is invested in research and development), Teva 'would likely be forced to delay or eliminate' Copaxone-related research as well as the research and development of new products currently in development which will lead to significant lost opportunities which, he says, are unquantifiable both for Teva and for patients.*

...

81. *Professor Hausman* [an economic expert] *outlines in his affidavit the impacts of the generic entry on the market for a drug and asserts that when a generic version comes on to the market it can have severe economic impacts on the branded product. Those impacts include causing an immediate and significant erosion of market share of the branded product and significant price erosion which lead to substantial economic losses to the owner of the branded product which are irreversible and 'extremely difficult to quantify'.*

...

85. ...[Professor Hausman] *opines that it would be extremely difficult, if not impossible, for Teva to remedy any price erosion without hurting its market reputation and relationships with purchasers. He also refers to the difficulty (if not impossibility) of attempting to calculate damages by trying to predict the future price and sales of Copaxone 40mg up to 2030. He asserts that an economist could not estimate future damages with 'sufficient precision' adequately to compensate Teva.*

86. *Professor Hausman then addresses the question of alleged likely loss of qualified patient support staff and resulting future lost sales. He asserts that if the Mylan product remains on the market the loss of revenue which will be suffered by Teva will 'almost certainly' require Teva to reduce the size of its 'Shared Solutions' patient support staff and its nursing force....*

88. *Mr. Hassler expands on these points in his supplemental affidavit. In support of his contention that the presence of the Mylan competing product on the market will cause 'real and concrete' harm to Teva, which he says has already begun....*".

66. It is not so much the detail of the foregoing that is important, so much as the shape of the heads of damage, or apprehended damage, advanced in a case where there are obviously differences, but there are also some obvious similarities. Moving on, Barniville J. observes, among other matters, as follows:

> "*125. First, I am satisfied that notwithstanding the averments of Mr. Hassler and Professor Hausman that the market for MS treatments in the United States is dynamic and competitive, this does not mean that it will be impossible to assess damages at trial. I find the evidence advanced by Mylan on this issue much more compelling. I am particularly persuaded by the evidence of Professor Hay that the loss of market share, for example, is a classic type of loss which is compensatable in damages.*"

67. So, as can be seen, the question of impossibility is a matter for my legal judgment on the basis of what is stated.

68. Barniville J. moves on as follows:

> "*127. Third, I am not at all persuaded that the alleged potential irreversible loss of market share and price reductions for Copaxone 40mg creates an impossibility of assessing damages....*
>
> *128. The evidence put by the parties before the court for the purpose of the interlocutory injunction application does not, in my view, support the contention that it would be impossible to assess damages because of the potential loss of market share by Teva....*
>
> *129. Fourth, I do not accept that any reduction in price which Teva may have to implement for Copaxone 40mg is not capable of being compensated in damages. On the evidence, if any such*

reductions have to be given by Teva, whether by way of discounts or rebates to TTPs or others, they will be objectively ascertainable. There is no reason why Teva cannot put such evidence forward in support of its damages claim. Nor am I persuaded that Teva has established as a matter of probability that any difficulty of calculating post-trial damages means that damages are an inadequate remedy. The courts can assess such damages and are assisted by experts called by the parties in doing so. Damages are regularly claimed in patent infringement proceedings and, in my view, in circumstances where there will be objective evidence as to such price reductions (if any) caused by the arrival of the Mylan product on the market, there is no reason why the court conducting the trial of these proceedings will not be in a position to assess damages both up to and after the trial. While that may not necessarily be a simple exercise and may indeed be one of some difficulty, it does not, in my view, cross the threshold of impossibility."

v. The *Neurim* Cases[8]

69. Here, Neurim was the first claimant and Flynn Pharma Ltd the second. They were the patentees. They claimed for a particular pharmaceutical formulation sold under the brand name 'Circadin'. The patent was due to expire on 12th August 2022, so as the hearing date in the first of the High Court cases was in June 2020, there was still some time, though not an awfully long time, left to run on the patent. At §11 *et seq*. of the judgment [2020] EWHC 1362 (Pat.), Marcus Smith J. observes as follows:

"*11. In these proceedings – commenced by Neurim and Flynn – Neurim and Flynn contend that Mylan intends to infringe the*

[8] *I.e. Neurim Pharmaceuticals (1991) Ltd* v. *Generics UK Ltd t/a Mylan* [2020] EWHC 1362 (Pat.), *Neurim Pharmaceuticals (1991) Ltd* v. *Teva UK Ltd* [2022] EWHC 1641 (Pat.), and *Neurim Pharmaceuticals (1991) Ltd* v. *Generics (UK) Ltd* [2022] EWCA Civ. 370.

Patent. They seek a declaration of infringement and injunctive and other relief. Mylan counterclaims for revocation…

12. 'Interim' interim protection has been obtained by Neurim and Flynn in the form of an undertaking from Mylan that 'holds the ring' until 20 May 2020, the date of the hearing before me. This was the date of Neurim and Flynn's application for an interim injunction until trial. Because the hearing before me overran, and argument continued until the early evening, that undertaking was, helpfully, extended by Mylan to 3 June 2020, when this judgment is formally to be handed down."

70. Marcus Smith J. then moves on to a section of his judgment entitled "*The Law as Stated in American Cyanamid*", which of course has been qualified in this jurisdiction by *Merck*. But a *Merck*-like evolution of the relevant law in the UK is anticipated by Marcus Smith J. who states, at 17:

"*In assessing whether damages are going to be an adequate remedy, it is essential that the court identify those aspects in which damages will not be an adequate remedy. Matters are rarely black and white, and it is implicit in Lord Diplock's use of the word 'adequate' that an injunction may nevertheless be refused if damages are not a 'perfect' remedy; but that there comes a point when damages as a remedy falls so far short of the perfect, that the remedy of damages can no longer be described as adequate.*"

71. That is a statement which is consistent with *Merck*. And it offers support for the proposition that matters can be estimated, trends can be looked at, projections can be examined, and none of that means that damages will be inadequate; in truth it is all perfectly consistent with how the courts normally assess damages.

72. Moving on, Marcus Smith J. observes as follows:

"*18. Hard fought and financially significant applications for interim relief will often involve hotly contested matters of fact*

that will not, or at least not in that form, be the subject of resolution at trial. In this case, there was (quite rightly and entirely unsurprisingly) considerable debate about the question of 'adequacy' of damages at both Stages 2 and 3 of the process described above. By way of example, both parties adduced some evidence as to what would happen to the market for Circadin (and Slenyto, although the market for this pharmaceutical is less well developed) were an interim injunction not to be granted. Neurim and Flynn contended....

(3) That the fall in market price would not be capable of being recovered by Neurim and Flynn. Thus, supposing an imminent entry into the market by Mylan, and assuming victory at trial in October by Neurim and Flynn, these 6 months between the beginning of June and the end of November (which is when I shall assume judgment would be handed down) would be sufficient to suppress the price of Circadin and Slenyto irretrievably for the remaining duration of the Patent when compared to pre-June 2020 levels."

73. Marcus Smith J. moves on to assesses loss by reference to period 1 and also losses in respect of period 2. At §66, he then observes as follows:

"*Leaving on one side the rather considerable number of questions that this assertion on the part of Mylan begs – I consider that there was no sufficient evidence before me to reach any such conclusion safely – the point seems to me an essentially bad one, at least on an application such as this:*

(1) The damages that are recoverable by the owner of a patent or an exclusive licensee are essentially assessed according to the ordinary rules. In Gerber Garments Technology Inc v. Lectra Systems, Staughton LJ stated: 'Infringement of a patent is a statutory tort; and in the

ordinary way one would expect the damages recoverable to be governed by the same rules as with many or most other torts. We were referred to Halsbury's Laws of England (4th ed.),Vol.12, para. 1128 and following, to establish the elementary rules (i) that the overriding principle is that the victim should be restored to the position he would have been in if no wrong had been done, and (2) that the victim can recover loss which was (i) foreseeable, (ii) caused by the wrong, and (iii) not excluded from recovery by public or social policy. The requirement of causation is sometimes confused with foreseeability, which is remoteness. The two are different..."

74. In the course of his assessment of the adequacy of damages, Marcus Smith J. then observes as follows:

"*In this case, it seems to me that damages will prove to be an adequate remedy to both Neurim and Flynn. I have reached this conclusion for the following reasons:*

(1) The general measure of damages in a patent infringement case is clearly stated. It is the standard tortious measure....

(2) In the present case, I can see no reason why Neurim and/or Flynn's losses during both Period 1 and Period 2 cannot properly be calculated, whether it is necessary to calculate lost revenues by reference to all three Medical Uses or individually by reference to each particular Medical Use. Clearly, Neurim and Flynn will have records of their sales to date of Circadin and Slenyto, and they will continue to keep such records. Equally, there is no difficulty in Mylan maintaining and (for the purposes of trial) providing to Neurim and Flynn records of its sales of the Generic Product, differentiating as far as can be done between Medical Use, and providing information as to the price at which the Generic Product sold. (It should be clear that, to the extent

necessary, I am minded to set out in the order consequential on this application the sort of information that Mylan must keep.)"

[In the case before me Mr Neill, in his affidavit, says that suitable information will be retained and made available to the court, much as the records of sales to which Marcus Smith J. refers were to be available. I will, as part of my order, order that the requisite records be retained so that there can be no doubt but that the documents will be available if and as necessary.]

(3) Thus, in Period 1, Neurim and Flynn will have sales figures (including as to price) for the sale of Circadin and Slenyto as at the beginning of Period 1 and will be able to show how those figures vary over the course of Period 1. Prima facie, *as it seems to me, Neurim and Flynn's loss will be calculated by reference to the difference between volume of sales and sales prices at the beginning of Period 1 and the lower volumes of sales, at lower prices, during the course of Period 1.*
(4) It may be that during Period 1, but for the intervention into the market of Mylan, Neurim and Flynn were anticipating an increase in the volume of sales and/or an increase in the price of individual units sold. I can see no reason why evidence on such points cannot be adduced, and why such increases cannot inform the losses that Neurim and Flynn claim.
(5) All of these losses can – in my judgment – be calculated by reference to information that is or will be in the hands of Neurim and Flynn. But, as I say, it would be appropriate to ensure that proper figures were maintained and disclosed by Mylan for the purposes of the trial of these proceedings.
(6) I turn, then, to the adequacy of damages for any losses sustained by Neurim and Flynn during the course of Period 2....
(c) If, therefore, the avoidance of irretrievable harm to the market position of a patent-holder was the test for an interim injunction, this would be an appropriate case for the granting of such an injunction.

(d) But that is not the test. The question is whether that irretrievable harm to market position cannot be compensated for in damages. I can see no reason why the process of quantification of loss for Period 2 will not be very similar to that for Period 1. Indeed, the process of quantification of loss for Period 2 will be an extension of or extrapolation from the process undertaken in relation to Period 1.

[As can be seen, this is a framework similar to that identified in this case by Mr Potter.]

...

(iii) The first special case: entry of other competitors

74. As I have stated, I proceed on the basis that Neurim and Flynn will succeed at trial, and that they will obtain from the trial judge a permanent injunction against Mylan, even if they fail to obtain an interim injunction from me on this application. That gives Mylan a 'first mover' advantage from the date of this judgment, and other generic manufacturers only a limited time period within which to follow Mylan into the market. As I have noted, Period 1 is a period of only six months.

75. Nevertheless, it seems to me that I ought to proceed on the basis that, whilst Mylan is the first mover, the rest of the generic herd is not going to be far behind, and that one effect or consequence of not granting an interim injunction against Mylan will be to open the door to competitors in addition to Mylan.

76. I was provided with some evidence on this.

This evidence is set out and then Marcus Smith J. continues as follows:

77. Once again, it seems to me that the parties were seeking to tempt me down a path of making specific findings of fact when

(i) the material before me was entirely insufficient for the purpose of making such findings and (ii) where the process itself was in any event unsuited to making findings of fact.

78. *It seems to me that Mylan's interest in the Circadin/Slenyto market is one that is likely to be replicated in other manufacturers of generic drugs, and that I should not presume that Mylan's 'first mover' advantage is so great as to preclude the entry into the market of yet another competitor.*

79. *Were another competitor to enter the market in Period 1, then I anticipate that whilst Neurim/Flynn's volume of sales and sales prices would diminish to a similar extent as if there were only a single competitor (i.e., Mylan), the cause of Neurim/Flynn's losses would not (in this case) necessarily be attributable only to Mylan. Mylan might very well be able to argue that it was the actions of another competitor that caused loss to Neurim and Flynn. I say nothing about the merits of such an argument, but I can certainly see causation of loss in Period 1 as being an issue that may (depending on the facts) cause Neurim and/or Flynn additional difficulties in terms of the recovery of their losses. It goes without saying that the extent of these losses will be heavily fact dependant; and this is one reason why Mylan's own sales figures during Period 1 may be of importance.*

80. *Period 2, as it seems to me, gives rise to rather different questions. Clearly, if Mylan is injuncted at the end of November 2020, so too will any other entrant onto the market. In Period 2, Neurim and Flynn will, once again, be alone in the Circadin/Slenyto market, but that market will – as I have described – have been damaged by Mylan's first entry into that market in Period 1. It seems to me that, as a matter of causation, the damage to Neurim and Flynn's market in Period 2 will be entirely attributable to Mylan.*

81. *In these circumstances, whilst I recognise that the entry of competitors additional to Mylan into the market will cause*

additional complications to the damages claim of Neurim and Flynn, these additional complications are not sufficient to persuade me that damages are not an adequate remedy.

...

90. My conclusion is that it would be materially harder to assess Mylan's loss than that of Neurim or Flynn. I do not say that it could not be done, but the uncertainties inherent in the process would be formidable, and considerably more difficult in my judgment than would be the case with the losses sustained by Neurim and Flynn were the interim injunction not to be granted.

[That then is a relative assessment done after the initial assessment. Marcus Smith J. then examines the issue of clearing the way, moving on to observe as follows in §91].

In short, I consider that this point narrows the difference between Neurim and Flynn on the one hand, and Mylan on the other, in terms of how adequate damages would be as a remedy. However, since I have concluded that damages would be an adequate remedy for Neurim and Flynn, this point makes no difference to my decision.

[Why so? Because these are principles that the courts are experienced in applying and have applied in other cases. So the rules for doing it are there and there is a method of doing it. There will be arguments as to how the principles fall to be applied; however, that is part of any case where damages are ultimately assessed, proceeding on the assumption that when assessed, (after a court has heard the arguments with regard to causation, foreseeability and everything else) that they represent just compensation for the wrong that has been done.]

75. This judgment was appealed and judgment given in [2020] EWCA Civ. 793, with Floyd L.J., giving judgment for the Court of that Appeal, observing, amongst other matters, as follows:

> *3.* [following a consideration of §89 of Marcus Smith J's judgment] *This did not mean, however, that a damages remedy to Mylan would be* ***in****adequate. An award of damages to Mylan would be materially more uncertain than an award to Neurim and Flynn*" [Emphasis in original],

and then, at §§37 *et seq*., having noted the factors considered by Marcus Smith J:

> *37. Mr Waugh argued that the judge had been wrong to put the consequential loss out of account. He ought to have accepted the evidence of Neurim and Flynn as to this loss. The evidence was expressed in conclusory terms as to what would happen to the businesses of Neurim and Flynn if they were to lose the revenues from Circadin. Circadin was effectively Neurim's sole source of revenue, and so it was entirely credible to suppose that large parts of its operation would be shut down if these revenues were lost.*
>
> *38. I am unable to accept these submissions. The judge was not bound to accept uncritically the evidence of Neurim and Flynn as to whether the consequential loss would occur. I would go further and say that he was bound to examine the claims made in the evidence of Neurim and Flynn with a critical eye, given the very short period of generic competition which they would face in the light of the expedited trial. Whether the consequential loss would occur would depend on (a) the scale of reduction in the revenue streams from Circadin and (b) whether that reduction in revenues could be sustained by Neurim and Flynn without cancelling the activities in question.*"

> [Here again one sees the approach adopted also in the Irish courts, a critical assessment, an understanding that one is not making findings of fact, that neither is one ignoring conflicts of fact, and no accepting of assertions as to loss without assessing them with a critical eye.]

76. Moving on, Floyd J. observes as follows, at §53:

> "*I would, however, comment briefly on some points in the judge's reasoning which were ventilated at the hearing but which are, in the event, immaterial. First, in paragraph 79, he said that a second competitor would cause the sales and price of Circadin to diminish 'to a similar extent as if there were only a single competitor'. The evidence of Dr Fakes was that a first competitor might reduce the price by 30-40% and a second competitor by 70-80%. Read literally therefore, each competitor could be seen as contributing a similar extent of price depression. As Dr Fakes went on to explain, however, the entry of a second or subsequent generic causes the price reduction to become 'more rapid and unpredictable (often called a 'price spiral').' In the light of my conclusion that this is not a price spiral case, this does not matter. Secondly, in the same paragraph the judge goes on to discuss the contribution to the damages caused by different infringers. This does not seem to me to have any bearing on the calculation of the total loss sustained by Neurim and Flynn, or render the computation of that sum more difficult in a relevant way. To that extent I think that the judge may have over-estimated the complications of the assessment of damages. Thirdly, the judge's point at [85] that the consequential loss was always going to arise in the relatively near future seems to me to be irrelevant. The fact that a loss will in due course be sustained without the intervention of a tortfeasor has no bearing on whether that loss should count, or whether it is unquantifiable, when the tortfeasor does inflict it. Again, however, given my conclusion about the consequential loss, that is not material either.*"

77. The parties in the above proceedings had yet another case before the English courts in [2022] EWHC 1641 (Pat.), this time on the on the basis of changed circumstances (as claimed by Neurim and Flynn). There, Mellor J. observes, among other matters:

> "*31.* *...*[I]*n my First Judgment I concluded that the loss suffered by the Claimants pre-expiry would be capable of being ascertained with a reasonably high degree of accuracy. I must consider this issue afresh in the light of the evidence on this application.*
>
> *32.* *The factual position concerns what happens if no injunction is granted. At the inquiry as to damages, the Court will have the sales volumes and prices of Neurim/Flynn and Teva respectively over the pre-expiry period, along with data as to the overall size of the market.*"
>
> [This, in effect, is what Mr Potter has said in his affidavit, and, if I might respectfully observe, it makes sense.]
>
> ...
>
> *47.* *Mr Campbell made a point a number of times that if no injunction was granted, Neurim/Flynn would lose its monopoly once and for all. He contrasted that with his characterisation of the position if Teva was injuncted: 'Teva will merely lose whatever money it would have made selling its infringing products.' Leaving aside the implicit appeal to the merits, in order to test whether his distinction gave rise to something which I should take into account when assessing the balance of irremediable harm, I asked him how does Neurim/Flynn's monopoly manifest itself other than through Neurim/Flynn's ability to exploit their monopoly by making sales at monopoly prices: in other words, why is it*

not also a question of money for Neurim/Flynn? I did not get a convincing answer which left me in the familiar position: the loss of the ability to exclude Teva has to be assessed using the American Cyanamid guidelines [in Ireland, the lead case, of course, is now Merck].

...

51. In the light of the evidence now available, the points I accepted at [82], namely those in [77] (Teva's sales fluctuate) and [78] (Teva's market share fluctuates) continue to apply and they are confirmed by the additional evidence from Teva in LR-5 and LR-6. Thus, even without considering any other factors, the conclusion I reached in the final sentence of [82] (damages not an adequate remedy for Teva, largely because the uncertainties in trying to ascertain their damages would be considerable) continues to hold. Although I stated previously that I was less impressed by Teva's third reason, concerning its reputation in the marketplace as a reliable supplier and its customer relationships, I still took some account of it. The evidence on this application persuades me that I underestimated this reason before, so it adds to the conclusion. However, the significance of Teva's customer relationships has greater significance to the post-expiry position, to which I now turn.

...

55. Thus the big difference between the factual and the counterfactual would be that the Court would not know what volumes and prices Teva would have achieved over the 7 weeks to expiry and their position on the verge of expiry. It

might be said that it would be a reasonable assumption that Teva would have retained (in the counterfactual) all its present customers and the sales which Teva would have made could be estimated from the sales made by Neurim/Flynn to those customers. That assumption would compensate Teva to a reasonably significant extent, but uncertainties would remain over what new customers and volumes Teva would capture in the interim period and hence over the assessment of the loss of Teva's first mover advantage. The sales which Teva achieve post-expiry in the factual (following an injunction) would not be a reliable guide to the sales Teva would have made in the counterfactual, precisely because of the loss of the first mover advantage. [One cannot read this text and fail to find an echo with the present proceedings.]

...

65. ...[I]*t is worth bearing in mind that Neurim/Flynn did start this action against Teva on 5 November 2021, although, as I indicated in my First Judgment, Neurim/Flynn was faced with a sufficient threat from Teva from early July 2021 onwards. It was Neurim/Flynn's decision not to seek interim injunctive relief on Teva's launch in mid-October 2021, even though Neurim/Flynn had sufficient information to bring an application prior to launch. I realise that Neurim/Flynn had been refused interim relief against Mylan more than a year before and Mylan had been on the market since September 2020. It is not easy to predict what would have happened if Neurim/Flynn had launched an application for interim relief against Teva in mid-October 2021, when the trial of the preliminary issues in the Second Mylan action was pending. I can see there would have been considerable obstacles (and resistance) to Teva being joined into that Second Mylan*

action. It is unlikely that Teva would have agreed to be bound by the outcome. However, just because one generic is on the market does not mean that the second entrant (Teva) would not be injuncted. After all, the relevant status quo at that point would have been that Teva was not on the market."

[It is the second last sentence in the just-quoted text that seems key to me: "[J]*ust because one generic is on the market does not mean that the second entrant...would not be injuncted.*" As previously mentioned herein, refusing an injunction in this case to one generic company does not mean that an injunction would be refused in another case to another generic company. If BMS wishes to bring a further injunction application against some other generic company, it is perfectly entitled to do so, and whichever judge decides any (if any) such future application will bring the law to bear on the particular facts at hand in that case.]

vi. *Actavis v. Icos*

78. Counsel for Teva referred me to the application for injunctive relief in *Actavis Group v. Icos Corporation* [2017] EWHC 2880 (Pat). This was an urgent application for an interim injunction to stop the launch by the claimants, three well-known generic organisations. Under the heading "*Unquantifiable loss to Lilly if the injunction is refused*", Carr J. observes as follows:

"*13. Lilly's case was a familiar one in battles between pharmaceuticals and generics. If an injunction is refused the price of 5 mg and 2.5 mg per day tadalafil will spiral downwards, most likely to only 10% of its existing price, a proposition which is borne out by what happened when Viagra became generic. That is not contested by the Claimants, who accept that the price will spiral downwards.*

14. *Lilly's next proposition is that when the price spirals downwards, it will be faced with two alternatives; either to maintain the current branded price, and save what part of the market it can based on brand loyalty and sacrifice the rest; or, alternatively, to compete on price. Both alternatives, it submits, will cause unquantifiable harm because either it will lose virtually all of the market or it will not be possible to put the price back up if the monopoly is restored. Lilly points out that this has been recognised by the courts in previous cases as significant unquantifiable harm.*

15. *There are certain aspects of this case which are different from other cases to which Lilly has referred. First, if the appeal to the Supreme Court is successful, the patent will only have a short period before it expires. The recent, well known case of Actavis v Lilly took two years one month from filing of the petition to the Supreme Court to judgment. In the present case, the patent will expire in April 2020. A similar period before judgment would mean that it would have less than six months before expiry. So discussion of a price rise during a period of restored monopoly is limited to a very short period. This does not create the difficulty of predicting changing market conditions where a patent has several years of monopoly.*

16. *Secondly, Lilly's prices for this particular dosage regimen per pack are fixed. There is no price reduction that is suggested in the evidence and Lilly do not, for example, reduce its prices to try to compete with parallel importers. On any damages inquiry, the price at which Lilly would have sold the patented product during the next few years will be known.*

17. *Third, the market for this dosage form, although the product is very successful, is flat; by which I mean it is settled both in value and quantity of packs. Sales were about £18 million over the last two years since introduction.*

18. *Turning to the first alternative contemplated by Lilly, where it maintains its price, any damages inquiry will be heard after*

the patent has expired. Mr. Speck accepts that every sale made by the generic companies will be a sale lost to Lilly, so that is precisely quantifiable. In terms of the amount of lost profit per sale, that can be calculated by reference to the fixed price currently charged by Lilly.

19. Dr Turner was understandably concerned that it might be argued that because of the sales which are about to start of generic tadalafil in 10 and 20 mg on-demand dosages, the Claimants might say the price of the lower daily dose would have fallen in any event. Mr. Speck, on instructions, has confirmed that this point would not be argued on any damages inquiry. Therefore, from Lilly's perspective, the enquiry, if it happens, would be extremely simple. In my judgment, Lilly has not established that it will suffer unquantifiable damage. Therefore, the injunction application fails for this reason as well."

79. Under the heading "*Unquantifiable loss to the Claimants*", Carr J. continues as follows:

"*20. If I am wrong about that, and Lilly is able to establish some unquantifiable loss, it appears to me that the unquantifiable loss to the Claimants, if an injunction were granted, considerably outweighs any unquantifiable loss to Lilly. This is because the Claimants find themselves in the position of what Mr. Speck has described as 'first movers'. That does not mean that one company will be first to the market, but rather that all three will be early to the market. The evidence suggests that when a generic company supplies a wholesaler, that wholesaler is likely to stick with that generic company. If the generic company is in early and establishes the first sales, that is likely to continue. Later entrants to the market are much less likely to make serious inroads. Therefore, it is very important to these claimants (although they may be in competition with others as well) to be able to launch as soon as possible.*

21. If an injunction were granted in two years' time, it is clearly foreseeable that there will be many other generic entrants to the market who, by that stage, will have obtained their own market authorisations. Therefore, the market conditions will be entirely different. That means the sales of this particular product will be difficult to quantify, and also that the sales of other products in the portfolio, which are sold in bundles, will be difficult to quantify. It will also be difficult to compare marketing initiatives, and volume discounts which the generic companies would, at that stage, be required to apply in order to sell the products with the current market conditions. Therefore, I consider that if I did grant the injunction, the Claimants' loss would be very difficult to quantify."

80. This case was not really prayed in aid by Teva. It was simply offered as a further example of how courts used to dealing with these type of cases, and used to assessing damages in these type of cases evaluate pleas of the type considered by Carr J.

vii. The Enforcement Directive[9]

81. This directive provides a minimum set of measures, procedures and remedies allowing effective civil enforcement of IP rights across the European Union, the intention being to ensure a standardised level of protection throughout the internal market. I was referred by both parties to provisions of interest, including the following:

Recital 3. "...[W]*ithout effective means of enforcing intellectual property rights, innovation and creativity are discouraged and investment diminished. It is therefore necessary to ensure that the substantive law on intellectual property, which is*

[9] *I.e* Directive 2004/48/EC of the European Parliament and of the Council of 29th April 2004 on the enforcement of IP rights (OJ L157, 30.4.2004, 45-86).

	nowadays largely part of the acquis communautaire, is applied effectively in the Community. In this respect, the means of enforcing intellectual property rights are of paramount importance for the success of the internal market."
Article 3 ("*General obligation*").	"*1. Member States shall provide for the measures, procedures and remedies necessary to ensure the enforcement of the intellectual property rights covered by this Directive. Those measures, procedures and remedies shall be fair and equitable and shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays. 2. Those measures, procedures and remedies shall also be effective, proportionate and dissuasive and shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.*"
Article 9 ("*Provisional and precautionary measures*").	*"1. Member States shall ensure that the judicial authorities may, at the request of the applicant: (a) issue against the alleged infringer an interlocutory injunction intended to prevent any imminent infringement of an intellectual property right, or to forbid, on a provisional basis and subject, where appropriate, to a recurring penalty payment where provided for by national*

law, the continuation of the alleged infringements of that right, or to make such continuation subject to the lodging of guarantees intended to ensure the compensation of the right-holder; an interlocutory injunction may also be issued, under the same conditions, against an intermediary whose services are being used by a third party to infringe an intellectual property right; injunctions against intermediaries whose services are used by a third party to infringe a copyright or a related right are covered by Directive 2001/29/EC; (b) order the seizure or delivery up of the goods suspected of infringing an intellectual property right so as to prevent their entry into or movement within the channels of commerce. 2. In the case of an infringement committed on a commercial scale, the Member States shall ensure that, if the injured party demonstrates circumstances likely to endanger the recovery of damages, the judicial authorities may order the precautionary seizure of the movable and immovable property of the alleged infringer, including the blocking of his[/her] *bank accounts and other assets. To that end, the competent authorities may order the communication of bank, financial or commercial documents, or appropriate access to the relevant information*."

Article 11 (“*Injunctions*”).	“*Member States shall ensure that, where a judicial decision is taken finding an infringement of an intellectual property right, the judicial authorities may issue against the infringer an injunction aimed at prohibiting the continuation of the infringement. Where provided for by national law, non-compliance with an injunction shall, where appropriate, be subject to a recurring penalty payment, with a view to ensuring compliance. Member States shall also ensure that right-holders are in a position to apply for an injunction against intermediaries whose services are used by a third party to infringe an intellectual property right, without prejudice to Article 8(3) of Directive 2001/29/EC.*”
Article 12 (“*Alternative measures*”).	“*Member States may provide that, in appropriate cases and at the request of the person liable to be subject to the measures provided for in this section, the competent judicial authorities may order pecuniary compensation to be paid to the injured party instead of applying the measures provided for in this section if that person acted unintentionally and without negligence, if execution of the measures in question would cause him*[/her] *disproportionate harm and if pecuniary compensation to the injured party appears reasonably satisfactory.*”

Article 13 ("*Damages*").	"*1. Member States shall ensure that the competent judicial authorities, on application of the injured party, order the infringer who knowingly, or with reasonable grounds to know, engaged in an infringing activity, to pay the right-holder damages appropriate to the actual prejudice suffered by him*[/her] *as a result of the infringement. When the judicial authorities set the damages: (a) they shall take into account all appropriate aspects, such as the negative economic consequences, including lost profits, which the injured party has suffered, any unfair profits made by the infringer and, in appropriate cases, elements other than economic factors, such as the moral prejudice caused to the right-holder by the infringement...*".

82. As can be seen from the above provisions, especially perhaps Art.3, the Enforcement Directive is not, as was contended for by BMS, a patentholder's charter. It respects the principle of proportionality (a fundamental principle of European law). It recognises that damages can be awarded and can be pitched so as to take account of all appropriate aspects. In short, there is nothing in the Enforcement Directive which in and of itself resolves the application before me. In a sense, the directive begs the question as to what is proportionate, fair and reasonable in this application. But equally it recognises that damages can be an appropriate remedy.

viii. *Biogen*

83. Turning next to *Biogen MA* v. *Laboratorios Lesvi SL* [2023] IECA 71, there the issue for consideration by the Court of Appeal was whether the appellants (Biogen) were entitled to an injunction to restrain the respondents from infringing, through the launch of a generic medicinal product, a patent held by the appellants. As was to be expected, the case involved an application of the *Merck* principles.

84. At para. 48 of *Biogen*, Costello J., for the Court of Appeal, observes as follows:

> "*48. The presumption of validity may be challenged and rebutted. If a party does not accept that a patent has been properly granted, it may seek the revocation of the patent from the Opposition Division of the EPO or a declaration of invalidity by a national court. The Patents Act provides a comprehensive and sophisticated system to challenge the validity of any patent. Similarly, under the European Patent Convention, a party may object to the Opposition Division of the EPO and appeal to the Technical Board of Appeal of the EPO. Both regimes permit interested parties to have a patent declared invalid in proceedings on the merits. If this occurs, then any product such interested party chooses to launch cannot infringe the prior revoked patent. Such procedure is referred to in some of the judgments as 'clearing the way/path'.*"

85. As to the presumption of validity, Costello J. immediately moves on to observe as follows:

> "*49. However, while such procedures exist, and while it appears that the intention of the drafters of the European Patent Convention and the Oireachtas in passing the Patents Act was that this would be the course of action ordinarily followed, an interested party may choose not to avail of it and to proceed on the assumption that the patent will ultimately be revoked and launch an infringing product 'at risk' in order to obtain a*

first mover advantage. As will be seen from a review of the decision in Merck Sharpe & Dohme, the failure to clear the way has been held by courts in the UK to weigh significantly against any party who opposes an injunction on the grounds of the alleged invalidity of a patent, though the position is less absolute in this jurisdiction".

86. It is clear from *Merck* that this is only one aspect to be taken into account (*i.e.* the fact that steps have been taken to clear the path is *a* factor to be taken into account in the balance of convenience).

87. Moving on, Costello J. observes as follows:

"*51.* ...[In *Astrazeneca AB v. Pinewood Laboratories Ltd* [2011] IEHC 159 it was] *reaffirmed that as a matter of patent law the fact that the parent patent has been revoked does not automatically mean that the divisional patent, in this case the 873 patent, is also invalid and will be revoked. It must be separately assessed and its validity determined by an authoritative body, be it the court or the EPO.*"

88. In the present case validity was determined by a court (this Court) in my judgment of 8th December last.

89. Continuing, Costello J. observes as follows:

"*52.* *...Under Article 9 of the Enforcement Directive, Member States are required to ensure that rightsholders may obtain interim or interlocutory injunctions to prevent any imminent infringement without first establishing the validity of that right. This is so even though, inevitably, given the nature of the regime, there will be cases where the intellectual property right is subsequently declared to be invalid. But that in no way means that if, during the period when the patent was registered, the patentee either exploited the patent or enforced*

the monopoly secured by the registered patent, the right-holder acted in a way that was not lawful or that it improperly obtained benefits".

90. Bringing that back to the present case, what this means is that if the patent continues to be registered, as it will do (that is the effect of the stay being granted), there is no prohibition on claims being made for an infringement of the Patent in the event that, as BMS hopes, my judgment of 8th December last happens to be reversed.

91. Moving on, Costello J. observes as follows:

"*53. It is to be noted that neither the Patents Act nor the European Patent Convention confer causes of action in relation to the reliance by a patentee on a validly registered patent which is subsequently revoked or declared invalid. Specifically, there is no provision which suggests that the earnings are in any way improperly obtained*".

92. BMS will benefit from this position also.

93. Moving on, Costello J. observes as follows:

"*71. A feature of Merck Sharp & Dohme to which 'weight should be given' was the fact that Merck was the holder of intellectual property, a right granted pursuant to an authorisation process provided by law. The Supreme Court held as a matter of law the SPC is valid and effective until declared invalid by a court of competent jurisdiction. This applies equally to the patent in this case....*

72: In my judgment it is an important observation which the trial judge in this case failed properly to apply in his assessment of the balance of justice. It is only if a generic manufacturer makes out a strong case for invalidity that this observation could be held no longer to apply."

[This observation, it seems to me, does not apply where there has been an actual declaration of invalidity.]

ix. *BMS v. Teva*

94. I turn next to the Court of Appeal's judgment in the appeal against the injunction granted pursuant to my judgment of 17th February last in the within proceedings. In §§52-53 of that judgment, Costello J. observes as follows:

> "*52. In my judgment, the High Court was entitled, on the evidence before it, to conclude that the damage which BMS would suffer in the first category would be compensatable by an award of damages.*
>
> *53. I would with respect disagree with his conclusion in respect of the second category, though that is not an essential finding to this judgment.*"

95. There was a surprising level of discussion at the hearing before me as to whether the observation at §53 is *obiter* or not. Short of a judge expressly stating that a comment is *obiter*, I cannot think of a sentence which would more clearly indicate that what was being said was *obiter* than for a judge to say that "[T]*hat is not an essential finding to this judgment*". Counsel for Teva asserted in his submissions of §53 that "[T]*hat's clearly* obiter" and he is correct in so asserting.

96. Moving on, Costello J. observes as follows:

> "*54. BMS, through the evidence of Mr. Cooke, identified the permanent negative impact on the market of a generic competitor, even where that competitor subsequently must withdraw their generic product. Mr. Potter does not engage with this evidence. It is credible evidence which has not been rebutted.*

...

> *58. Mr. Potter does not address Mr. Cooke's evidence that it would be impossible in practice for BMS to reinstate its original price after the generics were removed from the market, as market expectations will have changed and there would be a wholly different pricing environment. He does not address Mr Cooke's assertion that the effect of generic sales prior to the expiration of the intellectual property right would be to prematurely shorten the exclusive rights of the rights holder and that it would never be effectively possible to return the benefit of those rights*".

97. Neither in the application in which Costello J. decided the appeal nor, again, in these proceedings has BMS ever averred as to what it will do as regards pricing. Here, Mr Cooke, a distinguished and experienced witness, has averred that "*BMS will...be faced with the choice of dropping its price to try to preserve some element of its market against the possibility that Teva will be able to remain on the market, or watch its market share reduce drastically*" but he has not averred that prices would actually reduce. As a judge, I can only proceed on the evidence that is placed before me, not on unstated evidence which is left unstated for unidentified "*understandable reasons*" (I borrow from the phraseology of counsel for BMS at the hearing) which have never been stated (leaving aside for the moment that it has never been averred to that it is such understandable reasons that lie behind Mr Cooke's failure ever to aver to the fact that BMS's prices would actually reduce). Fundamentally, however, what seems most important is *not* that the reasons for Mr Cooke's hesitation are not known are but rather that he has never sworn to, in the previous application or in this one, that BMS would drop its price to meet the generic price.

98. Counsel for BMS submitted in the course of this application that it was understandable that Mr Cooke might not want to swear to this. But that is a submission, it is not evidence. BMS was free to swear to this point but it has not had Mr Cooke, or anyone else on the BMS side, aver to the fact that BMS would drop its price to meet the generic price. That creates an uncertainty hypothesis of BMS's creation and there is no reason why I should resolve this

uncertainty in its favour. In fact the evidence before me is that BMS has resisted the reduction of the reimbursement price. The HSE has written to BMS indicating that it will not, while the Patent exists, reduce the reimbursement price.[10] (And, for now, the patent will stand unrevoked on the register because I will be granting the form of stay that I have indicated that I will grant).

99. I note also in this regard that Mr Potter, an experienced individual, who previously worked with Eli Lilly and other major companies, so a man experienced in working with originators, has said it is possible to recoup the reimbursement price. (Mr Cooke has said that this could not be done because it might damage goodwill. But it is difficult to see that any pharmacy, in the face of a rise in prices following on a successful appeal against my judgment by BMS – if that appeal is successful – would decline to deal with BMS's product if, once again, it was the sole party providing that product.)

100. Returning to the substance of Costello J.'s judgment in the appeal against my judgment of 17th February last, she observes, among other matters, as follows:

> "*59. Mr Potter swore a second affidavit on 20 January 2023. This reveals that he was concerned to demonstrate that the calculation of damages is simply more difficult in Scenario 2 (where an injunction is granted and Teva succeeds in the revocation action) than in Scenario 1(where the injunction is refused and BMS succeeds in the revocation action). However, the test for this Court is not which scenario would involve the more difficult calculation, but rather whether in each alternative damages would provide an adequate remedy*."

101. During the proceedings before me, counsel for Teva read out the just-quoted text and matters then proceeded as shown hereafter:

[10] In an email of 10th July 2023, the HSE states, "*Under the terms of the 2021 IPHA Agreement the HSE is not in a position to unilaterally reduce the price of Eliquis until such a time that BMS accepts that Eliquis is a patent expired medicine*".

Counsel: *I think, in fairness, that's not correct and doesn't reflect* Merck. [Counsel then continued reading §59:]

> '*This misunderstanding by Mr. Potter of the question for consideration by the Court lessens the weight which the Court will place on his opinion.'*

But his opinion was only directed to identifying the factors that made damages quantifiable or unquantifiable in both cases. That opinion stands, even if it doesn't have quite the legal importance that it is said that he understood. Mr Potter, like anybody else, is asked to prepare a scenario, he's not a legal person, he is not offering how the Court would assess that in legal terms, what are the legal rules. But it doesn't impact on his assessment of what is quantifiable and not quantifiable, and then it's a matter for the Court to conclude.

Judge: *If I mentioned any of that in my judgment though, am I not getting dangerously close to disagreeing with the Court of Appeal?*

Counsel: *No, Judge. Because you're not, (a)...bound by an obiter* [statement]...[and] *(b) you are bound by the* Merck *case. The* Merck *case says it is relative. And that's why I drew your attention to that. So...in the first instance there is the question: Is it unquantifiable damage? And then the second question is...that's what Merck is all about...you say is it more unquantifiable*

for one rather than the other?...So that is plainly, and it may not be intended in that way, but if it is intended in that way, that is plainly inconsistent with Merck*, which you are bound to follow....*[T]*hat's the very task that* Merck *imposes on you*.

Judge: *Right, thank you*.

102. Moving on, Costello J. observes as follows:

> "62. ...[T]*here was no evidence on behalf of Teva which would have enabled the High Court or this Court to distinguish this case from the decision in Clonmel*."

103. However, there is now evidence that enables that distinction to be made.

104. Costello J. moves on to address an aspect of O'Donnell J's judgment in *Merck* that I have already dealt with above, and in §64 *et seq*. she deals with "*Teva's attempt to clear the path*". Costello J. does not, as I read her judgment, seek to depart from *Merck*, a course of action that was not in any event open to her under our system of binding precedent. The path has been partly cleared, but that is something of a side issue; the issue now is the presumption that was the important matter that swayed the balance in *Merck* (which presumption no longer survives following on my judgment of 8th December last).

105. Moving considerably forwards, Costello J. deals with first mover advantage at §108 *et seq*. She then observes, at §111:

> "*The weight to be attributed to Teva's first mover advantage cannot on its own outweigh the right of BMS to exploit its monopoly to restrain threatened infringement of its IP rights. As each of the other matters Teva contended for weighed in its favour have been rejected, this ground stands alone and cannot outweigh the rights of the SPC holder*."

106. But of course the monopoly right has been declared invalid by me in my judgment of 8th December and the presumption of validity of the Patent has gone.

x. My Judgment of 17th February Last

107. One of the more unusual experiences as a judge is being brought through a judgment that one has oneself authored. However, it was necessary in the course of the present application briefly to return to my judgment of 17th February last. Therein, I stated, among other matters, as follows:

> "*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; (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; (3) there would be damage that is not compensable at all, in particular the loss of exclusivity that goes with being an SPC holder.*
>
> *22. As to points (1) and (2) it seems to me that these are near-classic circumstances in which a court would assess damages.*
>
> [In the changed circumstances now before me and the evidence now before me, my conclusion as to points (1) and (2) must and does stand at this time. As to (3), the Patent was held to be invalid in my judgment of 8th December last. In that context, what O'Donnell J. said was that a party might suddenly find itself competing earlier than anticipated and without the possibility to plan. But here, on any version of events, BMS has had an opportunity to plan, thanks to the length of the

present proceedings; and they have not said, on affidavit, that they never planned for earlier than anticipated competition. That may be a factor that is relevant, *e.g.*, in relation to other generic companies, but not as regards Teva, which signified a relatively long time ago that it was intending to go on the market, and was eventually injuncted.]

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'. BMS, its own evidence suggests, has a choice in this regard and its own evidence is that it could elect to maintain its price....*

[I am, this time around, entitled to be even less impressed in this regard with BMS than I was the first time around, given that this has become a matter of particular controversy and yet its (notable) reticence continues to present.]

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

[Here, I was saying two things that the Court of Appeal did not address in the later appeal, *viz*. that we were in the realm of

assertion, and we were also in the realm of calculable pecuniary loss. Counsel for Teva observed, when considering this aspect of my judgment of 17th February:

> "*So, I'm not asking you to do anything that the Court* [of Appeal] *considers that it shouldn't do...*[Y]*ou are entitled, if something is* obiter*, to clarify the approach you will take. And that's an approach supported by McGovern J and...Judge Barniville...in the Commercial Court....It's an approach adopted in the English decisions. And indeed it's an approach adopted by Judge O'Donnell in* Merck*....But this whole price thing, and* [the suggestion that] *they* [BMS] *couldn't increase the prices* [in the face of generic pricing], *how can you decide the balance of convenience or the unquantifiability of damages on that when you're not told that that may never happen, that they will keep their reimbursement price? ...*[T]*hat would be very unjust, if I may say so, were that to happen, particularly in the changed situation that has now arisen*".]

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. 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.

[The entrance of other generics is now likely unless they are injuncted. But one cannot say that they will not be injuncted. And more generally, the circumstances are now different; there are factors relevant to Teva that it can pray in aid, *e.g.,* the balance of convenience, the partial clearing of the path, and the grant of the stay, which confers a significant benefit on BMS (despite Teva establishing invalidity). But in any event, if the previously considered decisions of McGovern and Barniville JJ. point to anything it is that, as I say in the above-quoted text and as I would reiterate here, it is not impossible to calculate damages, it would be challenging but not impossible.]"

xi. The First Affidavit of Mr Scott Cooke

108. Turning to Mr Cooke's first affidavit, some aspects of the subject matter that he treats with have already been touched upon. However, there are aspects of the affidavit that might usefully be considered at this juncture. So, for example, Mr Cooke avers as follows:

"*31. ...[I]f Teva is permitted onto the market, pharmacists will offer Teva's generic apixaban to patients first, even if the prescription specifies ELIQUIS, unless the clinical exemption applies. Taken together with the fact that the pharmacies do not tend to carry more than 5 days' worth of ELIQUIS and the very low prices at which pharmacies will be in a position to acquire Teva's generic product, a very substantial substitution...can be anticipated in a matter of days.*

32. *BMS will therefore be faced with the choice of dropping its price to preserve try to some element of its market against the possibility that Teva will be able to remain on the market, or watch its market share reduce drastically in a very short time*

[With respect, I do not see that much weight can be attached to what is in truth an artificial dilemma. After all, we are now many months into these proceedings and BMS must have some views as to what is likely to unfold and must have done planning in relation to it. It does not, for example, reveal anything about the considerations that made them maintain price in the UK, even though the prices were reduced very considerably there.]

...

36. *I respectfully repeat the view I expressed in my earlier affidavits that BMS would not be able to recover its original pricing if the price were forced down by regulatory action or even just by price competition from generics operators, all else remaining equal. If the reimbursement price was reduced it would not be possible to raise this again without agreement from the HSE which I believe would be unprecedented. If the reimbursement price was 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 without doing severe damage to commercial relationships.*

37. *...I am not aware of any company ever having [so] restored the price of a product.*

[I have dealt with this line of argument previously above.]

Loss of exclusivity.

38. *In my earlier affidavits, I gave evidence as to the impact of the loss of exclusivity for apixaban under the SPC that generic entry on the market would entail. As I already stated in that regard, the chief impact would be the rendering redundant of business plans for ELIQUIS made on the basis of the full statutory period of the SPC, and the loss of the ability to make further plans. I respectfully sat that this would be a very significant business impact and a systemic blow if it contributed to an inability to securely engage in such business planning for other products in the future.*

[Notably, while mention is made of the rendering redundant of business plans, one is not told what way that would happen. And again, as I noted above, this is not the type of situation contemplated by O'Donnell J. in *Merck* where a right-holder had a presumption of exclusivity and may not have had an opportunity to consider their plans: BMS has had ample opportunity to do so. I note too that while BMS states that there would be a significant business impact and a systemic blow, this is not substantiated. In truth, the chief impact would be the frustration of business plans made on the basis of a full statutory period of the SPC and the loss of the ability to make further plans. But that, with respect, is what happens if a patent and related SPC are invalid. Indeed, that must be something that every originator company plans for, given that it is in the nature of competition within the pharmaceuticals sector that generics may come on the market and may not be injuncted. Absent a presumption of validity, in the wake of a judgment that says its patent is invalid, without any substantiation of its averment that that there would be a significant business impact and a systemic blow, the only thing that Mr Scott seems to be

pointing to is that a company whose Patent has been held to be invalid would no longer be able to operate alone on the market. But that proposition merely begs the questions that I have been teasing out at length in this judgment.]

xii. The First Affidavit of Mr Neill

109. Mr Neill avers, among other matters, as follows:

"*10.* *By the time this application is heard it will be 22 months since Teva launched the Revocation Action seeking to achieve to achieve access to the Irish market and, critically, obtain first mover advantage, in an orderly and lawful mananer and it will be 11 months since the Injunction. In the meantime… the market has grown steadily. This is borne out by the following figures.* [The relevant IQVIA figures are quoted].

[Treating in effect with the contention by BMS that there would be significant generic entry, Mr Neill avers, among other matters, as follows:]

[11]*d.* *It appears that at least one generic intends and is ready to launch immediately. While my knowledge of Mylan's plans is obviously very limited, I understand based on the Cooke/Mylan affidavit that Mylan intended to launch its generic… product if Teva succeeded in its appeal of the original interlocutory injunction granted against Teva in February 2023. This appeal took place in April 2023. If the present application against Teva is refused, directions agreed between BMS and Mylan…require BMS to apply for the withdrawal of the interim injunction against Mylan within 24 hours, (excluding weekends and public holidays) of the High Court issuing its decision. While this is stated to be without prejudice to BMS' right to apply for reinstatement of the*

interim injunction, it (at the very least) contemplates a scenario where there is no such application by BMS. (BMS appears to have a choice to apply or not.) In that case, Mylam could enter the market a mere 24 hours after Teva, even though it has taken no steps to clear the way. Teva has no knowledge of whether Mylan has taken preparatory steps towards a launch in Ireland, or was permitted under an earlier undertaking, now spent.

[Notably, BMS would be entitled in the normal way to apply for an injunction if Mylan decided to go ahead in these circumstances.]

e. *The position as regards the other generics is very unclear. Although BMS has indicated that it would injunct other generics, if necessary, Teva is not aware of BMS bringing any application against any generic company other than Mylan. Further, Teva is not privy to correspondence between BMS and other generics or any undertakings that may have been given…*

[The correspondence between BMS and other generics has been furnished. It is not as unequivocal as BMS seemed to suggest. For example, it appears that the first generic company will not do anything until the expiry of the SPC (that has now fallen as a result of my holding the Patent to be invalid). The second says it has no current plans to launch and will give an undertaking as to notice. The third and fourth gave no response, which perhaps can be read either way. In any event, all of this, in one sense, is within BMS's control: it is the master of whether injunction applications are brought against generic companies and, as Mr Neill has averred, it has indicated that it will injunct other generic companies, if necessary. Perhaps the key point in all of this is that if generic

companies launch, that has two consequences. First, BMS has the opportunity of seeking to prevent that launch. And the status quo at that stage will be that Teva will be on the market and it will be over to the courts to decide whether to injunct each of the other generics on the basis of the particular facts pertaining to that generic company. Second, if the generic companies come on the market, it will still be possible to assess the damages suffered by BMS, in the manner explained by Mr Potter (to which I will come later below). There will then be clear evidence for whoever is assessing damages (if liability for damages arises) of what the position was/is on the market, enabling the deciding court to do what courts do, *i.e.* make a judgment as to what the losses are. This is the sort of thing courts often do. In competition cases, for example, it is done all the time: markets fluctuate; prices fluctuate; and, depending on the nature of the anti-competitive practice it may have a larger or smaller impact on price, and it may foreclose people from markets that would otherwise have developed. These are matters that are compensable in damages and, certainly in competition cases, I am not aware that anyone has ever said that damages cannot provide an adequate remedy in those circumstances. There may be cases where damages are more difficult to estimate or more unquantifiable than others. However, in general terms, these are things that a court is very well equipped to do, particularly if it has, in a sense, both sides of the picture, *i.e.* BMS's picture before the generic companies, and then what the generic companies did to the market share BMS had. As Mr. Potter avers, it is a question of reduction in value and reduction in price and you multiply one by the other and an answer is arrived at. Of course there may be some complicating factors, but that is the case in any market assessment and a judgment is made on that, depending on the evidence.]

...

47. *Mr Cooke claims that BMS will suffer permanent damage if the injunction is not extended....As in his previous affidavit, Mr Cooke does not aver that BMS will lower its price of the injunction is not extended, thereby permitting Teva to launch. Instead, he states a belief that current market conditions 'will result in an inevitable and very significant price drop for ELIQUIS if Teva' launches Apixaban Teva. He says that any such hypothetical price reduction is 'one that will not be recovered'.... However, as stated above and in the affidavit of Laura Reynolds, BMS did not seek an injunction against Teva in the UK market and did not drop its price following Teva's entry on the market.*

[I have already touched on the fact that Mr Cooke does not aver that BMS will lower prices and I referred also in passing to the fact that BMS did not drop its price following Teva's entry on the market in the UK. There is suggestion in the evidence before me that the UK is a very different market but no explanation of this. And it does not, with all respect, suffice in an affidavit to assert (in the way done here) that such a thing is the case but make no averments as to why it is the case, leaving the judge to engage in a guessing game, if she is prepared to do so, and I am not. Courts, I cannot but respectfully observe, proceed on evidence, not on bare assertion by a witness coupled with hoped-for judicial guesswork.]

...

[60]e. *Mr Cooke speculates that a reduction in BMS' reimbursement price would be irreversible 'without agreement from the HSE, which I believe would be unprecedented'.... However, that*

reversal is exactly what appears to have happened in exchanges between the HSE and BMS in July 2023. [In truth, I think this was more a case of the HSE getting a little ahead of itself in this regard, and pulling back when the truth of matters was put to it.] *In any event, that scenario will not reoccur given the statement by the HSE that it will not reduce the price unless 'BMS accepts that Eliquis is a patent expired medicine'. Furthermore, I do not believe that this would be so in circumstances where BMS would again have exclusivity with respect to an essential drug* [in the event of a successful appeal against my judgment of 8th December last]. *This belief is reinforced by the fact that BMS would adopt the normal practice engaged in by it and other pharmaceutical companies of not voluntarily reducing the list price but instead offering discounts which can easily be withdrawn when there is no longer any competitor.*

[I have already treated with the point in respect of the reduction in the BMS reimbursement price. Mr Neill indicates why he considers that this would not happen.]

...

Pharmacy Stocks

61. *For completeness, I beg to refer to para.[31] of the Cooke/Mylan affidavit, where he states that he understands that 'Irish pharmacists do not tend to carry more than five days' worth of stock of Eliquis at any one time'. This statement also appears at [59] of the Cooke/Mylan affidavit. In the Mylan application, directly following this statement, Mr Cooke goes on to state at para.[60] that generic apixaban 'would be capable of being stockpiled by pharmacies following its launch'. It is difficult to understand how this*

could happen given storage capacity within pharmacies and the averment made by Mr Cooke in relation to no more than 5 days' worth of stock being held by pharmacies at any given time.

[The five day period is something that Mr Cooke himself acknowledges]."

110. Other points of interest in Mr Neill's first affidavit include the following:

"*Changes in the DOAC market*

36. At paragraphs 11, 12, 13, 14 Mr Cooke refers to the patent status of other DOACs: rivaroxaban and dabigatran, and states that the expiry of the relevant patents renders matters 'more complex' and will have 'uncertain implications'....However, this is a diversion: these two molecules may or may not have an impact on the volume of apixaban sold. However, this will happen with or without the entry of generic apixaban.

37. Moreover, as stated in paragraph [11] of Mr Cooke's affidavit, dabigatran has been off-patent since August 2023. Two MAHs hold a licence for generic dabigatran, namely Accord and Clonmel Healthcare. The dates of these licences are 26th May 2023 and 10th November 2023 respectively. However, neither generic has a reimbursement price or has launched.

38. The following data shows that dabigatran volume sales in Ireland are very low in comparison to apixaban....

39. This discrepancy is not surprising. Apixaban is considered the DOAC of choice by the HSE Medicine Management Programme ('MMP'). For that reason, a decrease in price for apixaban is unlikely to change the prescribing patterns of healthcare professionals when selecting the most suitable

DOAC for a patient. They are already being asked to consider apixaban as first choice."

xii. The First Affidavit of Mr Potter

111. The next document worth noting is the first affidavit of William Potter. He was asked to consider various scenarios:

"*15. ...[1] The interlocutory injunction is not granted and Teva's apixaban is placed on the market, but no other generic is permitted to do so. At the final determination of appeal judgment is handed down, finding the patent is valid and infringed and, accordingly, Teva's apixaban is removed from the Irish market. BMS seeks damages from Teva which has marketed 'apixaban' in the interim, for losses it has incurred as a result of generic apixaban wrongly being allowed to be available on the Irish market.(Scenario 1A)*

[2] The interlocutory injunction is not granted and Teva's apixaban is placed on the market and other generics are also permitted to do so. At the final determination of the Appeal, judgment is handed down, finding the patent is valid and infringed and, accordingly, generic apixaban including Teva's is removed from the Irish market. BMS seeks damages from Teva and any other generic companies which have marketed apixaban for the losses it has incurred as a result of the generic apixaban wrongly being available on the Irish market in the interim.(Scenario 1B)

[3] The interlocutory injunction is granted and Teva is restrained from placing Teva's apixaban on the market until the final determination of the Appeal. The final determination of the Appeal results in the revocation of the Patent. Teva seeks damages from BMS for the losses it has incurred for wrongly being kept off the Irish market in the intervening period ('Scenario 2'). For the purpose of Scenario 2 I make the

assumption that BMS will also seek and be granted injunctions against all other companies attempting or threatening to launch a generic apixaban. This is based on the fact that BMS is seeking an injunction against Mylan and that I am instructed that BMS' counsel confirmed during the hearing of the injunction application in February 2023, and that BMS' solicitors have confirmed since in correspondence, that such injunctions would be sought.

...

Quantifiability of Losses in Scenario 1A

19. *BMS's loss is calculated in Scenario 1A 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 Teva's apixaban had not been launched into the Irish market (the counterfactual scenario). This is as described as Scenario 1 in my Previous Affidavits, where the calculations required, to assess loss are described in detail. I have recorded a summary of the key elements here in order to illustrate the calculation which requires:*

20. *Market volume in the factual scenario: This is the summation of the quantities of product sold in the factual scenario and is determined by the summation of the sales of BMS in Ireland, the sales of Teva in Ireland, plus an adjustment, if required and appropriate, to allow for sales of imported parallel imported product. These sales are not BMS sales, but rather sales of importers who have purchased apixaban originating from other European states where BMS entities put the product on the market.*

21. *BMS's price in the factual scenario: BMS will have access to its ex-factory selling prices for products sold in Ireland. If subject to paragraph 20 there is parallel imported product*

sold by other BMS affiliated entities elsewhere in Europe, the sales price of those products, if required to be taken into account, will need calculating or estimating, depending on the information available to the court. BMS will have access to the price realised by BMS entities making the sales of product in other EU markets that are ultimately supplied as parallel imported product in Ireland. The typical source markets will be known to BMS and using tracked data by IQVIA a reliable calculation or at least a reliable estimation may be made.

22. *The counterfactual market price is based on the price achieved by BMS and, if relevant, other BMS affiliated entities in the factual scenario prior to competition from Teva. This is expected to be a stable pricing environment in the counterfactual as a result of the absence of direct competitive forces for apixaban sales. This is because the counterfactual reinstates BMS' SPC and its sole supply position, and so there are no apixaban generics driving the price downward. The only competition is therefore from parallel imports of Eliquis and market competition from other DOACs. Given BMS's dominance, both in the apixaban market and the markets for the treatment of non-valvular and atrial fibrillation and for stroke prevention in Ireland and concerns about reference pricing, BMS is not expected to alter its pricing strategy. The pricing is applied to the total market volume as summarised in paragraph 20.*

23. *Using data described at paragraphs 20 and 21, the factual scenario profits of BMS may be calculated and using the data described at 20 and 22, a reliable estimate of the counterfactual profits of BMS may be made. Therefore, BMS'losses can be estimated with a high degree of confidence where appropriate adjustments can be made to take account of growth or other variations in the market.*"

112. This is the archetypal situation in which the court would assess damages, the information is there to enable it to do it and if, in the normal way, Teva was sued for infringement and BMS came to court, this is the way that the damages can be calculated. There may be elements that are more difficult to quantify but nothing that is unquantifiable.

113. Moving on, Mr Potter observes as follows under the heading "*Quantifiability of Losses in Scenario 1B*" :

> "*24. BMS' losses are calculated in the same way as Scenario 1A, calculating the loss in total. The number of participants does not change the process of the calculation described above and in my previous affidavits. Once the total loss is calculated, the proportion attributable to each of the generic companies entering the market must be decided.*
>
> *25. This apportionment can be made based on the quantity of products supplied into the market by each generics company on a pro rata basis.*
>
> *26. Therefore, as with Scenario 1A, the losses can be calculated with a good level of accuracy and the attribution of these to each of the generic companies can be made based on volumes as a suitable basis for allocation.*"

114. That is consistent with what the English courts say one should do. I cannot but note that we would have a very inadequate damages assessment system if a court could not cope with quantifying the losses in scenario 1A and 1B.

115. Moving on, Mr Potter proceeds to consider the "*Quantifiability of Losses in Scenario 2*", observing among other matters as follows:

> "*28. The key reasons why Teva's losses in scenario 2 are harder to estimate is as a result of the changing competitive landscape, the loss of first mover advantage and the enduring nature of the losses. Whilst the counterfactual size of the market may be reasonably assessed, the competitive situation that will*

determine the market shares of the respective companies which generic companies would have actually chosen to launch before the decision on appeal, the timing of their expected launches and the prices at which they may have launched will all be a matter of assertion or estimation, as no reliable factual benchmark can be established. This is because in Scenario 2, the factual situation does not allow any entry before the decision on appeal, and so a large number of generics will enter in rapid succession once the Appeal is determined. That would not be reflective of the counterfactual launches before the appeal."

116. Again what presents is a legal question. The other matters touched upon may complicate matters but they do not make it impossible to quantify losses or look at the comparative position between the parties.

117. Moving on, Mr Potter avers as follows:

"*31. Launch By Other Generics*

Dr Stomberg and Mr Cooke assert that other generics companies, not limited to Mylan and other companies with marketing authorisations would follow Teva into the market following a lifting of the interlocutory injunction against Teva....

32. Response

a. As described above and in my previous affidavits such additional competitors in Scenario 1B would have a greater impact on the quantum of loss suffered by BMS by increasing the rate of erosion of BMS' price and market share, but this does not make it harder to calculate as it is calculable in total and attributable between the generic companies on at the

suitable basis of the quantity of material sold into the market. Furthermore, each generic company not injuncted and launching at risk is liable for its actions, in damages.

b. I am informed that BMS has commenced proceedings to injunct Mylan and have previously made it clear in Court during the original injunction application in February 2023 and in correspondence since then that they would initiate similar proceedings against other generic companies that they feel are likely to make steps towards launching their generic apixaban products while the SPC is in force. Therefore it is far from certain that any or many companies would follow and the Scenario 1A where only Teva launches at risk is a realistic possibility [I assume because Mr Potter expects that the other would-be generic distributors would have been the subjects of injunctive relief.]

c. Other generics companies will make their own assessment on the validity of patent and SPC. They take the risk based on their own actions not on account of others' assessment of the position. Interpretation of how Teva and/or others assess the risk of their actions are therefore at best only a minor part of that assessment. Indeed Dr Stomberg...himself considers that a cascade of generic entrants is not likely.

33. Changes in the DOAC Market

Dr Stomberg and Mr Cooke assert that the DOAC market may change over time impacting competition and prices....

34. Response

a. There are aspects of the DOAC market that are changing over time, but many of the examples cited do not vary depending on whether there is generic competition or not. For example, complexities such as the patent expiry of

dabigatran...exist in both factual and counterfactual in any assessment of damages. Dabigatran is, in any case, a small and eroding part of the DOAC market representing only 3% of the DOAC market by volume (as averred by Mr Cooke in his affidavit in the Mylan proceedings...)

b. It is possible that a reducing price may stimulate an increase in the prescribing of apixaban as opposed to other DOACs, and so a counterfactual market may have slightly different dynamics to a factual one. This equally applies in all Scenarios 1A, 1B and 2. The assessment of the base position for a market in any counterfactual can be estimated using trend analysis and using expected differences from the factual. Further, as noted by Mr Cooke in his affidavit in the original injunction proceedings...apixaban is already the DOAC of choice, and so such market changes will have been underway over time in any event.

c. One source of high quality market analysis and insight will no doubt be BMS' own business plans and modelling. BMS will have forecasts of the market assuming its SPC remains in place, and having detailed knowledge of the clinical and market dynamics BMS will be well placed to assess how the market would be expected to develop. These forecasts would be a suitable basis for the counterfactual in Scenario 1A and 1B, though I am not aware if they have been disclosed in these proceedings. [They have not.]

35 *Early Temporary Generic Entry*

Dr Stomberg asserts that early, temporary, generic entry will increase the speed of generic launch when the SPC finally expires in scenario 1A or 1B as a result of the 'primed' market....

36. Response

a. While a temporary generic entry will quickly erode any level of branded prescribing that exists in the market place, it is also the case that the designation by HPRA of apixaban as interchangeable would result in a very fast conversion of the market to INN product as any prescriptions, including those branded as Eliquis, would be filled with generic product. Therefore any 'priming' of the market has essentially already been completed by HPRA in advance of any generic product launching.

b. I expect that the rate of INN vs. branded prescribing is already substantially converted to INN prescribing, again prior to any generic product launches. I am informed that MMP already recommend apixaban by its INN as the DOAC of choice, which accords with my expectation.

37. Return to Previous Pricing

Dr Stomberg and Mr Cooke assert that it would be difficult to return to a previous pricing equilibrium in the event that generic apixaban is removed from the market following an Appeal upholding the validity of the patent.

38. Response

a. BMS would be highly unlikely to alter its list price for reference pricing reasons, and instead would compete through discounts offered to wholesalers and pharmacists. This was also the approach taken by BMS in the UK where generic apixaban was launched after BMS chose not to pursue an injunction. Discounts to wholesalers and pharmacies are at BMS' sole discretion and it is my opinion that a reinstatement

of prior pricing on account of a successful appeal confirming the validity of the patent and SPC would not be severely damaging to commercial relationships with these customer groups.

39. Vigorous Competition if No Injunction

Dr Stomberg asserts that there would be vigorous competition if injunction is not continued....

40. Response

a. This is the only case in Scenario 1B and even then, it is understood...that BMS is expected to seek to injunct other generic companies planning to launch.
b. Even if there is a strong competition factor that is not an impediment to the accurate calculation of the loss to BMS in Scenario 1B, merely a factor that increases the quantum of loss.

41. Interchangeability Incentivises Generics to Launch Early

42. Response

a. It is true that the interchangeable designation may incentivise generics to compete and to launch early, substituting more expensive generics and originator brands. This is the intended consequence of the status. However, this additional competition is the case at any point that generics are able to launch and is not linked in any way to the actions of BMS, Teva or other generics. The HPRA designation as interchangeable is a move to secure best value to the State in any eventuality that does not complicate the calculations. The

process described above and in my previous affidavits is unaffected by this.

[As mentioned previously above, a confidential exhibit was placed before me by BMS during these proceedings which indicates that it has been in correspondence with certain generic suppliers from whom there either has been (i) no response in terms of a request for an undertaking not to market or (ii) an assurance that can be reversed on quite short notice. In other words, that correspondence shows that there is no solid assurance from those generic suppliers that they will not seek to come onto the market if the situation with Teva changes. I understand there to be eight generic suppliers who have marketing authorisations at this time, though that in and of itself does not mean that they are ready or about to launch. I note too that the evidence put forward in terms of that confidential exhibit is consistent with the fact that there will be an interval between the launch of Teva and possibly the launch of Mylan and the other generics, even if they launch.]

xiii. The Second Affidavit of Mr Cooke

118. In passing, continuing for a moment with the issue of first mover advantage, to the extent of course that other generics might seek to launch in or about the time that Teva would launch is, as I have already touched upon, a significant factor to be weighed up by me in deciding whether or not to grant the injunction sought. That is recognised in *Merck* as a significant factor and, of course, once first mover advantage is lost, it is gone and cannot be recovered. Mr Cooke in his second affidavit takes issue with the notion of first-mover advantage, averring as follows:

"*14. I respectfully believe that the first-mover advantage is not a permanent one and that the granting of an injunction would not occasion permanent damage to Teva. I also believe that Teva's position therefore stands in contrast to that of BMS...*".

119. I cannot but note that Mr Cooke gives no reason for this belief, suggesting his views in this regard to be, if I may respectfully observe, in the nature of but an article of faith.

120. I note also that at §20, Mr Cooke avers as follows, under the heading "*Calculability of Lost Volume*":

> "*20. The recourse to 'trends' appears to me to amount to an admission that estimated, not actual, damage is being assessed and therefore elements of damage would not be compensated for. The trends-based approach would also necessarily amount to a conservative approach based, as it would be, on past market performance. In the event that the market performance was not actually consistent with past periods, Mr Potter merely proposes that 'where appropriate, adjustments can be made to take into account growth or other variations in the market'...*
>
> [He continues in something of a similar vein at §§28-29]"j.

121. I cannot but respectfully observe that in any damages case where an aggrieved party suggests that 'We would have done better if this had not happened or that contract was not broken' a court has regard to trends and makes an assessment as to whether those are or are not reliable in the circumstances. If the projections are unduly optimistic, that court will not accept them as evidence of loss; if they are not unduly optimistic then it will have regard to them. But that is part of the normal damages assessment that takes place. So, Mr Cooke is identifying the tools that a court would be (and it would be) likely to use in estimating damages and arriving at conclusion as to the scale of those damages, but doing so on a well-recognised basis.

122. At §37, Mr Cooke avers as follows:

> "*Teva states that BMS would also compete through discounts. Mr Neill says, in particular,...that in his experience 'discounts fluctuate', 'it is not unusual for discounts to be offered and later discontinued' and*

ultimately that he does not accept in any statement that discounts and rebates would be 'impossible in practice to reverse'. That may well be the position for generics companies who trade principally on price. However, I am unaware of any originator company, reducing the price of its branded medicinal products, through discounts or otherwise, only to reinstate the higher price..."

123. I cannot but respectfully note that here again an opportunity presents for an explanation to be given to me as to what BMS would intend to do as regards pricing and it notably fails to do so. The same point arises to be made by me as regards §40, where Mr Cooke avers as follows:

"*Finally, I note repeated references to BMS's action*[s] *in the UK. For example, Mr Neill at paragraph 18 states that 'BMS did not seek an injunction in the UK' and at paragraph 19 that 'in the UK market, BMS have taken the decision not to decrease their List Price'. The issue of BMS not seeking an injunction in the UK in a different legal and factual context and subject to the UK regulatory regime and market dynamics was addressed in the context of the interlocutory injunction application and unsurprisingly that did not preclude the grant of an interlocutory injunction in this jurisdiction. In so far as the point is now made that BMS has decreased its list price in the UK that is consistent with the approach that BMS has taken to the reimbursement price for Eliquis® in Ireland, as described above*."

124. Again an opportunity presents for an explanation to be given to me as to what BMS would intend to do as regards pricing and there is a notable failure to do so. As to the granting of the previous injunction, as I have previously stated, this application for injunctive relief falls to be considered, with the various factors to be weighed, in the different circumstances now presenting, most notably on account of the issuance of my judgment of 8th December last.

xiv. The Second Affidavit of Mr. Neill

125. In his second affidavit, Mr Neill, among other matters, avers as follows, under the heading "*Dabigatran*":

> "*16. Mr Cooke suggests that the apixaban market is rendered more complex by the entry (or prospective entry) of other generic DOACs....Mr Cooke notes that Accord generic dabigatran was launched on 1st January 2024, and says that the implications that the availability of generic dabigatran will have for the DOAC market and the impact on Eliquis®, in the absence of generic apixaban being available, is unknown and difficult to predict....However, this is not the case. Generic dabigatran is unlikely to affect sales of apixaban...*".

xv. Dr Stomberg's Affidavits

126. At §16 of his first affidavit, Dr Stomberg avers, among other matters, as follows:

> "*Given the complex and changing commercial markets in which apixaban operates, there is a substantial risk of irreparable harm to BMS should a stay on the High Court order be refused. These harms include the potential for a cascade of competitive entry likely triggered should a stay be refused*.
>
> [Cascaded competitive entry is a matter that Mr Potter convincingly deals with as to how it would be dealt with if it were to occur.]
>
> ...
>
> *It would be a matter of speculation to assume that BMS' competitive situation with an SPC still in place could be reliably simulated after the fact from market conditions where generic entry was allowed to proceed before this dispute is concluded.*

[Mr Potter has explained why that would be done]."

127. Dr Stomberg later moves on to consider the role of information generated by Teva's litigation, observing among other matters as follows:

> "*27. Teva's potential generic competitors have not invested in challenging BMS' SPC for apixaban; they nevertheless benefit from Teva's efforts to remove entry barriers and 'clear the way' for apixaban generics in general. Teva's favorable decision in the proceedings against BMS' SPC for apixaban will become known to all registrants.*
>
> *28. Even though most participants will receive this information at the same or roughly the same time, it is not certain to serve as a bright-line moment that opens the floodgates to generic apixaban competition in Ireland. Other registrants may or may not choose to enter depending on the specifics of their risk assessment related to the possibility of reversal on appeal....What is not likely is a post-trial cascade of generic entry analogous to that which occurs when there is a certain date when all patent and regulatory exclusivity periods have been exhausted....*
>
> *28. The actions of other competitors may also communicate information relevant to the decisions of others.*"

128. Yet in Dr Stomberg's second affidavit he avers that:

> "6. *There is little reason...to suspect that other manufacturers would refrain from entering if Teva were allowed to do so*."

129. Dr Stomberg seems to be saying in the last-quoted text something that is qualitatively different from what he states in the above-quoted text where the whole process seems more nuanced and less certain.

130. In his first affidavit, under the heading "*Other Avenues of Irreparability*", Dr Stomberg avers, among other matters , as follows:

> "*37. ...BMS is seeking approval for paediatric indications for the use of apixaban.... An untimely loss of exclusivity can have the effect of disrupting plans and efforts along these lines that benefit patients in Ireland. More broadly, BMS expends effort to compete with other products in the anti-coagulant category and to further extend the reach of apixaban to treat under or untreated populations. When the economic benefits of those efforts are suddenly spread across competitors, this may cease to be an economically viable activity. This type of outcome could permanently and unpredictably alter the trend of growth for apixaban*."

131. As I understand matters, this happens irrespective of entry into the market. It is an obligation under the SPC.

132. When it comes to first mover advantage, Dr Stomberg seems to suggest that there is some confusion on the part of the Teva deponents, where they state that first mover advantage would give a 70-80% share of the apixaban market. (Stomberg, Aff.2, §12). However, Mr Neill, in his affidavit evidence, makes clear that what he is referring to in this regard is the share if there were no other entrants. The share will reduce if there are other entrants. But yes, if Teva gets the opportunity of moving first (or early) they will have a higher market share (in or about 40% if they are first movers).

133. Another issue raised by BMS is that of parallel imports. In his second affidavit, Dr Stomberg deals with this issue at §§21-22. Two points might usefully be made in this regard. First, there are parallel imports happening right now. However, this is a market phenomenon that courts are well-used to dealing with. At the moment parallel imports likely take from BMS's profits or revenue and, based on historical performance, a court can make a judgment as to what the likely parallel imports would be over the next year if BMS remained on the market as the exclusive supplier. That would be the base for calculating the damages on scenarios 1A and 1B. But there would be evidence in relation to that. The same would be the

case with dabigatran. These are factors that a court can take into account. Second, if there are generics on the market, parallel imports seem likely to impact upon reliance on generics.

134. Fundamentally, the existence of parallel imports adds a level of complication; however, it is not something that cannot be quantified.

xvi. Some General Submissions by Counsel for Teva

135. Close to the completion of his oral submissions, the lead senior counsel for Teva made some general submissions in terms that I found most helpful in deciding how to decide this application for injunctive relief, and with which, having regard to all the facts and evidence before me, I respectfully agree:

> "[1] *There have been changes* [since the last injunction application]*, but those changes don't impact in any material way on the difficulty of calculating the damages that would be suffered by BMS in scenario 1A and 1B. Mr Potter has explained why that is so. You can use your judgment as to whether you agree with it and your experience. We say that holds. If that is correct in terms of lost revenue, all of that can be replaced, including now on the additional evidence you have....*
>
> [2] [As to the calculation of damages]....[f]*irstly, you did conclude in your first judgment that that can be measured in damages. That's supported by those other cases. And it's implicitly...supported by* Merck*, which identifies that there are very few cases where you can't make a calculation of damages. Mr Potter has now responded, in any event, to that and explained how that is done by way of discount, so it doesn't affect the reimbursement price, and how you can explain to the pharmacists why you're raising it. So, you can make a judgment on that, even if it hasn't been done before.*

[3] *The fact of the matter is there is now a second set of affidavits. The* [High] *Court, if it is to consider an element of the damages as being unquantifiable or unduly complex, is entitled to say, 'In order to do that, I need to know what is likely, I have not been told what is likely and if they maintain the reimbursement price, there is no complexity, it doesn't arise at all.'*

[4] ...[I]*t would be unjust on this second round to apply* [the clearly *obiter* comment of the Court of Appeal considered previously above]...*and say that answers the situation that is there now. It doesn't.*

[5] *Yes, the interchangeability has changed, but....but even let's say everyone is going to come on the market; it's been explained how damages can be calculated in that way, how damages can be apportioned between the various wrongdoers. So, those changes don't alter anything in favour of BMS. But in fact, in terms of the damages, you did find that previously that the damages were unquantifiable, to an extent with regard to my client, and certainly much more difficult to calculate. That has been supported by the additional evidence of Mr Potter where he clarifies the matters and explains how it is so. And in fact, if it is the case that generics are likely to enter the market if not injuncted, that very factor will make my client's* [*i.e.* Teva's] *damages all the more difficult to calculate....*

[6] ...[W]*e do go back, Judge, to what is the task that you have. Even if you feel bound and can't distinguish, in the light of what I have said and more particularly the changed circumstances...*[including the] obiter *comment* [of Costello J. in the appeal against my judgment of 17th February of last year where]...*she expressly says it's not essential to the decision...and you say that damages on both sides, there is a draw, as you said previously – and I would urge that you*

wouldn't do that – you then come to look at the other balance of convenience factors.

[7] ...[W]*hat has to be decisive in that instance is there is no longer a presumption of validity. I don't know how it can be maintained that something that has been declared to be invalid by the same court or any other court – because we respect the system of decision at first instance, subject to review – that it can now be said to be presumptively valid. If that is the case, that significant weight in the balance of convenience identified by Judge O'Donnell goes...and that becomes a weight in our favour*...[It is] *a factor...he said, if you've got a strong case where there have been a succession of decisions abroad or you can convince the court you have a strong case. Well, we have, because we have won. So that then becomes a factor.*

[8] *This loss of exclusivity which was referred to...O'Donnell* [J.] *clearly explains what that is. That is the exclusivity that you enjoy if you have the monopoly. But it's...circular reasoning....*[b]*ecause if they don't have the monopoly, you don't have a loss of exclusivity*.

[9] ...[A]*s was said* [by Costello J.] *in the Court of Appeal, what you are really talking about is loss of revenue that will be generated from the monopoly. And that can be calculated in damages.*

[10] [This is more in the nature of an amplification upon point [7]]. *When you have the presumption of validity, the court says usually 'We won't allow you do that, we'll give an injunction against you, because the patent holder has the presumption of validity. But that no longer applies....So...we say the injunction should now be looked at afresh and...should not be granted.*

[11] *The other strong factor in the balance of convenience...is that BMS is...getting the advantage of a stay....*[T]*he considerations of balance of convenience in the stay are different from the balance of convenience considerations that now apply against me where the ...*[patent] *is...invalid. And that's very different from saying to somebody who wants to go...to appeal I'm going to deprive you of all benefit of the patent that you got until that appeal is determined, and even if it's reinstated, you could have everybody on the market and then you don't have the benefit of any undertaking as to damages....That doesn't arise in the case of the injunction, for the obvious reason that we're required to give an undertaking as to damages and they can be calculated in that way....*

[12] [There was suggestion]...*by* [counsel for BMS]...*yesterday that...large elements of damages will not be compensated; I don't know what is being referred to. There is no evidence of that. On the evidence, all those are capable of being answered.*

[13] [As to the] *suggestion that price depression is very likely....there's no averment that* [BMS]...*would reduce prices to pharmacies and it can't ask you to operate on that basis....*

[14] [T]*here was a lot of evidence BMS could have put before you about what happened in England. They could have said it's different in this way and that way but allowed you to assess it. Because that is a situation where they didn't seek an injunction, didn't seek a stay and there is evidence as to what happened. And that seems to us to be a deficiency in their presentation of the case in that regard*."

D. Conclusions

136. Arising from all that I have stated in the preceding pages, there are, I believe, five key reasons why BMS's application for injunctive relief must fail:

(1) the main ground for my granting an injunction in my judgment of 17th February last (and indeed the main reason why it was upheld on appeal) was the fact that BMS had a property interest in the presumptively valid SPC. But following on my judgment of 8th December last, there is now a "*firm assumption*" (*AK v. US* [2022] IECA 65, §53) that the patent is invalid (with the result that the SPC also falls).

(2) In the previous application for injunctive relief, I rejected near-identical evidence relied upon by BMS to that now before me in support of its claims that it would suffer irreparable harm in the event that the injunction was refused. Here, by reference to the evidence before me, I reach the same conclusion (rejection). Indeed, I am buttressed in doing so this time round by the fact that (i) (as touched upon at some length previously above) BMS continues not to make any averment that it would lower prices if Teva were to launch generic apixaban, and (ii) the HSE has confirmed in writing that it will not impose price reductions until BMS accepts that the Patent has expired.

(3) again based on the evidence before me, I find that the harm caused to Teva by the grant of an injunction could not be compensated in damages; and the position, if anything, has got worse for Teva. It has spent the better part of three years trying to clear the path, its efforts have been vindicated in my judgment of 8th December, and it is in jeopardy of losing first mover advantage.

(4) it seems to me that Teva should now be entitled "*to reap the commercial reward for its acumen in identifying the frailty in the SPC and being willing to back its judgement*" (to borrow from O'Donnell J. in *Merck*, §55).

(5) all the foregoing being so, it seems to me that Teva (if the requested injunction was now to be granted) would suffer far more greatly than BMS (if the requested injunction was now to be granted), not least though not only where any loss to BMS can be calculated in damages, which calculation would not be without difficulty but is certainly not impossible and is entirely within the gamut of the types of loss (if loss is suffered and falls to be the subject of a future award for damages) that courts are competent to deal with and accustomed to dealing with.

137. Having regard to these factors and to all the other factors that I have considered in the course of this judgment, I respectfully decline to grant the injunctive relief now sought.

138. As with my previous judgments in these proceedings, I will give the parties time to consider whether there is any commercially sensitive information contained in the version of the judgment now being circulated to them that ought not to be made public and/or any obvious typographical errors that require to be corrected. If the parties could revert to me in this regard by 24th February 2024, I would be grateful.

139. I will hear the parties as to costs.