THE COURT OF APPEAL

CIVIL

[Approved]

[No redaction needed]

Court of Appeal Record Number: 2024/31

High Court Record Number: 2021/4758P

Costello J. **Neutral Citation Number [2024] IECA 143**

Noonan J.

Allen J.

BETWEEN/

BRISTOL-MYERS SQUIBB HOLDINGS IRELAND UNLIMITED COMPANY

PLAINTIFF/APPELLANT

– AND –

NORTON (WATERFORD) LIMITED T/A TEVA PHARMACEUTICALS IRELAND

DEFENDANT/RESPONDENT

JUDGMENT of Ms. Justice Costello delivered on the 13th day of June, 2024

Introduction

1. By a judgment delivered on 8 December 2023 in the patent proceedings (2021 No.1 PAP), ([2023] IEHC 744) the High Court held that Irish Patent No. EP (IE) 1 427 415 *("the patent")* is invalid. As a consequence, the Supplementary Protection Certificate No. 2011/032 *("the SPC")* held by the plaintiff/appellant *("BMS")* is also invalid, as the patent is the basic patent underpinning the SPC. The SPC protects the medicinal product Eliquis®

(active ingredient apixaban) which is a hugely successful anti-coagulant medicine. If not invalidated, the SPC is due to expire on 19 May 2026.

2. By order dated 2 February 2024 (perfected 7 February 2024) the High Court granted a stay on the revocation of the patent from the register until the first directions hearing of the appeal by BMS in the Court of Appeal. Barrett J. ([2024] IEHC 91) refused to renew the pre-trial injunction which he had given in February 2023 restraining the launch by the defendant *("Teva")* of its generic product and he granted a limited injunction up to 4pm on 9 February 2024 restraining Teva whether by itself or its directors, officers, servants or agents from launching, offering or putting on the Irish market a generic version of BMS's medical product Eliquis. He did not restrain Teva from importing or stocking such products or taking other steps preparatory to the launch of its product.

3. The order of 2 February 2024 was perfected on 7 February 2024. BMS filed two notices of appeal on 8 February 2024, the first against the judgment revoking the patent and the second against the refusal of an interlocutory injunction restraining the launch of Teva's generic medicinal product pending the determination of the appeal. The parties agreed to continue the stay on the revocation of the patent until the determination of the appeal; and to continue the injunction pending the appeal by BMS against the refusal of the injunction until the appeal could be heard and determined by the Court of Appeal, on BMS's undertaking to continue to take steps to seek to ensure no other generic is permitted to launch, or to take preparatory steps to launch, a generic version of apixaban pending the determination of the injunction appeal.

4. The appeal in respect of the refusal of the injunction was heard by this Court on 12 and 13 March 2024 and judgment was reserved.

Jurisdiction of an appellate court in relation to discretionary orders of the High Court

5. The approach which this Court is required to take when considering an appeal from a decision of the High Court to grant or refuse an interlocutory injunction is well settled (see *Betty Martin Financial Services Ltd. v. EBS DAC* [2019] IECA 327; *Lawless v. Aer Lingus* [2016] IECA 235; *Collins v. Minister for Justice, Equality and Law Reform* [2015] IECA 27; *Clare County Council v. McDonagh* [2020] IECA 307 and *Word Perfect Translation Services Ltd. v. Minister for Public Expenditure and Reform* [2021] IECA 305). To quote Whelan J. from *Clare County Council* (at para. 32):

> *"In summary therefore, a party seeking to set aside an interlocutory order of the High Court made in the exercise of its discretion must establish that an injustice will be done unless the order is set aside. In making its assessment, this court will place great weight on the views of the trial judge but is untrammelled by any* a priori *rule restricting the scope of that appeal…."*

If an appellant establishes that an injustice will be done if the decision of the High Court remains in effect, then this Court ought to intervene.

Principles to be applied in an application for an injunction pending appeal

6. In *Harding v. Cork County Council* [2008] 4 I.R. 318 Clarke J. (as he then was) in the High Court confirmed that the High Court in an appropriate case has jurisdiction to continue an injunction or to grant new or different injunctions so as to preserve the position pending an appeal. It is not disputed that it was open to both the High Court and this Court pending the hearing of the appeal to this Court to grant the injunction sought by BMS notwithstanding the decision of the High Court that the patent in suit is invalid.

7. The principles to be applied in considering whether or not to grant such relief have been set out by Clarke J. in *C.C. v. The Minister for Justice and Equality* [2016] 2 I.R. 680.

Speaking for the Supreme Court, Clarke J. referred to the statements of McCarthy J. in *Redmond v. Ireland* [1992] 2 I.R. 362, and *Emerald Meats Ltd. v. Minister for Agriculture* [1993] 2 I.R. 443 that the fundamental consideration is that the court maintains a balance with a view to ensuring that justice is not denied to either party. Clarke J. continued at para. 36 of the report:

> *"As in all cases, the first question is as to whether there is any stateable or arguable basis for the appeal itself. If there is, then the Court has to assess the potential injustice which may result from, on the one hand, intervening in favour of the appellant only to find that the appellant loses, as opposed to not intervening in favour of the appellant only to find that the appeal is successful."*

8. I should observe that there is no suggestion in *C.C.* that this is a jurisdiction which should be exercised sparingly: insofar as *Cosma v. Minister for Justice, Equality and Law Reform* [2007] 2 I.R. 133, which was relied upon by the High Court, says to the contrary, it must be regarded as no longer good law and having been overtaken by *C.C.*

9. It is not disputed that BMS has arguable grounds of appeal. This was accepted by the trial judge, though he remarked that this was a low threshold. While this may be so, it is the threshold mandated by the Supreme Court and is therefore the only threshold which any appellant must satisfy.

10. In *C.C.* Clarke J. continued that the test whether there should be a stay or another intervention (an injunction) pending an appeal is the same as that identified in *Okunade v. Minister for Justice* [2012] 3 I.R. 152. He observed however that the precise way in which the overall approach may apply may differ depending on the context. He observed that the context may include the nature of the proceedings, the nature of the interference sought from the court, and the stage which the proceedings have reached.

11. An issue in this appeal is the weight which should be attributed to the outcome of the trial at first instance when a court has found that the appellant has a stateable or arguable appeal and is considering the question of the potential injustice of either granting or refusing the injunction sought. At para. 44 of *C.C.* Clarke J. cautioned as follows:

> *"It follows that the very process of a trial can easily lead to a significant narrowing and refinement of the kind of issues which remain open on an appeal such that it may well be possible for a court to place much greater weight on the strength or weakness of the potential appeal compared to the situation which would have pertained were the court attempting to assess the strength or weakness of the underlying case pre-trial. But whether it would be appropriate, in accordance with the established jurisprudence, to give added weight to an assessment of the strength or weakness of the potential appeal will be very dependent on the circumstances of the case itself. In some cases there may well not be any great narrowing or refinement. The issues which remain, even if purely legal, may involve the type of case described by Lord Diplock which required 'detailed argument and mature consideration'. In such cases it is clear that the court should not attempt to place in the balance the strength or weakness of either a case (pre-trial) or an appeal (prior to the appeal being heard)."* (Emphasis added.)

12. At para. 45 Clarke J. observed:

> *"There may be cases (but it will by no means always be the case) where the consequence of there having been a trial with findings of fact and/or law may lead to a very different type of assessment being capable of being carried out as to how those principles and that test are to apply pending appeal. But whether that is so is case-specific."*

13. In *Krikke v. Barranafaddock Sustainability Electricity Ltd.* [2020] IESC 42, the Supreme Court considered the question of a stay on an order of the High Court pending appeal. O'Donnell J. (as he then was) stated in para. 16 that in circumstances where there is an unavoidable risk of injustice to either side, *"in difficult circumstances, some weight should be attributed to the decision of the trial court, and the limitations on the scope of appellate review."* He referred to para. 62 of his judgment in *Merck Sharpe & Dohme v. Clonmel Healthcare* [2020] 2 I.R. 1 *("Merck")* to which I shall return. He indicated that the court *"... may be entitled to consider whether it has been demonstrated either that the appellant's case is strong, or that the harm the appellant will suffer is out of all proportion to the damage to the public interest of not being able to enforce the decision of the High Court for some months pending the decision on appeal."* It is important, when reading this passage, to recall that O'Donnell J. placed great emphasis on the fact that *Krikke* concerned an application under s.160 of the Planning and Development Act 2000 to restrain the unauthorised development of a windfarm and the vital interest of the public in the enforcement of planning law. The judgment accepts that the court may both give weight to the decision of the court below and to the appellant's case, if it is shown to be strong.

14. O'Malley J. gave the principal judgment in *Krikke*. At para. 101 she acknowledged that the court considering a stay pending an appeal may form some view of the possible outcome of the appeal but cautioned *"provided, again, that the issues are not such as to require detailed argument and mature consideration."* Where an appeal involves complex issues, detailed argument, and mature consideration, then the court considering whether or not to grant a pre-appeal injunction should proceed with caution, though acknowledging that the outcome at first instance *"must count for something"* in the appellate court's considerations.

15. The judgments in *Okunade, C.C.* and *Krikke,* all emphasise the importance of the particular statutory context which may impact upon the court's assessment of the balance of justice in relation to the particular appeal pending before the court.

An injunction restraining infringement of a patent pending appeal where the patent has been found to be invalid

16. The High Court observed that no example of such an application in this jurisdiction was cited to him and none was cited to this Court on appeal. I therefore accept that there is no authority on this specific point from this jurisdiction. The authorities cited by both parties were persuasive and not binding on this Court.

17. The appellant placed great weight on the decision of the Court of Appeal in England and Wales in *Novartis AG v. Hospira UK Limited* [2014] 1 W.L.R. 1264 *("Novartis")* and in particular the judgment of Floyd L.J. That judgment considered the principles to be applied on an application for an injunction pending appeal where an originator, whose patent had been found by the High Court to be invalid, was seeking to restrain a generic from launching an allegedly infringing product pending appeal. Having reviewed the prior authorities, Floyd L.J., at para. 41, summarised the relevant principles which in his view the court should apply to the grant of what is now referred to in England as an interim injunction pending appeal where the claimant has lost at first instance as follows:

> *"(1) The court must be satisfied that the appeal has a real prospect of success.*
>
> *(2) If the court is satisfied that there is a real prospect of success on appeal, it will not usually be useful to attempt to form a view as to how much stronger the prospects of appeal are, or to attempt to give weight to that view in assessing the balance of convenience.*
>
> *(3) It does not follow automatically from the fact that an interim injunction has or would have been granted pre-trial that an injunction pending appeal should be*

granted. The court must assess all the relevant circumstances following the judgment, including the period of time before any appeal is likely to be heard and the balance of hardship to each party even if an injunction is refused or granted.

(4) The grant of an injunction is not limited to the case where its refusal would render an appeal nugatory. Such a case merely represents the extreme end of a spectrum of possible factual situations in which the injustice to one side is balanced against the injustice to the other.

(5) As in the case of the stay of a permanent injunction which would otherwise be granted to a successful claimant, the court should endeavour to arrange matters so that the Court of Appeal is best able to do justice between the parties once the appeal has been heard."

18. Of particular relevance to this appeal were his observations condemning as an error the fact that the trial judge had given weight to the fact that the merits had been decided at first instance and that it was not possible to say that the appeal was more than *"plainly arguable"*. At para. 47 Floyd L.J. said:

"Once [the trial judge] was satisfied that the appeal had real prospects of success, he should, on the facts of the present case, have gone on to consider the balance of hardships in accordance with the principles I have set out above. He should not have put a weight into the scales against the claimant merely because they could not satisfy some higher threshold on the merits."

He specifically held that the trial judge erred in weighing in the balance of convenience the fact that the patent had been declared invalid.

19. In *Novartis* the appeal against the refusal of an interim injunction pending the appeal against the declaration of invalidity was allowed on the following basis:

"61… I consider that this is a case where the court should grant an injunction pending the appeal to restrain the sale of the defendant's product. The judge was in my judgment plainly right that this was a case where, had the defendant sought to launch before trial, they would have been restrained until trial. The damage to the claimant was both more certain to occur and greater in magnitude than the damage to the defendant. Although there would be difficulties of knowing for certain whether the defendant had lost a first mover advantage, it does appear from the information given to us on this appeal that at least one and probably two other generic companies are in a position to market products the subject of authorisations. In those circumstances the possibility of the period between now and trial being one during which the defendant would have been able to enjoy the benefits of being a first mover seems rather more remote.

…

63. The unquantifiable damage to the claimant seems to me to outweigh that to the defendant. From the evidence, an immediate downward price spiral, even in the period between now and the hearing of the appeal, seems highly likely if not inevitable. The fact that the claimant can divert sales to [another company] does not vitiate this conclusion. They will still be faced with the fact that the market will have become accustomed to lower prices, and restoring their monopoly position will, if possible at all, be accompanied by harm of other kinds.

64. I am not persuaded by either of the public interest points. As to the first point, appeals are the norm rather than the exception in this type of case. It is not unreasonable to expect generic companies to plan on the basis that there will be an appeal. To do so will not make the process of clearing the way any more expensive, as Mr Speck at one point suggested it might. It means only that generic companies

will have to disclose their intentions to the innovator in time for an appeal to take place, or, if this is not possible, seek an appropriately expedited hearing to take this into account. …"

20. While this authority is not binding, it is persuasive, and it does involve an analysis of the principles to be applied on an application such as this, and therefore is of relevance to this Court's consideration of the principles. The first of Floyd L.J.'s points in para. 41, (1) is a threshold test. In England the question is whether the appeal has a real prospect of success and in Ireland the question is whether the appellant has an arguable or stateable appeal. The fact that the thresholds are different does not alter the principles to be applied to an application of this nature once the relevant threshold is met.

21. With regard to (2), the approach in this jurisdiction is slightly different. In accordance with *Krikke*, *Okunade* and *C.C.*, the judgment at first instance *"must count for something"* in the balance of justice. But it cannot be decisive or be afforded such weight as would distort the assessment of the balance of justice to be made by the court. The court must proceed on the basis that it is possible that the appellant may succeed on the appeal and, as is clear from the judgments of Clarke J. referred to above, the real concern is to arrange matters so as to cause the least risk of injustice to the parties. It is not *per se* an error to weigh in the balance of justice the outcome at first instance (as in *Novartis*) but, in complex litigation such as this case, the court should be slow to place great weight on the outcome (*Krikke*). This is because appeals in patent litigation invariably will be complex and will involve detailed argument and require mature consideration. As a result it will rarely be possible or appropriate to form a view at the hearing of the application for an interlocutory injunction pending appeal of the strengths or weaknesses of either side to the appeal.

22. In my judgment, the points at (3), (4) and (5) are good law in this jurisdiction and provide helpful guidance to either a High Court judge invited to grant an injunction pending appeal or a panel of this Court faced with a like application. In particular, point (5) – that the court should endeavour to arrange matters so that the Court of Appeal is best able to do justice between the parties once the appeal has been heard – resonates with the test in this jurisdiction and has the benefit of underscoring the fact that the decision-maker should bear in mind the possibility that the appellant may succeed on appeal.

23. The manner in which these principles were applied in *Novartis* is worthy of consideration in the context of the specific arguments advanced in the application to this Court for a pre-appeal injunction and will be considered later in this judgment.

The decision of the High Court

24. The judgment is discursive, running to 131 pages. However it is difficult to discern precisely what factors the trial judge weighed in the balance of justice in favour of granting the injunction, what against, the weight he attached to each, and how he resolved that the balance of justice favoured the refusal of the relief pending the appeal. During oral argument of the appeal, the Court asked counsel for Teva to identify where in the judgment the trial judge had weighed factors which counsel said had been properly assessed. Counsel was unable to do so, save to point to the concluding paragraph, para. 136. It is appropriate to set this out in full.

> *"* *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 not 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."

Discussion

(1) Weight attached to the decision under appeal

25. The main ground for refusing the injunction was the fact that in the pre-trial application for an injunction Barrett J. accepted that BMS had a property interest in the presumptively valid SPC but that following on from his judgment of 8 December 2023 there was "*now a 'firm assumption' that the patent is invalid"*. At para. 51 of the judgment Barrett J. identified the fact of his judgment as being *"a significant difference in the circumstances in which the parties now find themselves versus those in which they were before"*. He says that he has declared the patent to be invalid and that this *"cannot be ignored"* and that the *"declaration of invalidity is important in the context of the considerations"* to be taken into account *"when determining the balance of convenience"*.

26. It seems to me that this significantly overstates the weight which may properly be attached to the outcome of the trial at first instance. As is clear from the decision in *C.C.,* the first question the trial judge was required to ask was whether there was an arguable basis for the appeal itself. The trial judge accepted that it was common case that there are

arguable grounds of appeal. Applying *C.C.*, once either an appellant has established, or it has been accepted, that they have stateable or arguable grounds of appeal, the court should then proceed to consider where the balance of justice lies. In complex litigation such at this, the court should proceed with caution and avoid weighing the prospects of success of either party to the appeal; though the outcome at first instance may be weighed in the balance as it *"must count for something".* While in *Krikke* the Supreme Court acknowledged that the decision of the trial judge *"must count for something"*, neither *Krikke* nor *C.C.* described it as an *"important consideration"* when considering whether to grant or refuse an injunction pending appeal.

27. It was accepted by Teva and by the trial judge that BMS has arguable grounds of appeal; though the trial judge observed that this was not exactly a demanding threshold. However, it is the threshold established by the Supreme Court and it is therefore the applicable one, whether demanding or not. As the trial judge considered the strengths of Teva's case on the appeal (which he implicitly did by emphasising the significance of his declaration of invalidity), he ought also to have assessed the strength of BMS's arguments on appeal. Nowhere in his judgment does he do so. In my judgment, this is a significant failure properly to assess BMS's application.

28. In any event, this is a case where it is not possible to evaluate at this stage the prospects of either party on the appeal. As O'Malley J. cautioned in *Krikke* and O'Donnell J. noted in *Merck,* where the issues are complex it may not be possible or appropriate to attempt to weigh in the balance the strengths or weaknesses of the parties' positions on the appeal. The appeal in this case remains immensely complex. It has been assigned an unprecedented four days for hearing. While the priority issue no longer forms part of the case on appeal, it would be a gross mischaracterisation of the appeal to describe it as being significantly narrowed or refined. It is certainly not possible on this application

to place much greater weight on the strength or weakness of the appeal than pre-trial. That being so the prospects on the appeal for either party ought not to have been taken into consideration when determining where the balance of justice lay.

29. Further, in emphasising the importance of the outcome of the trial at first instance, the High Court did not even address, never mind follow or distinguish, the decision of the Court of Appeal of England and Wales in *Novartis,* where Floyd L.J. expressly condemned the decision of the High Court in that case because the trial judge had weighed in the balance of justice the outcome of the trial at first instance. In this case, the trial judge does not appear to have afforded this persuasive authority any consideration, if only to explain why he disagrees with it.

30. In my opinion the entire balance conducted by the High Court is tainted by the undue weight he placed on the outcome of the trial at first instance.

(2) Presumption of validity of the SPC

31. The High Court judgment is replete with references to the fact that the presumption of validity in respect of the SPC is *"gone"* because of the decision at first instance and therefore no longer falls to be assessed as part of the weighing of the balance of justice. This is the trial judge's main ground for refusing the injunction (para. 136(1)). In my opinion this shows a failure to apply the approach mandated by the Supreme Court since *C.C.*

32. The trial judge has either misunderstood or misapplied various *dicta* which say that a court should give effect to *prima facie* valid measures. The *dicta* on which the High Court relied refer to the *"measures"* the subject of the challenge in the proceedings, not the decision of a court at first instance which is a subject of an appeal. Of course, the decision at first instance is a *prima facie* valid "*measure"* unless it is overturned by an appellate court, but that is not the decision to which reference was made in *Okunade*, *Krikke* or *C.C.*

33. The trial judge failed to approach the question of whether to grant an injunction pending appeal, bearing in mind that the appeal may succeed. If the invalidity decision was so crucial in that assessment, that would always preclude a pre-appeal injunction. Such an *a priori* approach is clearly inconsistent with the assessment process mandated by *C.C.* If the appeal is successful, then the SPC will always have been valid. A successful appeal will then confirm the right to exclusivity which BMS would then be entitled to protect by a permanent injunction. The court must weigh this possibility and the value of this possible outcome on the BMS side of the scales. Thus it is not correct to say that the presumption of validity is gone and therefore should not figure in the court's assessment of the balance of justice because it may be restored. The High Court judge erred, in my view, when he excluded it from the scales entirely.

34. Further, the High Court judge said that the stay on the revocation of the patent conferred a *"significant benefit"* on BMS. This – he suggested – is so, because if it succeeds on appeal, it will not have a difficulty in being restored to the register (never having been removed from it) and secondly it still has *locus standi* to apply to restrain other generics from launching their generic products in the intervening period.

35. It is the registered right which gives a patentee the right to sue for infringement and enforce its right to exclusivity. The High Court granted a stay on revocation *inter alia* to enable BMS to seek injunctive relief against other generics. If BMS has a sufficient interest in the patent to seek an injunction against other generics notwithstanding the invalidity decision of the High Court, then, it seems to me, it must have an equally sufficient interest to seek an injunction against Teva. While its *locus standi* is not an issue in this appeal, it begs the question as to what is the status of this right where there has been a declaration of invalidity but a stay on the revocation of the patent pending appeal.

36. In argument, Teva contended that BMS enjoyed a right which was less than validity or presumptive validity; it amounted to an arguable ground that it had an intellectual property right. No decision of any court was opened in support of this submission. In my judgment a registered right is either valid and enforceable or invalid and unenforceable and it cannot have a shadowy half-life. In particular, I do not accept that it is a watered down right. Tellingly, no case to support this proposition was opened, though for nearly 30 years in the United Kingdom and also in this jurisdiction it has been the practice to apply for the suspension pending appeal of the revocation of a patent which has been declared invalid at first instance .

37. Even if, as counsel for Teva submitted, BMS enjoys a lesser form of right pending appeal by reason of the fact the patent was not removed from the register, it was, as counsel for BMS argued, *"something"*, and, as such, ought to have been weighed in the scales on the BMS side. In my judgment it was not correct for the trial judge to place nothing in the scales on BMS's side in relation to its registered right and to place Teva's success at first instance on its side of the scale.

(3) Exclusivity

38. In my view the trial judge failed properly to weigh BMS's right to exclusivity and he dismissed it from his consideration on the grounds that BMS had lost at first instance. He failed to have proper regard both to the fact BMS may succeed on appeal and the reality that the exclusivity may not be capable of being restored or may not be restored without significant irreparable harm. At para. 60 of *Merck*, O'Donnell J. observed that Merck's right was not simply to recover income and profit pending the expiry of the SPC in the case. It was a right to a monopoly.

> *"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."*

Such a loss, according to BMS, is not capable of being compensated by an award of damages. However, in refusing a pre-appeal injunction, the High Court refused to recognise this very matter – which it had concluded in February 2023 was incapable of being compensated in damages – as a factor to which weight should be afforded. This is particularly significant and was pivotal to its decision to refuse the injunction. The trial judge said that the monopoly right only applied to a *valid* SPC and that as he had found that the SPC in the case was invalid, BMS had no right to exclusivity. Accordingly, when determining whether or not to grant the injunction sought, he failed to identify or to weigh the risk to BMS – if the appeal were to succeed – of the loss of that right, on the grounds that it no longer applied.

39. In my judgment, he erred in so doing because if BMS succeeds on appeal (a) the right to exclusivity will be restored but (b) it may have been irreparably damaged in the intervening period. It follows therefore that the trial judge ought to have weighed this when assessing where the balance of justice lay in the application before him and the failure to do so was a serious error.

40. The trial judge also failed to weigh in the balance of justice the risk to BMS of the loss of exclusivity because – contrary to what he had concluded in February 2023 – he said that BMS's losses could be adequately compensated in damages and because BMS had adequate time to plan for generic entry. In my judgment this was a further error in assessing the issue of the right to exclusivity. As is clear from para. 60 in *Merck*, the registered right is more than a right to an income stream. It is a right to exclusivity. The trial judge misinterpreted the balance of para. 60 as being merely the right to plan. O'Donnell J. in *Merck* continued:

> *"It follows that the SPC holder will know the precise date on which its rights will expire, and one of those rights, therefore, is to be able to plan for that eventuality so*

that it may maximise its position in the market both until that period and the period immediately after expiry. If Clonmel is held to have wrongly launched the 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." (Emphasis added.)

O'Donnell J. expressly recognised that the right to plan is *"one of those rights"* enjoyed by an SPC holder. In this case, BMS submitted, and I agree, that in the interval between judgment and the determination of the appeal, BMS is in the same position as Merck was, as described in para. 60. If BMS succeeds on the appeal this will restore the right to exclusivity, which includes the right to be protected by a permanent injunction. BMS submitted that this was not decisive, but it is a factor which ought to have been weighed in its favour and it was not. I agree with this submission.

(4) The significance of the grant of an SPC

41. In discussing the fact that an SPC is granted pursuant to a process provided for by law, each party to the appeal emphasised para. 62 of *Merck*, but disagreed as to the correct interpretation of the passage and thus of its significance to this appeal. It is appropriate to quote it in full:

"One feature of this case, to which, in my view, weight should be given, can be viewed in three different, though related, ways. That is the fact that Merck is the holder of an SPC granted pursuant to an authorisation process provided for by law and which involves the consideration both of the application for the 599 patent by the Controller of Patents, and the subsequent application for the SPC. As a matter of law, the SPC is valid and effective until declared invalid by a court of competent jurisdiction. Just as in Okunade v. Minister for Justice *[2012] IESC 49, [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 SPC is invalid. Another way of valuing this factor is that it represents the status quo ante. *In this case, there was no unreasonable delay in the commencement of the proceedings, and the* status quo *must therefore be taken to be the position which existed prior to Clonmel's launch. Finally, the same factor comes into play if consideration is given to the question of clearing the way. For the reasons discussed above, this cannot be treated as a single dispositive argument and, for example, in cases where the defendant might plausibly contend that his product did not infringe a patent, it might be of lesser weight. Here, however, the only issue is validity and, moreover, that issue itself is to be determined within the limited confines of Article 3 of the regulation. Since, by definition, any generic challenger will have to have taken preparatory steps both of a practical and regulatory nature, it is, in my view, a legitimate factor to which weight should be given to consider that no steps have been taken to clarify the essential matters upon which Clonmel's right to launch the product depends: those concerning the question of the validity of the SPC."*

42. O'Donnell J. said that a feature of the case could be viewed in three different, though related, ways. The feature he is discussing is the fact that Merck is the holder of an SPC, granted pursuant to an authorisation process provided for by law.

43. The first way this feature can be viewed is that as a matter of law the SPC is valid and effective until declared invalid by a court of competent jurisdiction. O'Donnell J.

referred to the decision of *Okunade* and concluded that it was not unreasonable to give the presumption of validity greater weight in the balance than the interests of Clonmel which would only arise after it was determined that the SPC was invalid. In this appeal Teva submitted that the High Court, clearly a court of competent jurisdiction, had declared the SPC invalid and accordingly this *"feature"* could no longer be given greater weight in the balance than the interests of Teva.

44. It is to be borne in mind that *Merck* was concerned with the principles applicable to an application for an injunction pre-trial. The approach in *Okunade* is expressly endorsed. In *C.C.* the Supreme Court said that the principles applicable to an application for an injunction pending an appeal are the principles set out in *Okunade*, though they may be applied differently depending on the facts and the circumstances. I do not believe that O'Donnell J. in *Merck* intended to state that once a court at first instance declared a patent to be invalid, then a court considering an application for an injunction pending appeal was no longer to have regard to the invalidated registered right which might be restored following a successful appeal because this feature was removed *entirely* from its considerations.

45. Secondly, in para. 62 O'Donnell J. said that *"[a]nother way of valuing this factor is that it represents the* status quo ante*."* This factor, in my judgment, is the fact that Merck was the holder of an SPC granted pursuant to an authorisation process provided for by law. It does not refer to the presumption of validity of an SPC, as was contended by Teva. That was the first of the ways this feature of an SPC right could be assessed. Indeed it would make no sense for a *presumption* to represent the *status quo ante.* I am satisfied that in assessing the least risk of injustice pending appeal, this factor or feature – that the right at issue in the appeal is a right granted pursuant to an authorisation process – can be given weight as representing the *status quo ante:* that is, the factual position existing prior to

generic launch. The trial judge erred in saying that his judgment changed the *status quo*. This is not what the *status quo ante* means. It is clear from the judgment of O'Donnell J. in *Merck* that the *status quo* must be taken to be the position which existed prior to the generic launch. If the *status quo ante* is said to have been altered by the outcome of the trial at first instance, this amounts to weighing that decision in the balance of justice in a manner which is inconsistent with *C.C.* and *Krikke.* It is affording it a sort of wild card status which changes everything. That is not the approach a court should take to an application for an injunction pending appeal and is not, in my view, supported by para. 62 of *Merck.*

46. I am satisfied therefore that the trial judge erred in failing to attribute any weight to the fact that the right at issue was one which, although found to be invalid at first instance, might yet be restored following appeal. Further, he erred in concluding that the *status quo ante* had been altered by his decision and now favoured the refusal of an injunction, rather than supported the granting of the relief pending appeal.

(5) Generic Entry

47. The trial judge accepted that in light of his invalidity decision and given the significance of apixaban, it was probable that other generics would come on to the market if they were not injuncted. This is undoubtedly so. The risk of this development has increased since February 2023 when he gave judgment granting BMS a pre-trial injunction. The evidence at the trial of the action was that in 2024 two other generic manufacturers – Mylan and Rowex – had obtained reimbursement prices. Mylan is intent on entering the market with its generic apixaban and BMS obtained an interim injunction from the High Court restraining it from launching its generic product. Ultimately agreement was reached between BMS and Mylan that the injunction against Mylan would continue but that if the stay on the revocation of the patent was not granted or was lifted, or

if Teva was not restrained from launching its generic product, then BMS will apply within 24 hours to withdraw the interim injunction against Mylan. BMS reserved the right to apply to reinstate the interim injunction against Mylan pending the determination of the Mylan interlocutory injunction. As stated previously, eight generics have medical authorisations, while Teva, Mylan and Rowex have published reimbursement prices. Others may have unpublished reimbursement prices and be closer to launching their products, though this remains speculation until any such reimbursement prices are published.

48. All of this means that eight generics have taken significant steps to enable them to launch generic products to compete with Eliquis and three have satisfied nearly all the required regulatory pre-launch conditions. There is already a significant incentive for generic manufacturers to try to gain a share of the market of this *"blockbuster"* drug. The potential rewards are immense and the incentive has been increased by an interchangeability decision of the Health Products Regulatory Authority *("HPRA")*. The HPRA has determined the Eliquis 2.5mg and 5mg and each of the currently licensed generic apixaban products (save for that most recently licensed) are *"interchangeable"* within the meaning of ss.4 and 5 of the Health (Pricing and Supply of Medical Goods) Act, 2013 as amended. In an unprecedented move, the products were listed as such on the List of Interchangeable Medicinal Products published on 8 November 2023 before any such products were in fact available to the market in the State. Pursuant to ss.7 to 11 of the 2013 Act, pharmacies will be required to offer the cheapest (to the State) available interchangeable product regardless of whether the prescription specifies the product in the common name or the brand name. Where the HSE has set a reference price for interchangeable products under s.24 of the 2013 Act, that reference price operates as a (low) cap on reimbursement for pharmacies for the supply of interchangeable products.

Unless the clinical exemption applies or the patient is willing to pay the difference between the reference price and the reimbursement price (both of which are likely to be the exception rather than the rule), the cheapest product must be supplied. This will never be the branded product. Thus, the net effect of placing products on the interchangeable list is to greatly speed the transfer of supply of a medicinal product from the branded to the generic product.

49. The confidential exhibits show correspondence between the solicitors for BMS and other generic companies. One confirmed in October 2021 that it did not intend to violate the marketing protection of Eliquis and would not perform any act that would constitute a placing on the market of any of its products until the expiry of the marketing protection period in May 2026 – which BMS's solicitors took as meaning that it would not carry out restricted acts while the compound patent or SPC remained in force. One confirmed in May 2022 that it had *"no current plans"* and another in February 2024 that it had *"no immediate plans"* to launch any product containing apixaban in Ireland; and both confirmed – as they had been asked to do – that would give three weeks' notice of any such intended launch. Two did not reply. But the fact remains that the parties both expect that unless they are restrained from launching, multiple generics will seek to enter the market.

50. In considering this evidence the trial judge simply said that he could not presume that any generic launch would not be injuncted and did not consider the matter further. In my opinion, it was incumbent upon him to do so.

51. As matters stand, the prospect of BMS obtaining injunctions restraining other generics from launching generic products is diminished by (a) the revocation judgment (on the basis that the trial judge refused an injunction pending appeal), (b) the fact that Teva would be on the market; which thereby alters the *status quo ante* for any subsequent

application by BMS against another generic manufacturer and, (c) the trial judge's finding as a reason to refuse the injunction application before him that damages *were* an adequate remedy for BMS. It is difficult to conceive how BMS could satisfy another judge (or Barrett J., as the patent judge) that damages would be inadequate compensation for its loss of exclusivity in the face of such a finding. That being so it begs the question how it could obtain an injunction against any other threatened generic launch. In para. 109, pp.106 – 107 of the judgment, the trial judge observed that:

> *"Perhaps the key point in all of this is that if generic companies launch, that has two consequences. First, BMS has the opportunity to seek 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 court to do what courts do, i.e. make a judgment as to what the losses are."* (Emphasis added.)

Thus Barrett J. expressly found that damages are an adequate remedy for BMS. He did so again at para. 136(5). At the very least, the decision of the High Court both to revoke the patent and to refuse the injunction, and the fact that Teva (if not restrained by this Court) will be on the market, will make it considerably more difficult for BMS to obtain an injunction restraining any other launch. It follows therefore that there is a far greater risk of further generic entry and accordingly of a price spiral. The possibility of (further) generic entry has been greatly increased by the combined effect of the judgments of the High Court and the probability of restraining it greatly reduced. This presents a greater risk

of uncompensable damage to BMS and one which was not recognised by the trial judge or taken into account when considering the balance of justice on the application before him. To my mind, this was an error in the assessment of the balance of justice in this application.

(6) The test of the adequacy of damages as a remedy

52. What is meant by the adequacy or inadequacy of damages for the purposes of assessing whether to grant or refuse an injunction is *not*, as the trial judge repeatedly stated, whether there exists *a method to* calculate damages. It is set out by O'Donnell J. in *Merck* at paras. 45 – 47:

> *"[45] …[I]nadequacy of damages is a ground upon which a permanent injunction may be refused. It must follow, therefore, that damages are not a perfect remedy, and cannot be a complete answer to an application for an injunction whether permanent or interlocutory. It should be recalled that the basic role for the intervention of equity in any case is that the common law remedy is inadequate. I consider that the correct test is that set out at p. 58 of Spry,* Equitable Remedies *(4th ed., Sweet & Maxwell, 1990):*
>
> > *'The precise question that has been asked is <u>whether the relegation of the plaintiff to such remedies as he has in damages or other legal remedies would leave him in as favourable position in all relevant respects</u> as would exist if the obligation in question were performed* in specie*.'*
>
> *[46] There is still substance in the test advanced by Lord Redesdale in* Harnett v Yielding*(1805) 2 Sch. & Lef. 549 at pp.553- 554:*
>
> > *'Unquestionably the original foundation of these decrees was simply this: that damages at law would not give the party the compensation to which he was entitled, that is, <u>would not put him in a situation as beneficial to him as if the</u>*

agreement were specifically performed. On this ground, the court, in a variety of cases, has refused to interfere where, from the nature of the case, the damages must necessarily be commensurate to the injuries sustained.'

[47] This does not mean that an equitable remedy, whether specific performance or injunction, must be granted, but simply that, in the exercise of the court's discretion, it may decide to award damages rather than relief in specie*, and other discretionary considerations may mean that it is just to leave a party to his or her remedy in damages. The sole question at this stage, however, is whether the remedy in damages can be said to be necessarily commensurate with any possible injury so as to preclude the possibility of the grant of an injunction. In this regard, it is noteworthy that in* American Cyanamid v. Ethicon Ltd. *[1975] A.C. 396 itself, at pp. 408-409, Lord Diplock observed that:*

'Save in the simplest cases, the decision to grant or refuse an interlocutory injunction will cause to whichever party is unsuccessful on the application some disadvantages which his ultimate success at a trial may show he ought to have been spared and the disadvantage may be such that the recovery of damages to which he would then be entitled either in the action or under the plaintiff's undertaking would not be sufficient to compensate him fully for any of them.'" (Emphasis added.)

53. In my judgment, when considering whether damages are an adequate remedy the *"sole question*" is whether the remedy in damages can be said to be *"necessarily commensurate with any possible injury"*. If that is so, then this precludes the possibility of the grant of an interlocutory injunction. On the other hand, if damages are an inadequate remedy because they fail to meet this threshold, this does not mean that an injunction *must* be granted. The court must weigh this inadequacy of damages as a remedy together with

other considerations and form an overall view whether it is just to refuse or grant the relief sought. The test is the same whether the court is considering an application for a pre-trial injunction or for an injunction pending an appeal (see *C.C.*). It follows that the question for this Court (and for the High Court) is whether the remedy in damages is necessarily commensurate with any possible injury or, as it was put by O'Donnell J. at para. 61 of *Merck "where damages, while available, cannot be considered to be said to be a full or adequate remedy for [the originator] so as to exclude the necessity to seek an injunction."*

54. In my view the trial judge did not approach the question of whether damages were an adequate remedy for BMS by applying this test. He applied the incorrect test and accordingly his assessment in this regard cannot withstand scrutiny.

55. In para. 60, at p.52 of the judgment under appeal, the trial judge held that *"just because there may be some element that is unquantifiable [this] is not decisive"* because *"in assessing damages one might take into account trends and make a calculation…"* and accordingly there is no *"insuperable deficiency… in that calculation process."* In support of this conclusion the trial judge relied on paras. 27, 33, 36 and 37 of the judgment in *Merck.* However, in my judgment he fundamentally misreads the judgment of the Supreme Court. Commencing at para. 28, O'Donnell J. analysed the decision in *American Cyanamid Co. v. Ethicon Ltd.* [1975] A.C. 396 ("*American Cyanamid*") and set out the approach which had been adopted by lawyers applying the judgment up to that point in time. At para. 31 he described this in the following terms:

> *"[31] ….Once it is established that there is a serious issue to be tried, then it was normally no part of a court's function when considering an application for an interlocutory injunction to attempt to anticipate the outcome of the case. Instead, the court should proceed to assess the balance of convenience. As to that the governing principle related to the adequacy of damages, this involved considering two*

hypotheses and balancing the outcome. If the plaintiff was refused an injunction but succeeded at the trial would he or she be adequately compensated by the award of damages at the trial? On the other hand, if the defendant was restrained by injunction, but nonetheless succeeded at the trial, would he or she be adequately compensated by the award of damages pursuant to the undertaking for damages which the plaintiff would have been required to give at the time of the grant of the injunction? In either case, it was also relevant to consider if the party was capable of meeting any award of damages if made.

[32] This has been the basic approach which resolves many applications for interlocutory injunctions, and remains a valuable guide to analysis of any application. There is a clear logic to it. As long as the outcome of the case is unknown, a court must take steps to avoid any possible injustice being created by the length of time it will be necessary to take before a decision can be rendered. ...

[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 would be 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. This was*

only appropriate, however, if there was no credible dispute that the strength of one party's case was disproportionate to that of the other."

56. All of these passages, which were referred to by the trial judge, set out O'Donnell J.'s analysis of the approach *which had been taken* by the courts following the decision in *American Cyanamid.* However, at para. 36, he specifically departed from this structured approach in the following terms:

"[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 of 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 that 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." (Emphasis added.)

57. The critical point is that if damages are found to be inadequate for both parties then that fact needs to be placed in the scales, along with any other relevant factors to be weighed in the balance. It may be that the risk of irreparable harm is greater on one side than on the other. This means that it is afforded greater weight in the assessment of the balance of justice, but not that the lesser risk of irreparable harm is discounted altogether. It is important to bear in mind O'Donnell J.'s pertinent observation in para. 37 that *"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." In other words, the fact that a method can be devised to calculate losses sustained is not the same as saying an award of damage will necessarily be commensurate with any possible injury a party may sustain if an injunction is granted or refused.

58. The test which O'Donnell J. affirms in *Merck* as to whether damages provide an adequate remedy is failed if there are some elements of harm which a party may sustain which are unquantifiable. This is inconsistent with what the trial judge stated at para. 60, at p.52 of his judgment.

59. Finally, to emphasise what was stated by O'Donnell J. in *Merck*, where a court concludes that damages would not be or would be an inadequate remedy for a party, this does not mean that an injunction must either be granted or refused but merely that it is a factor that must be considered by a court determining where the balance of justice lies.

(7) Are damages an adequate remedy for BMS?

Assessment of the evidence by the trial judge

60. I cannot agree with the conclusions of the trial judge at para. 136(5) that any loss to BMS can be calculated in damages. He reached this conclusion based upon the affidavit evidence sworn both in support of the pre-trial injunction application and the pre-appeal injunction application. This Court is not bound by his conclusions on this point nor is it required to afford his assessment of the affidavit evidence any deference as it is in a position to assess the evidence itself. In reaching his conclusion the trial judge maintained his rejection of *"near identical evidence"* from BMS to that which he had rejected in February 2023 that damages would not be an adequate remedy (save the loss of the then-presumptively valid property right in the SPC).

61. In my judgment on Teva's appeal from the decision of the High Court to grant a pre-trial injunction in February 2023, [2023] IECA 173 I held:

"53. I would with respect disagree with [the trial judge's] conclusion on the evidence in respect of the second category, though that is not an essential finding to this judgment.

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. …

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 succeed in the revocation action. There was no countervailing evidence from Teva in relation to the second category of damages which would warrant the High Court reaching a different conclusion. The conclusion is underscored by the observations of O'Donnell J. in Clonmel."

62. Two matters require to be stated. The fact that the Court of Appeal was overturning the trial judge's assessment of part of the evidence on the adequacy of damages for BMS was not essential to the judgment because the Court was upholding the decision of the trial judge to grant an injunction. Therefore, it was not necessary to overturn the High Court's assessment of the adequacy of damages for BMS to resolve the appeal. In that strict sense, that part of the judgment was not necessary to the decision.

63. However, over five pages, this Court analysed the evidence as to the adequacy of damages as a remedy for the loss BMS said it would sustain if the injunction were refused and concluded that the evidence *did* establish that the losses BMS would sustain if Teva were not injuncted would not be compensable by an award of damages. The response of the High Court when faced with this assessment of the evidence by the Court of Appeal was to say that it was *obiter* and therefore not binding on him and to simply ignore it. The

trial judge did not reassess the earlier evidence in the light of the clear and comprehensive analysis of that evidence of unquantifiable damages in the judgment of the Court of Appeal. The analysis is simply dismissed without comment, and not cited in his judgment. The trial judge did not assess the new evidence to see whether the additional affidavits made good the deficiency in the evidence from Teva identified by this Court. This Court was not – as suggested by the trial judge (and deprecated) at p.108 of his judgment – engaging in a guessing game. At para. 103, p.98 the trial judge baldly states there was new evidence but does not attempt to identify how this evidence altered the assessment made by the Court of Appeal of the earlier evidence. In fact, he says that he reached his conclusions on *"near-identical evidence"*. He made no attempt to distinguish the facts before him in January 2024 on the pending appeal injunction application to those in February 2023 on the pre-trial injunction application on this issue, other than to deprecate the fact that no deponent for BMS specifically averred that faced with generic competition on the market BMS would reduce its sale price to pharmacists and wholesalers. In my judgment this approach was neither sufficient nor appropriate in the circumstances.

64. I have considered the additional evidence filed on behalf of Teva in opposition to BMS's application for a pre-appeal injunction. Mr. Neil refers in his first affidavit at para. 60(e) to:

> *" … 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"*.

Mr. Neil does not dispute the likelihood that BMS would reduce the price at which it provides Eliquis to the pharmacies and wholesalers and *expects* it to respond by way of discount. At para. 60(d) he says:

"…[I]t is common for pharmaceutical companies to compete by way of discounts to pharmacies (as opposed to price reduction)"

He notes that these discounts are not published but says that it is not unusual for discounts to be offered and later discontinued. He does not accept that it would be impossible to withdraw or reverse the discounts.

65. Mr. Potter responds to the assertion that it would be difficult for BMS to restore its previous pricing as follows:

"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 United Kingdom where generic apixaban was launched after BMS chose not to pursue an injunction. Discounts to wholesalers and pharmacies are at BMS's 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 customers groups."

66. Mr. Potter, then, would expect BMS to compete through discounts and he simply says that as it is BMS's choice, it may reinstate the prices and this *"would not be severely damaging."* He does not explain this statement and he does not refer to the basis for his opinion or cite any examples where it has occurred or explain whether it has or has not impacted on relations with its pharmacies and wholesalers. He does not contradict the evidence of Mr. Cooke at para. 61 of his first affidavit nor does he address the issues highlighted in para. 58 of the judgment of this Court [2023] IECA 173:

"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."

67. BMS argues that multiple generic entry, if it were to occur, would greatly complicate the assessment of damages. This, according to BMS, reinforces the argument that in the circumstances of this case damages would be an inadequate remedy for BMS. Mr. Potter says that it is *"far from certain"* that other generics would come onto the market (apparently on the basis that it would be open to BMS to apply to injunct those other generic manufacturers). But he does not address the fact that seven generic manufacturers in addition to Teva have obtained marketing authorisations and that Mylan and Rowex have obtained reimbursement prices from the HSE, nor does he consider the likelihood of BMS succeeding in any such applications if Teva were already on the market. I have already addressed the increased difficulties presenting to BMS if Teva is not injuncted and launches its generic product and BMS subsequently seeks to injunct other generics from further generic launch. Mr. Potter does not address the complexities of the price spiral which is likely to result and in particular the difficulties of attributing proportions of the losses sustained by BMS to individual generics, but simply says that each generic should be liable for a fraction of BMS's losses based upon *pro rata* sales volumes for each generic company on a monthly basis. He also says that multiple generic entry is irrelevant to the quantum of BMS's losses – which may be arguable – but it is very relevant to the ability of BMS to *recover* all of its losses. He does not address the increasing complexity of attribution of loss to individual generics in a downward price spiral which – as O'Donnell J. identified in *Merck* – involves a hypothesis upon a

hypothesis. He therefore does not address whether damages will be an adequate remedy for BMS in respect of all the losses which its deponents say it will incur.

68. In his second affidavit, at para. 23, Mr. Potter interprets Mr. Cooke (for BMS) as indicating that BMS will maintain its list price but will compete by the application of discounts. He says that this *"is as I would expect and accords with my previous affidavits".* He suggests that Ireland would not become a low price jurisdiction for Eliquis but would become a high discount one. He says that it is usual in the pharmaceutical industry to offer such discounts retrospectively and to closely control wholesale supplies with a view to minimising parallel imports.

69. In this second affidavit Mr. Potter avers (for the first time) that the damage to BMS's pricing will not be permanent and that, in the event it succeeds on appeal, it will be able to restore the price at which it sells to pharmacists and wholesalers. At para. 24 he avers:

> *"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 [Teva is not injuncted and either Teva or Teva and other generics come on the market and BMS then succeeds on appeal] 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 right 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 (or it could be explained to them) 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 at the company's sole discretion without significant impact on wholesale relationships and goodwill."

70. Mr. Potter therefore accepts that there would be some impact on wholesale relationships and goodwill and he simply says that the wholesalers would just have to accept BMS's unilateral decisions. He does not address the evidence given by Mr. Cooke that market expectations would have changed and that there would be a wholly different pricing environment.

71. Mr. Cooke says that he is not aware of an originator ever restoring price in comparable circumstances in Ireland while Mr. Potter's evidence relates to the market in the United Kingdom.

72. In passing I should note that in *Novartis*, Floyd L.J. set out the High Court's consideration of the balance of unquantifiable harm in that case. He described the arguments as *"the familiar ones in the pharmaceutical patent field. On the claimant's side it was maintained that the claimant would suffer harm from the effect of the defendant and other generic companies under cutting its monopoly price. <u>It would have to reduce its prices or lose market share.</u> It would be difficult to raise its prices again if successful on appeal. If it did so, it would face damage to its reputation."* (Emphasis added.) Floyd L.J noted that the High Court accepted that *"it was very likely that the claimant would be unable to restore their prices fully without significant harm to their reputation."*

73. At para. 63 of his judgment, Floyd L.J. held:-

"The unquantifiable damage to the claimant seems to me to outweigh that to the defendant. From the evidence, an immediate downward price spiral, even in the period between now and the hearing of the appeal, seems highly likely if not inevitable. …They will still be faced with the fact that the market will have become

accustomed to lower prices and restoring their monopoly position will, if possible at all, be accompanied by harm of other kinds."

I quote this passage from the judgment merely to illustrate the fact that the arguments advanced by BMS are familiar and credible and have been accepted by the High Court and the Court of Appeal in England. They also seem to be at variance with Mr. Potter's evidence as to the experience in the UK of price restoration.

74. It is also important to highlight that in *Novartis* neither the High Court nor the Court of Appeal objected to the fact that the originator presented its case that it would suffer unquantifiable damage in the alternative: i.e. that it would have to either reduce its price or lose market share. It was accepted by both the High Court and the Court of Appeal – without requiring the originator to state definitively that it would defend its market share by reducing its sales price – that it was very likely that the originator would be unable to restore its prices fully without risking serious harm to its reputation and that restoring its monopoly position, even if possible, would be accompanied by harm of other kinds. This is precisely the situation here and it is difficult to understand why the trial judge refused to accept the evidence of BMS that it would *either* be faced with loss of its market *or* it would have to greatly reduce its sales price – each of which involve a significant loss – on the basis that BMS did not positively aver that it would respond by cutting its price. In my judgment he erred in his assessment of the evidence by rejecting it when the case was presented as an unavoidable choice of two evils. There was nothing improper in BMS so presenting its case and no reasonable basis for rejecting its evidence.

75. The trial judge did not decide the injunction application on the basis that the new evidence advanced by Teva remedied the omissions previously highlighted by this Court. Indeed, it is notable that he did not decide that this was so. Rather, he rejected the case advanced by BMS that the discounts or rebates would be applied *at all* on the basis that no

witness from BMS definitely stated that it *would* reduce its sales prices to pharmacists or wholesalers, whether by way of discounts or rebates.

76. I am satisfied that the evidence previously given by BMS was ample and credible and established that damages would not adequately compensate BMS in the event that the injunction was refused and it ultimately succeeded in the revocation action. The additional evidence of Mr. Neil and Mr. Potter does not alter this conclusion. In my view it was not appropriate of the trial judge to reject the evidence of BMS on the basis that the deponents for BMS did not positively aver that BMS would reduce/discount its sales price to wholesalers and pharmacists. It is remarkable that in this keenly contested litigation both Mr. Neil and Mr. Potter state that it is common for pharmaceutical companies to compete by offering discounts/rebates rather than reducing list prices and that they expect BMS to do so or that it is likely BMS will do so if faced with generic competition. Mr. Potter says *"this is as I would expect and accords with my previous affidavits".* Thus the evidence from Teva effectively supported the evidence of BMS as regards the likely response of BMS to generic entry. As I have stated, in *Novartis,* no objection was taken to the fact the originator said it would either have to reduce its prices or lose market share. No case was opened on the appeal where a court adopted the approach of the trial judge to this issue, in effect demanded as a pre-condition to obtaining an injunction that an originator must positively aver that it will reduce its sales prices if it is faced with generic competition.

77. In my view, it was an error of the trial judge to have decided the application on the basis he did – that he rejected the claim that BMS would suffer irreparable damage on the basis that BMS's deponents failed to aver definitively that BMS would reduce its sales price. This meant that he failed to weigh in the balance a very significant factor which was simply omitted altogether from his assessment of the balance of justice.

Weighing the inadequacy of damages as a remedy as part of the assessment of the balance of justice

78. This omission reflects a wider error in the trial judge's approach to damages as a remedy for either side and the balance of justice. The decision of the Supreme Court in *Merck* reflects a change in the approach from that which had evolved in the application of *American Cyanamid.* Previously, when courts were applying the principles in *American Cyanamid* and *Campus Oil v. Minister for Industry & Energy (No.2)* [1983] I.R. 88, a very structured assessment was conducted. The court considered whether damages would be an adequate remedy for the plaintiff and then whether there would be an adequate remedy for the defendant. If damages were inadequate for both, the court then assessed whether the inadequacy was greater on one side or the other. This remains the approach in England and Wales.

79. As I have already explained, *Merck* changed the approach in this jurisdiction. If damages are an inadequate remedy for the plaintiff, then that goes into the scales in favour of granting an injunction. If damages are an inadequate remedy for the defendant, that goes into the scales on the other side. Other factors will be weighed in the balance for and against an injunction depending on the facts in each case. The court must weigh all of the factors in the scales in favour of an injunction against all of the factors against. A court may give greater or lesser weight to some factors than others but they should all be assessed. It is not appropriate to weigh in isolation the inadequacy of damages to a plaintiff against the inadequacy of damages to a defendant and to decide the case by reference to that alone. This approach was rejected by O'Donnell J. in *Merck* and was what was conveyed in para. 59 of my previous judgment.

80. The trial judge excluded entirely from his assessment of the balance of justice the inadequacy of damages as a remedy for BMS, not only on the basis that any harm it may

suffer is capable of being remedied in damages but also because he determined that Teva's potential irreparable harm was greater than BMS's irreparable harm. I regard this as a failure properly to apply the approach set out in *Merck.*

(8) Multiple generic entry and damages

81. Furthermore, in my view the trial judge failed to afford proper weight to the complexity of calculating damages in the case of multiple generic entry and therefore erroneously concluded that BMS could be compensated in damages for the loss it would sustain if multiple generic entry ensued. To a large extent this turns on the question of the probability of multiple generic entry and its possible timing. Teva accepted that multiple generic entry was likely following the revocation decision and would occur if other generics were not injuncted. The trial judge accepted that this was so but held that he could not presume that, if this were to occur, BMS could not apply for and obtain injunctions to restrain entry by other generics even in circumstances where Teva would be on the market. He did not contemplate the possibility that other generics would not be restrained and would enter the market and the possible loss that this would occasion to BMS. It was a question of risk and it required to be weighed. The judge accepted Mr. Potter's argument that generic manufacturers who entered the market would be liable to BMS in damages on a *pro rata* apportionment should it succeed on appeal. This leaves out the very important fact that the generics are highly likely to dispute between themselves and with BMS as to who is liable for any particular proportion of loss and that the resolution of these disputes is likely to be very complex and it is by no means certain in the end that all losses sustained by BMS would actually be recoverable from all of the generics.

82. To my mind the trial judge gravely underestimated the complexities a price spiral was likely to cause. This was succinctly set out in para. 25 of Dr. Stomberg's replying

affidavit of 5 January 2024, where he referred to multiple generic entry as being likely to cause 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."*

This is a well-recognised phenomenon and it has been accepted by the courts in England as such and as a complicating factor. In my judgment on the appeal from the pre-trial injunction I referred at para. 61 to the judgment in *Merck* and the complexity of multiple entry. That complexity has since increased as there are now potentially eight generic entrants. As was observed by O'Donnell J. in *Merck*, the more complex the calculation and the greater the number of variables, the more likely the court of trial will be forced to make an estimate or compound one hypothesis with another to make the best assessment of damages it can, and therefore it is better not to leave a party to a remedy in (imperfect) damages.

83. The likelihood of multiple generic entry and the increased complexity attendant upon such developments has increased since February 2023. There are now eight generics with medical authorisations and three with published reimbursement prices. In addition the HPRA delivered its interchangeability decision on 8 November 2023. Thus if Eliquis or

indeed any generic version of apixaban is prescribed, a pharmacist must dispense the least expensive form of apixaban to the patient unless either the prescribing doctor specifies that the branded product is to be supplied or the patient requests that the branded product be supplied and agrees to pay the difference in the price. The least expensive form of apixaban will never be the originator, it will always be a generic. The effect of the interchangeability decision – and indeed its intention – is to greatly speed up the transfer which will occur upon any generic entry from the branded to a generic product.

84. Mr. Neil estimates that possibly within a matter of days and certainly within a matter of a few weeks it is likely that approximately 80% of the market will be met by generics. If this were to occur it would result in a huge loss to BMS even if generic entry were permitted for only a short period of time. It follows therefore that the critical question is whether it is likely, in the event that it were to succeed on the appeal, that BMS would be able to restore its position. The greater the market disruption the less likely it is to be able to restore its pre-generic launch position in the market. In my view it is highly unlikely that BMS would be able to restore its position without sustaining significant harm to its reputation and its relations with pharmacists and wholesalers and the evidence to the contrary is weak and unpersuasive. The High Court failed to address BMS's argument about price suppression and the difficulty of price restoration, the change in market expectations, and the fact that a wholly different marketing environment would have been created in the interval, because he did not accept that any of this would occur because of the failure of the deponents for BMS to positively aver that BMS would respond to the generic entry and resulting price competition by reducing its prices. In my view in so doing he fell into error. As a result, the trial judge erred in his failure to weigh this potential irreparable loss in the scales in favour of an injunction pending the determination of the appeal.

(9) Inconsistency between the first and second injunction judgments of the High Court

85. When BMS sought a pre-trial injunction in February 2023, the High Court accepted that the loss of exclusivity which would follow if Teva were not restrained from launching could not be compensated in damages and therefore granted the relief sought. When, by reference to substantially the same evidence, BMS sought an injunction pending appeal, the High Court rejected the same argument. The trial judge referred to para. 60 of *Merck* where O'Donnell J. identified one of the rights enjoyed by the holder of an SPC as the ability to plan for the expiration of the monopoly right at a known date. In his judgment of February 2024, the trial judge said that BMS had had the opportunity to plan for generic entry due to the length of time the proceedings had taken and therefore cannot complain at the loss of exclusivity at this point in time. It therefore followed, according to the High Court, that there was no harm which could not be adequately compensated by an award of damages.

86. I accept the submissions of counsel for BMS that this is inconsistent with the conclusions of the trial judge in the judgment granting a pre-trial injunction. If the right to exclusivity merely amounted to a sufficient period of time to plan for competition and that was all that BMS required in order to protect its right, then, on the facts in February 2023 it had had sufficient notice to plan for generic entry on the market because the infringement proceedings were commenced by Teva in March 2021 and Teva had made clear that, unless restrained, it intended to launch its generic product in mid-2022 and the application for an injunction restraining the launch was heard on 2 February 2023. If that factor was critical and operative post-judgment, it was equally operative pre-trial in February 2023 and should, on the basis of the High Court reasoning in February 2024, have led to the refusal of the injunction in February 2023.

87. However, in my judgment the trial judge erred in holding – and Teva never argued – that a period of time to plan was an operative factor because that is not what *Merck* says and it cannot be correct. It boils down to the proposition that a generic manufacturer would be entitled to infringe a patent by simply giving adequate notice of its intention to launch its product. The ability to plan is one of the incidents of the right to exclusivity, but not its essence.

88. Effectively, the trial judge was saying that if a right has been found to be invalid at first instance, then the patentee can have no right to exclusivity and its loss cannot be weighed in the balance of justice. However, the invalidity decision may be overturned on appeal and the right to exclusivity thereby restored. But if generic entry is not restrained in the interval, irreparable harm will have been caused to a rights holder who subsequently succeeds on appeal by the temporary loss of exclusivity. As previously discussed, the court must approach the assessment of the adequacy of damages on the basis that the appellant may succeed on appeal. If that occurs, BMS's right to exclusivity will be upheld as a matter of law, and accordingly, the court must consider whether as a matter of fact it will have been destroyed; whether it can in practical terms be restored; and whether any harm it would have suffered could be compensable. These matters – which incidentally weighed heavily in *Novartis* – were not considered by the High Court and were dismissed summarily.

(10) The assessment of Teva's losses if it is restrained from entering the market

89. On the other side of the scales the trial judge weighed the inadequacy of damages as a remedy for Teva. By the time the application for the pre-appeal injunction was heard, it was accepted by Teva that multiple generic entry was now far more likely than it had been in February 2023 and, in recognition of Mylan's declared intentions and readiness to launch its generic product, Teva was obliged to adapt its case and to accept that it was

unlikely to enjoy first mover advantage, but could still obtain early mover advantage. It was by then likely that if neither were injuncted there were going to be at least two generics on the market very shortly. (Incidentally it thereby implicitly accepted that if it is not restrained from launching, it is unlikely that Mylan will be injuncted). It followed that the value of the first mover advantage which Teva asserted was necessarily becoming increasingly remote and less valuable. As a result, while the loss of that advantage was not capable of being compensated by an award of damages, it was now a lesser loss than the prospect of enjoying first mover advantage.

90. The trial judge weighed on Teva's side of the scales the fact that it *"has spent the better part of three years trying to clear the path, its efforts have been vindicated… and it is in jeopardy of losing first mover advantage* (para. 136(3)).

91. In *Merck,* O'Donnell J. considered a number of English authorities in relation to clearing the path, including *Novartis,* noting that the Court of Appeal of England and Wales granted an injunction pending appeal in circumstances where the High Court had found the patent in question to be invalid. In particular, he set out para. 54 of Floyd L.J.'s judgment:

> *"The way to market for a generic manufacturer is not clear until all arguable objections from the patentee have been eliminated. If the generic manufacturer allows the trial of the action at first instance to coincide with the intended launch date he runs the risk that a successful appeal could get in the way, even if judgment at first instance is given in his favour."*

It is abundantly clear that in England and Wales clearing the path means clearing it until all appeals have been exhausted. The Supreme Court was plainly aware that this was so and it was aware that an injunction could be granted pending an appeal in circumstances where the High Court had found the patent in question to be invalid. O'Donnell J. nowhere

indicated that he considered that *"clearing the path"* in Ireland entailed anything less than it entailed in England and I therefore am of the view that he did not depart from this understanding of the expression.

92. The trial judge held that the proposition that the path is not cleared until all appeals are disposed of is a *"deficient proposition"* because – he said – no question could ever arise as to an injunction if the path was fully cleared. Two points need to be made. First, this understanding of clearing the path was recognised and accepted by the Supreme Court in *Merck*. It was not open to the High Court to dismiss this in such terms. In addition, in the judgment delivered on the pre-trial injunction appeal this Court held that the path is not cleared until all appeals have been exhausted and this was accepted by counsel for Teva.

93. That judgment too was binding on the High Court, however much the judge may have disagreed with this statement of the law. This Court also then held that a partial – i.e., incomplete – clearing of the path does not count for very much in the balance of justice in an application for an interlocutory injunction. Notwithstanding the fact the High Court has declared the patent to be invalid, the path has not been cleared, as that phase is used in this jurisdiction. The High Court fell into error in holding to the contrary and affording Teva's partial clearing of the path significant weight.

94. Further, this Court has previously held in this litigation that a court cannot weigh both a generic's efforts to clear the path and its claim to first mover advantage as they are mutually inconsistent: one seeks to end the monopoly for the market as a whole and the other depends on one generic being on the market while the erstwhile monopoly is maintained against all others. Teva accepted the judgment of this Court on this point and did not argue that both factors should be weighed in its favour. Notwithstanding this, in his conclusions at para. 136(3) the trial judge said that Teva:

"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."

In light of the above, it is very difficult to understand how or why the High Court erred as it did in attributing weight to both of these two inconsistent factors.

(11) Status quo ante

95. The trial judge did not consider the *status quo ante* as he held (para. 136(5)) that any loss to BMS could be calculated in damages while it was common case that damages would be an inadequate remedy for Teva. For the reasons I have explained, I do not agree and the trial judge erred in a number of ways in reaching that conclusion. In my judgment, damages are inadequate as a remedy for both sides in this case. As was observed in para. 62 of *Merck*, in such circumstances, it is often useful for a court to see whether the balance of justice favours the maintenance of the *status quo ante* in those circumstances.

96. The *status quo ante* in this case is the factual situation which existed prior to the litigation when Teva was not on the market. This has not been altered by the outcome of the trial at first instance. It is an error to say that the *status quo ante* in January 2024 had changed because of the judgment declaring the patent to be invalid. That is a matter for the appeal. The *status quo ante* reflects a factual situation and the factual situation in this instance is that there is a monopoly market and Teva is not on it. In my opinion the trial judge erred in his identification of the *status quo ante* and as a result erred in his overall assessment of the balance of justice on this application.

97. In my judgment, for all of the reasons discussed, the judgment of the High Court cannot be upheld and an injustice will be done if the order of the High Court is not set aside. It is therefore appropriate for this Court to intervene and to allow the appeal.

Should this Court grant the injunction sought?

98. The Court must next consider whether or not to grant the relief which the High Court refused. It was accepted by Teva (and the trial judge) that BMS have arguable grounds of appeal. I will not consider the question whether it has strong grounds of appeal due to the proximity of the appeal at the time of writing and because it is not necessary to do so in order to decide the question posed.

99. It is necessary to consider whether the balance of justice lies in favour of or against granting the injunction sought. In the scales against the granting of an injunction are the fact that damages are an inadequate remedy for Teva and that there will be significant difficulties in calculating such damages. Secondly, Teva succeeded at first instance and this should count for something: though as I have earlier explained, it cannot weigh to any great extent in the balance, not least because that would be contrary to *C.C.* The appeal in this case is extremely complex and it will require detailed argument and careful consideration to resolve. Accordingly this is not a case where a court should attempt to place in the balance the strengths and weaknesses of the respective cases on the appeal, and in resolving where the balance of justice lies in this instance I do not weigh in the balance the prospects of either party. Thirdly, Teva is no longer likely to obtain first mover advantage, though early mover advantage – a less valuable advantage – remains possible. This is due to the fact that its position has been overtaken by events and if it were to enter the market shortly after the delivery of this judgment, it is clear in my view that it will in all probability be closely followed by Mylan (and possibly some other generics). I appreciate that BMS would, in compliance with its undertaking, seek to injunct any other generic entry onto the market, but in circumstances where (a) BMS's monopoly would have been lost, (b) Teva would be on the market and (c) if, notwithstanding this Court's conclusion that damages are an inadequate remedy for BMS, it nonetheless concludes that

the balance of justice lies in favour of refusing an injunction to protect an existing monopoly, it seems to me that the task of persuading a judge to injunct other generics will be significantly harder than in this case. Therefore, I would regard Teva's advantage as being one of an early mover rather than as a first mover. This is less valuable than the first mover advantage it would have enjoyed had it been permitted to enter the market in February 2023. While the potential loss to Teva of early mover advantage is a matter to be weighed by the Court in Teva's favour, it is a fact that as the litigation has progressed it is now less valuable than previously it might have been.

100. BMS disputed that the evidence establishes that the loss of first mover/early mover advantage is permanent. I am not persuaded that, on the facts in this case, much turns on this point. It is accepted that if Teva is prevented from entering the market and it succeeds on the appeal, that it will have suffered loss which cannot be adequately compensated in damages. While that loss will be greater if it can show that it is permanent and not merely temporary, it is nonetheless uncompensable by an award of damages and so on any view of the matter it must be assessed as a factor to be weighed in the scales against the grant of an injunction. At best the argument goes to the weight to be accorded to such loss. I am not persuaded by BMS's argument on this point and so I consider this loss is to be weighed in the balance of justice on Teva's side of the scales.

101. For the reasons I have explained both in this and in my previous judgment, I do not attribute any significant weight to the partial clearing of the path by Teva.

102. On BMS's side of the scales are the following matters. First, damages would be an inadequate remedy in the event that it were to succeed on appeal but Teva had entered on the market and thereby *de facto* destroyed its monopoly. It could not be compensated for the resultant loss of exclusivity. Some element of harm cannot be adequately compensated by an award of damages. This is particularly so as regards the possible impact of multiple

generic entry and price depression. In my opinion there are good grounds for believing that if it is successful on the appeal, BMS would not be able to restore the monopoly as it existed prior to generic entry. The pricing environment and the market expectations would have radically altered. This situation is exacerbated by the likelihood of multiple generic entry and the resulting price spiral, each of which are likely to be intensified by the interchangeability decision of the HPRA. Even though BMS has *locus standi* to restrain further generic entry by reason of the fact that the order revoking the patent has been stayed, the prospect of obtaining an injunction against other generics will be more difficult if Teva is on the market. There is, accordingly, a greater probability that BMS may not succeed in restraining other generic entry and therefore it is more likely to sustain incalculable losses at an even greater level.

103. A further very significant factor to be taken into account is that by the time this appeal was heard on 12 March 2024 the substantive appeal had been listed for hearing for four days, commencing on 13 May 2024, which mitigated the extent, if not the risk, of potential injustice to both parties. The early hearing date for the substantive appeal also brought into sharp focus the competing risks of injustice. The risk to Teva – if the appeal were to fail – was that its launch would be further postponed by a number of months. The risk to BMS – if the appeal were to succeed – was that it would suffer irreparable damage to its brand and price.

104. In my judgment it is not possible to protect both BMS and Teva from the risk of injustice. However, in my judgment, the balance is not finely balanced but rather it clearly favours BMS. This is so for all of the multiple reasons I have set out. The damage to BMS is both more certain to occur and greater in magnitude than the damage to Teva. Given the interchangeable decision of the HPRA and the readiness of Mylan and Rowex (and possibly more generics) to launch generic products, an immediate and sharp downward

price spiral in the interval between now and the decision on appeal is highly likely. If BMS prevails, it would therefore be confronted with a market which would have become accustomed to lower prices and as was observed by Floyd L.J. in *Novartis* where restoring its monopoly position *"will, if possible at all, be accompanied by harm of other kinds."*

105. If, I am wrong in that conclusion, and that the balance ought to be considered a fine one, then a counsel of prudence suggests that the appropriate course is to maintain the *status quo ante*, which is the monopoly market with no generic entrant.

106. In either case, I am firmly of the view that the balance of justice favours the granting of an injunction restraining Teva from launching its generic product pending the determination of the appeal.

107. I appreciate, as did O'Donnell J. in *Merck*, that this judgment may be read as suggesting that no generic can ever get on the market until it successfully exhausts the appeal process. As O'Donnell J. says, different facts may alter the equation and therefore the outcome. It may well be difficult for a generic who has not entered the market to succeed in the face of a rights holder seeking to protect its monopoly. The best way for the courts to minimise the risk of injustice to such a generic is to seek to expedite the procedures and to list the trials and appeals for as early a date as is possible and for judgments to be delivered as soon as possible thereafter. That had been done in this case, both in the High Court and in this Court - such delays as occurred in this case were attributable to pre-trial procedural disputes. It does not mean the court should refuse an injunction where an originator seeks to defend its position, even where it has failed at first instance, because of the unavoidable time such proceedings inevitably take and the fact that a generic may as a practical reality lose the opportunity to achieve first mover advantage.

108. As BMS has been wholly successful on the appeal, my provisional view is that it should be entitled to the costs of the appeal. If Teva wishes to contend otherwise it should contact the office of the Court of Appeal within 10 days of the delivery of this judgment and request a short hearing on the costs. In such an event, Teva should file written submissions of no more than 1500 words within seven days of its request for an oral hearing and BMS shall have seven days thereafter to file a replying submission of no more than 1500 words.

109. Noonan and Allen JJ. have authorised me to indicate their agreement with this judgment.