THE COURT OF APPEAL

CIVIL

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Court of Appeal Record Number: 2023/67

High Court Record Number: 2021/4758P

Costello J.
Noonan J.
Allen J.

Neutral Citation Number [2023] IECA 173

BETWEEN/

BRISTOL-MYERS SQUIBB HOLDINGS IRELAND UNLIMITED COMPANY

PLAINTIFF/RESPONDENT

-AND-

NORTON (WATERFORD) LIMITED T/A TEVA PHARMACEUTICALS IRELAND

DEFENDANT/APPELLANT

JUDGMENT of Ms. Justice Costello delivered on the 29th day of June 2023

1. This is an appeal from the Order of the High Court of 23 March 2023 restraining the defendant *("Teva")* from infringing Supplemental Protection Certificate No. 2011/032 *("the SPC")* in respect of the plaintiff's *("BMS")* medicinal product Eliquis® (whose active ingredient is Apixaban) pending the determination of proceedings challenging the validity of Irish Patent No. EP (IE) 1 427 415 *("the patent")* and the SPC in respect of the product. The trial is currently listed to commence on 4 July 2023 and is listed to run for 4 weeks.

Background

2. BMS is the owner of the rights in the SPC which protects the active ingredient in BMS's product, Eliquis®, namely Apixaban. Apixaban is an anticoagulant agent which treats and prevents the formation of blood clots. It works by inhibiting the factor Xa enzyme. Factor Xa is an important enzyme in the biological pathway that leads to the coagulation of the blood. Apixaban was discovered following extensive research and substantial costs, including clinical trials, leading to the development and authorisation of Eliquis®. Eliquis® is the largest brand by revenue for BMS. The market is very valuable and expanding in Ireland. The list price value of Eliquis® in Ireland for 2021 was €47,521,689.

3. Eliquis® is sold as a 2.5mg or 5mg film coated tablet in Ireland and it is a direct oral anti-coagulant product. In Ireland it is licensed and reimbursed by the Health Service Executive for three main conditions in adult patients:

(a) Prevention of venous thromboembolic events in adult patients who have undergone elective hip or knee replacement surgery (indication is approved for the 2.5mg tablets only);

(b) Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation, with one or more risk factors, such as prior stroke or transient ischaemic attack; age greater than or equal to 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class greater than or equal to II); and

(c) Treatment of deep vein thrombosis and pulmonary embolism, and prevention of recurrent deep vein thrombosis and pulmonary embolism in adults.

4. In order to place a medicinal product on the market, the manufacturer must obtain a marketing authorisation. As regards Apixaban in Ireland, five generic suppliers, in addition to Teva, have obtained marketing authorisations for generic Apixaban products.

5. The vast majority of sales of Eliquis® in Ireland take place under one of the State funded reimbursement schemes. The HSE approves medicines for reimbursement under the schemes. The setting of reimbursement prices is governed by the Health (Pricing and Supply of Medicinal Goods) Act 2013. A framework agreement, referred to as the Generic Medicines Framework Agreement, was entered into by Medicines for Ireland (which represents the generic and bio-similar medicines industries in Ireland) and the Department of Health, the Department of Public Expenditure and Reform and the HSE. It came into effect on 1 December 2021. Under the Generic Medicines Framework Agreement the reimbursement price for new generic medicines must be no greater than 40% of the 1 October 2021 price of the equivalent branded original medicines. Thus, the introduction of generic products results in products being available at a fraction of the price payable by the HSE in respect of the branded products.

6. BMS holds various intellectual property rights relating to Apixaban, including the patent and the SPC which is based on the patent. The patent expired on 17 September 2022. Unless revoked as a result of the action by Teva, the SPC will remain in force until its expiry on 19 May 2026, subject to potential for a paediatric extension until November 2026.

7. Teva is a manufacturer of generic medicines. In March 2021 it indicated that it intended to launch a generic medicinal product, Apixaban Teva. It commenced proceedings seeking the revocation of the patent and of the SPC based upon the patent on 19 March 2021. As is more fully discussed below, BMS instituted these infringement proceedings thereafter. It is common case that Teva has no infringement defence to these proceedings as its product is generic Apixaban and it admits that it comes within the claims of the patent and is therefore caught by the SPC. Teva's only defence is to assert that the patent, and therefore the SPC, is invalid. Teva has no separate ground of challenge to the SPC.

The progress of the proceedings

8. Teva issued revocation proceedings on 19 March 2021 challenging the validity of the patent and the SPC *("the revocation proceedings").*

9. Teva pleads that the claims of the patent do not describe a patentable invention in that the patent did not involve an inventive step having regard to matter which formed the state of the art at the priority date; that the specification of the patent does not disclose the invention in the claims of the patent clearly enough and completely enough for it to be performed by a person skilled in the art at the priority date (or the application date); and that the matter disclosed in the specification of the patent extends beyond that disclosed in the application. During the course of argument these grounds of challenge were referred to in shorthand as the plausibility issue.

10. On 12 April 2021 the revocation proceedings were entered into the Commercial List of the High Court and directions were made on consent. On 11 June 2021 a defence was delivered and on 2 July 2021 a reply to defence was delivered. On the same day, Teva's solicitors sought a hearing of the revocation proceedings on an expedited basis and confirmed that its current intention was to launch its generic brand of Apixaban on the Irish market in mid-2022 or as close to that date as possible. By letter dated 15 July 2021 the solicitors for BMS sought an undertaking from Teva that it would not launch its generic product prior to the determination of the proceedings and threatened that if an undertaking was not forthcoming then BMS would issue proceedings seeking an injunction and related relief in respect of such indicated launch. In order to facilitate the expeditious progress of the proceedings BMS's solicitors agreed directions in the revocation proceedings and agreed to the request for a trial date of June/July 2022. On 26 July 2021, when the proceedings were mentioned to the judge in charge of the Commercial List, he fixed the hearing date for the trial of the revocation proceedings for 21 June 2022.

11. The undertaking sought by BMS was not provided by Teva, so BMS instituted infringement proceedings on 26 July 2021 seeking a declaration that the two products which Teva had indicated it intended to launch would infringe the SPC; an injunction restraining Teva from infringing the SPC; and an inquiry as to damages and related relief. Barniville J. (as he then was) gave a return date for the application for entry into the Commercial List of the infringement proceedings of 7 September 2021. The Statement of Claim was delivered on 3 August 2021 together with the Particulars of Breaches. An appearance was entered the following day and Notices for Particulars were raised and replied to on 3 and 17 September 2021 respectively. The infringement proceedings were duly admitted into the Commercial List. The defence was delivered on 1 October 2021.

12. On 18 October 2021 Teva amended its Particulars of Objection in the revocation proceedings introducing a new claim in relation to the priority date. This was referred to in submissions as the Priority Issue. The patent upon which the SPC is based claims a priority date from U.S. filing U.S. 324165 (filed on 21 September 2001 *("US 165"))* in the names of Donald J Pinto and Mimi L Quan, the original applicants. Teva asserts that the right of priority arising from US 165 was not assigned from the original applicants for the patent to Bristol-Myers Squibb Company prior to the filing date of the patent. Instead, it is said, the right of priority arising from US 165 was assigned by the original applicants to Bristol-Myers Squibb Pharma Company and, that on 23 April 2007 – long after the filing date of the patent by Bristol-Myers Squibb Company – US 165 was assigned from Bristol-Myers Squibb Pharma Company to Bristol-Myers Squibb Company. Accordingly, it is said, Bristol-Myers Squibb Company was therefore not the owner of US 165 at the filing date. This, it is said, is critical as, in the intervening period between the priority date of US 165 – 21 September 2001 – and the application by Bristol-Myers Squibb Company for the patent – which was filed on 17 September 2002 – there was an intervening patent filing which destroyed the

novelty of the patent. Accordingly, Teva says the patent is invalid as it cannot validly claim priority based upon US 165.

13. BMS consented to the application to amend the Particulars of Objection and an order was made on 18 October 2021 permitting the amendments.

14. On 29 November 2021 the parties reached an agreement on discovery and on 17 December 2021 the court made an order by consent that BMS make discovery of certain categories of documents by 21 February 2022. Category 9 related to the documents relevant to the priority issue. The court brought the trial date forward to 15 June 2022 to allow an additional four days to the duration of the case to reflect the additional time needed to accommodate the priority issue.

15. From about November 2021, agreement in relation to the progress of the proceedings became harder to obtain. There were disputes in relation to the mode of trial and the adequacy of replies to Notices for Particulars and delay in making discovery and in the exchange of witness statements and expert reports. On 19 May 2022 Teva served a Notice of Interrogatories. It requested BMS to reply by 9 June 2022 (there was no direction from the court fixing the date for the furnishing of replies as leave to deliver interrogatories was not required). This too gave rise to disputes.

16. It became clear that the trial would not be able to proceed on 15 June 2022. On 2 June 2022 the court informed the parties that a Commercial List judge with a particular expertise in the field, O'Moore J., had volunteered to try the case commencing in September, 2022, and on that basis the trial was rescheduled to commence on 19 September 2022. Teva's counsel then informed the court that the directions were *"pretty much fulfilled"* as of that date. Unfortunately, as is more fully set out in the judgment of the High Court, that was not, in fact, the case. Unsworn replies to the Notice for Interrogatories were delivered by BMS on 29 June 2022. Teva became dissatisfied both with the discovery made by BMS and

the answers to the interrogatories. In addition, BMS sought to file a new witness statement of Ms. Sandra Leung to address the priority issue.

17. In July 2022, a number of issues still remained outstanding. On 22 July 2022 O'Moore J. ruled that if the outstanding issues were not resolved by 27 July 2022, the trial date of 19 September 2022 would be vacated and any motions to be issued by the parties would be heard in late September in lieu of the trial commencing at that time. As matters were not resolved, the trial date was vacated and O'Moore J. directed that any further pre-trial motions, including the application by BMS to admit the witness statement of Ms. Leung, be issued by 19 August 2022. The trial was provisionally listed for 11 October 2022. In accordance with the directions of O'Moore J., three motions were issued: Teva's motion for further and better discovery/strike out the defence of BMS; Teva's motion to compel replies to interrogatories; and BMS's motion seeking leave to deliver the witness statement of Ms. Leung. It was clear that these could not be resolved in time for the trial to proceed in October 2022.

18. On 20 September 2022 the October trial date was vacated. The three motions were heard on 27 September and 12, 13 and 14 October 2022.

19. O'Moore J. ordered BMS to make further and better discovery of the documents within Category 9 by 12 January 2023 and to reply to interrogatories 5.20 and 5.22 by 12 January 2023. He refused to order that BMS reply to interrogatories 5.4, 5.5, 5.17, 5.18 and 5.19. He permitted BMS to adduce the evidence of Sandra Leung and directed her witness statement to be delivered by 6 p.m. on 20 October 2022. Teva was ordered to deliver any additional witness statements by 26 January 2023.

20. On 7 November 2022 the trial was provisionally listed for four weeks commencing on 20 June 2023. This was subsequently altered to a listing on 4 July 2023 by order of McDonald J. on 5 December 2022.

21. In November 2022 Teva decided that it would no longer wait until the determination of the revocation proceedings before launching its generic product and on 29 November 2022 its solicitors informed the solicitors for BMS that it was prepared to launch its generic product in four weeks. Accordingly, on 2 December 2022 BMS issued a motion in the infringement proceedings seeking an interlocutory injunction to restrain Teva from infringing the SPC. This motion proceeded with commendable speed and was heard by the High Court (Barrett J.) on 2 February 2023.

22. Meanwhile, on 11 January 2023 BMS applied for an extension of time in which to complete discovery in relation to Category 9. O'Moore J. ordered that BMS make further and better discovery within a period of eight weeks, bringing it up to 9 March 2023. He then ordered that if BMS wished to seek a further extension of time, it must set out the basis for this in a detailed affidavit or affidavits and make the deponent or deponents available for cross examination if sought and/or required.

23. Discovery in respect of Category 9, and the replies to the two outstanding interrogatories were delivered on 9 March 2023. At the hearing of the appeal, Teva placed great emphasis upon certain new documents discovered *(the "new documents")* and the replies to the interrogatories, both as to their relevance to the priority issue and the fact that they had not been disclosed to Barrett J. during the hearing of the application for the interlocutory injunction or generally.

24. Barrett J. delivered judgment granting the injunction sought on 17 February 2023 (again with commendable expedition). The order was perfected on 23 March 2023 to facilitate an appeal even though the scope of BMS's undertaking as to damages had not yet been resolved and a further hearing was required in order to allow the High Court to rule on this issue.

25. Teva issued its Notice of Appeal on 23 March and the respondent's notice was filed on 4 April 2023.

26. The issue in relation to the failure to disclose the new documents relevant to the priority issue was raised for the first time in correspondence dated 6 April 2023.

The judgment of the High Court

27. In his judgment, Barrett J. quoted extensively from the evidence filed by the parties in paras. 1-13 (55 pages). From paras. 14 -17 he considered the decision of the Supreme Court in *Merck Sharp & Dohme Corporation v. Clonmel Healthcare Limited* [2019] IESC 65, [2020] 2 I.R. 1 *("Clonmel")*. The judge identified twenty-six key elements of the decision of O'Donnell J. including that injunctive relief is an equitable and flexible remedy (Distilled Observation 2); that whether or not to grant an injunction is not a matter of applying strict mechanical rules (Distilled Observation 4); that the adequacy of damages is to be considered as part of the balance of convenience (balance of justice) (Distilled Observation 5); and that the fact that there may be difficulty in the calculation of damages does not mean that damages are an inadequate remedy. However, this does not mean that that it must be completely impossible to assess damages before such damages can be said to be an inadequate remedy. The fact that it is possible to award damages does not preclude the grant of a permanent injunction and should not be understood as an absolute bar to the grant of an interlocutory order. (Distilled Observation 9 and 10).

28. Barrett J. quoted from the judgment of O'Donnell J. in *Clonmel* at paras. 55 and 56:-

> *"The interests of the SPC holder and the interests of the generic challenger are both interests in acquiring a position in the market. The difference between them is that the SPC holder has a right conferred by a process of law which is*

presumptively valid: something which, if anything, ought perhaps to favour Merck.

...

I recognise that the interest of Clonmel in exploiting a first-mover advantage is something of value which is to be considered and given weight in the application for an interlocutory injunction, since it will necessarily be lost if an injunction is granted. ... That, however, is the high point of Clonmel's case. If it is wrong in its contention that the 001 SPC is invalid, then its conduct constitutes an actionable wrong. However, I cannot see how that interest can be said to outweigh the right of Merck (if it in turn is correct) to exploit its monopoly, granted, on this hypothesis, in accordance with law."

29. Barrett J. also quoted from para. 60 as follows:-

"The rights of a valid SPC holder are to exclude all competitors with products covered by the SPC until the last day of the SPC. It follows that the SPC holder will know the precise date on which its rights will expire, and one of those rights, therefore, is to be able to plan for that eventuality so that it may maximise its position in the market both until that period and the period immediately after expiry. If Clonmel is held to have wrongfully launched its product and yet was not restrained by injunction, then Merck will lose that significant benefit. The expiry of the SPC, as a matter of fact, if not law, would be determined by the fact of entry by Clonmel: a circumstance for which Merck would not be able to plan or take defensive steps in advance. In the event that no injunction was granted, but the validity of the SPC was upheld, it would be necessary, therefore, to carry out essentially the same speculative calculation in reverse, and attempt to assess how Merck might have exploited its monopoly position pending expiry and

defended its position in the market post-expiry, if it had not been deprived of the ability to control the date of expiry of the 001 SPC."

30. At Distilled Observation 24, the High Court judge noted that the possibility of entry of up to four other generic producers was of relevance to the Supreme Court's considerations in *Clonmel*. The Supreme Court did not consider that damages would be a full or adequate remedy for either party and additionally noted that both parties had sufficient resources to pay any damages awarded. It followed that the balance of potential irreparable harm favoured neither party decisively. O'Donnell J. observed that while the question of the adequacy of damages to either party and the capacity of the parties to pay them was often the single largest element in the balance of convenience, and would often be decisive, there are other factors which can be relevant and which, in a closely balanced case, may tip the balance. (Distilled Observation 25). Barrett J. noted that O'Donnell J. identified the three ways in which weight should be given to the fact that a party is the holder of an SPC granted pursuant to an authorisation process provided for by law and which involves the consideration both of the application for the patent by the Controller of Patents and the subsequent application for the SPC. First, it is appropriate to take into account the ostensible validity of the rights of the SPC holder and to give them greater weight in the balance than the interests of the generic producer, which only arise after it is determined that the SPC is invalid. Second, the position in which the SPC holder possesses its ostensible rights represents the *status quo ante* (in a case where there has been no unreasonable delay in the commencement of the proceedings). Third, where the only issue is validity, it is a legitimate factor to which weight should be given to consider that no steps had been taken to clarify the essential matters upon which the generic producer's right to launch the product depended, i.e. those concerning the question of the validity of the SPC. (Distilled Observation 26).

31. Barrett J. observed that in cases where the balance of convenience may be finely balanced, it may be appropriate (1) to have regard, even on a preliminary basis, to the strength of the rival arguments as they may appear to the court, (2) in intellectual property matters where the same issue may have been addressed in other European countries, or the same issues adjudicated in other comparable jurisdictions, to take into account the outcome of such litigation. (Distilled Observation 27)

32. Finally, he cited in full the outline of the eight steps which O'Donnell J. identified might be followed by a court in considering an application for an interlocutory injunction:-

> *"(1) …[T]he court should consider whether, if the plaintiff succeeded at the trial, a permanent injunction might be granted. If not, then it is extremely unlikely that an interlocutory injunction seeking the same relief pending the trial could be granted.*
>
> *(2) The court should then consider if it has been established that there is a fair question to be tried, which may also involve a consideration of whether the case will probably go to trial. In many cases, the straightforward application of the approach in American Cyanimid… and Campus Oil v Minister for Industry (No 2) [1983] I.R. 88 will yield the correct outcome. However, the qualification of that approach should be kept in mind. Even then, if the claim is of a nature that could be tried, the court, in considering the balance of convenience or balance of justice, should do so with an awareness that cases may not go to trial, and that the presence or absence of an injunction may be a significant tactical benefit.*
>
> *(3) If there is a fair issue to be tried (and it probably will be tried), the court should consider how best the matter should be arranged pending the trial, which*

involves a consideration of the balance of convenience and the balance of justice.

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

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

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

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

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

33. Having analysed the decision in *Clonmel*, the High Court judge proceeded to analyse the case before him in the manner outlined by the Supreme Court. He first noted that it was common case that there was a fair issue to be tried (para. 18). He identified the task before

him as being to regulate matters most justly as between the parties pending trial (para. 19). He considered that the question of the adequacy of damages was part of the balance of justice. At para. 20 he held that:

> *"On balance…the scales of convenience are equally weighed on both sides, i.e. that neither side has shown that it would be more or less difficult to compute damages for it than it would be for the other."*

34. The judge identified three ways in which BMS maintained that it would suffer were the interlocutory injunction to be refused and it succeeded at trial in upholding the validity of the SPC:-

> *"(1) BMS maintains that there would be a challenge in calculating the loss suffered;*
>
> *(2) BMS maintains that it would suffer permanent damage through a collapse in process/market share were Teva now allowed to enter the market with a generic that costs a fraction of the BMS product;*
>
> *(3) there would be damage that is not compensable at all, in particular the loss of exclusivity that goes with being an SPC holder."*

35. He rejected points (1) and (2) on the grounds that they were:-

> *"Near-classic circumstances in which a court would assess damages. The evidence before me suggests that it is essentially a mathematical exercise that could be approached and completed logically."*

36. The judge did not accept that BMS would suffer permanent damage through being forced to introduce discounted prices in response to the entry of Teva on the market. Even if it did so, he rejected the contention that it would never be able to reverse the price reductions, should BMS succeed in the revocation proceedings. He held that in any event this remains in the realm of pecuniary loss which was eminently calculable and recoverable as damages.

He accepted that the calculation of BMS's losses would be more challenging if any generic producers were to enter the market but held that whilst the launch of a second or further generic was a possibility, the evidence fell a long way short of indicating that it was likely and, in the event that it were to occur, it would not make the calculation of damages impossible.

37. In regard to the third point, the loss of exclusivity, he simply held that BMS would not be adequately compensated by damages.

38. Barrett J. held that Teva would not be adequately compensated by damages if the interlocutory injunction were granted and it later succeeded in the revocation proceedings. Teva did not appeal the conclusion that damages would not afford Teva adequate compensation, but it did appeal against the reasons he gave for reaching this conclusion. It was contended that the High Court judge misunderstood and failed to properly to weigh the evidence and its conclusions. However, as BMS did not cross-appeal in relation this finding, it is not necessary to deal with this aspect of the appeal as his conclusion is accepted by both parties. Accordingly it is not necessary to set out his reasons for his conclusion.

39. At para. 32 of his judgment Barrett J. observed that the injunctive application was concerned with a situation *"in which Teva seeks not so much to 'clear the path' but to arrive at the end of the path before it has been cleared, i.e. it wants to bring a generic to market without duly clearing away the boulder that sits in the path at this time in the form of an ostensibly valid SPC."*

40. At para. 33 he noted that the trial of the revocation action will take place during the lifetime of the SPC, so that the gravamen of Teva's complaint is that it would like to launch its generic for some commercial reasons best known to itself at a time when the SPC remains extant. The point in time when Teva came to commence Teva's revocation proceedings was a matter within Teva's control.

41. However, the judge accepted that Teva had cause for complaint as to how BMS had conducted itself in the proceedings:-

> *"There was 'to-ing and fro-ing' between the parties at the hearing as to how the proceedings have been conducted to this point (and that finds echo in the affidavit evidence considered previously above). However, it seems to me that certain points cannot be disputed as a matter of historical fact when one has regard to that evidence: BMS defaulted on the delivery of witness statements; it failed to make discovery on time; it failed to reply to interrogatories on time; it failed to comply with its discovery obligations; it was ordered to make further and better discovery; it had to be ordered to deliver further responses to interrogatories; and only a couple of days before the trial was due to commence last year it announced that it had a new witness of fact."*

42. Notwithstanding this finding, he said that he did not see:-

> *"…that BMS had at any point acted in a malign or improper manner or with any intention to defy the court or to ignore court orders. How it has acted has not always been optimal and may yet fall to be reflected in costs. But at worst it is guilty of more procedural 'misdemeanours' than one would wish for (and one has to remember that even the best-run cases have undesirable episodes/delays in the run-up to trial and sometimes even during the trial)."*

43. Barrett J. noted that it had not been asserted that any members of BMS's legal team had at any point acted other than with the utmost propriety and he himself noted that both legal teams had also acted with complete propriety. He held that there was no egregious behaviour by BMS and rejected the argument that *"the necessary price to be paid by BMS for any (if any - and here I see no) egregiousness would be, in effect, to forfeit the benefits of its SPC through the refusal of the injunction it now seeks."*

44. A matter which had given him *"very considerable cause to pause"* was the fact that the equivalent patent had been declared invalid in England in proceedings entitled *Sandoz Ltd v. Bristol-Myers Squibb Holdings Ireland Unlimited Company* [2022] EWHC 822. He noted that it was incumbent upon him to give weight to the decision. But he noted that there may or may not be differences between English and Irish law when it comes to plausibility and that the priority date argument had not been raised in the English proceedings and might yet offer an additional ground for the revocation proceedings to succeed. He noted that the decision of the English High Court had been appealed and that the SPC in this jurisdiction remains presumptively valid and that there was a public interest in the observation of a process whereby the path is cleared, and products then come to the market rather than products coming to the market when the path clearing is still underway.

45. Barrett J. then proceeded to adopt the eight-step approach outlined in para. 65. He said that in considering the balance of convenience, nine key factors stood out as favouring the granting of the injunction sought by BMS:

> *"(1) Teva intends to engage in intentional infringement of BMS's SPC.*
>
> *(2) Such infringement will cause loss to BMS that to some extent is not compensable in damages.*
>
> *(3) The SPC enjoys a presumptive validity.*
>
> *(4) The 'first mover advantage' that Teva wishes for at this time is an advantage that would see it infringe BMS's presumptively valid SPC.*
>
> *(5) BMS is not seeking to injunct Teva from doing anything that Teva has a prima facie legal right to do.*
>
> *(6) If Teva succeeds in the revocation proceedings, the calculation of Teva's damages will be complex; however, calculating BMS's damages will likewise be complex should BMS succeed.*

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

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

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

46. For these reasons, he then granted the injunction sought.

Merck Sharpe & Dohme v. Clonmel Healthcare Limited

47. In 2019 in the case of *Merck Sharpe & Dohme Corporation v. Clonmel Healthcare Limited* [2020] 2 I.R. 1, the Supreme Court revisited the principles for the granting of interlocutory injunctions and, having reviewed the jurisprudence in considerable detail, emphasised the essential flexibility of the remedy and emphasised that an injunction should not be granted merely because an applicant can *"tick the relevant boxes"* of arguable case, inadequacy of damages and the ability to provide an undertaking as to damages, while likewise stating that an injunction should not be refused merely because damages may be awarded at trial. That case involved an application for an interlocutory injunction to restrain

the launch of a generic drug prior to a determination of the validity of the SPC in respect of a particular product, Inegy. It is common case in this appeal that the principles discussed by O'Donnell J. (as he then was) writing for the court, are the principles applicable to this appeal. In the recent decision of this Court in *Biogen MA Inc. v. Laboratorios Lesvi S.L.* [2023] IECA 71, *("Biogen")* this Court considered that judgment in great detail from paras. 54 -78. I do not propose to repeat the analysis set out save insofar as emerges in the discussion of this appeal.

48. BMS argued that *Clonmel* governed the decision in this case and meant that an injunction ought to be granted and the trial judge's decision accordingly ought to be upheld. On the other hand, Teva argued that the case could be distinguished from *Clonmel* on a number of grounds and that, while the trial judge correctly identified the principles, he erred in his application of the principles in *Clonmel*; that an injunction ought to have been refused, and therefore the appeal should be allowed.

Distinguishing features identified by Teva

49. Teva argued that there was no automatic assumption that an SPC holder is entitled to an injunction to restrain infringement pending the determination of the revocation proceedings. It argued that the judge erred in failing to find that damages were an adequate remedy for BMS, specifically by reference to the evidence of Mr. William Potter. Secondly, it said that the judge failed properly to weigh the fact that Teva had attempted to clear the path but was prevented from doing so by the obstruction of BMS with the result that it could not get on the market in a timely fashion through no fault of its own. Thirdly, it was (strongly) asserted that BMS does not come to court with clean hands. This allegation was based on the actions (or inactions) of BMS which had resulted in the loss of trial dates; the failure by BMS to disclose the new documents in advance of the hearing of the interlocutory injunction; and, thirdly, that the discovery as originally made was not properly made and

would have imperilled a fair trial had the trial proceeded without discovery of the new documents. Fourthly, it was urged that the trial is imminent and that this was a reason why an injunction was refused in the case of *Smithkline Beecham plc v. Genthon BV* (Unreported, High Court, Kelly J., 28 February 2003) and this decision ought to have been followed in the High Court. Fifthly, it was said, Teva had established a strong case on invalidity on the priority ground to which the judge failed to give adequate weight, and the strength of that case was reinforced by the new documents. Sixthly, it was said the judge failed to give proper weight to the first mover advantage which Teva would have enjoyed had it been free to launch its generic product at risk prior to the determination of the revocation proceedings.

Would BMS be adequately compensated by damages if the interlocutory injunction was not granted?

50. As discussed above, the High Court judge identified essentially three ways in which BMS contended that it would suffer damages were Teva to be allowed to launch its generic product on the market and the patent is later found to be valid. He rejected the first two bases on the grounds that they were *"near classic circumstances in which a court would assess damages"*. In doing so, he accepted the evidence of Mr. William Potter in his first affidavit at paras. 4.1 and 4.5. Mr. Potter explains that BMS's loss could be calculated as the difference between the actual profits BMS earned (the factual scenario) and the amount it would have earned in a counter factual scenario where no directly competing generic products (including Apixaban Teva) had been launched into the Irish market. He averred that the profits of the factual scenario are known and that profits in the counter factual scenario can be calculated with a good level of accuracy based on assumptions that can be made with a high degree of confidence based on facts and data available from the factual scenario. On the basis of those assumptions, he averred that it was essentially a mathematical exercise to calculate BMS's loss that arises in *"this well-defined period between launch of*

Apixaban Teva and the restoration of BMS's position." In paras. 4.1.1 through to paras. 4.1.16 Mr. Potter sets out in considerable detail how this may be calculated. This evidence was accepted by Barrett J. and forms the basis of his rejection of BMS's argument that damages would not be an adequate remedy in respect of what the High Court characterised as its first head of damage.

51. Teva, in substance, submits that Mr. Potter's evidence provides a complete answer to BMS's claim that it would not be adequately compensated by an award of damages. It argues that the judge was wrong to simply conclude that the loss he identified as the third category of loss was not quantifiable without further analysis. In the absence of such analysis, it argues that the decision ought not to be upheld by this Court.

52. In my judgment, the High Court was entitled, on the evidence before it, to conclude that the damage which BMS would suffer in the first category would be compensatable by an award of damages.

53. I would with respect disagree with his conclusion on the evidence in respect of the second category, thought 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. At para. 4.3 of his first affidavit Mr. Potter said that:-

> *"Once judgment that the Patent is valid and infringed is handed down, BMS is at liberty to increase its selling prices back to its price pre generic entry without delay and would therefore do so."*

55. Mr. Scott Cooke, General Manager of Bristol-Myers Squibb Pharmaceutical Ltd., in an affidavit sworn on 2 December 2022 stated at para. 48 that:-

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

And at para. 55 and following:-

"…On premature generic entry, BMS will be faced with a most unattractive choice - which will involve very significant harm to it either way - between seeking to maintain its price pending trial of the action or competing with the generic, which it would in reality likely have to do. Assuming BMS chose to compete in an effort to maintain its market share, any attempt later to restore the pre-generic launch price following the trial of this action would be severely damaging to its reputation, commercial relationships and wider commercial interests and I believe would be practically impossible. Even assuming BMS lowers its price to compete, it would, be unpredictable to what extent it could maintain its market share in any event given the very deep discounts likely to be offered by generics.

…

57. I do not believe that it would be possible retrospectively to quantify the losses that BMS would suffer in the event that Teva launches a generic apixaban product and is subsequentially removed from the market even after a short time (following the trial), or that in these circumstances BMS could simply reinstate its original price after generics are removed from the market, assuming BMS is successful at trial.…

58. …The market will not be the same after a generic entry and price-cutting as it was before. Market expectations will have changed and the reality is there would be a wholly different pricing environment…

59…even assuming the reimbursement price is not reduced, and BMS instead reduced its price by way of discounts and rebates to wholesalers and pharmacists, it would be impossible in practice for BMS to reverse these either.

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

56. Notwithstanding these averments of Mr. Cooke, Mr. Potter concluded at para. 4.5 that:-

"[BMS's] losses are restricted to a defined and relatively short period between the launch of Apixaban Teva and the date on which the final determination of the Revocation Action judgment is handed down finding the Patent is valid and infringed. Taking this into account, it is my opinion that the losses incurred by BMS in [this scenario] can be readily estimated with reasonable accuracy."

57. At para. 4.4 Mr. Potter states that, in his opinion, the losses incurred by BMS:-

> *"are restricted to only occur in the period from the time of the generic companies' earliest product launch until the date on which judgment is handed down holding that the Patent is valid and on which generic apixaban is removed from the Irish market".*

He does not accept that there will be any subsequent losses sustained by BMS.

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

59. Mr. Potter swore a second affidavit on 20 January 2023. This reveals that he was concerned to demonstrate that the calculation of damages would be more difficult in Scenario 2 (where an injunction is granted and Teva succeeds in the revocation action) than in Scenario 1 (where the injunction is refused and BMS succeeds in the revocation action). However, the test for this Court is not which scenario would involve the more difficult calculation, but rather whether in each alternative damages would provide an adequate remedy for BMS and Teva respectively. This misunderstanding by Mr. Potter of the question for consideration by the court lessens the weight which the Court can place on his opinion. The assessment is not a relative test; it is the same exercise conducted in respect of each party, but it is not a comparative test: if damages are an inadequate remedy for both, that is the end of the analysis of damages as a remedy.

60. In relation to the evidence of Mr. Cooke concerning price suppression, at para. 16 of his second affidavit, Mr. Potter agrees that price competition as described by Mr. Cooke *"is very likely the response that BMS will make to the entry of generic apixaban regardless of when this entry occurs and regardless of how many generic entries there are."* He gives no evidence to support his assertion that it would nonetheless be possible for BMS to reverse its price reductions other than to observe that:-

"Neither Mr. Cook (sic) nor Mr. Dodd give clear reasons why this would not be possible other than to state that impacts on goodwill and reputation would prevent this."

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

> *"Merck's right was not simply to recover income and profit pending the expiry of the 001 SPC. The rights of a valid SPC holder are to exclude all competitors with products covered by the SPC until the last day of the SPC. It follows that the SPC holder will know the precise date on which its rights will expire, and one of those rights, therefore, is to be able to plan for that eventuality so that it may maximise its position in the market both until that period and the period immediately after expiry. If Clonmel is held to have wrongfully launched its product and yet was not restrained by injunction, then Merck would lose that significant benefit. The expiry of the SPC, as a matter of fact, if not law, would be determined by the fact of entry by Clonmel: a circumstance for which Merck would not be able to plan or take defensive steps in advance."*

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

63. I am satisfied that there was ample, credible evidence before the High Court to conclude that damages would not adequately compensate BMS in the event that the injunction was refused and it ultimately succeeded in the revocation action. There was no countervailing evidence from Teva in relation to the 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*. The fact that the High Court judge did not expand his reasons for reaching this conclusion does not mean that the injunction granted should be discharged on appeal. If one reads the extensive quotes from the evidence and consideration of the judgment in *Clonmel*, the reasons for his conclusion are clear and Teva could not credibly assert otherwise. The point is essentially one of form rather than substance. For these reasons, I would reject this ground of appeal.

Teva's attempt to clear the path

64. From March 2021 Teva made it clear that it hoped to launch its generic product in the middle of 2022 but that it intended to clear the path prior to launching its generic product, Apixaban Teva. I have already set out in detail the progress of the proceedings and the circumstances which led to the vacating of three trial dates in June, September and October 2022. On 29 November 2022 Teva notified BMS that it intended to launch its generic within four weeks, at a time when the path had not been cleared. As was stated by Floyd L.J. in *Novartis AG v. Hospira UK Ltd.* [2014] 1 W.L.R. 1264, cited in *Clonmel* at para. 21:

> *"54. 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."*

65. A launch of its generic product today would *prima facie* infringe BMS's SPC. Self-evidently, Teva has not cleared the path. It undoubtedly has taken steps to do so but as is clear from the quote from *Novartis*, even if judgment at first instance is given in its favour (i.e., after trial), it will not have cleared the path, as the first instance decision may be overturned on appeal.

66. Teva argues that it should get credit for the steps that it has taken to date in the sense that these should weigh positively in its favour in the balance of justice, even though they have not completed the task. No authority was opened to this Court in support of this proposition. It would appear to be completely contrary to *Novartis* and to the decision in *Clonmel*. No cogent argument was advanced to this Court as to what weight, if any, should be given to a generic manufacturer who has tried to clear the path, given an undertaking not to launch its product pending the determination of the validity of the relevant IP right, and then changed its mind- in this case because the earlier trial dates were lost and the new trial date was fixed for 4 July 2023. The court was given no explanation for its change of heart and counsel submitted simply that *"[t]he fact we have spent two years trying to get these proceedings on cannot be worthless."*

67. I cannot agree. If a generic seeks to clear the path it must do so until *"all arguable objections from the patentee have been eliminated".* Otherwise, it launches at risk and it cannot then claim to have cleared the path. At all times Teva says it planned to launch its generic product in mid-2022 but its self-selected timeline did not allow time for the reserved judgment of the High Court to be delivered and for the virtually guaranteed appeal to be brought by the unsuccessful party. When time is allowed for the High Court's reserved judgment, an appeal, the hearing of an appeal and time to write a reserved judgment following the appeal, it is fair to say that even had the trial commenced in June 2022 and concluded in July 2022, the path could not have been cleared, in the sense of all arguable

objections of the patentee being eliminated, until July 2023, and possibly longer. In my judgment, Teva's expectations were, in all the circumstances, unduly optimistic and unrealistic.

68. It is also important to bear in mind the observation of O'Donnell J. in para. 60 in *Clonmel* that the expiry of the SPC, as a matter of fact, if not law, would be determined by the fact of entry of the generic manufacturer.

69. Teva has elected to seek to launch its generic product before it has concluded clearing the path and therefore it cannot as a matter of fact contend that it has cleared the path or that its launch is not now a launch at risk which infringes a *prima facie* valid SPC. I therefore would attribute little if any weight, in assessing the balance of justice between the parties, to its efforts to clear the path.

BMS does not have clean hands

70. The greater part of Teva's oral submission were directed towards this ground of appeal. In the High Court, Teva's case was that BMS had *"thwarted"* its attempt to clear the path and to have an early trial of the revocation proceedings with the result that the trial dates in June, September and October 2022 all were vacated. It complained that BMS failed to meet deadlines, and delayed in providing discovery, in replying to interrogatories and in providing witness statements. In July 2022, at the eleventh hour, it sought to introduce a new witness as to fact. It had to be ordered to make further and better discovery of documents relevant to the priority issue on 12 October 2022 and to reply to two further interrogatories. All of this was acknowledged by Barrett J. in his judgment at para. 33. Teva complained that he failed to give adequate weight to these findings.

71. Considerable emphasis was placed at the hearing of the appeal on the new documents discovered on 9 March 2023 in relation to the priority issue. Teva says this is a crucial issue in the case where BMS bears the burden of proof and is the *"sole guardian of the facts"*. It

is accepted that if BMS loses on the priority issue then the patent and the SPC are invalid. The new documents were first identified by BMS's solicitors on 26 and 27 January 2023 as discoverable along with other e-mails which were identified on unknown dates after 2 February 2023. Teva says that these new documents are crucial to the priority issue and are irreconcilable with BMS's pleadings, submissions and witness statements furnished to date. It contends that BMS was aware of the existence of the new documents and of the importance of the new documents and did not refer to them when it applied for an interlocutory injunction on 2 February 2023 and did not disclose the existence of these new documents to either Teva or to the High Court.

72. Finally, Teva contends that a fair trial was imperilled by the actions of BMS because, up until the Order of O'Moore J. on 12 October 2022, BMS insisted that it had made proper discovery and that the trial could proceed on the basis of the discovery it had made. Had Teva accepted this position, the hearing would have proceeded without these new documents which, according to Teva, undermine BMS's defence on the priority issue. As a result, it is said, Teva's right to a fair trial was imperilled by the wrongful action of BMS.

73. Before considering this issue, it is first necessary to consider the priority issue in the proceedings.

74. Teva explains its position as follows: if a party filing a patent application wishes to rely on an earlier patent application for priority, the party must show that it is the owner or successor in title of the owner of the priority patent. Succession must have taken place before the later application is made (European Patent Convention, Article 87(1)). In this case, the patent application was filed on 17 September 2002 *("the filing date")* by Bristol-Myers Squibb Company claiming a priority date of the 21 September 2001 based upon a prior patent, US 165. Between the priority date and the 17 September 2002, there was an intervening patent filing which destroyed the novelty of the patent, so BMS needs to rely on

US 165 to avoid revocation of the patent. US 165 was owned by Bristol-Myers Squibb Pharma Company *("BMS Pharma")* and not by Bristol-Myers Squibb Company on the filing date.

75. BMS pleaded that Bristol-Myers Squibb Company has equitable title in all assets held by any BMS entity by reason of its ownership of those entities and its right of control and by laying out the policy of IP ownership for BMS Pharma.

76. In reply to the request for Further and Better Particulars dated 25 January 2022, BMS stated as follows:-

> *"Under the law of the State of Delaware, the residence of all of the relevant Bristol- Myers Squibb companies in this matter, including Bristol-Myers Squibb Pharma Company (formerly DuPont Pharmaceuticals Company) and the applicable law regarding the powers and functions of those companies and the ownership of the assets between them, a parent company can direct that a wholly-owned subsidiary manage its proper and affairs in the manner that the parent company requires.*
>
> *In this case, Bristol-Myers Squibb Company assumed control over the intellectual property of Bristol-Myers Squibb Pharma Company including by determining the manner in which it was to be held.*
>
> *Under Delaware law, this power to control and direct the use and disposal of the said intellectual property constituted Bristol Myers Squibb Company as its beneficial owner."*

77. By letter dated 1 February 2022, solicitors for Teva raised further and better particulars which were replied to on 7 February 2022 as follows:-

"5.1. ***Please clarify whether it is the Respondent's case that Bristol-Myers Squibb Company was the beneficial owner of US '165 by reason of the existence of a power to control its subsidiaries' property;***

Without prejudice to the legal argument to be made at trial, as a result of its 100% ownership of Bristol-Myers Squibb Pharma Company and as a matter of the law of Delaware, Bristol-Myers Squibb Company had the right to direct that Bristol-Myers Squibb Pharma Company manage its property and affairs in the manner that Bristol-Myers Squibb Company requires; this right was actively engaged by Bristol-Myers Squibb Company in respect of the intellectual property of Bristol-Myers Squibb Pharma Company by laying out the policy governing the manner in which the intellectual property of Bristol-Myers Squibb Pharma Company was to be held. Under the law of Delamare these matters constituted Bristol-Myers Squibb Company as beneficial owner of US '165.

5.2. If it is so asserted, please particularise the essential factual and legal basis of that claim;

As already particularised the right of control of Bristol-Myers Squibb Company over intellectual property of Bristol-Myers Squibb Pharma Company arose under Delaware law as a result of its acquisition of 100% ownership of that entity. As indicated, upon acquisition, Bristol-Myers Squibb Company exerted its right of control by laying out the policy as to how patents were to be held as between companies such that ownerships of existing patent and trademark rights related to the pharmaceutical business of Bristol-Myers Squibb Pharma Company should remain in that company"

78. Teva also raised interrogatories which were initially answered by Mr. Scott Brown, attorney at law on behalf of BMS on 29 June 2022. On 20 October 2022 O'Moore J. directed BMS to provide responses to two interrogatories.

79. In his replies to interrogatory sworn on 10 March 2023 Mr. Brown stated as follows:

> *"6. Interrogatory 5.20 and 5.22 had been answered to the best of my knowledge information and belief on the basis of the discovery that had then been made. The efforts that have been undertaken pursuant to the Order of 20 October 2022 however and as part of, and in conjunction with, the Respondent's task a further discovery under the separate Order of Mr. Justice O'Moore of 20 October 2022 in respect of discovery, have resulted in the identification of emails and an administrative training manual for paralegals which address issues which relate to the subject matter of the October 2001 emails. I was not aware of these materials prior to that exercise and in particular when I swore my first affidavit or confirmed instructions in relation to subsequent responses provided in correspondence by the Respondent's solicitors."*

80. He then answered 5.22 stating that:-

> *"…the "said policy', that is, the decision to maintain legal ownership in Bristol Myers Squibb Pharma Company in respect of existing rights already residing there and to put new patents and trade marks in the name of Bristol-Myers Squibb Company was evidenced in writing in the following materials which I outline in the paragraphs below."*

81. He exhibited eleven documents comprising a number of e-mail chains from various dates in 2002 commencing 21 January 2002 and an e-mail dated 2 June 2002 enclosing an administrative training manual and the training manual of 6 June 2002. These are the new documents.

82. Teva claims that the new documents show that cases which claim priority to a filing date prior to 10 January 2001 should be in the name of Bristol-Myers Squibb Pharma Company and that *"all subsequent filings worldwide claiming this priority should be in the name of BMS Pharma."* Teva says the new documents show that the policy and the decisions of BMS were totally different to the case pleaded. The new documents are said to show that BMS had a deliberate policy which required US 165 to be in the name of Bristol-Myers Squibb Pharma (which it was) and the application for the patent to be in the name of Bristol-Myers Squibb Pharma, rather than Bristol-Myers Squibb Company and that this is not what happened. What occurred was not consistent with the case pleaded and particularised by BMS, according to Teva. For these reasons, Teva claims that the failure to make discovery of the new documents in the original affidavit of discovery and the subsequent failure to disclose the new documents prior to the hearing of the interlocutory injunction on 2 February 2023 weigh heavily against the grant of any equitable relief in favour of BMS.

BMS's conduct up to 26 January 2023

83. Both the revocation proceedings and subsequently the infringement proceedings were very closely case managed in the Commercial List by judges with particular expertise in patent litigation. While O'Moore J. ordered BMS to start again and to make further and better discovery in relation to Category 9, the category relevant to the priority issue, he did not hold that there had been anything improper in the conduct of the litigation or anything akin to a deliberate attempt to frustrate the trial or to *"thwart"* Teva's attempts to clear the path. On 12 October 2022 he said:-

> *"But it seems to be plain that there has been a failure, a continuing failure to make proper discovery in respect of Category 9. I don't feel that in the evidence available to me that I would describe it as a wilful default, or even the form of*

negligence speculated upon by Mr. Justice Collins and others as constituting a reason to strike out a pleading or part of a pleading…

…

But for the purposes of the court having confidence in the discovery to be made, given the errors accepted, correctly so, by the lawyers representing the Bristol Myers Squibb in the patentee's interest here, and, in particular, given the episode that occurred in July of this year when there was a misunderstanding, described as kindly as I can, in respect of information provided to Teva's solicitors and to the Court, there are a range of reasons why proper discovery must now be made."

84. He emphasised that the full discovery exercise was to be started afresh and there was to be the maximum level of transparency in respect of things like search terms and custodians and so on. He then reminded the parties that:

"… perfection in the discovery process is typically an unreasonable and disproportionate expectation and that is particular so in circumstances where the documents go back over two decades…"

85. O'Moore J. also dealt with the application to compel replies to interrogatories. He declined to make an order striking out the defence or part of the defence of BMS in the revocation proceedings and he declined to make a wasted costs order. He adjourned these applications to the trial of the action. In other words, he believed that the further consequences, if any, of these defaults, were best left to the trial judge, and in all likelihood will be addressed when the court considers the issue of costs.

86. Barrett J. expressly held that BMS had not at any time *"acted in a malign or improper manner or with any intention to defy the court or ignore court orders"* (para. 34). He expressly held that both teams had always acted with complete propriety (para. 35).

87. I would agree with Barrett J. that the failures by BMS to meet admittedly very tight deadlines are not of the order of egregious behaviour that Teva would have this Court believe. This is clear from the history of litigation set out above. Likewise, the fact that a plaintiff was ordered to make further and better discovery with the resulting loss of a trial date is not of the order of default which would disentitle such a plaintiff to an injunction which a court was otherwise minded to grant. It is to be borne in mind that the threshold for striking out a defence for failure to make discovery is a high one: the court must be satisfied that there has been intentional conduct the purpose and effect of which is to prejudice the opposing party and that in fact the ability of the other side to go to trial was prejudiced as a result (*Murphy v. J. Donohoe Ltd (No 2)* [1996] 1 I.R. 123). When O'Moore J. heard the motion to strike out the defence and/or direct further and better discovery, he directed further and better discovery but did not strike out the defence or any part thereof. There has been no appeal from his decision, and he was best placed to assess the level of error or culpability in BMS's approach to its obligations to make proper discovery.

88. In conclusion, I am not satisfied that Barrett J. erred in his assessment of the conduct of BMS up to the date of the hearing before him and that the conduct was not such as would disentitle BMS to an injunction which the court otherwise concluded it was appropriate to grant.

Failure to disclose the new documents between 26th and 27th January 2023 and 2 February 2023

89. Some of the newly discovered documents were identified as relevant to the priority issue and therefore discoverable during the review process on 26 and 27 January 2023. Teva says that BMS's advisors should immediately have realised not merely that the new documents were discoverable, but that they were crucial to the priority issue and inconsistent with its case to date as pleaded, with its witness statements as delivered and its replies to

interrogatories as furnished up until that date. As such, it is said, BMS ought to have disclosed them to Teva in advance of the extended deadline for discovery (9 March 2023) prior to the hearing of the application for the interlocutory injunction on 2 February 2023. In the alternative, at the very least, they ought to have disclosed the new documents to the High Court at the hearing of the injunction. BMS failed to do so and, according to Teva, this is a basis upon which this Court ought now to intervene and allow the appeal and discharge the injunction granted (in ignorance of this non-disclosure of relevant documents) by the High Court.

90. In support of this proposition, Teva relied upon the decision of the High Court in *Belohn Limited* [2013] IEHC 157. This was the judgment of Hogan J. in the High Court on an application by Bank of Scotland plc to set aside the appointment of an interim examiner to Belohn Ltd. made on foot of an *ex parte* application made on 23 March 2013. Hogan J. emphasised the provisional nature of orders made *ex parte*, referring to the leading decisions of the Supreme Court in *Adam v. Minister for Justice* [2001] 3 I.R. 53 and *D.K. v. Crowley* [2002] 2 I.R. 744. He emphasised that in the interests of fair procedures, a person affected by such orders must have a right to apply to the High Court to have such orders set aside. One of the grounds upon which the bank sought to set aside the *ex parte* appointment of an interim examiner was on the grounds of non-disclosure. At para 65 Hogan J. held:

> *"For these reasons I am satisfied that the non-disclosure came about as a result of a bona fide error and oversight and that no personal blame should in that regard attach to either the petitioners or their advisers. Yet the objective relevance and materiality of this communication cannot be gainsaid. It was, after all, the alleged failure of the receiver to hand over these documents which were said to constitute 'exceptional circumstances' for the purpose of s. 3A. While I accept that there was a dispute as to the extent to which documents*

generated by the receiver during the six month period of the receivership should be handed over, the receiver's willingness to abide by orders of this Court in that regard cannot properly be doubted. In these circumstances, given the objective materiality of the non-disclosure of this correspondence from the Bank's solicitor, it would be unjust to allow the order which was actually made to stand."

91. For these reasons Hogan J. set aside his *ex parte* order made under s. 3A of the Companies (Amendment) Act, 1990.

92. It is, of course, uncontroversial to state that an order obtained on foot of an *ex parte* application may be set aside for (even accidental) non-disclosure of relevant material and that the applicant for such an order has a duty to disclose relevant material. I know of no such principle where the application is for an *inter partes* order such as an interlocutory injunction, where the respondent has been afforded ample opportunity to respond to the case made by the moving party. I emphasise that this observation applies to the non-disclosure of relevant material at a contested interlocutory hearing and not the misleading of the court which is an altogether different and far graver matter and where different considerations apply. If a party wishes to advance the case that its opponent has misled/attempted to mislead the court, it must do so by reference to evidence which would enable a court to reach such a serious conclusion. Absent such evidence, the court cannot properly so find, and absent such evidence, non-disclosure of relevant material in an *inter partes* application does not disentitle the moving party to the relief sought: evidence of misleading the court is required.

93. It is also worth observing that frequently, interlocutory injunctions are granted prior to any application for discovery and yet there is no positive obligation to disclose discoverable, relevant documents on some precautionary principle as a precondition to obtaining the relief sought. Of great significance is the fact that Teva opened no authority

to the court to support the proposition that the failure by an applicant for an interlocutory injunction to disclose relevant documents to the court disentitled the moving party to the relief sought or would justify vacating any injunction so granted. In the absence of such authority and where there is no evidence of BMS attempting to mislead the High Court, I am not satisfied that a failure to disclose documents which a respondent party – but not the moving party – considers to be crucial affords a ground for vacating an order granted after an *inter partes* hearing or overturning the order on appeal.

94. Furthermore, BMS says that Teva is asking the court to hold BMS to a higher standard than that which applies to Teva. Teva had the new documents from 9 March 2023. It filed its Notice of Appeal on 23 March 2023, fourteen days later, and it makes no reference to the non-disclosure of the new documents as a basis for allowing the appeal/discharging the injunction. Despite the fact that Teva did not identify the relevance of these documents in fourteen days, Teva says nonetheless that the failure of BMS's reviewers to appreciate the significance of the new documents in the seven days between 26 January 2023 (when the first of the documents was identified as discoverable) and 2 February 2023 (the date of the hearing), and the failure to disclose the new documents to Teva and the court is evidence of such *mala fides* as to warrant the withholding of equitable relief on the basis that it did not come to court with clean hands.

95. BMS says its case on the priority issue is not based upon the new documents – it is Teva who believes that they undermine BMS's case. Counsel for BMS submits that if Teva did not recognise the importance of the new documents to Teva's case in the fourteen days after they were discovered, it is hardly fair to criticise BMS for failing to do so in the seven days prior to the hearing of the application for an interlocutory injunction, *a fortiori* when it was in the midst of both trying to complete discovery with twenty two reviewers and prepare for an injunction application to be heard on 2 February 2023. The new documents were

discovered on 9 March 2023 in accordance with the order of O'Moore J. and addressed in the replies to interrogatories of Mr. Scott Brown sworn on 9 March 2023.

96. I see some merit in these submissions. Counsel for Teva did not explain to the court why it failed to raise the issue of non-disclosure of the new documents until 6 April 2023, and simply replied in answer to a query from the court that he would ask leave to amend his notice of appeal if necessary. It is difficult to understand why Teva should be permitted to amend its notice of appeal during the hearing of the appeal six weeks after it received the documents, but that BMS should be damnified for failing to disclose them seven days after identifying that they were discoverable and in advance of the deadline for making further and better discovery six weeks later.

97. In submissions to the court, counsel for Teva declined to say that Teva was accusing BMS of dishonesty, but nonetheless maintained that its conduct amounted to a further instance of coming to court without clean hands. In my judgment, Teva cannot have it both ways. If the conduct (in this case, failure to disclose the new documents) is sufficiently grave as to lead to the conclusion that BMS came to court with unclean hands, this can only be on the basis of something akin to knowing and wilful withholding of materials with a view to misleading the court i.e., a dishonest purpose. Teva's complaint is not based upon inadvertence, as this could not be characterised as unclean hands. But Teva has not appealed the finding that the legal representatives acted with complete propriety, even after it identified the significance it attaches to the new documents and the failure to disclose them. Its position has been characterised by a lack of clarity which is, to say the least, unhelpful in the circumstances. The court is entitled to know its position with greater clarity.

98. It is well accepted that the court has a discretion to refuse an injunction on the basis that a party has come to court otherwise than *"with clean hands"*. In *Curust Financial Services Limited v. Loewe-Lack-Werk* [1994] 1 I.R. 450, Finlay C.J. observed that:-

"This phrase must of necessity involve an element of turpitude and cannot necessarily be equated with a mere breach of contract."

99. This test had been applied consistently since 1994. In my judgment, the actions of BMS in failing to disclose the new documents in all the circumstances fall far short of the threshold set in *Curust*. Neither the failure to disclose the new documents nor the defaults of BMS which have delayed the trial and required the High Court to order it to make further and better discovery and to reply to two outstanding interrogatories come anywhere near this bar. It would be unjust in my view to refuse an injunction based upon either the conduct of the litigation to date or the failure to disclose the new documents in advance of the hearing of the application for an interlocutory injunction, six weeks before the deadline for filing discovery.

Jeopardising a fair trial

100. The third strand of Teva's argument that BMS came to court with unclean hands is that BMS stood over the adequacy of its discovery up to October 2022 and sought to have the trial of the revocation proceedings heard on the basis of the flawed discovery which it had made at that stage in the proceedings. In my judgment, this was a matter which was dealt with in the four days during which O'Moore J. heard the motions in relation to discovery and interrogatories and the filing of a new witness statement. The trial dates in September and October had already been vacated and he was aware that the trial would not proceed until after the further and better discovery which he ordered to be made was completed. In those circumstances, O'Moore J. was best placed to determine whether or not the appropriate response of the court was to strike out part of BMS's defence to Teva's revocation action or to make the less draconian orders which he actually made. He declined to make an order striking out BMS's defence and directed that further and better discovery be made. There was no appeal against that order. If this Court were to accede to Teva's

request it would in effect amount to a partial granting of the relief which O'Moore J. declined to grant, i.e., striking out the defence to the invalidity claim. The discharge of the injunction would facilitate Teva launching its generic product at risk and this would have the effect in fact, if not in law, of terminating BMS's monopoly rights based upon the SPC. Teva has had the benefit of the appropriate remedy in respect of BMS's prior default in relation to discovery. It is not appropriate that this should form some sort of springboard to justify a further remedy i.e., the withholding of an injunction which ought otherwise to be granted to restrain the infringement of BMS's rights under the SPC, which is precisely what would have occurred had BMS's defence been struck out.

Relevance of an early trial

101. Teva says that the trial of the revocation proceedings is imminent, and this is a reason to refuse the injunction. It says so by reference to the decision of the High Court in *SmithKline Beecham plc v. Genthon BV,* where an early trial of the infringement action was one of the bases for refusing the injunction sought. In that case, the allegedly infringing product had been on the market for some time, whereas in this case, the injunction was sought and granted on a *quia timet* basis. In my judgment, the imminence of the trial favours an order preserving the *status quo ante* rather than facilitating a launch of a generic product which infringes the intellectual property right of BMS, where that property right enjoys a presumption of validity and the challenge to the validity will be heard in a few weeks. When Teva decided to launch at risk it knew the trial date and it knew that the question of validity would be decided within months (at first instance). It also knew that the SPC would not expire until 19 May 2026. It follows that there is no urgency based upon the imminent ending of the monopoly period. In my judgment this is the very situation where it is appropriate to preserve the *status quo* where the product is <u>not</u> on the market pending the resolution of the validity challenge. This is particularly so as the evidence from the experts

on both sides establishes that a generic entrant may hope to gain as much as 40% to 50% of the market in as little as five months. Thus, to facilitate the entry of Teva on the market for even a short period between now and the decision of the High Court in the revocation proceedings would be to risk inflicting significant damage upon BMS (which may be compensatable in part by damages) but also which may permanently alter the market and result in unquantifiable damage to BMS.

The strength of Teva's case on the priority issue

102. Teva invites the court to conclude that the new documents show that it has a very strong case on the priority issue and that this is relevant to the balance of justice. It argues that the new documents are clearly inconsistent with the case made by BMS on the priority issue.

103. The priority issue will fall to be determined by reference to either Delaware law or federal law: not Irish law. Teva has filed no expert evidence at all on this central issue. Submissions of Irish counsel cannot fill the gap. It is simply not possible for this Court to make even a tentative assessment of the strength of Teva's case in the circumstances. The Court cannot assess the significance of the new documents by reference to Irish law. The laws of either Delaware or federal law of the United States are foreign laws which must be proved as a matter of fact. This is fatal to Teva's argument on this issue. In *Biogen* at para. 77, I stated:-

> *"77. … the threshold test is that the case for invalidity must be strong and/or that there have been successive determinations on the merits invalidating the right. Absent evidence to support a finding of a strong case for invalidity or a number of judgments on the merits to that effect, the threshold for weighing the argument for invalidity is not met and the court therefore ought not to weigh this argument in its assessment of the balance of justice."* (Emphasis added)

104. In para. 95 of *Biogen*, I pointed out that there was no independent expert evidence to support the respondents' argument in that case that they had a strong case for invalidity so that they should not be restrained from launching the generic in that case. I held:-

> *"95. ...If they wish to establish that they have a strong case for invalidity in order to resist the injunction sought, this requires that there be evidence as to invalidity and this in turn must be independent expert evidence. Absent such evidence, a court cannot be satisfied that the threshold has been met."*

105. In addition, the courts have consistently cautioned against embarking on a mini trial at the interlocutory stage of proceedings. In *Mylan Ireland Healthcare Limited v. Merck Sharp & Dohme Limited Liability Company* (Court of Appeal: 14 March 2023, *ex tempore*, Haughton J.), at pages 199 – 200 of the transcript, Haughton J. stated:-

> *"In my view, the sort of assessment of the relative strengths of the parties that it is appropriate to a wider assessment where the balance of justice lies is one that should be relatively limited and should not cause the court to engage with competing interpretations of patent or expert views as to its true inventive reach where there may fairly be said to be arguments on both sides and/or where the issues may be said to be complex. The court should not embark on a mini trial at the interlocutory stage. Where it can reasonably be concluded that there is scope for differing interpretations of the patent, or the matter is complex and not capable of being fairly decided at an interlocutory hearing, the court should fall back on the presumption of validity and the weight to be afforded to same per O'Donnell J. in MSD v. Clonmel, and leave to the trial of the action the issue of which interpretation should prevail. I find support for this approach in para. 62 of his judgment."*

106. The priority issue in this case is complex, both factually and legally. In my judgment, the caution urged by Haughton J. against the temptation to conduct a mini trial on the merits of the case is particularly relevant in the context of this application. It reinforces my view that the alleged strength of Teva's case on the priority issue does not afford a basis for refusing the injunction in the circumstances of this case.

107. As I am of the view that this Court cannot conclude that Teva's case for invalidity is strong, it is necessary to consider whether there have been successive determinations in Teva's favour in respect of a similar challenge in other jurisdictions. When the appeal was heard there had been decisions on the merits in the High Court in England and Wales, and in Sweden. Since the Court reserved judgment, the Court has been notified of further decisions by courts in Norway and France and the Court of Appeal in England and Wales on the merits, and of a decision in the Netherlands granting an interlocutory injunction. The decision in the Netherlands is not one to which great weight can be attached simply because it is not a determination on the merits of the challenge to the validity of the patent and the SPC. The High Court and Court of Appeal in England and Wales have declared the patent to be invalid on grounds of plausibility, largely by applying the majority judgment of Lord Sumption in *Warner-Lamberts Co. LLC . v Generics (U.K.) Ltd.* [2018] UKSC 56. The case in England did not include a priority challenge. On the other hand, the courts of Sweden, Norway and France have each dismissed the challenges to the validity of the patent where the challenges were based on both plausibility and the priority issue. In summary, therefore, it cannot be said that there have been successive determinations on the merits invalidating the right at issue at the date of the writing of this judgment. It follows that the threshold for weighing the argument for invalidity is not met and the court ought not to weigh this argument in its assessment of the balance of justice. Therefore, this ground of appeal must be rejected.

First mover advantage

108. Teva submitted that the High Court judge erred by failing to give sufficient weight to the first mover advantage which it would have enjoyed if he had refused to grant an injunction. It was acknowledged in *Clonmel* that this is of value and something which should be weighed when assessing the balance of justice. It is necessary to consider precisely what the advantage asserted by Teva is in order to consider this ground of appeal. It is common case between the experts that where a generic manufacturer succeeds in obtaining a declaration of invalidity and thereafter launches its generic product, there is very little actual first mover advantage as usually other generics will rapidly follow suit. At para. 12 of his second affidavit sworn on 20 January 2023, Mr. Potter avers that:

> *"Dr. Stomberg [an expert witness of behalf of BMS] also confirms in paragraphs 14 to 15 that the key to profits is the timing of entry for generic companies, and at paragraph 18 he notes that a favourable decision against the SPC would create a situation where all generics get the information simultaneously. Taken together these statements underline the fact that first mover advantage exists in favour of Teva if it were permitted to launch, and that little or none of this remains if a preliminary injunction is granted."* (Emphasis added.)

109. This means that had Teva proceeded with its original strategy of seeking to clear the path and launch its generic products after a declaration of invalidity, then it would effectively have enjoyed little or no first mover advantage, but it would have *"got on the market"*. It follows that the first mover advantage upon which Teva relies in this appeal is the first mover advantage where it launches at risk as the first generic manufacturer into the market in advance of any declaration of invalidity. It is thus apparent that by asking the court to weigh in its favour both its efforts to clear the path and its interest in a first mover advantage, Teva is seeking to rely on two mutually exclusive factors. The purpose of the appeal is to facilitate

a launch at risk where the path has not been cleared. That being so, there is room to weigh the loss to Teva of the first mover advantage but not at the same time, to weigh in its favour, its incomplete attempt to clear the path. If clearing the path is to weigh in its favour, then it must fully clear the path and in those circumstances, there is little or no first mover advantage. Teva must elect which argument to pursue, as they are mutually inconsistent. It has not done so.

110. If this Court were to proceed on the basis that it should disregard any arguments advanced by Teva in relation to its attempts to clear the path (for the reasons discussed above) and to focus on the weight to be attributed to the loss of first mover advantage, I do not believe that this approach would assist Teva. In *Biogen* I stated:-

> *"71. A feature in Merck Sharpe & Dohme to which 'weight should be given' was the fact that Merck was the holder of an intellectual property right granted pursuant to an authorisation process provided for by law. The Supreme Court held that as a matter of law, the SPC is valid and effective until declared invalid by a court of competent jurisdiction. This applies equally to the patent in this case. Following the decision in Okunade v. Minister for Justice [2012] IESC 49, [2012] 3 I.R. 152, O'Donnell J. said it was '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.'*
>
> *72. In my judgment this is an important observation which the trial judge in this case failed properly to apply in his assessment of the balance of justice. <u>It is only if a generic manufacturer makes out a strong case for invalidity that this observation could be held no longer to apply.</u>"* (Emphasis added.)

The issue of the respective weight to be attributed on the one hand, to the presumptive validity of the IP rights, and, on the other hand, to the value of first mover advantage prior

to the expiry or revocation of the IP, was addressed by O'Donnell J. in *Clonmel* at para. 56 which I quoted in para. 64 of my judgment in *Biogen*. At para. 65 in *Biogen* I concluded:-

> *"65. It is thus clear that the interests of the generic challenger and the interest of the IP holder are not equal. The interests of the IP holder derive from a right conferred by a process of law which is presumptively valid. O'Donnell J. holds that the interests of the generic challenger do not outweigh those of the IP rightsholder."*

111. The weight to be attributed to Teva's first mover advantage cannot on its own outweigh the right of BMS to exploit its monopoly to restrain threatened infringement of its IP rights. As each of the other matters Teva contended weighed in its favour have been rejected, this ground stands alone and cannot outweigh the rights of the SPC holder. For this reason, I do not accept that the High Court judge erred in the weight he attributed to Teva's claimed first mover advantage and I would reject this ground of appeal.

The respondent's cross-appeal

112. The respondent-cross appealed the judge's finding that the evidence put forward to support the likelihood of BMS having to drop its price to compete with Teva if Teva were permitted onto the market with generic Apixaban pre-trial was insufficient in the absence of sworn evidence from BMS that it categorically would do so in that event (para. 22). It also cross-appealed that the judge erred in disregarding, as mere assertion, the evidence filed on behalf of BMS in respect of its alleged inability to restore its price once it was dropped in response to generic competition and in finding that the original price could be re-established (para. 24). Thirdly, it cross-appealed the finding that the damage caused by such a permanent price drop would be easily calculable. The cross-appeal was put forward only and if insofar as this Court might make findings that tend to undermine the decision of the judge. As I am disposed to dismiss the appeal by Teva and to uphold the decision of the High Court, it is not necessary to address the issues raised in the cross-appeal.

Conclusion

113. It is common case that there is a fair question to be tried as to the validity of the patent and the SPC which protects BMS's medicinal product Eliquis®. The issue in the appeal is whether the lesser risk of injustice lies in favour of or against restraining Teva from launching an infringing product pending the trial of the revocation proceedings which are listed to commence on 4 July 2023.

114. While the High Court rejected some of the grounds upon which BMS contended that an award of damages would not adequately compensate it for the losses it would incur if the injunction were refused and it succeeded at trial, he held that damages would not provide an adequate remedy for the losses attributable to its loss of its monopoly rights. There was credible uncontroverted evidence to support this conclusion and there was no basis for this Court on appeal to overturn his conclusion in this regard.

115. The judge did not err in attaching little weight to the efforts by Teva to clear the path prior to launching its generic products. The path has not yet been cleared and the path will not be cleared, within the meaning of the jurisprudence, until all arguable objections of the patentee have been disposed of, including the conclusion of any appeal. The credit afforded to a generic manufacturer in the case law is where they have actually cleared the path, not where they have attempted to launch prior to the conclusion of that process. That being so, on the facts of this case, this ground of appeal fails.

116. The allegation that BMS has sought equitable relief while coming to court with unclean hands has not been established. Neither the judges who were case managing the litigation, nor the judge who heard the motion to strike out the defence of BMS for failure to make proper discovery, nor Barrett J. were persuaded that the errors which occurred were deliberate or showed *mala fides* on the part of BMS. The lawyers were not criticised by any judge with knowledge of the litigation. The failures by BMS to meet various deadlines and

to make timely proper discovery were deprecated but were not such as to deprive BMS of the right to injunctive relief which it was otherwise appropriate to grant. The judges in the High Court were well placed to assess the level of delinquency and this Court should be slow to overturn their respective exercise of discretion. Teva has not made out a strong enough case to justify such interference by this Court.

117. The failure of BMS to disclose the new documents in advance of the hearing of the application for an interlocutory injunction was not evidence of *mala fides*. In circumstances where it expressly confirmed that it was not alleging dishonesty, Teva cited no authority to support its contention that BMS was under a duty to disclose relevant documents in advance of the date for making discovery for the purposes of seeking a contested interlocutory injunction. There was no evidence of turpitude and thus no basis for concluding that the failure to disclose the new documents in advance of the hearing resulted in it coming to court with unclean hands. It is not a basis to allow the appeal.

118. In circumstances where the infringing product is not on the market and the trial of the validity of the patent is due to commence in a very short time, the preservation of the *status quo ante* reflects the course of least injustice.

119. The question of the validity of the patent in the face of the priority challenge will be decided on the basis of Delaware or U.S. Federal law. As foreign law requires to be proved as a matter of fact, in the absence of any evidence as to the relevant foreign law on the priority issue, it is not possible for an Irish court to form any view as to the strength or otherwise of the respective positions on the priority issue. Therefore, this is not an issue to which any weight in favour of refusing the injunction can be attached.

120. The preponderance of foreign judgments on the validity of the patent uphold rather than invalidate the patent and the SPC, and therefore the question of decisions from other relevant jurisdictions does not assist Teva’s case on appeal.

121. The first mover advantage has been held by the Supreme Court to be an interest which does not outweigh that of the presumptive right of the IP holder. Therefore, the High Court did not err in its assessment of the relative weight to be afforded to the first mover advantage, on the one hand, and the patentee's right in a presumptively valid property right granted as a result of a legal process, on the other hand.

122. The High Court did not err in its approach to its task or in its weighing of the evidence or the arguments. It was entitled to exercise its discretion as it did and no sufficient reason to interfere with that exercise has been put froward. For all of these reasons I would dismiss the appeal and affirm the order of the High Court.

123. As BMS has been entirely successful in this appeal my provisional view is that it is entitled to the costs of the appeal against Teva, to be adjudicated in default of agreement. In line with the practice of the Commercial Court, there should be a stay on execution of the order until the determination of the proceedings. If Teva wishes to contend for a different order as to costs, it should contact the office of the Court of Appeal within seven days of the delivery of this judgement requesting a short hearing on the question of the costs of the appeal and a date for the hearing will be notified to the parties. If a hearing is sought and the Court makes an order as provisionally indicated, the party requesting the hearing may be ordered to pay the costs of such hearing.

124. Noonan and Allen JJ. have each read this judgment in draft and authorised me to record their agreement with the judgment and the proposed order.