



THE COURT OF APPEAL
CIVIL

[Approved]
[No redaction needed]

Court of Appeal Record Number: 2023/279

High Court Commercial Record Number: 2021/4758P
Neutral Citation Number [2024] IECA 49

Costello J.
Noonan J.
Allen J.

BETWEEN/

BRISTOL MYERS SQUIBB HOLDINGS IRELAND UNLIMITED COMPANY

PLAINTIFF/APPELLANT

- AND -

**NORTON (WATERFORD) LIMITED T/A TEVA PHARMACEUTICALS
IRELAND**

DEFENDANT/RESPONDENT

JUDGMENT of Ms. Justice Costello delivered on the 1st day of March 2024

1. This appeal concerns the scope of an undertaking as to damages offered to the High Court upon an application for an interlocutory injunction pending the trial of the action and, in particular, whether the High Court should have required the appellant to extend the undertaking as to damages to compensate entities who are not parties to the proceedings but who may suffer loss as a result of the injunction sought. The issue arises in the following circumstances.

Background

2. The appellant (“BMS”) is part of a large international pharmaceutical group. It is the proprietor of an Irish patent (Patent No. EP (IE) 1 427 415) which relates to the compound apixaban. It is also the proprietor of a Supplementary Protection Certificate Number 2011/032 (“the SPC”) in respect of the medicinal product comprising apixaban which is supplied in the State under the brand name Eliquis. The respondent is a biopharmaceutical company incorporated in Ireland (“Teva”). It is part of the international Teva Group of Companies. Teva wished to launch a generic product, Apixaban Teva, and it instituted proceedings seeking to revoke the patent and the SPC. BMS instituted these proceedings seeking to restrain Teva from infringing its presumptively valid SPC¹. In November 2022, Teva gave BMS four weeks’ notice of its intention to launch its generic product. On 2 December 2022, BMS issued a motion seeking the following relief:

“An interlocutory injunction restraining the Defendant whether by itself or its directors, officers, servants or agents from infringing Supplemental Protection Certificate No. 2011/032 (the “SPC”) and in particular by making, offering, putting on the market and/or using and/or importing or stocking for the aforesaid purposes, a generic version of [BMS’s] medicinal products Eliquis (active ingredient apixaban).”

3. The application was supported by grounding affidavits including that of Mr. Scott Cooke sworn on 2 December 2022. At para. 93 of his affidavit Mr. Cooke stated:

“I understand that an undertaking to be responsible for any damages sustained by the Defendant between the grant of the pre-trial injunction and the trial of the action or other order is generally required in an application such as this. I confirm that the Plaintiffs [sic] is willing to give such an undertaking in this case.” (emphasis added)

¹ As this judgment concerns an interlocutory order pending trial, I shall treat the SPC as presumptively valid notwithstanding the fact the High Court has in the intervening period ruled the patent invalid and BMS has appealed the finding.

4. Replying affidavits were filed on behalf of Teva including affidavits of Ms. Laura Reynolds sworn on 20 December 2022 and two affidavits of Mr. William David Potter sworn on 19 December 2022 and 20 January 2023 to which I shall refer later in this judgment. No issue was taken with the undertaking as to damages offered to the court by BMS. The application was heard on 2 and 3 February 2023 and in a reserved judgment delivered on 17 February 2023 ([2023] IEHC 159) the High Court concluded that it would “grant on the terms sought, the injunction that BMS has come seeking.” (emphasis added)

5. Teva wished to appeal the decision as soon as possible. Under cover of a letter dated 24 February 2023 Teva’s solicitors furnished BMS’s solicitors with a draft order. The draft recast the undertaking as to damages offered by Mr. Cooke in his affidavit of 2 December 2022. The draft order read:

“And noting the Plaintiff’s undertaking to the Court and to the Defendant to pay compensation for any and all loss suffered as a result of the making of this Order, if and when the Order is subsequently set aside or discharged”. (emphasis added)

6. The draft order would have extended the undertaking as to damages; it was not confined to loss and damage suffered by the defendant arising from the making of the order.

7. BMS’s solicitors replied on 1 March 2023. They rejected the draft order furnished and attached a version “*with some changes which reflect the usual form of such orders*”. They formulated the undertaking as follows:

“And noting the Plaintiff’s undertaking to abide by any Order which this Court may hereafter make as to damages in the event of this Court being of opinion that the Defendant shall have suffered any damage by reason of this Order which the plaintiff ought to pay.”

8. On 20 March 2023, Teva’s solicitors enclosed a further revision of the draft order and stated that:

“The purpose of the amendment to the language of the undertaking is to ensure that all losses sustained by the Defendant (including losses via and through entities related to the Defendant) as a result of the grant of the injunction are unambiguously covered by the terms of the undertaking. (emphasis added)

We consider that it would be unworkable for the injunction and undertaking to list every individual entity in the Teva Group which may directly or indirectly be restrained in their activities by the injunction and every entity which may suffer a loss arising from the injunction. Nevertheless, it is unequivocally the case that entities other than the Defendant will be subject to the injunction (as envisaged by the reference to ‘servants and agents’ in the draft order) and that the harm caused to the Defendant may in turn cause and/or manifest itself in, damage to other related companies.

Therefore, the enclosed draft Order at Schedule 1 aims to ensure that the benefit of the undertaking as to damages that may ultimately be ordered by a Court extends to the Defendant in the Proceedings and its ‘related companies’ as more particularly defined in section 2(10) and (11) of the Companies Act 2014.” (emphasis added)

9. BMS would not agree to extend the scope of the undertaking as to damages they had openly offered to the High Court and which had been accepted by the High Court in deciding to grant the injunction sought.

10. On 23 March 2023 when the matter was before the High Court to finalise the order, counsel for Teva confirmed that the draft order it furnished on 24 February 2023 “*would have covered off what we are now dealing with ... We proposed from the outset that the*

undertaking should be broad enough to cover any and all losses suffered as a result of the making of the order.”

11. Ultimately, the High Court perfected its order while reserving the determination of the scope of the undertaking as to damages for a further hearing and ruling. This enabled Teva to expedite its appeal to this court. The appeal was heard on 24 April 2023 and by a reserved judgment delivered on 29 June 2023 ([2023] IECA 173) the injunction was upheld. The issue of the undertaking as to damages did not feature in the appeal.

12. Meanwhile, the High Court directed Teva to file an affidavit setting out why the undertaking as to damages should be extended and to whom. Ms. Reynolds swore a further affidavit on 6 April 2023 which I shall consider later in this judgment. BMS elected not to file a replying affidavit. The application in relation to the scope of the undertaking as to damages was heard by the High Court on 21 June 2023 and on 26 June 2023 ([2023] IEHC 376) the trial judge delivered his judgment.

13. Barrett J. held that the form of the undertaking proposed by Teva was the appropriate form of undertaking to be provided in return for the injunction that he had granted. The order was perfected on 28 July 2023 and the operative part provides:

“It is ordered that the undertaking as to damages given by the Plaintiff in connection with the Interlocutory Injunction that is the subject of the Order dated the 23rd day of March 2023 should not be limited to loss suffered by the Defendant but should also extend to loss suffered by the Defendant’s related companies as defined in the Companies Acts, subject to the following propositions on which the undertaking rests:

- *the undertaking (a) does not refer to indirect loss (b) refers to loss simpliciter, and (c) the normal rules of causation will apply to a damages inquiry in the normal way, and (d) the Defendant will still have to prove its loss;*

- *the Plaintiff's interests are fully protected insofar as they can argue all of the points they want to make at the damages hearing where the court will have at large jurisdiction to look into causation, quantum, etc;*
- *the Order is intended merely to preserve all of the parties' interests in a damages hearing; and*
- *the Defendant is not seeking (and will not seek) enhanced damages in any way;”*

14. BMS appealed this order to this court. In the meantime, the invalidity action has been heard and determined by Barrett J. In a reserved judgment delivered on 8 December 2023 ([2023] IEHC 744) he held that the underlying patent was invalid.

15. BMS has lodged an appeal against this decision and sought a stay on the order and an injunction further restraining the launch of Teva's generic products. The application for an injunction pending the determination of the appeal will be heard on 12 and 13 March 2024 and the substantive appeal is fixed to be heard over four days commencing on 13 May 2024.

16. The appeal in respect of the order of 28 July 2023 directing BMS to give an extended undertaking as to damages was heard by this court on 30 January 2023 and judgment was reserved.

The relevant legal principles

17. At the hearing of the appeal it was common case that the courts have jurisdiction in appropriate cases to require a party who seeks an injunction to give an undertaking as to damages which extends to the losses which may be sustained by a party other than the enjoined party. The jurisdiction is to be found in The Supreme Court of Judicature Act (Ireland) 1877, s.28(8) which provides:

“[A]n injunction may be granted...by an interlocutory order of the Court in all cases in which it shall appear to the Court to be just or convenient that such order should

be made and any such order may be made either unconditionally or upon such terms and conditions as the Court shall think just...”

18. Neither party could identify a precedent in this jurisdiction where the court in fact required the moving party to give an undertaking as to damages to cover the losses of a non-party. This is the first time that the courts have addressed the principles which ought to apply and the factors to be considered when addressing an argument that the undertaking as to damages offered to the court ought to be extended in this manner.

19. The courts have recognised that where an interlocutory injunction is sought the court seized of the application necessarily has an incomplete picture of the evidence and possibly of the legal issues which will be determined at the trial of the action. Nonetheless the court must do the best it can but recognises that things may appear different after trial. Thus, a court may grant an interim or interlocutory injunction based on the affidavit evidence and the legal submissions of the parties at an early stage in the proceedings but ultimately conclude that the plaintiff was not entitled to the injunctive relief granted. In the parlance of the cases, the injunction will have been “*wrongly*” granted, though it is important to emphasise that this does not mean that the court erred in granting the interlocutory injunction in question: it merely reflects the reality that the decision must be made relatively early in the proceedings on incomplete evidence and that the outcome of trial may show that the plaintiff in fact was not entitled to an injunction.

20. This may result in serious injustice to the enjoined party and it would be unjust were it to be left without a remedy. The courts developed the practice of requiring a party who seeks an injunction to give the court an undertaking that it will pay the losses suffered by the defendant if it turns out after trial that the injunction ought not to have been granted. This then became an established practice.

21. The legal principles in relation to an undertaking as to damages were recently considered by Barniville J. (as he then was) in the High Court in *Nolan v. Dildar Limited*. [2020] IEHC 243 (“*Nolan*”). He first said that the purpose of requiring the party seeking the interim or interlocutory injunction to provide an undertaking as to damages is to strike a “*fair balance between the respective rights of the party seeking the interim or interlocutory injunction and of the party against whom the orders are made*”. He noted that the undertaking was described in *Cheltenham & Gloucester Building Society v. Ricketts* [1993] 1 W.L.R. 1545 (“*Cheltenham*”) as the “*price which the person asking for an interlocutory injunction has to pay for its grant*”. This statement has been approved by Clarke J. (as he then was) in the High Court in *Estuary Logistics v. Lowenergy Solutions Ltd.* [2008] 2 I.R. 806 (“*Estuary Logistics*”) and by Laffoy J. in the High Court in *Caldwell v. Tracey* [2012] 2 I.R. 417 (“*Caldwell*”).

22. Secondly, Barniville J. noted that the undertaking as to damages is given to the court and not to the party against whom the interlocutory injunction or order is made, citing *Cheltenham, Estuary Logistics, Caldwell* and the judgment of Peart J. in *IBRC v. Quinn* [2013] IEHC 437 (“*IBRC*”).

23. Thirdly, he observed that the undertaking as to damages is not intended to be a complete indemnity for “*the parties affected by the orders made*” (and referred to *IBRC*, para. 76). It should be observed that when Peart J. in *IBRC* says the undertaking as to damages was not intended to be a complete indemnity to the defendant, he was not concerned with an undertaking as to damages extending to a party who was not enjoined by the court order. At para. 76 Peart J. quoted with approval from the judgment of Diplock L.J. in *F. Hoffmann-La Roche & Co. A.G. v. Secretary of State for Trade and Industry* [1975] A.C. 295 at p. 361 as follows:

“76. ...As Diplock L.J. stated in *Hoffmann-La Roche* at page 361:

‘... the defendant may have suffered loss as a result of having been prevented from doing [the enjoined act] while the interim injunction was in force; and any loss is likely to be damnum absque injuria for which he could not recover damages from the plaintiff at common law. So unless some other means is provided in this event for compensating the defendant for his loss there is a risk that injustice may be done.’

It is to mitigate this risk that the court refuses to grant an interim injunction unless the plaintiff is willing to furnish an undertaking”

24. In *Nolan*, Barniville J. continues that generally an undertaking as to damages will not be limited in amount and the ultimate calculation of the undertaker’s liability on foot of the undertaking will depend on similar rules to those applied by the courts in assessing damages for breach of contract.

25. Barniville J. observed at para. 237 that generally when receiving an undertaking as to damages and granting an interim or interlocutory injunction, the court must be satisfied of the ability of the party giving the undertaking to meet a claim on foot of it and that, in the exercise of its overall discretion, the court can refuse to grant an interlocutory injunction if it is not satisfied that the party giving the undertaking as to damages will be in a position to honour it: (*Martin v. An Bord Pleanála* [2002] IEHC 82 and *Szabo v. Kavanagh* [2013] IEHC 491).

26. Furthermore, a party who gives an undertaking as to damages has an obligation to draw the attention of the court to any material change for the worse in its financial position. This is so because of the significance of the undertaking as to damages in the exercise by the court of its discretion as to whether to grant an interim or interlocutory injunction.

27. The seventh point Barniville J. identifies is particularly relevant to the issues in this appeal:

“...[T]he onus of demonstrating to the court that the undertaking as to damages provided is or would be inadequate in terms of the losses which would be likely to be suffered as a result of the granting of the interim or interlocutory injunction rests with the party alleging such inadequacy. In other words, the party or parties against whom the interim or interlocutory injunction is granted and who seeks to challenge the adequacy of the undertaking as to damages must demonstrate evidentially the losses which they contend will be suffered as a result of the order for the purpose of demonstrating that the undertaking is inadequate.” (emphasis added)

He referred to the judgment of Hardiman J. in *Dunne v. Dun Laoghaire Rathdown County Council* [2003] 1 I.R. 567 (“*Dunne*”) (which I discuss below) as illustrative of the “*onus of proof which rests upon the...defendants to demonstrate the alleged inadequacy of the undertaking as to damages given by the plaintiffs and to the nature of the evidence required in order to substantiate their concerns in relation to the ability of the plaintiffs to meet any liability on foot of that undertaking.*” (emphasis added).

28. He notes that in certain circumstances where the court has a concern in relation to the ability of a party to meet its obligation on foot of an undertaking as to damages, it may require the undertaking to be fortified or supported by some form of security or payment into court. He emphasises that this was not the normal situation and that the occasions when such a fortified undertaking might be required were “*very few*” and had to be supported by a “*proper evidential basis*”.

29. In principle, it is possible to apply to the court to revisit the issue as to the adequacy of the undertaking as to damages and the court may consider whether the undertaking should be adjusted, varied or fortified. In that regard he referred to changes in circumstances or “*matters moved on*”.

30. In *Nolan* the moving party was asking the court to review the adequacy of the plaintiffs' undertaking as to damages. The court declined to vary its order. Barniville J. held that when asked:

“...to exercise a discretion to review the adequacy of the plaintiffs' undertaking as to damages, the court is entitled to consider, as among the factors to be taken into account, the failure to challenge the adequacy of the undertaking at the time and, more particularly, the significant delay in raising the issue again. I am not satisfied that the Kenny defendants have provided an adequate or indeed any real explanation for that delay.” (emphasis added).

This underscores that the appropriate time to raise this issue is at the hearing of the application for an injunction, and not later.

31. While the delay was an important factor in his decision, it was not the only factor as he was, in any event, not satisfied that the relevant defendants in *Nolan* had put forward sufficient material to discharge the onus which was on them to demonstrate evidentially that the plaintiffs would not be in a position to honour their undertaking as to damages.

32. The importance of evidence in support of a claim that the undertaking as to damages offered will not suffice adequately to compensate a defendant in the event that the injunction proves to have been “*wrongly granted*” was emphasised in *Dunne*. Hardiman J. was very explicit in identifying what is required of a party so contending. In that case the defendant challenged the adequacy of the plaintiffs' undertaking as to damages. Hardiman J. said at p. 579 of the report:

“It is stated that delay in the motorway project would be expensive and more generally prejudicial, and there is no doubt that this is so. But there is no statement as to the precise way in which this claimed injunction and the proceedings commenced will

delay the motorway. Nor has the defendant advanced any precise legal or factual basis for the losses it says will be incurred should an injunction be granted.

...

In my view it is not sufficient, either from the point of view of establishing a balance of convenience or attacking the undertaking, simply to mention huge sums of money without relating them either to the specific relief sought or to the specific liability for which the plaintiffs, by virtue of their undertaking, may become responsible.”

(emphasis added)

33. At p. 581 he held that:

“...the purported damage and expense must, in my view, be established and not simply invoked...The mere mention of an enormous sum of money as the total cost of the scheme does not in any way constitute evidence as to the balance of convenience of this particular case. No doubt there will be inconvenience arising from the grant of an injunction but the defendant has not adduced evidence from which one could rationally assess whether this will be of a trivial, or of a near catastrophic nature.” (Emphasis added)

34. He observed that the same point applied in relation to the challenge to the adequacy of the undertaking as to damages.

35. It is clear that the assessment of the undertaking as to damages and the argument that the undertaking offered is inadequate are central to the court’s decision whether or not to grant an injunction. Where there is a challenge to the adequacy of the undertaking as to damages offered, the court must be provided with evidence which enables it to “*rationally assess*” that challenge. A mere assertion is insufficient, there must be an evidential basis related to the specific relief sought or the specific liability for which the plaintiffs by virtue of their undertaking may become responsible.

36. In *Estuary Logistics* Clarke J. in the High Court had to consider whether to enforce an undertaking as to damages where an interlocutory injunction was discharged prior to trial. In the absence of any relevant Irish authority, he accepted the judgment of the Court of Appeal of England and Wales in *Cheltenham* as representing the law in relation to the enforcement of an undertaking as to damages in this jurisdiction as well. He quoted extensively from the judgment of Neill L.J. and the following extract is relevant to this appeal:

“(1) Save in special cases an undertaking as to damages is the price which the person asking for an interlocutory injunction has to pay for its grant. The court cannot compel an applicant to give an undertaking but it can refuse to grant an injunction unless he does. (2) The undertaking, though described as an undertaking as to damages, does not found any cause of action. It does, however, enable the party enjoined to apply to the court for compensation if it is subsequently established that the interlocutory injunction should not have been granted. (3) The undertaking is not given to the party enjoined but to the court. (4) In a case where it is determined that the injunction should not have been granted the undertaking is likely to be enforced, though the court retains a discretion not to do so...”

37. In *IBRC* Peart J. was asked to discharge an interlocutory injunction on the basis that after the injunction had been granted and before the case came to trial the plaintiff had gone into liquidation and was insolvent. It was said that this meant that the undertaking as to damages given at the time the injunction was granted was now worthless and accordingly the injunction ought to be discharged. Peart J. observed at para. 75 of his judgment:

“...the need for the plaintiff to give an undertaking as to damages is to strike a fair balance as far as possible between the plaintiff’s right to be protected from damage and loss which could not be adequately compensated by an award of damages against

the defendant, and the defendant's right to be compensated for loss and damage he may suffer as a result of the injunction, in the event that the plaintiff is unsuccessful at trial, and if it is shown that the injunction ought not to have been granted. It is part of the Court's consideration as to where lies the balance of convenience." (Emphasis added)

He emphasises that the assessment of the undertaking as to damages offered to the court by the plaintiff is part of the consideration by the court of the balance of convenience and thus whether or not to grant the injunction. This is an important element of the overall assessment of the application for an injunction and Peart J. observes at para. 78:

"...In normal circumstances, the Court cannot insist on an undertaking, but in the absence of one being offered the injunction will normally be refused, because an undertaking is the price which a plaintiff pays for the granting of the injunction."

38. Peart J. notes that the court may grant an injunction where no undertaking is offered (as in *Hoffmann-La Roche*) but it may also refuse to grant an injunction which would otherwise be granted where it is satisfied that the undertaking as to damages offered by the plaintiff "*is of no real value*", citing *Pasture Properties Ltd. v. Evans* [1999] IEHC 214. This underscores the fact that the question whether the undertaking as to damages offered by the plaintiff is sufficient or appropriate falls to be considered when the court is determining whether or not to grant the injunction sought, and not afterwards.

39. Peart J. said that the undertaking as to damages "*is not intended as a complete indemnity to the defendant*" and that it is an undertaking given to the court, not to the enjoined party (see para. 76) and he quoted the passage from Diplock L.J. cited above, emphasising that the undertaking as to damages is to mitigate the risk of injustice to a defendant in the event that it proves that the plaintiff was not entitled to the injunction he sought.

40. All of the Irish cases emphasise that the court is concerned to do justice between the parties and to minimise the risk of injustice in the event that the decision to grant or withhold the injunction sought proves, at trial, to have been the wrong choice.

41. In *Merck Sharp & Dohme v. Clonmel Healthcare Ltd.* [2020] 2 I.R. 1 (“*Merck Sharp & Dohme*”) O’Donnell J. (as he then was) speaking on behalf of the Court stated at para. 36 that:

“the preferable approach is to consider adequacy of damages as part of the balance of convenience, or the balance of justice, as it is sometimes called.”

42. This means the adequacy of damages to either the plaintiff or the defendant, the latter arising from the undertaking as to damages offered in exchange for the injunction sought. The question of loss which may be suffered by third parties or related non-parties was not considered at all in the comprehensive judgment of the Supreme Court and it is to be inferred that no argument was raised in that case (which also involved an injunction restraining the launch of a generic drug pending the resolution of the validity of the SPC conferring monopoly rights) that the undertaking as to damages should extend to any such persons.

43. At para. 60, when discussing the position of the generic manufacturer in that case (Clonmel) and if it was restrained from launching its product pending the trial of the action challenging the validity of the SPC in question, O’Donnell J. said:

“It is true that if Clonmel was restrained pending the trial and the 001 SPC is nevertheless determined to be invalid, Clonmel will never be able to gain the position of a first mover generic manufacturer which it sought to achieve by its launch in April 2018, and it will therefore be necessary to attempt a difficult estimation of both its likely profit if it had done so, and its position in the market, which would necessarily extend beyond the April 2019 expiry date.” (emphasis added)

44. There was no suggestion that the court would have to consider the possible losses sustained by other members of the group by reason of the order restraining the manufacturer of the generic from launching its product.

45. In this case, the parties agree that the question of an extended undertaking as to damages – as is sought by Teva – is a wholly novel application and that it has never been considered before by an Irish court. Neither counsel could identify any case in which an injunction was granted where the undertaking as to damages offered by the plaintiff to the court extended to the losses which strangers to the litigation might sustain by reason of the restraining of the defendant from taking certain actions. This is all the more remarkable given that the parties accept that a jurisdiction to make such an order has existed since at least the Supreme Court of Judicature Act (Ireland) 1877 (and is set out in O.50, r.6(1) and (2) of the Rules of the Superior Courts). This is particularly so given the number of applications in recent years for injunctions to restrain the manufacturers of generic medicines from launching their generic products onto the market on the grounds that this would infringe the monopoly rights of the rights holders. In all such cases the moving party has offered the usual undertaking as to damages i.e. an undertaking to abide by any order which the court may make as to damages in the event that the court is of the opinion that the defendant shall have suffered any damage by reason of the injunctive order which the plaintiff ought to pay. An extended undertaking as to damages does not appear to have been previously sought. All of these cases have been vigorously contested by very able teams of lawyers without it having been suggested that the interests of justice required that the undertaking as to damages offered by the applicant for the injunction to restrain the alleged infringer ought to extend to cover the losses not just of the restrained generic manufacturer (the putative infringer) but also to the other companies in its group who might lose out on the profit they

would have made from the sales of the generic but for the fact their sister company was restrained from marketing or manufacturing it.

46. To underscore the novelty of Teva's application for an extended undertaking as to damages in this case we need only turn to the decision of Barniville J. (as he then was) in *Teva Pharmaceuticals Industries Ltd. v. Mylan Teo*. [2018] IEHC 324. The plaintiff in that case was an international pharmaceutical company incorporated in Israel which specialised in the development, manufacturing and marketing of generic and proprietary pharmaceuticals and active pharmaceutical ingredients. It sought an injunction restraining Mylan Teo., part of the Mylan Group, from manufacturing a generic version of Copaxone, Teva's drug for the treatment of relapsing forms of multiple sclerosis. One of the issues the High Court had to consider was whether damages would be an adequate remedy for Mylan, if it turned out that the injunction had been wrongly granted. At para. 141 Barniville J. sets out the submissions of the Israeli Teva company on this issue. Notably, its first submission was:

"[I]t contends that any damage caused as a result of the grant of an interlocutory injunction to Teva will not be suffered by the defendant, Mylan Teo, but rather by MPI or other Mylan-related entities in the US which, Teva submits, is not relevant in the context of this application. Teva submits that the affidavits filed on behalf of Mylan do not address any specific harm to Mylan Teo in the event that the injunction were granted."

It was thus urging on the court that the potential losses which might be sustained by Mylan related entities which were not parties to the litigation in the High Court were not relevant when the court came to assess the adequacy of damages as a remedy for Mylan. This seems to be the opposite of the position adopted in these proceedings.

47. Mylan contended to the contrary. The judgment continues:

“153. Finally, Mylan disputes the contention that it is appropriate only to look at the position of the defendant...that it is open to the court to consider the effect of an interlocutory injunction on identified third parties and to cater for any harm to such third parties by requiring an appropriately tailored undertaking as to damages as a condition of granting the interlocutory injunction.

...

155. ...I agree with the submission advanced by Mylan that to confine consideration of the harm caused by the grant of the interlocutory injunction only to a defendant chosen by the plaintiff, in circumstances where other related or associated entities will suffer harm, would be inappropriate as it would encourage the selective targeting of defendants and the exclusion of defendants who would suffer harm by the grant of an interlocutory injunction to enable a plaintiff to make the point that no harm was suffered by the chosen defendant.

...

However, as a matter of principle, it seems to me that a court cannot blind itself or be blinkered in considering the harm that may be caused by the grant of an interlocutory injunction by reference only to the entity which a plaintiff has chosen to sue.

156. In my judgment, therefore, it is appropriate to consider the potential loss or harm not only to the defendant, Mylan Teo, but also to other Mylan entities in the United States.” (Emphasis added).

48. Barniville J. therefore recognised that the court can have regard to the potential impact of the injunction sought on entities other than the party a plaintiff has chosen to sue when deciding *whether or not to grant the injunction*. Those parties were identified, and the issue was raised and fully argued at the hearing. Barniville J. did not consider the question of

whether the scope of the undertaking as to damages offered by Teva to the defendant, Mylan Teo., should extend to other companies in the Mylan Group. He simply concluded that damages would be an adequate remedy both for Teva and Mylan Teo. and did not consider the wider members of the Mylan Group. In that instance, he refused the application.

49. The Courts of England and Wales have considered the question of whether the undertaking as to damages given by a claimant should extend to cover the damage caused to non-parties. In *Allied Irish Bank v. Ashford Hotels Ltd.* [1997] 3 All E.R. 309 it was held that the court had jurisdiction to require the parties seeking injunctive relief to give a cross-undertaking as to damages for the benefit of third parties, not merely the party enjoined, though it declined to do so in the circumstances of that case.

50. The issue of the scope of an undertaking as to damages was considered by Jacob L.J. in *SmithKline Beecham plc v. Apotex Europe Ltd.* [2007] Ch 71 (“*Apotex*”). The claimants brought an action against the defendants for infringement of their patent which covered a process for making a particular form of paroxetine hydrochloride and applied for an interim injunction. It was known that two Canadian companies, affiliated to the defendants but not parties to the proceedings, were due to manufacture a generic pharmaceutical, containing paroxetine hydrochloride, which they intended to market in the United Kingdom. On the grant of the injunction the claimants gave cross-undertakings as to damages, undertaking to comply with any order the court “*may make if the court later finds that this order for an injunction has caused loss to the defendants and decides that the defendants should be compensated for that loss*”. Until the determination of the action the defendants undertook to the Court not to deal in the United Kingdom in any pharmaceutical preparation containing the claimants’ patented product. The judge hearing the patent action held the patent not infringed and invalid. The day before the hearing to determine the final order, the Canadian companies, in order to obtain the benefit of the cross-undertakings as to damages, applied to

be joined as defendants in the action. One of the issues in the case was whether the cross-undertaking as to damages ought to have extended to third party losses suffered by the Canadian companies. Jacob L.J. affirmed that the court had jurisdiction to require a party seeking an interim injunction to give a cross-undertaking as to damages for the benefit of third parties affected by the injunction. He also confirmed that since the cross-undertakings were given to the court and therefore gave rise to no notional contract between the parties, a party identified in a cross-undertaking as one who the injunctor would compensate could claim compensation for having been himself prevented from doing the restrained act but not also on behalf of others who had been adversely affected by the injunction.

51. I agree that this is correct in principle. The undertaking as to damages is to compensate the party for the loss *it* sustained as a result of being wrongfully restrained. It cannot claim compensation for loss it has not sustained. Jacob L.J. held that the undertaking as to damages is to compensate the injunctee and those parties (if any) identified in a cross-undertaking as to damages as those whom the moving party would compensate. Absent the express identification of such a person as being covered by the undertaking, the undertaking as to damages to compensate the injunctee will not suffice to capture loss sustained by any such identified third party.

52. Commencing at para. 23 of the judgment, the Court of Appeal considered the nature of a cross-undertaking and it is worth setting it out extensively as it considers the issues presenting as a matter of principle:

“23. ...The practice of requiring a cross-undertaking from a plaintiff who sought an interlocutory (now called ‘interim’) injunction developed in the 19th century. The reason was that the court at the interlocutory stage did not know who the ultimate winner would be. So if an injunction was granted but the case ultimately failed, the person enjoined would have a remedy.

24. *The legal justification of the practice stems from the discretion of the court to grant or withhold an injunction given by what is now section 37(1) of the Supreme Court Act 1981 (repeating earlier enactments to the same effect):*

“The High Court may by order (whether interlocutory or final) grant an injunction ... in all cases in which it appears to the court to be just and convenient to do so.”

The court in effect says to the plaintiff (now ‘claimant’) seeking an interim injunction: ‘I will not grant you an interim injunction unless you give the cross-undertaking.’ See e.g., per Lord Diplock in F Hoffmann-La Roche v Secretary of State for Trade and Industry [1975] AC 295, 361. It follows that the court cannot impose a cross-undertaking on a claimant against his will – it is the ‘price’ he must ‘pay’ for the grant of the injunction.

25. *A party who is granted an interim injunction but who ultimately loses the full trial is not regarded as a wrongdoer because he got an interim injunction. Sometimes, for convenience and want of a better term, the expression ‘wrongful injunction’ is used, but in truth there is nothing wrongful about it. The decision whether or not to grant it is made on the basis of a necessarily incomplete picture. The decision depends on all the circumstances of the case, generally whether or not damages to an ultimately victorious claimant would be an adequate remedy, whether the claimant can show a serious issue to be tried and so on.*

....

Lord Diplock put it broadly in NWL v Woods [1979] 1 W.L.R. 1294, 1306:

‘In assessing whether what is compendiously called the balance of convenience lies in granting or refusing interlocutory injunctions in actions between parties of undoubted solvency the judge is engaged in weighing the respective risks that

injustice may result from his deciding one way rather than the other at a stage when the evidence is incomplete.

26. *But a number of particular considerations do call for mention in the context of this case. First is that the existence of the cross-undertaking in damages is a very material consideration in whether or not an injunction should be granted. The fact that an ultimately unsuccessful claimant will have to compensate the defendant for having ‘wrongly’ stopped his proposed activity is a major factor in assessing the balance of risk.*

27. *Second is that the position of third parties or the public who may be affected by the injunction is a matter which the court can take into account in exercising its discretion. This is so in limited circumstances even for a final injunction, see, e g, Miller v Jackson [1977] QB 966 and Chiron Corpn v Organon Teknika Ltd (No 10) [1995] FSR 235.*

28. *Next is that third parties unconnected with the dispute (‘neutrals’) who may incur expense in complying with the order may specifically be covered by a cross-undertaking. This was first required by Robert Goff J in a freezing order case, Searose Ltd v Seatrain UK Ltd [1981] 1 WLR 894. The practice in freezing order cases of requiring from the plaintiff an express undertaking to indemnify any third party affected by the order against all expenses reasonably incurred in complying with the order and all liabilities flowing from such compliance was endorsed by this court in Z Ltd v A-Z and AA-LL [1982] QB 558.*

.....

30. *But what is clear is that until this case, it has always been assumed that an outsider (as I will call a legal entity which is not a party to the proceedings) does not have a claim as of right against a party who obtained a ‘wrongful’ interim injunction*

which caused him expense or damage. The only possible exception to that is Lord Denning MR's statement that a party who gives notice of a freezing injunction to a bank or innocent third party enters into an implied contract whereby he will pay for the costs of that party complying with the order: see Z Ltd v A-Z and AA-LL [1982] QB 558, 575.

31. Next the court has jurisdiction to require a party seeking an interim injunction to give a cross-undertaking for the benefit of third parties affected by the injunction: see Allied Irish Bank v Ashford Hotels Ltd [1997] 3 All ER 309. This stems from the discretionary nature of the jurisdiction conferred by section 37 of the 1981 Act.”
(emphasis added)

53. The parties whom Jacob L.J. described as outsiders do not have a claim “*as of right*” against the party who obtained the injunction even though the injunction has caused the outsider expense or damage. Secondly, the court is engaged in weighing the respective risks that injustice may result from its decision one way or another and the fact that an ultimately unsuccessful plaintiff will have to compensate the defendant from having “*wrongfully*” stopped the proposed activity is a “*major*” factor in assessing the balance of risk. Thirdly, it is open to the court, in the exercise of its discretion, to require the moving party to give a cross-undertaking as to damages for the benefit of the third party affected by the injunction. In the case cited, the parties were clearly identifiable and known. Fourthly, as he explains later in the judgment, this extension of the cross-undertaking to neutrals who may be adversely affected by the order is new and the applicable principles require to be worked out by the courts and are not settled.

54. At paras. 77 and 78, Jacob L.J. addressed the question of extending the undertaking as to damages to outsiders, in that case the Canadian companies who had lost sales as a result of the grant of the injunction,:

“77. The principles about who can successfully intervene and ask for such an undertaking and whether such an intervener can be put on terms as to costs or the like are far from worked out. They may need development on a case-by-case basis. I understand that the current practice of the Patents Court when an application for an interim injunction in respect of a pharmaceutical is sought is to require the patentee to give notice to the Department of Health of the application in case it wishes to seek such an undertaking. To date there has been no ruling on the point.

78. One consideration which may matter is whether the person applying is himself a potential infringer. In many intellectual property cases there is a chain of potential infringers starting with the manufacturer (or importer) running through middlemen to the ultimate consumer. That is so in patent cases unless the ultimate consumer can avail himself of the defence given by section 60(5)(a) of the 1977 Act – that his use is for a private and non-commercial purpose. Even keeping a patented product can infringe: section 60(1)(a). So if the claimant picks on only one member of the chain as a target for an interim injunction, it might be said that he was artificially limiting his liability on the cross-undertaking and the others in the chain should have the benefit of one too, perhaps on terms as to costs if the action succeeds. On the other hand the position of non-infringers, such as third party foreign manufacturers, may be different. I say no more for the present, for it was not argued by Mr Strauss that the Canadian companies would not have been granted a cross-undertaking if they had intervened.”

55. Jacob L.J. touched on just some of the questions which a court may have to address on such an application, depending on the particular facts of the individual case. Others also could arise. The crucial point is that the court must identify the relevant principles applicable to its decision, which cannot follow as a matter of course.

56. Jacob L.J. rejected the submission that if the cross-undertaking as to damages had to be given not only to actual injunctees but third party intervenors who might be adversely affected, this would operate as an undesirable deterrent to a party who needed an interim injunction in the following terms in para. 80:

“80. I am not impressed by this. First there are all the difficulties which I have mentioned about multiple claims to a single pot. The so-called ‘advantage’ is fraught with practical difficulties on top of the intellectual difficulties. Second I cannot see that the ‘deterrent’ is necessarily a bad thing. A party who may have to recompense third parties significantly damaged by an interim injunction, is likely to weigh carefully whether he really has a case which he is likely to win at trial, as opposed to one which raises no more than a ‘serious issue to be tried.’”

57. This passage was referred to by BMS in the context of the Enforcement Directive – Directive 2004/48/EC – and it was said that it could not be followed as it conflicted with Article 9(7) of the Directive as interpreted by CJEU.

58. Jacob L.J. then considered the argument that there would be an imbalance between the party seeking the injunction and the third parties benefitting from an undertaking as to damages extended to cover the damage caused to them:

“81. Another argument was based on the fact that a successful claimant in a patent action is entitled to elect the remedy of an account of profits made by the infringer rather than damages, see section 61(1)(d) and section 61(2) of the Act. Mr Strauss suggested that there ought to be some sort of symmetry – a ‘wrongly’ injuncted defendant ought similarly to be able to claim the profits made by the patentee if his action fails. I do not see why. That might even put the defendant in a better position than if he had never been sued. Moreover the appeal to symmetry works the other way as regards restitutionary claims by third parties. Here, for instance, if there had been

no interim injunction but GSK had succeeded at trial, there is no way that the Canadian companies, as non-defendants, could have been required to disgorge their profits.”

59. While the cross-undertaking as to damages in that case was not extended to the Canadian companies, the Court of Appeal took the opportunity to explore some of the principles and issues which fall to be considered on such an application. It would appear that this judgment was not debated in the two later judgments which were followed by Barrett J. in the High Court.

60. The first of these was the decision of Birss J. in the High Court in *Actavis Group PTC EHF v. Boehringer Ingelheim Pharma GmbH & Co. KG* [2013] EWHC 2927 (Pat) (*“Actavis”*). As part of clearing the path litigation, Actavis gave an undertaking not to commence marketing of the combination product protected by Boehringer’s SPC. An issue arose as to *“the appropriate form of the cross-undertaking to be offered”* by Boehringer. Actavis sought an undertaking extending to *“and/or any third party who applies under paragraph 4 of this Order.”* Paragraph 4 of the order essentially covered any losses which might be sustained by either any company within the Actavis Group of Companies or any customer or potential customer who would have been supplied, whether directly or indirectly by the claimants or any other company within the Actavis Group of Companies, including ultimate potential customers thereof, but for the interim undertakings given by the claimants.

61. Boehringer objected that the undertaking as to damages sought was too wide and that the third parties needed to be identified and that there was no evidence either identifying the parties or supporting the alleged need for the extended undertaking. Counsel for Actavis said that the Actavis group was *“a certain class of persons”* and therefore was identified and that *“setting the cross-undertaking up in this way avoids a problem which might*

otherwise arise” from possible future restructuring of the group. Birss J. set out his decision in paras. 33-35 of the judgment:

“33. In considering the matters which the Practice Direction requires, the court ultimately is undertaking the exercise of discretion with the aim of doing justice not just to the parties before the court, but generally. If a class can be identified at this stage for whom justice demands a cross-undertaking should cover before an injunction is ordered or an undertaking accepted, then the court should require the cross-undertaking to be drafted accordingly. For example, in the case of freezing orders, as I understand it, it is common practice and has been for many years that the cross-undertaking in question is drafted so as to extend to cover the expenses of persons, such as banks, which they might incur in complying with the order.”

34. However, it seems to me that for the court to exercise this discretion, it needs to know, in some way at least, who the relevant persons are. They do need to be identified at least in some suitable way and also the court needs to know what may be the nature of the potential loss or harm which is said may potentially arise.”

35. A cross-undertaking has been called the price of an injunction and, in the end, it seems to me that the person paying that price needs to know with reasonable certainty what it is. It could be, in a given case, that the price demanded would be too high. A party seeking an interim injunction, or accepting undertakings in lieu of an interim injunction, is entitled to be wary of an indeterminate and open-ended cross-undertaking in favour of persons unknown.” (Emphasis added)

62. It is important to note that the practice direction applicable in England and Wales does not apply in this jurisdiction and while the court in England and Wales may be required by the practice direction to exercise its discretion with the aim of doing justice not just to the parties before the court but generally *when considering the scope of an undertaking as to*

damages, I do not believe that that is the case in this jurisdiction. Certainly, it does not appear to have featured in any of the Irish authorities which I have discussed. I emphasise that I am not considering the discretion of the court whether or not to grant an injunction, where it is well established that in an appropriate case the court may have regard to the interests of persons who are not parties to the litigation and indeed to the interests of the world at large, if their interests may be adversely impacted by the proposed order. The Irish authorities cited have had a narrower focus when considering the undertaking as to damages. The cases to date have emphasised that the purpose of requiring a party to give the court an undertaking as to damages is to enable the court, in due course if appropriate, to make an order that the plaintiff should compensate a defendant for loss it may sustain as a result of the injunction which, in the event, may have been wrongly granted.

63. *Actavis* shows that the court should consider the possible extension of a cross-undertaking as to damages *before* an injunction is ordered or an undertaking accepted. Birss J. also pointed out that for the court to exercise this discretion it needs to know who the relevant persons are and what may be the nature of the potential loss or harm which it is said may potentially arise.

64. Birss J. ordered that the undertaking as to damages should extend to all the companies in the Actavis Group but not to customers or potential customers. He explained why he extended the undertaking as to damages from Boehringer to all the companies in the Actavis Group in para. 37 as follows;

“37. ...I am told on instructions by Mr. Meade that the Actavis Group will be buying the API (that is to say, the raw chemical ingredients) in from third parties and will then manufacture the tablets and sell them. It seems to me that it is unreal for the patentee (the defendant) to say that they need to know precisely which companies in the Actavis Group will be undertaking these tasks. The tasks in question are clear. I

can understand, as Mr. Meade submits, that when an injunction of this kind has to last for a significant period of time, it is quite possible that a group such as the Actavis Group will undertake restructurings in such a way that it would mean that although today the Actavis Group knows who exactly is going to sell the product, in future the chain of companies which might be involved will change. It would be extremely inconvenient, and ultimately pointless, to require the companies in the position of Actavis in this case to keep coming back to court every time they may or may not be involved in any kind of restructuring in order to reorganise the companies for whom the cross-undertaking of (sic) benefit. The reason I say that is because the patentee in this case knows that this cross-undertaking is a cross-undertaking in favour of the group who is going to sell the product in question. The nature of the loss that the group would rely on in any claim on the cross-undertaking is not going to change during the course of the action and the pendency of this undertaking and cross-undertaking. Accordingly, it seems to me that the concept underlying the language proposed by Actavis in this case is a fair and proper one and the language proposed achieves the desired objective... I should emphasise that it does mean, in my judgment, that the cross-undertaking is now being granted for the benefit of those companies even though they may not be identified until after judgment.” (emphasis added)

65. It is to be noted that there was no evidence before the court in relation to the factual matters upon which the court based its judgment. It was based on instructions of counsel who informed the court of possible developments and the fact that that “*it was quite possible*” that the group may restructure. Birss J. said that the nature of the loss that the group would rely on in any claim on the cross-undertaking was not going to change during the course of the action. It is unclear what this conclusion is based upon, and it is certainly inconsistent with the evidence in the case in hand. To my mind, this undermines to a

significant extent the usefulness of this decision as a precedent, as the reader is left with the impression that the High Court did not require much from Actavis in the way of information, never mind evidence, to justify extending the cross-undertaking to the entire group of companies. Certainly, as will appear later in this judgment, there was nothing in the evidence in this case to suggest that it would be “*extremely inconvenient*” or “*pointless*” to require Teva to come back to court to identify a company which, it might say, by reason of a restructuring of the Teva Group, should now benefit from the undertaking as to damages given by BMS to the court.

66. The other case relied upon by the High Court and Teva was *Warner-Lambert Company LLC v. Actavis Group PTC EHF* [2015] EWHC 485 (Pat) (“*Warner Lambert*”). The claimant brought an action for patent infringement and sought – what is now in England called – an interim injunction restraining Actavis, the defendant, from infringing the patent. The injunction was refused. The patentee filed further evidence and applied for different interim relief, this time against NHS England, seeking in essence an order that NHS England issue guidance concerning the prescribing of a pharmaceutical preparation known as pregabalin. Pregabalin was sold by Warner Lambert under the trademark Lyrica. It could be used for treating both pain or neuropathic pain, and generalised anxiety disorder and epilepsy. The concern was that a number of generic manufacturers threatened to launch (or had launched) products which infringed the patent. The problem of possible infringement of the rights holder’s monopoly was addressed by the issuing of guidance by NHS England to pharmacists with the result that they were required to dispense Lyrica rather than the generic pregabalin for treating pain. The question was whether the cross-undertaking in damages to be given by Warner Lambert should extend beyond the NHS England and the Department of Health to include the generic companies – the Actavis Group of Companies, the Teva Group of Companies and Doctor Reddy’s.

67. Arnold J. accepted the two reasons advanced by counsel for Teva to the effect that the benefit of the cross-undertaking should extend to Teva. The first was that the effect of the order was intended to be and was likely to be that prescribers would prescribe pregabalin for treating pain by reference to the brand name Lyrica rather than the generic name, pregabalin. If prescribers did so, then the pharmacists would be obliged to dispense Lyrica rather than generic pregabalin for treating pain. If it then turned out that the patent was invalid, Teva ought not in those circumstances to have been prevented from making sales of generic pregabalin which pharmacists would otherwise have dispensed for the treatment of pain. Secondly, even if the patent was valid, the possibility could not be excluded that the guidance would have the effect of Lyrica being prescribed and dispensed at the expense of generic pregabalin in circumstances which did not amount to infringement of the patent. While Arnold J. thought this was improbable, he said the possibility “*cannot be excluded*”. For both of these reasons, he held that the benefit of the cross-undertaking should be extended to Teva. He then said, apparently without further debate, “*Counsel for Teva also submitted that, for similar reasons to those in Actavis v. Boehringer, the benefit should extend to all companies in the Teva Group. Again I accept this.*” There was no further analysis in relation to the merits or need to extend the undertaking as to damages to all the companies in the group. For the same reason he extended the cross-undertaking to all the companies in the Actavis group and Dr. Reddy’s.

68. Thus, Warner Lambert is an example of a case where the undertaking as to damages was extended to parties who were not enjoined but who were thought likely to be adversely affected by the injunction. The decision appears to have been based upon submissions and the intended effect of the order, rather than on any evidence specifically identifying the loss likely to be occasioned by the order. However, it adds little to the analysis a court should undertake when considering, as a matter of principle, whether it is appropriate to extend an

undertaking as to damages to all the companies in a pharmaceutical group when a generic manufacturer is restrained by an interlocutory injunction from launching a generic medicinal product.

The evidence justifying the extension of the undertaking as to damages to all the companies in the Teva Group

69. As I have earlier explained, when BMS applied for the injunction in this case, Mr. Cooke on behalf of BMS, offered the usual undertaking as to damages. No issue was taken with the scope or extent of the undertaking offered until after judgment granting the injunction had issued. Barrett J. permitted Teva to file a further affidavit addressing the alleged need for an extended undertaking as to damages after he had delivered his judgment. Ms. Reynolds swore a further affidavit on 6 April 2023. She said that she is a solicitor of Teva UK Limited and she is Associate General Counsel, European IP and Regulatory Litigation at Teva UK and that she was making the affidavit on behalf of the defendant whom she referred to in her affidavit as Teva Ireland. The essence of the case advanced by Teva Ireland is in paras. 5 and 10 – 12 of her affidavit. She avers:

“5. ...Teva Ireland’s position is that inclusion of Related Companies in the undertaking in damages is proportionate and necessary to ensure that all losses sustained by Teva Ireland (including losses via and through entities related to Teva Ireland) as a result of the grant of the Injunction are unambiguously covered by the terms of the undertaking. There are two bases for this:

(a) It would be unworkable for the injunction and undertaking to list every individual entity in the Teva Group of Companies which may directly or indirectly be restrained in their activities by the Injunction and every entity which may suffer loss arising from the Injunction. It is unrealistic to expect that the corporate structure of an international pharmaceutical company such as the

Teva Group of Companies, would remain static for the period of the injunction and it would not be an efficient use of Court resources for the parties to appear before this Honourable Court each time a company with the Teva Group of Companies sought to be included in the undertaking as to damages ('Point 1 '); and

(b) Due to the reference to 'directors, officers, servants or agents' in the Injunction that entities other than Teva Ireland (the sole Defendant in these Proceedings) will be subject to the Injunction and that the harm caused to Teva Ireland may in turn cause and/or manifest itself in, damage to Related Companies ('Point 2 ')."

70. In paras. 10 – 12 she elaborated in relation to Point 1 –

“DIRECT AND INDIRECT LOSS TO OTHER TEVA GROUP COMPANIES

10. While Teva Ireland will suffer the initial loss/damage because of the Injunction, there are arrangements in place in respect of profit sharing within the Teva Group of Companies which will result in indirect loss to other companies within the Teva Group of Companies. In broad terms, whilst Teva Ireland would have, but for the injunction, made and accounted for sale of Apixaban Teva to customers in Ireland, a significant proportion of the margin (i.e. profit) would have been transferred (by transfer pricing) to another company in the Teva Group of Companies. The structure of these arrangements is highly confidential, and I do not believe that particularising the terms of any such arrangement at this point will assist the court. I am informed that a damages inquiry itself may be the appropriate forum for further detail to be provided.

11. In addition to this, and as is clear from the case law and from my own experience, structures within multinational pharmaceutical companies change over the years and thus, the fact that Teva Ireland is now the MA [marketing authorisation] holder and

the company intending to commercialise the product, does not necessarily mean that it will remain so.

12. In those circumstances, it cannot be said to this honourable Court with any certainty that the Teva Group of Companies internal structure will not change. Any such change would mean the party likely to suffer the damage may not ultimately be Teva Ireland, but another entity within the Teva Group of Companies.”

71. As regards the second point, she averred that *if* BMS has secured the benefit of an injunction *extending beyond* restraining Teva Ireland Ltd., then the undertaking in damages (being the *quid pro quo* for that injunction) should reflect this and that, as the directors, officers, servants or agents are restrained by the injunction, without the extension Teva seeks, “*the undertaking in damages is insufficient*”.

72. No replying affidavit was filed by BMS.

The perfection of two orders of the High Court

73. As I have previously indicated, most unusually, the High Court order granting the injunction – but excluding the precise scope of the undertaking as to damages – was perfected to enable Teva to appeal the grant of the injunction as soon as possible. Teva did not wish to wait until the dispute concerning the scope of the undertaking as to damages was resolved and the order then perfected in the usual way before it could appeal. In ease of Teva, both BMS and the court agreed to this unorthodox approach.

74. Teva’s appeal against the grant of the injunction was heard by this court on 24 April 2023 and judgment was delivered on 29 June 2023. In the meantime, the High Court gave judgment on the scope of the undertaking as to damages on 26 June 2023 which for all practical purposes, amounts to the same time. The order of the High Court on the scope of the undertaking as to damages was perfected on 28 July 2023 and a notice of appeal was filed on 3 November 2023.

75. In the meantime, the revocation proceedings were heard in the High Court throughout June and July 2023 and judgment was delivered on 8 December 2023 declaring the patent to be invalid. The appeal from the judgment of Barrett J. in relation to the scope of the undertaking as to damages was heard by this court on 30 January 2024 and judgment was reserved.

Decision of the High Court

76. Barrett J. concluded that the High Court had jurisdiction to direct BMS to furnish an extended undertaking as to damages and this conclusion was not contested on appeal.

77. The trial judge considered the decisions of the High Court of England and Wales in *Actavis* and *Warner Lambert* to which I have referred and quoted extensively from the judgment of Birss J. Barrett J. stated that he “*was presented with an injunction application in which, after I indicated that I would grant the injunction in proceedings to which one Teva entity was party, a dispute arose as to the form of the undertaking, the suggestion being that it should extend to multiple Teva parties.*” He noted that the issue raised by *Actavis* at para. 31 of Birss J.’s judgment was the same issue raised by Teva in these proceedings. Barrett J. applied Birss J.’s test and asked whether the proposed undertaking fails to provide “*reasonable certainty*” and whether it is “*indeterminate and open-ended*”? He answered both questions in the negative. He then quoted from *Warner Lambert* and noted that Arnold J. held that the benefit of the cross-undertaking as to damages should extend to the three generic manufacturers and all the companies in their respective groups. At the hearing in the High Court Teva sought the expanded undertaking in the terms cited in para. 64 of his judgment. At para. 73 he held:

“... *It seems to me that if there was any doubt, by reference to Actavis, as to whether this is an appropriate case for the form of undertaking canvassed for by Teva, the similarity between what was ordered in Warner Lambert and what is being sought*

here yields the inexorable conclusion that the justice of matters requires that the form of undertaking to be asked for by the court in this case ought to be that canvassed for by Teva.”

78. Barrett J. repeatedly stated in his judgment that the undertaking would not cover indirect loss, that the undertaking referred to “*loss simpliciter and the normal rules of causation will apply at a damages inquiry in the normal way and Teva will still have to prove its loss.*” At para. 89 of his judgment, he rejected the objection to a hypothetical restructuring within the Teva Group as not affording a proper basis for extending the undertaking as to damages in the manner sought by Teva:

“... [I]t may be that [Teva’s] governing board could decide today, next week, next month, whenever, to engage in some level of restructuring for whatever reason, which reason may not even exist today. It is this natural commercial uncertainty that Teva wishes to see covered by the undertaking. What one is at in the proposed undertaking is to regulate what is to happen in a future that (being in the future) cannot be fully known by reference to presently known and/or even anticipated facts.”

He rejected the submission that the issue of the scope of the undertaking as to damages must be assessed before the injunction can be given. He said it was no different to the usual way in which injunctions are heard and undertakings as to damages confirmed. At para. 109(v), he accepted that he could not direct BMS to give the expanded undertaking but went on to say:

“...if BMS decline to agree to the form of undertaking that I consider to be appropriate, i.e. to pay the ‘price’ that I consider appropriate for that injunction (to use a metaphor employed by BMS at the hearing) then a fairly predictable sequence of events seems likely to occur thereafter.”

79. Barrett J. said that Teva had provided affidavit evidence “*buttressed by extensive submissions as to why the proposed form of undertaking is required*”. For that reason, he rejected the submissions that Teva had not discharged the onus of showing why the usual understanding of the damages was not sufficient and should be departed from.

80. At para. 127 Barrett J. noted for the avoidance of doubt that he did not regard the application for the proposed undertaking as involving a collateral attack on his judgment or an abuse of process.

Discussion

81. BMS appealed the judgment and order of the High Court. Part of its argument was that the order was contrary to Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights as interpreted by the CJEU in *Case C-688/17 Bayer Pharma AG v. Richter Gedeon Vegyészeti Gyár Nyrt. and Exeltis Magyarország Gyógyszerkereskedelmi Kft.* ECLI:EU:C:2019:722. This argument was advanced in the High Court and rejected. As I believe it is possible to determine this appeal without recourse to this argument, I shall not address the case made by either side on this point. Having said this, I wish to recognise the skilful and helpful submissions of counsel for both parties on this issue. However, in the circumstances the point is best left to be resolved in a case where the resolution of the issue is necessary to determine the case and therefore it is appropriate that I say nothing in relation to the merits of the arguments either way.

Timing

82. In my judgment the High Court fell into error in considering the issue of expanding the undertaking as to damages after it had delivered judgment and concluded, on the basis of the evidence before it and all the arguments advanced, that it would grant the relief sought, on the terms on which it had been sought. The undertaking as to damages offered by a

plaintiff is an essential matter to be weighed by the court in deciding whether or not to grant the injunction (*IBRC, Nolan, Dunne, Apotex*). The undertaking as to damages is required to mitigate the risk of injustice which an enjoined party might otherwise suffer if it were to succeed at trial but be left without any recourse for the loss and damages it sustained by reason of the injunction. It is to compensate the enjoined party for that possible loss that the court usually requires, as the price of the injunction, that the moving party gives an undertaking as to damages.

83. If a party contends that the undertaking as to damages offered will not fulfil this *quid pro quo* function because there is no substance to the undertaking as to damages, the party must make that case to the court before the court reaches its decision whether or not to grant an injunction (“*Dunne*”). It seems to me that if a party contends that the undertaking as to damages offered is inadequate because it does not encompass all of the damage that will be caused by the grant of the injunction – specifically because it is confined to the loss which the enjoined party alone may sustain – it is equally incumbent on that party to raise that argument to the trial judge while the issue whether or not to grant the injunction remains live. It is possible that an extension of the undertaking as to damages to other parties who are not before the court, of the kind contemplated in this case, could, in certain circumstances tilt the balance in favour of granting an injunction which a court might otherwise be minded to refuse. The alternative hypothetical is also possible. The point is that the issue must be weighed when the court is deciding whether or not to grant the injunction. The scope and extent of the undertaking as to damages as the price of the injunction goes to the heart of the court’s balance of the risk of injustice in granting or withholding the injunction. Substantive consideration of the undertaking as to damages cannot be divorced from the substantive consideration of whether to grant an injunction at all.

84. Equally, once a court has reached a decision on the issue to grant an injunction, an attempt to raise an issue of the parties who should be covered by an undertaking as to damages offered by the plaintiff to the court may amount to a collateral attack on the decision of the High Court. The High Court has already decided that it was appropriate to grant the injunction on the basis of the evidence and the arguments before it and implicitly has accepted that the “*price*” offered by the plaintiff in offering the usual undertaking as to damages is appropriate and adequate. If the High Court subsequently determines that other parties should be covered by the undertaking as to damages, that price necessarily has changed. It may be that the price has risen too high and the party who originally successfully obtained an injunction may be forced to surrender it on the basis that it is not prepared to pay the increased higher price. Thus, raising this issue after the court has decided to grant (or has already granted) an injunction has the potential to result in the subsequent discharge of the injunction other than in circumstances where there has been a material change in circumstances.

85. In this case Barrett J. decided it was appropriate to grant the injunction on the basis of the evidence and the arguments before him. This included the undertaking as to damages given by Mr. Cooke in the usual way. The undertaking was unambiguous. No issue was taken by Teva with the scope of the undertaking offered. It was not suggested that it was insufficient to do justice because it did not cover the companies in the Teva Group who might suffer loss. Very detailed evidence as to the adequacy of damages for BMS and the inadequacy of damages for Teva was given on behalf of Teva. Mr. Potter swore two detailed affidavits where he analysed the quantifiability of damages resulting from two scenarios: Scenario 1, being where no injunction was granted and the generic product placed on the market and Scenario 2, being where an injunction was granted and Teva was restrained from placing the generic product on the market until the final determination of the revocation

action. In relation to Scenario 2 he stated: *“Teva seeks damages from BMS for the losses they have incurred for wrongly being kept off the Irish market in the intervening period”*. He makes no reference to any company other than the defendant. He then analyses how losses might be calculated in para. 5.1.4 and para. 5.1.5 of his affidavit which is set out in p. 52 of the judgment of the High Court of 17 February 2023. He says that the court will have to estimate the extent to which Teva (and any other generic companies that would have launched at risk of being liable to BMS for damages) would secure market share from BMS, as well as the price at which that share is likely to have been secured and he referred to the identity of companies competing against BMS and each other for that business. He makes no reference to losses impacting other companies within the Teva Group of Companies by reason of an injunction restraining the defendant from launching its product.

86. The whole question of the adequacy of damages and counterfactuals were explored in great detail and in depth. Teva’s entire case referred to Teva, the defendant. It was never suggested that other companies in the group would suffer loss if the injunction was granted and it was never suggested that the undertaking as to damages offered was inadequate because it did not extend to cover all the losses which could or would be caused by the grant of the injunction, but merely covered the losses which the defendant might sustain. At the hearing before the High Court of the application for the interlocutory injunction, this issue was simply not averted to.

87. On the basis of the evidence and arguments the High Court delivered a carefully considered judgment which weighed in detail all of these arguments and the evidence. The trial judge concluded that he was prepared to grant the injunction sought on the basis of the undertaking as to damages offered by BMS. There was nothing remarkable about this as it was in standard terms.

88. The issue of the scope of the undertaking as to damages was only raised after Teva had lost the injunction application in the High Court. Counsel for Teva assured this court that the argument was not deliberately withheld. It was submitted that the argument as to the scope of the undertaking as to damages was not relevant or necessary to be raised when the question of whether or not to grant an injunction was being debated. For the reasons I have set out above, I do not agree. It was a critical consideration for the court.

89. Further, it appears that it was always Teva's intention, if it was unsuccessful in opposing the injunction, to seek to extend the undertaking as to damages to all companies in the Teva Group. This emerges from the terms of the first draft order which was tabled as a form of order which would reflect the judgment but which recast the undertaking as to damages to be offered by BMS to the court. It was deliberately and materially changed from that offered to extend to an undertaking by BMS to pay all losses arising from the grant of the injunction, not merely losses sustained by Teva as a result of the injunction. When asked why the undertaking offered had been expanded in this way, counsel could only say she could not comment on the genesis of the draft order. She then added that it was "*standard in U.K. proceedings*" and that the parties "*would have been aware of that*". It appears that Teva assumed that standard UK practice would transfer to this jurisdiction in its entirety. It also appears that it so assumed without the benefit of advice from counsel.

90. It is difficult to reconcile this position with the fact, as was readily conceded, that this is a wholly novel application in this jurisdiction and that there is no known case where an extension of an undertaking as to damages of this kind has even been sought, never mind granted, in this jurisdiction. In *Teva v. Mylan*, Teva itself had objected to the extension of its undertaking as to damages to other companies in the Mylan Group as being irrelevant.

91. Furthermore, the authorities in this jurisdiction are quite clear: where a party challenges the adequacy of the undertaking as to damages offered by a party seeking an

injunction, the party alleging any inadequacy must do so during the hearing of the injunction application when the question whether or not an injunction should be granted is still live, and must do so by reference to appropriate supporting evidence. (See *Dunne and Nolan*).

92. In addition, there is a risk, to put it no higher, that extending the scope of the undertaking as to damages to the losses which may be occasioned to non-parties by reason of the grant of the injunction after a court has decided to grant the injunction, of increasing the cost or price of the injunction to such an extent that a party may conclude that the price is now too high and it must surrender the injunction which it had previously obtained. As Barrett J. observed in his judgment, if BMS is not prepared to give the expanded undertaking “*then a fairly predictable sequence of events seems likely to occur thereafter*”. This point is not answered by showing that a particular plaintiff is in fact prepared to pay the greater price for the injunction if required to do so; it is a question of when the debate ought to be had.

93. For these reasons, in my view, the trial judge erred in permitting Teva to raise this issue after he had delivered his judgment of 17 February 2023. If Teva had wished to raise the issue it was incumbent upon it to do so while the issue of whether or not to grant an injunction was still live. Consideration of the adequacy of an undertaking as to damages is an essential element in the overall assessment of whether or not to grant an injunction and therefore the two questions cannot be decoupled or divorced.

Insufficient evidence

94. A party who challenges the adequacy of the undertaking as to damages offered must assert why the undertaking is inadequate and must establish this by reference to evidence. This is clear from the decisions in *Dunne and Nolan*. As an order of this kind is the exception to the rule, the evidence must be such as to justify a rare departure/exceptional order. The evidence must be of “*sufficient precision*” to enable the court to conclude that the undertaking as to damages offered is inadequate. The court must be able to “*rationality*”

assess the contention that the undertaking as to damages offered will not properly compensate that party. The onus of demonstrating to the court that the undertaking as to damages provided is or would be inadequate in terms of the losses which would be likely to be suffered as a result of the granting of the injunction rests with the party alleging such inadequacy.

95. In my judgment, Teva's evidence falls far short of what is required in this regard. Ms. Reynolds' first point is that the inclusion of the related companies in the undertaking as to damages is necessary to ensure that all losses sustained by Teva Ireland "*(including losses via and through entities related to Teva Ireland)*" as a result of the grant of the injunction are unambiguously covered by the terms of the undertaking. A number of points occur. The undertaking cannot cover loss not sustained by Teva Ireland. Secondly, the loss covered is the loss directly sustained, not indirect loss suffered by Teva or another entity. Thirdly, Ms. Reynolds is expressly referring to loss sustained by Teva Ireland – not any other companies in the Teva Group. It follows that this paragraph cannot justify extending the undertaking as to damages to cover losses sustained by *other* Teva companies. Therefore, the basis upon which she says the undertaking as to damages should be extended to all the related companies is simply irrelevant and does not justify the extension of the offered undertaking.

96. Second, her first basis (para. 5(a)) is simply a bare repetition of the submissions made to Birss J. in *Actavis*. I do not believe that it can be applied uncritically to this case. She baldly asserts without any information whatsoever that it would be "*unworkable*" to list every individual entity in the Teva Group which may "*directly or indirectly*" be restrained in their activities by the granting of this injunction. I do not accept this to be so without evidence. Teva Ireland was preparing to launch its products. Its plans must have been at a very advanced stage. It would have identified the companies which would be involved in

the distribution and sale of Teva Apixaban. If it chooses for its own commercial reasons not to provide this information to the court, then it must accept the consequences.

97. If any of the companies who were lined up to participate in the manufacture, marketing, distribution and sale of Teva Apixaban should be replaced in the chain by a different company in the group, it will be perfectly possible to vary the order recording the undertaking as to damages and to replace the former company with the latter. I do not accept that this would involve major inconvenience, certainly not compared to the rest of this litigation. It could not be described as unworkable. It would be a relatively straightforward procedural step. It is not a case of requiring or expecting the Teva Group to remain static during the period of the injunction, especially as, at the time the affidavit was sworn, the trial was due to commence in less than three months.

98. The second basis upon which Ms. Reynolds advances the case for the expanded undertaking as to damages is set out in para. 5(b) of her affidavit. The argument is extremely difficult to understand. This form of words is absolutely standard in an order restraining a company. The order in this case restrains the defendant “*whether by itself or its directors, officers, servants or agents*” from infringing the SPC. It is phrased in these terms to prevent a director, officer, servant or agent of a company who would not otherwise be personally restrained from carrying out the very act the court seeks to enjoin circumventing the order. In my judgment there is no merit in this objection at all.

99. In any event, the basis upon which Ms. Reynolds contends for the extension clearly relates to the “*harm caused to Teva Ireland [which] may in turn cause and/or manifest itself in, damage to Related Companies*”. There is no attempt to link the order restraining the defendant – whether by itself or its directors, officers, servants or agents – to any company which may have been intended to play a role in the marketing, distribution or sale of Teva Apixaban. This is precisely the criticism made of the respondent in *Dunne* and just as in that

case the respondent had failed to make out its claim that the undertaking as to damages offered in that case was inadequate, so too has Teva in this case failed to discharge the onus on it to establish that the normal undertaking as to damages is inadequate because of the inclusion of the standard restrictions in it.

100. Ms. Reynolds's affidavit makes reference to direct and indirect loss to other Teva Group companies. On its face she refers to indirect loss to other Teva Group companies. This was expressly excluded by the High Court which emphasised that the extended undertaking as to damages only covered direct losses, not indirect losses.

101. In para. 10 of her affidavit, Ms. Reynolds says that Teva Ireland will suffer the "initial" loss/damage. She then says that there are (unspecified) arrangements in place in respect of profit sharing within the Teva Group of Companies "*which will result in indirect loss to other companies*". She asserts that a "*significant proportion of the margin (i.e. profit) [from the sale of Apixaban Teva to customers in Ireland] would have been transferred (by transfer pricing) to another company*" in the group. No further information is given for reasons of confidentiality.

102. All this establishes is that one other company in the group will suffer from the loss of sales of the product by reason of the injunction restraining Teva Ireland. Transfer pricing is not explained. As was made clear in *Dunne* the purported damage must be established and not simply invoked. The onus on Teva was to advance a "*precise legal or factual basis*" for the apprehended losses to other companies in the Teva Group by reason of the injunction restraining Teva Ireland. They must "*demonstrate evidentially*" the losses they contend will be suffered as a result of the order "*for the purpose of demonstrating that the undertaking is inadequate*". The terse paragraph does not provide any justification for extending the undertaking as to damages to all the related companies. It is not clear why the other company may not be identified while keeping all the other details of the arrangement confidential.

This is Teva's choice. The court must work with the evidence that has been adduced. In my judgment it falls far short of what is required by *Dunne* and *Nolan*. I therefore cannot agree with the trial judge that the affidavit has been "*bolstered*" by extensive submissions. Submissions are no substitute for evidence and evidence is required to enable the court to "*rationally*" assess the argument. It is simply impossible so to do on the basis of the evidence adduced. The court is told virtually nothing of the intended involvement of other companies in the Teva Group in the sale of the medicinal product on the market. It is also entirely possible that some or all of these companies could be infringers of the SPC. This could be a relevant factor in the court's assessment of the overall risk of injustice and is a factor to be considered when determining the appropriate scope of the undertaking as to damages (*Apotex*).

103. In paras. 11 and 12, Ms. Reynolds refers generally and vaguely to the possibility of restructuring the companies in the Group. The height of the case is "*it cannot be said...with any certainty*" that the "*internal structure*" of the Group will not change. Even if the structure were to change, it is perfectly possible to apply to court to address this theoretical future change as required: in my judgment it is not a basis to require BMS to give an undertaking as to damages in respect of the whole Teva Group. Not every re-organisation or merger will alter the companies which may be adversely impacted by the continuance of the injunction. This is simply a disproportionate order in response to a hypothetical which is utterly unsubstantiated.

104. In her concluding paragraph, Ms. Reynolds says that without the extension to Teva Ireland's related companies "*there is a risk that the injunction will cause harm which will not be compensated if the Patent is ultimately held to be invalid*". This statement is simply not justified on the basis of the evidence adduced in support of the argument.

105. For these reasons, I am of the view that Teva has not discharged the onus of demonstrating to the court that the undertaking as to damages provided by BMS is or would be inadequate in terms of the losses which would be likely to be suffered as the result of the granting of the injunction and accordingly for this reason too I would allow the appeal.

Does the English practice represent the law in this jurisdiction?

106. The Irish case law makes clear that when the court is considering the adequacy of the undertaking as to damages offered by a party seeking an injunction its primary concern is to do justice as between the parties. Specifically, when considering this net issue, it is not concerned with doing justice generally. When considering the balance of justice and whether to grant an injunction at all, the possibility of adverse impacts of the relief sought on non-parties and the world at large can, and do, in appropriate cases form part of the consideration whether or not to grant or withhold an injunction. The role of the undertaking as to damages is more nuanced: it is primarily to assist the court to do justice between the parties. As was stated in *Nolan*, the court is striking a balance between the respective rights of the parties. The undertaking as to damages is not intended to be a complete indemnity. The court recognises that injunctions may be granted where damages are an inadequate remedy for the enjoined party. It follows that an undertaking for damages will not be inadequate merely because an enjoined party can point to an uncompensatable loss.

107. That is not to say that, as a matter of principle if an identified non-party intervened in the proceedings and made the case, substantiated by evidence, that the undertaking as to damages offered by the plaintiff should extend to compensate it for losses it may suffer as a result of the granting of the injunction that, in any given case, a court could not consider whether the undertaking offered by the plaintiff should extend to compensate that party as well as the enjoined defendant(s). But that is not the same as approaching the assessment of

the scope and adequacy of an undertaking as to damages offered from the standpoint of doing justice generally, as in *Actavis*.

108. Furthermore, any such departure from the normal undertaking as to damages must be supported by evidence which warrants the extension of the undertaking as to damages in question in the manner sought. To that extent, in my view, Irish law differs to the law of England as expressed by Birss J. in *Actavis* and followed by Arnold J. in *Warner Lambert*.

109. I accept that the issue of a non-party intervening in the proceedings for the purposes of seeking an order extending the benefit of the undertaking as to damages to it may pose problems which will have to be teased out on a case-by-case basis. This may involve the court directing that such a party be put on notice in advance of the hearing of the application for an interlocutory injunction. It will be important to try to avoid any such application requiring the court to reconsider the balancing of competing interests which it has undertaken when originally considering the application and recalibrating that balancing act by requiring, *ex post facto*, a plaintiff to pay a greater price than that which the court had previously found acceptable.

110. As Jacob L.J. observed in *Apotex*, these are complex issues which require to be addressed and considered by the court as a matter of principle and resolved on a case-by-case basis.

111. At most, the English cases relied upon by the High Court are persuasive authorities, and this court is not bound to follow them. If the argument is persuasive, frequently it will do so. However, I am not persuaded we should follow the decision of Birss J. in *Actavis* first, and most importantly, because it is clearly not based upon any evidence but on counsel's instructions relayed to the court. As I have already observed, that is insufficient in this jurisdiction. Second, it is based upon the terms of a practice direction (which has no equivalent here) which requires the court when considering the scope of the undertaking, to

“do justice generally”, per Birss J., which is not the law in this jurisdiction. For these reasons I believe that the High Court afforded too much weight to the judgments in *Actavis* and *Warner Lambert* and paid insufficient regard to *Dunne* and *Nolan* and thereby erred in principle in the exercise of its discretion so that this court ought to intervene and reverse the decision on this ground also.

Admission of evidence after judgment

112. The High Court delivered its reserved judgment on 17 February 2023. Some seven weeks later the trial judge permitted the losing party to adduce further evidence to address an issue which it had failed to raise before or during the hearing of the application for the injunction. In my opinion, in the circumstances this was an error. Parties are required to advance all of the evidence upon which they rely which addresses all of the issues they wish to raise in relation to the matters presenting in the application. A party cannot in effect unilaterally bifurcate the hearing by leaving over to a later date the consideration of an aspect of the matter for consideration after judgment. This is not to deny that the court may direct a modular hearing if it thinks this is appropriate or that certain matters are to be dealt with sequentially as part of its general management of the litigation. Also, after judgment, the court may require updated information on affidavit or direct that a confirmatory affidavit be filed. None of this is objectionable. That is not what occurred in this instance. The decision not to adduce evidence or raise any objection to the form of the undertaking offered by BMS to the court was a unilateral, conscious decision by Teva regarding the manner in which it opposed the application for an injunction. In my judgment the trial judge ought not to have permitted it to conduct the litigation in this manner and I would respectfully disagree with his observation that this is commonplace or reflects the usual practice in the courts following the delivery of a decision to award an injunction. What occurred here was very different to

the usual submissions as to the precise form of an order and this was accepted by counsel for Teva who freely accepted that the application was a novel one.

Form of the order

113. Finally, I should observe that the form of the perfected order of the High Court is inappropriate. The curial part of the order should clearly set out the order of the court and no more. It should not contain any commentary, gloss or explanation. This in effect is what is set out in the latter part of the order as perfected and it should not have been included.

Conclusion

114. The court has jurisdiction to request a party who seeks an injunction to give the court an undertaking as to damages as the price for the injunction. So too, the court has the jurisdiction to request the moving party, as the price of the injunction sought, to undertake to compensate a party or parties who is/are not enjoined (and who may not be a party to the proceedings) but who may suffer loss or damage as a result of the order in the event that the moving party does not succeed at trial.

115. The substantive consideration of the undertaking as to damages offered to the court by the plaintiff cannot be separated from the substantive consideration of whether to grant or withhold the injunction. If a defendant contends that the undertaking offered is inadequate to compensate for the losses the injunction is likely to cause if the defendant ultimately succeeds at trial, the defendant must raise that issue for the trial judge to consider when the question of the grant or refusal of the injunction remains live. Teva first sought to contend that the scope of the undertaking as to damages offered by BMS should extend to all the companies in the Teva Group after the High Court had already determined that it would grant the injunction sought on the terms of the undertaking as to damages offered by BMS to the court. The issue was decided and Teva may not come thereafter and seek to alter the decision of the High Court.

116. The onus of demonstrating to the court that the undertaking as to damages offered to the court is or would be inadequate in terms of the losses which would likely to be suffered as a result of the granting of the injunction rest with the party alleging such inadequacy. The party must demonstrate evidentially the losses they contend will be suffered as a result of the order for that purpose. The evidence must be sufficient to enable the court to assess rationally whether the undertaking offered suffices or whether the court ought, exceptionally, to require the moving party to give a fortified or expanded undertaking, as the case may be. The evidence adduced by Teva fell far short of what was required to establish the need for the novel, far-reaching order it belatedly sought in this case.

117. Given that the adequacy and scope of the undertaking as to damages offered to the court falls to be assessed and decided when the issue whether or not to grant an injunction is still live, the High Court erred in permitting Teva to file an affidavit in support of its application for an extended undertaking as to damages after the court had delivered its reserved judgment and concluded that it would grant the relief sought on the terms offered by BMS.

118. The form of the order as drawn is inappropriate. The order should recite the terms of the court's order, not the reasons for it. It should not provide a gloss on the meaning of the order, which in effect is what the second page of the order of 28 July 2023 amounts to.

119. I have decided the appeal on the basis that the question of the adequacy and extent of the undertaking as to damages was not raised during the hearing of the application for the injunction and the evidence adduced (even if admissible) did not suffice to establish that the undertaking as to damages offered was not adequate to compensate for the loss which is likely to be suffered by reason of the injunction in the event that Teva succeeds at trial. Accordingly, I have refrained from considering the question whether an expanded

undertaking as sought by Teva is compatible with EU law which will be decided in a future case should the issue arise.

120. My preliminary view is that BMS has been wholly successful in the appeal and accordingly is entitled to the costs of the appeal, to be adjudicated in default of agreement. If Teva wishes to argue for a different order as to costs, its solicitors may contact the office of the Court of Appeal within 10 days of the delivery of this judgment and request a short hearing as to costs. In that event, the parties will be notified of the date of the hearing and should file written submissions of no more than 1500 words addressing the question of the costs of the appeal four days before the date for the costs application.

121. Noonan and Allen JJ. have read this judgment in draft and authorised me to indicate their agreement with same.