THE COURT OF APPEAL

CIVIL

[Approved]
[No Redaction Needed]
Record Number: 2022 No. 249

Costello J.
Noonan J.
Allen J.

Neutral Citation Number [2023] IECA 71

BETWEEN/

BIOGEN MA INC. AND BIOGEN INTERNATIONAL GMBH

PLAINTIFFS/
APPELLANTS

- AND -

LABORATORIOS LESVI S.L. AND NEURAXPHARM IRELAND LIMITED

DEFENDANTS/
RESPONDENTS

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

1. The issue for consideration in this appeal is whether the appellants are entitled to an injunction to restrain the respondents from infringing the appellants' European Patent No. 2 653 873 ("the 873 patent") by the launch of their generic medicinal product ("the generic").

Background

2. The appellants are each part of the international Biogen group of companies, which is a global biotechnology business involved in the research of neurological and

neurodegenerative diseases. The medicinal products at issue in these proceedings are used in the treatment of multiple sclerosis.

3. On 7 February 2008 a member of the Biogen group filed an application for a patent for the treatment of multiple sclerosis with the active ingredient dimethyl fumarate ("DMF") with the European Patent Office (the "EPO"). On 29 May 2013, EP 2 137 537 ("the parent patent") was granted by the Examination Division of the EPO. On 30 January 2014 Tecfidera® was authorised as a medicinal product in Europe for the treatment of multiple sclerosis. Tecfidera® was protected by the parent patent.[1]

4. Opposition papers were filed against the parent patent and on 13 June 2016 the parent patent was revoked by the Opposition Division of the EPO on the grounds of added matter and lack of inventive step. Biogen appealed this decision and the Technical Board of Appeal of the EPO affirmed the revocation of the parent patent on 20 January 2022. The reasons for the decision were published on 3 June 2022.

5. The 873 patent is a divisional application of the parent patent. An application to recognise the patent was filed but the examination of the application was adjourned pending the determination of the appeal of the parent patent. Third parties wrote to the Examining Division of the EPO objecting to the grant of the 873 patent on the grounds that the parent patent had been revoked and the divisional patent, it was said, suffered from the same infirmities and thus no patent should be granted. On 28 April 2022 at an oral hearing in

[1] The appellants also relied upon regulatory data protection to protect their interest in Tecfidera®. Since January 2014 Tecfidera® had its own independent global marketing authorisation. By virtue of Article 14(11) of Regulation (EC) No. 726/2000, where a product has its own independent global marketing authorisation, pre-clinical and clinical data underlying the authorisation of the product cannot be used to assess and authorise a generic product for a period of 8 years (in the case of Tecfidera®, ending in February 2022), and no generic product can be placed on the market for a period of an additional 2 years. The appellants assert that Tecfidera® was originally protected by both the parent patent and Article (14)11 and that it is entitled to rely on the latter notwithstanding any frailty in patent protection. The respondents dispute this and were successful before the General Court of the EU. The appellants appealed to CJEU and since the appeal was argued before this Court the CJEU delivered its judgment on 16th March, 2023 in Joined Cases C-438/21 to 439/21 Pharmaceutical Works Polpharma S.A. dealing with the assessment of the existence of a global marketing authorisation and allowed the appeal. However as I believe the issues in this appeal may be resolved solely by reference to the 873 patent, I shall not consider this separate issue in this judgment and thank the parties for bringing the judgment to the attention of the Court.

respect of the 873 patent, the Examining Division of the EPO indicated that it intended to grant the patent. The minutes of the hearing were published on 12 May 2022. On 23 June 2022 a committee of three members of the Examining Division of the EPO, one of whom had been part of the panel which affirmed the revocation of the parent patent, issued its decision to grant the 873 patent. The grant of the 873 patent was published in the European Patent Bulletin on 20 July 2022. Accordingly, the 873 patent has been in force in Ireland since 20 July 2022. If not revoked, it will expire on 7 February 2028.

6. Biogen MA, the first appellant, is the proprietor of the 873 patent. Biogen International, the second appellant, is the exclusive licensee of the 873 patent in Ireland.

7. The 873 patent protects the medical product, Tecfidera®, the active ingredient of which is dimethyl fumarate ("DMF"). Tecfidera® is the only DMF product currently available on the market in Ireland used to treat multiple sclerosis. Multiple sclerosis is an inflammatory auto immune disorder affecting the central nervous system. It causes a loss of function to the nervous system and a loss of communication between the brain and the body. There is no cure for MS and the primary purpose of MS treatment is to reduce the frequency of relapses in symptoms and to slow the progress of the disease.

8. The Health Service Executive operates a High Tech Ordering and Management Scheme ("the High Tech Scheme") for the provision of certain medicinal products. It publishes a list of agreed prescribable medicinal products which are reimbursed by the HSE. When clinicians prescribe a treatment, they must choose a specific product on the list. The order must be approved by the HSE before the order for the medicine can be placed by a pharmacy with a wholesaler. The medicine will be dispensed to the patient by the pharmacist once it is supplied by the wholesaler. The wholesaler is reimbursed by the HSE to the value of the agreed reimbursement price of each particular medicine. Thus, the HSE – and not the

individual patient – incurs the cost of the medicinal product prescribed, which it agrees with the individual supplier.

9. The respondents are engaged in the manufacture and sale of pharmaceuticals *inter alia* for disorders affecting the nervous system. The respondents decided to launch in the State a medicinal product known as dimethyl fumarate neuraxpharm, a generic version of Tecfidera® (the "generic"). The generic contains dimethyl fumarate and is used in the treatment of multiple sclerosis, and *prima facie* it infringes the 873 patent. On 13 May 2022 the Health Products Regulatory Authority granted the first named respondent a licence (bearing Licence Number EU/1/22/1637/001-002) to supply dimethyl fumarate neuraxpharm, the generic. On 27 July 2022 the first respondent's generic was included on the HSE's list of agreed prescribable medicinal products to be dispensed under the HSE's High Tech Scheme with effect from 1 August 2022. Subsequent to the institution of these proceedings, the respondents confirmed that they intended to launch the generic in the week commencing 1 August 2022 in advance of other generic manufacturers in order to secure "first mover advantage". In this regard the respondents noted that licences have been granted for the supply of dimethyl fumarate to other manufacturers including Mylan IRE Healthcare Limited and Polpharma SA.

10. The respondents believe that the 873 patent is invalid – they say manifestly so – as it suffers, according to the respondents, from the same defects which resulted in the revocation of the parent patent. They therefore elected to launch the generic without first obtaining an order of invalidity in respect of the 873 patent.

11. The appellants apprehended that the respondents intended to launch their generic. They sent letters on 5 May, 24 June and 20 July 2022 to the first respondent and Neuraxpharm Germany setting out the fact that the Examining Division of the EPO had indicated during oral hearings that it intended to grant (and subsequently, had granted) the

873 patent, that it covered pharmaceutical compositions comprising DMF for use in treating MS at a dosage of 480mg per day, and that the patent would not expire until February 2028. They sought undertakings that neither the first named respondent nor its affiliates would manufacture, import or market the generic while the 873 patent was in force. The letter of 24 June 2022 informed the first named respondent of the decision to grant the 873 patent and that it would be considered granted in Ireland on 20 July 2022, the date of publication in the European Patent Bulletin. The letter reiterated the request for an undertaking in the terms of the earlier letter. This letter was followed up on 20 July 2022. It sought confirmation that the first named respondent and its affiliates did not intend to manufacture, import or market the generic in Ireland and undertakings to that effect by 5 p.m. on Monday 25 July 2022. They expressly warned that in the event of a failure to do so or if their client learned that the respondents had applied for reimbursement price approval that their client reserved the right to take any action necessary to protect and enforce its rights.

12. No replies were received to any of the letters and the appellants remained in the dark as to the intentions of the respondents.

13. As stated above, on 27 July 2022 the first respondent's generic was included in the HSE's list of agreed prescribable medical products to be dispensed under the High Tech Scheme with effect from 1 August 2022. The appellants responded immediately by issuing a Plenary Summons on 28 July 2022 and applying on 29 July 2022 *ex parte* for an injunction restraining the respondents from infringing the 873 patent.

14. O'Moore J. granted an interim injunction on the morning of Friday 29 July 2022. The application for interlocutory relief was made returnable for the next business day, Tuesday 2 August 2022. He ordered that notice of the grant of the injunction and of the application for an Interlocutory Order be effected by e-mail by 2 p.m. on 29 July, 2022. The e-mail addresses were obtained from the Neuraxpharm Group websites and, in respect of the second

named defendant, an Irish company, from the CRO BIC Annual Return Form. The applicants duly served the respondents at the three e-mail addresses, but not until 2.53 p.m.

15. On 2 August 2022 the appellants applied to Owens J. for interlocutory orders. There was no appearance on behalf of the respondents. Owens J. granted interlocutory injunctions restraining the respondents from launching the generic until the trial of the action. Lawyers for the appellants suggested that the order provide for liberty to apply upon the respondents giving 48 hours' notice to the appellants. The High Court granted liberty to apply on 72 hours' notice.

16. It subsequently emerged that the respondents first became aware of the order of O'Moore J. and the hearing on 2 August 2022 on the afternoon of 2 August 2022, after the hearing before Owens J. had concluded. The respondents immediately sought to re-enter the matter and to have the interlocutory injunction discharged.

Decision of the High Court

17. On 26 October 2022 the High Court, Twomey J., discharged the order of Owens J. granting an interlocutory injunction restraining the launch of the generic on the grounds that it would be unjust to continue the injunction in all the circumstances. The order had been obtained in the absence of the respondents as they only became aware of on the afternoon of 2 August 2022 of the application for an interlocutory injunction moved that morning. He was satisfied that the respondents did not ignore the notice of the application. The judge found that the fact that they had not responded to pretrial correspondence did not disentitle them to an opportunity to be heard on the application for an interlocutory order which would have very significant financial consequences for them for a period of circa 18 months. In the circumstances justice required that the interlocutory injunction granted on 2 August 2022 in the absence of the respondents be discharged and he would hear the application *de novo*.

18. Twomey J. then considered whether an injunction ought to be granted restraining the infringement of the 873 patent pending the trial of the action. He noted that the parent patent had been revoked by the Opposition Division of the EPO and by the Technical Board of Appeal and said that *"*the patent underlying Tecfidera®, should not have been granted". A section of the judgment is headed "Taxpayer pays significant sums to Biogen on basis of unlawful monopoly in Tecfidera®" and at para. 41 he stated:-

> *"…it seems likely that Biogen was paid significant sums of money by the Irish taxpayer on the basis of a monopoly to which it was not entitled. This, it could be argued, is not <u>just</u> and so it is a matter which, although not dispositive of this application, can weigh in the balance when deciding what amounts to <u>justice</u> for Biogen in this case."* (Emphasis in original.)

19. Twomey J. proceeded to apply the principles in relation to the granting of an interlocutory injunction set out by the Supreme Court in *Merck Sharpe & Dohme v. Clonmel Healthcare* [2019] IESC 65, [2020] 2 I.R. 1 *("Merck Sharpe & Dohme")*. He first noted that there was no real dispute between the parties that the appellants had established a fair issue to be tried regarding whether the respondents had infringed the 873 patent. He held that it was clear that the connected issue, raised by the respondents, whether the 873 patent is valid, also met this threshold. He accepted that if the appellants were to succeed at trial that the appellants would obtain a permanent injunction against the respondents. The real issue for resolution was the adequacy of damages as a remedy for both parties and the balance of justice. He accepted that the adequacy of damages is part of the balance of justice test. Having considered the evidence from both parties he concluded that damages would be an adequate remedy for both of them if it turned out that the injunction was wrongly refused or granted at the interlocutory stage and held that both parties would be in a position to meet any award of damages which might be made at trial.

20. In relation to "the rest of the balance of justice*"*, the trial judge noted that the 873 patent has a presumption of validity and, referring to para. 63 of *Merck Sharpe & Dohme*, that the arguments against invalidity needed to be strong before they could weigh against the grant of the injunction. At para. 66 he held that *"*on a tentative basis*"* the respondents' case for the invalidity of the 873 patent was strong. He reached this conclusion firstly because it is a divisional patent of the parent patent which has been declared to be invalid due to a lack of an inventive step. He noted that the respondents' lawyer, Dr. Ortel, had averred that if the narrower patent (the parent patent) was not based on an inventive step, then this applied *a fortiori* to the broader patent and that the minor difference in wording between the patents did not affect the Opposition Division's reasoning which led to the revocation of the parent patent. He said that *"[w]hile this Court is not in a position to make a definitive finding in this regard, it is in a position to make a tentative finding that this reasoning appears strong."*

21. Twomey J. acknowledged that the Examining Division of the EPO granted the 873 patent and that it had discounted the opposition of third parties to the grant. While the trial judge recited the decision of the EPO, he made no further comment or observation on this fact or the weight he attached to it.

22. Likewise, regarding the presumption that the 873 patent is valid, he noted the position and the decision of the CJEU in *Phoenix Contact GmbH & Co. KG v. Harting Deutschland GmbH & Co. KG Case C-44/21 ("Phoenix")* at para. 41 that *"[I]t must be borne in mind that filed European patents enjoy a presumption of validity from the date of publication of their grant."* He then held:-

> *"Indeed, it seems to this Court, were it not for the unusual factors in this case, this Court would have to treat this decision of the Examining Division as granting the 873 patent a presumption of validity, which would be dispositive in favour of the grant of the injunction."*

23. How the unusual factors he discusses thereafter outweigh the rights of the holder of a presumptively valid patent are not clear. The trial judge refers to other factors which he considered were relevant to whether an injunction ought to be granted but which do not relate to the respondents' case for invalidity and thus which do not – and do not purport to – rebut the presumption of validity. He records that the respondents did not clear the way (or the path as it is also described) before planning to launch the generic and that the appellants are no longer relying on the 873 patent in the United Kingdom. He discusses judgments from other jurisdictions which, he suggests, "*have rebutted the presumption in this case"* and notes that in two cases the courts refused to grant injunctive relief whereas in a third, relief was granted. Twomey J. said that although the decisions are *"of some relevance"* they are not crucial because they do not deal with the validity of the 873 patent as envisaged by O'Donnell J. in *Merck Sharpe & Dohme* at para.63, when he referred to the relevance of decisions on the validity of the patent in other jurisdictions. Twomey J. cautioned that the test for granting an injunction in the other jurisdictions is not the same as in Ireland but went on to say that:-

> "*Nonetheless it is, at least, of some relevance, when considering the balance of justice, to note that courts in two separate EU countries have refused Biogen an injunction preventing the sale of a generic drug, despite the presumption of validity which attaches to the [873] patent, while a court in one EU country has granted such an injunction."*

24. It is not clear precisely how these factors feed into the trial judge's conclusion that the appellants were not entitled to injunctive relief. At para. 60 he says that *"[b]y far the strongest factor is… the fact that Biogen has had seven years' monopoly in Tecfidera® to which it was not entitled.".* In para. 61 he identifies the task for the court as being *"to do justice, in particular between the parties (and, as noted hereunder, to a lesser degree*

perhaps, to the public interest)". In para. 74 he refers to the uncontroverted evidence of the respondents that the appellants have *"more than recouped"* their investment in Tecfidera®.

25. From para. 75 Twomey J. sets out his consideration of the public interest/taxpayers' interest in considering the balance of justice.

> *"75. When considering the balance of justice, there is of course the fact that Biogen in these proceedings is seeking to protect a monopoly over Tecfidera that is presumed to be valid. This is because it is based on the Divisional Patent that is presumed to be valid. However, this factor cannot be considered in isolation, particularly from the public interest.*
>
> *76. In this case, the public interest is the financial interests of the State/taxpayer. In this regard, it is to be noted that the State plays a crucial role in any dispute about patents, in the sense that it is the State which grants a monopoly, by its laws, to the holders of a patent. The patent holders can then enforce that monopoly (by seeking an injunction, as in this case) against third parties. The monopoly is granted for good public policy reasons, namely to encourage innovation. In many instances, of course, the State will suffer financially as a result of having to pay monopolistic prices for goods or services which benefit from the 'state monopoly' so granted. However, the State in its pursuit of the public interest is content to subject itself to these monopolies for good public policy reasons.*
>
> *77. However, <u>these public policy reasons do not apply to the same degree to a situation where an innovator manages to obtain a patent to which it is not entitled and therefore a monopoly to which it is not entitled, by falsely claiming an inventive step.</u> Indeed, it could be argued that it is unjust that the State, which has set up the intellectual property architecture to permit legal monopolies, is financially prejudiced*

by having to pay monopolistic prices for unlawful monopolies, which only come to light many years after a patent is successfully challenged (as in this case).

78. In this regard, it seems to this Court that in considering the balance of justice, this Court can consider the public interest, particularly when one bears in mind that one is dealing with an equitable remedy (an injunction), which is granted at the discretion of the court. In this context, it is to be noted that the leading authority on interlocutory injunctions, O'Donnell J.'s judgment in Merck, expressly refers to the public interest at para. 13:

> *"Patent law and patent extension by SPC provide a monopoly as a reward and incentive for innovation and for the disclosure of the teaching involved, leading in this case to the development of beneficial products. However, once a monopoly comes to an end, whether by natural expiration or by determination of invalidity, there is a* ***strong competing public interest in encouraging entry to the market by generic alternatives****, particularly since in Ireland, as in many European countries, the bulk of the* ***cost of the drugs is met from the public purse****. When a pharmacist substitutes a generic alternative for a branded product, the cost to the health budget is correspondently reduced."* (Emphasis added.)

26. The trial judge concludes that O'Donnell J. here saw no issue in having regard to the public interest when considering the grant of an interlocutory injunction and that there is a legitimate public interest in reducing the cost to the taxpayer of the costs of drugs. He draws a similar conclusion from the decision in *Gilead Sciences Inc. v. Teva BV* [2019] IEHC 683 *("Gilead")* para. 70, while acknowledging that McDonald J, was concerned with the revocation of a SPC. At para 81 and 82 he concludes:-

"81. Against this backdrop, while not determinative of the question of whether to grant an interlocutory injunction or not, nonetheless it is clear that the public interest is of some relevance when deciding what is meant by 'justice' in the 'balance of justice' part of the test for an interlocutory injunction. This is particularly so in cases such as this one where the balance is fine.

82. The public interest in this case is not simply the fact that the monopoly over Tecfidera, which Biogen seeks to protect by injuncting Neuraxpharm, will cost the taxpayer circa €8 million. On its own this is perhaps not particularly significant. However, what is more significant is the fact that this is the same monopoly that was unlawful for the previous seven years and which is likely to have cost the taxpayer significant sums of money and which will cost that same taxpayer many millions of euro if it is continued (albeit under a different and presumptively legal patent)."

(Emphasis added.)

27. The trial judge then refers to *"the injustice of the taxpayer having overpaid for a drug based on an unlawful monopoly for the previous seven years"* and opined that *"favouring [the respondents] by refusing the injunction, with the ancillary benefit to the public interest, does not seem to this Court to be inflicting an injustice on Biogen."* In reaching this conclusion he has regard to the fact that the appellants can recover damages from the respondents. At para. 86 he says the fact that the taxpayer will benefit from the refusal of the injunction is not a decisive factor:-

"The decisive factor in the balance of justice is the fact that Biogen has benefited from an unlawful monopoly created by an invalid Parent Patent and it is now seeking to benefit from a monopoly with a patent that is derived from that invalid Parent Patent."

(Emphasis added)

28. The trial judge set aside the order of Owens J. and he refused to grant the interlocutory injunctions sought by the appellants, but he stayed his order vacating the Order of Owens J. for two weeks. The appellants appealed and applied for an order extending the stay pending the determination of the appeal. This Court was able to list the appeal for hearing in early course and, on that basis, the respondents did not oppose the continuation of the stay on Twomey J.'s order vacating the order of Owens J. Thus, the injunction of the High Court of 2 August 2022 restraining the respondents from launching their generic has continued in place until the delivery of this judgment.

The arguments on appeal

The appellant's arguments

29. The appellants' case on appeal was that this case was essentially indistinguishable from *Merck Sharpe & Dohme* and the trial judge failed properly to apply that authority to this case. In particular, the appellants argued that he refused interlocutory relief in respect of the 873 patent because of "an adverse view*"* taken by him of the owner of the 873 patent "arising from the ownership of… [the] Parent Patent", a different property right which had ceased to exist by the time the proceedings issued.

30. Secondly, the appellants argued that the trial judge failed to give due weight to the fact that the 873 patent is an independent patent and presumptively valid regardless of the fact that it is a divisional patent, and the parent patent has been revoked (see *Merck Sharpe & Dohme* and *Case C-44 21 Phoenix Contact GmbH & Co. K.G. v. Harting Deutschland GmbH & Co. K.G. ("Phoenix")*). They argued that to overcome this presumption it was necessary for the respondents to show a *"strong case"* that the 873 patent was invalid. The only judgment dealing substantively with the validity of the 873 patent, it is said, was the decision of the EPO to grant the patent. The judgments of courts in other Member States referred to by the High Court were interlocutory judgments which did not determine the

validity of the 873 patent and there were conflicting decisions. Therefore, according to the appellants, applying the decision of O'Donnell J. in *Merck Sharpe & Dohme*, this was not sufficient to rebut the presumption of validity. Furthermore, it was said, the court would require independent expert evidence in order to satisfy itself that the strong case threshold was met and there was no such evidence before the trial judge. Specifically, it was said, the evidence of Dr. Ortel, the respondents' German lawyer, is not that of an independent expert and accordingly it cannot validly form the basis of a conclusion that the respondents had made out a strong case that the 873 patent is invalid.

31. Thirdly, the appellants argued that the trial judge erred in concluding that the monopoly enjoyed by Tecfidera® protected by the parent patent between 1 March 2015 and 20 July 2022 was *"unlawful"* and that this was the *"strongest factor by far"* (para. 60) and the *"decisive factor"* (para. 86) warranting the refusal of the interlocutory injunction to restrain infringement of the 873 patent. The appellants contended that this was not a factor to which the court should have had regard and certainly *"came nowhere near"* the threshold of conduct which warrants the refusal of injunctive relief which ought otherwise to be granted.

32. Fourthly, the appellants contended that quite apart from the 873 patent, the product Tecfidera® was protected by regulatory data protection which, separately from any I.P. rights, entitled the appellants to an injunction to restrain the unauthorised use of their data. As I have stated earlier, as this case can be resolved by a consideration of the 873 patent and the rights and interests of the parties in relation thereto, I do not propose in this judgment to deal with this separate, distinct claim. Resolution of the issues presenting are best left to a case where such resolution is necessary to determine the dispute.

33. Fifthly, the appellants submitted that the trial judge incorrectly adopted the saving of taxpayers' money as the real foundation for his entire approach to the application and

misapplied the decisions in *Merck Sharp & Dohme* and *Gilead* in concluding that the public interest in securing cheaper drugs can override a patent (or an SPC) in advance of the hearing and a determination that the claim made in the patent (or SPC) is invalid. The appellants argued that this must be inappropriate because such an approach will invariably favour the refusal of interlocutory relief as against a generic. This, it is said, would amount to a derogation from Article 9(1) of Directive 2004/48/EC ("the Enforcement Directive") and the decision of the CJEU in *Phoenix*.

34. Sixthly, it was submitted that the trial judge erred in concluding that damages were an adequate remedy and that this was contrary to the findings in *Merck Sharp & Dohme* which rejected the similar argument that a patent right was effectively a right to an income stream, and that the untimely and unplanned termination of the patent holder's monopoly right gave rise to damage which could not be compensated by damages.

35. Finally, counsel for the appellants submitted that the trial judge erred in discharging the injunction granted by Owens J. on 2 August 2022 on the grounds that the respondent was attempting *"to steal a march"* by getting on to the market even though it knew that the 873 patent *"stood as an obstacle in its path"*. It argued that the trial judge effectively condoned tactics *"that are the antithesis of what the legal system is designed to achieve, namely the orderly resolution of disputes between parties with diverging and conflicting views as to their respective entitlements"*. The order of Owens J. ought to have been upheld on the basis that the respondents had failed to clear the path and obtain an order revoking the 873 Patent.

36. I add for completeness that the notice of appeal and the appellant's written submissions suggested that although the respondents had obviously been taken by surprise by the hearing on 2 August 2022, Twomey J. ought not to have heard the respondents in opposition to the

orders sought, or, perhaps, ought to have dealt with the matter as an application to vary the order of 2 August 2022. This was not, however, seriously pursued at the oral hearing.

The respondents' arguments

37. The respondents emphasised that an appeal against the refusal to grant an interlocutory injunction is not a re-hearing of the application. They submitted that if there is an error in principle the appellate court can properly interfere with the High Court's exercise of its discretion but that where the assessment of discretionary factors is at issue, it should only interfere if there is injustice. Counsel referred to the decision in *Merck Sharpe & Dohme* where O'Donnell J emphasised the essential flexibility of the remedy. Counsel cautioned that the Supreme Court was not saying that in every case where an IP rightsholder seeks an injunction to restrain infringement which is resisted on the grounds of alleged invalidity that the balance of justice favours the granting of an injunction; that the balance of justice is a fine one and it is one which is capable of being affected the individual circumstances presenting in the individual case. The court may have regard to a whole range of factors.

38. The respondents assert that the trial judge was entitled to have regard to the grant, exploitation, and revocation of the parent patent in assessing the balance of justice and, in particular, to have regard to the *"unfair monopoly"* which Biogen enjoyed in Tecfidera® during the currency of the parent patent.

39. Further, he was entitled to consider the public interest in assessing the balance of justice.

40. The respondents' principal argument was that they had established a strong argument that the 873 patent is invalid for the reasons which led to the revocation of the parent patent. They argued that the invention disclosure is the same in both patents and that replacing the word *"consisting"* with *"comprising"* does not and could not *"cure the deficiency"* in the parent patent; it does not change the fact that there is still added matter and it is not *"likely"*

to cure the absence of an inventive step. The respondents relied upon a decision of the Dusseldorf Regional Court of 30 November 2022 in *Biogen MA Inc v Zentiva Pharma GmbH* which refused to grant an injunction to Biogen. The court did so on the grounds that it had *"doubts"*, notwithstanding the fact the Examining Board admitted the patent to grant, as to *"an inventive step"* and accordingly held that it was *"likely"* that the 873 patent would be revoked.

41. The respondents said that the High Court fairly determined that it was not in the interests of justice for Biogen to have the benefit of extending its monopoly for a second time to await the determination of the validity of the 873 patent due to the strength of the arguments as to invalidity. In debate with the court, counsel for the respondents said that they were not required to adduce independent expert evidence as to the alleged invalidity of the patent because *"it is not a matter of expert opinion because there isn't actually a dispute as to expert opinion"*

42. The respondents were asked whether they relied on an additional factor to support their argument that the balance of justice in this case favoured the refusal of the injunction. Counsel said that damages were an adequate remedy for the appellants-as well as the respondents- due to the transparency and stability of the market and the ability of the respondents to meet any award as to damages and therefore the trial judge was correct to refuse to grant the injunction sought.

Observations on aspects of the patent regime relevant to this appeal

43. Prior to considering the issues raised on this appeal in detail, it is useful to set them in context, by briefly referring to some relevant aspects of the patent regime in the E.U. and Ireland and the facts in that context. The Examining Division of the EPO granted the 873 patent on 23 June 2022. The decision was published on 20 July 2022 and accordingly the 873 patent became operative in the State from that date. It enjoys a rebuttable presumption

of validity from the date of the publication of the grant. In *Phoenix,* a judgment of the CJEU of 28 April 2022, the court held at para. 41 that:

> *"…filed European patents enjoy a presumption of validity from the date of publication of their grant. Thus, as from that date, those patents enjoy the full scope of the protection guaranteed, inter alia, by Directive 2004/48". (Emphasis added.)*

44. Therefore, the fact that the 873 patent had only recently come into effect when the appellants applied for injunctive relief in no way detracted from its entitlement to protection under the Enforcement Directive or the Patents Act 1992 (as amended). As the owner of a presumptively valid patent, the appellants are entitled to the full scope of this protection, which would include the injunction sought in these proceedings.

45. In *Phoenix* the CJEU considered the significance and effect of Article 9 of the Enforcement Directive. Article 9(1) provides:-

> *"Member States shall ensure that the judicial authorities may, at the request of the applicant:*
>
> *(a) issue against the alleged infringer an interlocutory injunction intended to prevent any imminent infringement of an intellectual property right…",*

46. At para. 30 of the judgment in *Phoenix* the court noted that this provision requires Member States to ensure that the competent judicial authorities may, at the request of the applicant, issue against the alleged infringer an interlocutory injunction in order to prevent any imminent infringement of an intellectual property right. At para. 32 the court said that Article 9(1)(a), read in conjunction with Recital 22 of the Enforcement Directive, requires that the provisional measures available to a rights owner under national law *"must enable the infringement of an intellectual property right to be immediately terminated, without awaiting a decision on the merits. Those measures are particularly justified where any delay would cause irreparable harm to the holder of such a right. Thus, the 'time' factor is of*

particular importance for the purposes of effective enforcement of intellectual property rights." (Emphasis added.)

47. The court expressly rejected the proposition – as provided by German law – that a patent may only enjoy interim judicial protection where the validity of the patent has been confirmed by a decision given at first instance in patent validity proceedings. The judgment endorses the right of a patent holder to restrain imminent infringement of the patent *"without awaiting a decision on the merits."*

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

49. However, while such procedures exist, and while it appears that the intention of the drafters of the European Patent Convention and the Oireachtas in passing the Patents Act was that this would be the course of action ordinarily followed, an interested party may choose not to avail of it and to proceed on the assumption that the patent will ultimately be revoked and launch an infringing product *"at risk"* in order to obtain a first mover advantage. As will be seen from a review of the decision in *Merck Sharpe & Dohme*, the failure to clear the way has been held by courts in the United Kingdom to weigh significantly against any

party who opposes an injunction on the grounds of the alleged invalidity of a patent, though the position is less absolute in this jurisdiction.

50. The 873 patent is a divisional patent of the parent patent. It is a free-standing property right. In *Astrazeneca AB v. Pinewood Laboratories Limited* [2011] IEHC 159 Kelly J. (as he then was) considered an application for discovery in a dispute involving the validity of a divisional patent. At p.12 of the judgment, he held:-

> *"Astra are correct when they point out that each patent stands or falls on its own merits. Each divisional patent must have claims which are different. The patentee cannot have the same claim in different patents. But that said, it is clear that there is an extraordinarily close relationship between the parent and the divisional patents. Each have the same basic disclosure but with different claims."*

51. Kelly J. thus reaffirmed that as a matter of patent law the fact that the parent patent has been revoked does not automatically mean that the divisional patent, in this case the 873 patent, is also invalid and will be revoked. It must be separately assessed and its validity determined by an authoritative body, be it the court or the EPO. In this regard, it is worth recalling that the Examining Division of the EPO declared the parent patent to be invalid on grounds of added matter and lack of inventive step on 20 January 2022 for the reasons published on 3 June 2022. One of the members of the Technical Board of Appeal who reached that decision sat on the Examining Board, which granted the 873 patent. They did so having considered and rejected submissions opposing the application based upon the revocation of the parent patent. This underscores – if it were necessary – that it does not follow from the fact that the parent patent was revoked that the divisional patent is also invalid for the same reasons. The validity of that patent must be independently assessed.

52. It is also important to consider how the grant and the protection of intellectual property rights in general operates. Patents are granted to protect *inventions.* If there exists any

information in the public domain which teaches the matter disclosed in the patent at the priority date this destroys a claim to novelty. This means that there is a premium to apply for a patent at the earliest viable date to ensure against inadvertent invalidity on grounds of novelty (among other matters). An application for a patent may be refused. It will only be granted if the expert body assessing the application is satisfied that it ought to be granted. If the patent sought is granted, then the rightsholder is entitled to monopoly protection for the duration of the patent. This is the reward for publishing the teaching disclosed in the patent to the world at large. The patent may be challenged, and it may be revoked. However, if it is revoked, that does not imply that the applicant for the patent has acted improperly or that the monopoly rights enjoyed during the period of registration of the patent are in some way tainted or illicit. Interested persons who believe that a patent has been wrongly granted have ample opportunity to seek the revocation or declaration of invalidity of a patent on many different grounds. Under Article 9 of the Enforcement Directive, Member States are required to ensure that rightsholders may obtain interim or interlocutory injunctions to prevent any imminent infringement of an intellectual property right without first establishing the validity of that right. This is so even though, inevitably, given the nature of the regime, there will be cases where the intellectual property right is subsequently declared to be invalid. But that in no way means that if, during the period when the patent was registered, the patentee either exploited the patent or enforced the monopoly secured by the registered patent, the rightsholder acted in a way that was not lawful or that it improperly obtained benefits to which it was not entitled at the expense of others.

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

suggests that the earnings of the IP holder in such circumstances are in any way improperly obtained or involve any unjust exploitation of third parties.

***Merck Sharpe & Dohme v. Clonmel Healthcare* [2019] IESC 65, [2020] 2 I.R. 1**

54. The issues in this appeal were considered in great detail in the recent decision of the Supreme Court in *Merck Sharpe & Dohme* and much of the argument in this appeal concerned the proper interpretation and application of the judgment of O'Donnell J. (as he then was) who gave the sole judgment of the Court with which the other members agreed. That appeal concerned an application for an interlocutory injunction to restrain the launch of a generic equivalent of a product in respect of which the plaintiff was the holder of a Supplemental Protection Certificate ("SPC") named "Inegy". The defendant was a producer of generic pharmaceuticals and, prior to the expiration of the plaintiff's SPC, launched its generic equivalent of Inegy onto the market. The defendant did not take steps to clear the path for its product prior to its launch by seeking the revocation of the plaintiff's SPC for Inegy or a declaration of non-infringement in respect of its product. The plaintiff sought an interlocutory injunction restraining the defendant from launching its generic product on the basis that the product infringed its rights under its SPC. The SPC was approaching the end of its life and the defendant was anxious to obtain first mover advantage in the post monopoly stage. By the agreement of the parties, the appeal before the Supreme Court was confined to whether or not an interlocutory injunction should have been granted to the plaintiff as the position then stood when the application came before High Court in April 2018 free from any constraints which might be contended to apply when an appellate court is invited to review the decision of a trial judge on an interlocutory application.

55. O'Donnell J. noted that the underlying objective justifying the grant of a patent is to provide a monopoly for a limited period in order to encourage invention and the dissemination of knowledge, which is beneficial to the wider community (para. 7). It was

recognised that not all patents may lead to a commercially viable product and that there may be a significant delay between the date of registration of the patent and obtaining marketing authorisation which has the effect of significantly reducing the period during which patent protection is of benefit. With this in mind, the EU grants Supplementary Protection Certificates under Regulation (EC) 469/209 of the European Parliament and Council for medicinal products. At issue in the case before him was the right enjoyed under an SPC as opposed to under the patent. There were perhaps five generic manufacturers poised to enter the market once any valid intellectual property protection for Inegy expired. O'Donnell J. noted that the law in Ireland, as in many other countries, seeks to reconcile *"two competing public interests"*. In para. 13 he held:-

> *"Patent law and patent extension by SPC provide a monopoly as a reward and incentive for innovation and for the disclosure of the teaching involved, leading in this case to the development of beneficial products. However, <u>once a monopoly comes to an end, whether by natural expiration, or by determination of invalidity</u>, there is a strong competing public interest in encouraging entry to the market by generic alternatives, particularly since in Ireland, as in many European countries, the bulk of the cost of the drugs is met from the public purse. When a pharmacist substitutes a generic alternative for a branded product, the cost to the health budget is correspondently reduced."* (Emphasis added.)

56. The Supreme Court recognised that there is a public interest in rewarding and incentivising innovation and the disclosure of the teaching involved which is secured by providing a monopoly for a limited period to a patent holder (and by extension to the holder of an SPC). The second *"competing public interest"* comes into play *"once a monopoly comes to an end"*: the entry into the market of generic alternatives with resulting reduction in the costs of drugs. The judgment makes no distinction between a monopoly coming to an

end by natural expiration or by a determination of invalidity. In particular, there is no suggestion that the monopoly enjoyed up to the determination of invalidity is not one of the two competing public interests identified by the Court nor that it is not entitled to protection while it exists. While the public interest in the lower cost of generic drugs is acknowledged, it arises after the protection expires and does not trump the property right of the IP rightsholder during the currency of the protection.

57. In that case, Clonmel argued that damages were readily quantifiable and would be an adequate remedy for Merck as it would be possible to quantify the loss of profit in the lost sales to Merck from the date of Clonmel's entry into the market until the date of the expiry of the SPC. It argued that the SPC, even if valid, gave Merck *"what could probably be described as an income stream"*. On the other hand, it said that damages would not be an adequate remedy for it as it would lose its first mover advantage and would no longer be able to enter the market as it hoped in April 2018 but would rather be required to enter the market with other generic competitors. In those circumstances, it was said, it would be difficult, if not impossible, to assess how the market would have developed had Clonmel been able to enter the market in 2018. Clonmel relied upon the decision in *Curust Financial Services Ltd. v. Loewe-Lack-Werk* [1994] 1 I.R. 450, p. 468, and argued that the damage to Merck would therefore be *"clearly and exclusively a commercial loss, in…a stable and well-established market"* and accordingly an injunction should not be granted since the damages could readily be assessed.

58. Merck, on the other hand, relied heavily on authorities from United Kingdom courts dealing with injunctions restraining entry by generic competitors. Those courts have accepted the argument that damages will not provide an adequate remedy for the patent holder and have endorsed the view that if a generic manufacturer intends to introduce its product it could avoid all the problems of an interlocutory injunction if it cleared the way

first where litigation was bound to ensue. That was what the procedures for revocation and declaration for non-infringement were for.

59. In *Teva Pharmaceutical Industries v. Actavis U.K. Ltd.* [2015] EWHC 2604 (Pat) Arnold J. held at para. 42 that

> *"on both of the contrasting hypotheses, one side is going to suffer harm which will be difficult to quantity, and therefore the risk of irreparable harm. In those circumstances, the court's task is to adopt the course which appears least likely to cause the risk of ultimate injustice."*

Accordingly, he concluded that a counsel of prudence was to preserve the *status quo*. He stated:-

> *"In that connection it seems to me that an important fact to take into account is Actavis'* (sic) *failure to undertake what is a familiarly known as "clearing the path.""*

60. O'Donnell J. in *Merck Sharpe & Dohme* observed that the stark difference between the approaches of Merck on the one hand and Clonmel on the other was illustrated by the fact that if either argument was accepted it would establish a very strong presumption indeed *"if not an absolute rule"* either in favour of or against the grant of an injunction.

61. The court proceeded to analyse the decision in *American Cyanamid v Ethicon Ltd.* [1975] A.C. 396 and at para. 36 O'Donnell J. concluded:-

> *"36. In my view, the preferable approach is to consider adequacy of damages as part of the balance of convenience, or the balance of justice, as it is sometimes called. That approach tends to reinforce the essential flexibility of the remedy. It is not simply a question of asking whether damages are an adequate remedy.... There may be cases where both parties can be said to be likely to suffer some irreparable harm, but in one case it may be much more significant than the other. On the other hand, it is conceivable that while it can be said that one party may suffer some irreparable harm*

if an injunction is granted or refused, as the case may be, there are nevertheless a number of other factors to apply that may tip the balance in favour of the opposing party."

62. In relation to the difficulty of calculation of damages O'Donnell J. stated at para. 48:-

"The fact that it is in theory possible to gather every feather does not mean that it is not more convenient to stop the pillow being punctured in the first place … the fact that it is not completely impossible to assess damages should not preclude the grant of an injunction to the plaintiff in an appropriate case."

63. From para. 54 onwards O'Donnell J. addressed the issue of the balance of convenience. He held that the interests of the SPC holder and the interests of the generic challenger are both interests in acquiring a position in the market. The difference between them is that the SPC holder has a right conferred by a process of law which is presumptively valid; something which, if anything, ought perhaps to favour Merck (para. 55).

64. O'Donnell J. addressed the interest of Clonmel in exploiting a first mover advantage in para. 56, noting that it is something of value which is to be considered and given weight in the application for an interlocutory injunction since it will necessarily be lost if an injunction is granted. He held:-

"If Clonmel is correct, therefore, in its belief that the SPC is invalid, then it should be entitled to reap the commercial reward for its acumen in identifying the frailty in the SPC and being willing to back its judgment by investing in the product to the point of making both the regulatory application for approval and the practical preparations to launch a product in April 2018 rather than await the expiry of the 001 SPC a year later. That, however, is the high point of Clonmel's case. If it is wrong in its contention that the 001 SPC is invalid, then its conduct constitutes an actionable wrong. <u>However, I cannot see how that interest can be said to outweigh the right of Merck (if</u>

it in turn is correct) to exploit its monopoly, granted, on this hypothesis, in accordance with law…. I do not see, therefore, that the case can be resolved by preferring that interest (which may or may not be valid) to the legal right to monopoly of Merck (which itself may or may not be invalid). The fact, indeed, that Merck's right is one which arises pursuant to a lawful procedure for the grant of a patent and SPC, and which is valid until otherwise declared invalid by a court, is also relevant to the balance of convenience." (Emphasis added)

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

66. In relation to the argument that a generic challenger should always clear the path and that failure to do so should favour the grant of an injunction restraining the launch of the generic, O'Donnell J. said at para. 57 that *"while I consider that weight should be given to the 'clearing of the path' argument, it cannot be accepted without qualification as dispositive of the issue … [I]f full weight is to be given to Clonmel's interest in capturing a first-mover advantage, then it must be recognised that clearing the way poses some problems for Clonmel … since, of necessity, any such proceedings would clear the way not just for Clonmel itself, but for any other generic who would be (sic) to that extent a free ride on Clonmel's action."*

67. O'Donnell J. considered that *"given the essential symmetry of the parties' interests"*, in neither case would damages be a fully adequate remedy and that the likelihood of some irreparable harm being occasioned to the successful party was also equally balanced between the parties. He acknowledged that Clonmel would never be able to gain the position of first mover generic manufacturer if restrained and if it transpired that the SPC was invalid, and it

would be necessary to *"attempt a difficult estimation of both its likely profit if it had done so and its position in the market."* He acknowledged that there would be a similarly difficult calculation to be made if Merck succeeded at trial but did not obtain an interlocutory injunction. At para. 60 he held:-

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

68. O'Donnell J. expressly acknowledged a potential loss to a right which does not sound in damages as such, which he describes as *"significant"*, and which would be lost. This applies with equal force to the holder of any patent or SPC which protects a medical product in respect of which a generic manufacturer seeks to launch a generic product prior to the expiry of the relevant IP.

69. At para. 61 he held:-

> *"I consider that this is a case where damages, while available, cannot be considered to be said to be a full or adequate remedy for Merck so as to exclude the necessity to seek an injunction. I also consider that damages will not be an adequate or full remedy for Clonmel if an interlocutory injunction is granted and it is then determined that the SPC was invalid. Furthermore, it is plain that both parties have sufficient resources*

to pay any damages awarded. I do not consider, therefore, that the balance of potential irreparable harm favours either party decisively."

70. In my view there is no difference between the position of the parties in the case before this Court and the parties in *Merck Sharpe & Dohme*. In each case damages are available in the sense that each party would be in a position to satisfy an award of damages in favour of the other, and it cannot be said that the balance of potentially irreparable harm favours either party decisively.

71. A feature in *Merck Sharpe & Dohme* to which *"weight should be given"* was the fact that Merck was the holder of an intellectual property right granted pursuant to an authorisation process provided for by law. The Supreme Court held that as a matter of law, the SPC is valid and effective until declared invalid by a court of competent jurisdiction. This applies equally to the patent in this case. Following the decision in *Okunade v. Minister for Justice* [2012] IESC 49, [2012] 3 I.R. 152, O'Donnell J. said it was *"not unreasonable to give this greater weight in the balance than the interests of Clonmel which only arise after it is determined that the SPC is invalid."*

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

73. O'Donnell J. continued by stating that another way of giving value to the fact that the IP in issue has been granted pursuant to an authorised process provided for by law is that it represents the *status quo ante*. In *Merck Sharp and Dohme*, as in these proceedings, *"there was no unreasonable delay in the commencement of the proceedings, and the status quo must therefore be taken to be the position which existed prior to Clonmel's launch."* This is

a factor which applies with equal force to the facts in this case and it does not appear to have been adequately weighed in the balance by the High Court.

74. O'Donnell J. in *Merck Sharpe & Dohme* held that the same factor comes into play if consideration is given to the question of clearing the path. He held:-

> *"For the reasons discussed above, this cannot be treated as a single dispositive argument and, for example, in cases where the defendant might plausibly contend that his product did not infringe a patent, it might be of lesser weight. Here, however, the only issue is validity and, moreover, that issue itself is to be determined within the limited confines of Article 3 of the 2009 Regulation. Since, by definition, any generic challenger will have to have taken preparatory steps both of a practical and regulatory nature, it is, in my view, a legitimate factor to which weight should be given to consider that no steps have been taken to clarify the essential matters upon which Clonmel's right to launch the product depends: those concerning the question of the validity of the SPC."*

75. It seems to me that identical considerations apply in this case. The failure to clear the path cannot be treated as a single dispositive argument. In this case the only issue is the validity of the patent as the respondents seek to launch a generic product. The respondents have taken preparatory steps of a practical and regulatory nature, as had Clonmel, and it seems to me that it must follow that this is a legitimate factor *"to which weight should be given"* in this case. It is not apparent that the trial judge in fact weighed this factor in reaching his decision.

76. In relation to the assessment of the rival arguments as to the validity of the IP at issue in an interlocutory application, this was addressed at para. 63 of the judgment:-

> *"In cases where the balance of convenience may be finely balanced, it may be appropriate to have regard, even on a preliminary basis, to the strength of the rival*

> *arguments as they may appear to the court. Certainly, if it was apparent that Clonmel's case for invalidity was strong, and/or if there had been successive determinations in Clonmel's favour of a similar challenge in other jurisdictions, then that might weigh against the grant of an injunction."* (Emphasis added)

77. Pausing there, it is important to note that the threshold test is that the case for invalidity must be strong and/or that there have been successive determinations on the merits invalidating the right. Absent evidence to support a finding of a strong case for invalidity or a number of judgments on the merits to that effect, the threshold for weighing the argument for invalidity is not met and the court therefore ought not to weigh this argument in its assessment of the balance of justice. Second, where this threshold test is met it might weigh against the grant of an injunction. On the facts in *Merck Sharpe & Dohme* Clonmel's case had not been shown *"to have that degree of strength which would outweigh the factors in favour of the grant of injunction."*

78. Accordingly, the Supreme Court concluded that if the case was considered as of April 2018 that an interlocutory injunction ought to have been granted, subject to Merck's undertaking in respect of damages and directions for a speedy trial on the issue of validity.

Discussion

79. The issues in the case have narrowed on appeal. It is accepted that the appellants have raised a fair issue to be tried that the proposed launch of the generic will infringe the 873 patent. It is also not disputed that the respondents have raised a fair issue to be tried as to the validity of the patent. The trial judge found that damages would provide an adequate remedy for each party and that both would be in a position to satisfy any award of damages which might ultimately be made. While the appellants appealed this finding, the respondents have not cross appealed, so the adequacy of damages as a remedy for the respondents is no longer an issue. The real dispute on appeal was the trial judge's assessment of the balance of justice,

the weight he gave or failed to give to various factors – including the adequacy of damages as a remedy for the appellants – and whether he had regard to matters to which he ought not to have had regard in reaching his assessment.

80. Applying the decision in *Merck Sharpe & Dohme*, it seems to me that the following factors weigh in favour of granting the injunctions sought:-

(1) The right asserted by the appellants is *"one which arises pursuant to a lawful procedure for the grant of a patent… and which is valid until otherwise declared invalid by a court."* It is a right to which greater weight should be given than the interests of the generic manufacturer whose interest only arises after it is determined that the patent is invalid (para. 62).

(2) The interest of a generic manufacturer in a first mover advantage does not outweigh the rights of the patent holder.

(3) The patent enjoys a presumption of validity under EU law (*Phoenix*). It is entitled to interim and interlocutory protection without awaiting a decision on the merits of the validity of the patent (Article 9). It is entitled to the full panoply of protection from the date of registration (*Phoenix*).

(4) A divisional patent is separate from its parent and any challenge to the validity of the divisional patent must be separately determined (*Astrazeneca*). While the revocation of the parent patent will be relevant to the assessment of the validity of the divisional patent, the divisional patent enjoys a presumption of validity unless and until the divisional patent is separately determined to be invalid.

(5) There are procedures available to enable an interested party to challenge the validity of a patent. Where a generic manufacturer *"launches at risk"*, it elects not to avail of the procedures available to ensure that there is an orderly resolution of disputes as to validity. Effectively, for their own gain, they seek to

pre-empt the process and to obtain first mover advantage over other generic manufacturers (as well as possibly prematurely terminating the presumptively valid monopoly enjoyed by the rightsholder). Thus, the failure to clear the path is a factor to which weight should be given (para. 62).

(6) Where, as in this case, there has been no undue delay in seeking an injunction, the granting of an injunction will uphold the *status quo ante* (being the position prior to the launch of the generic product) and thus will recognise the value to be attributed to the holder of an intellectual property right granted pursuant to a lawful process (para. 62). It also accords with the policy of the Enforcement Directive and the decision in *Phoenix*.

81. The issue of the adequacy of damages to provide a remedy for the appellants if they ultimately succeed at trial will be considered further below.

82. It is necessary to determine whether these factors are outweighed by countervailing factors as assessed by the trial judge. As O'Donnell J. observed at para. 64, the balance is a fine one and the circumstances of particular cases may lead to different outcomes. The trial judge held that but for "*the unusual features*" of the case, the presumptive validity of the grant of the 873 patent "*would be dispositive*" of the application for an injunction.

Unlawful monopoly based upon the parent patent

83. The most important of these unusual features, according to the trial judge, was the fact that Biogen was paid significant sums of money by the taxpayer *"on the basis of a monopoly to which it was not entitled"* by reason of the revocation of the parent patent. *"This"*, he said, *"is not <u>just</u> and so it is a matter which… can be weighed in the balance when deciding what amounts to <u>justice</u> for Biogen in this case."* (para. 41). He held that this was the *"strongest factor"* (para. 60) and the *"decisive factor"* (para. 86) in his decision to refuse to

grant an interlocutory injunction. In my judgment, the trial judge erred in principle in having regard to this factor at all and *a fortiori* in concluding that it was the decisive factor against the granting of an injunction.

84. On the evidence before the High Court there was nothing unlawful in the conduct of Biogen in its application for and its exploitation of the parent patent. It applied for registration and the EPO granted registration of the parent patent. Thereafter the rightsholder was entitled to enjoy the rights conferred by registration to apply for a marketing authorisation of the product protected by the claim in the parent patent, Tecfidera®, and to supply the product on the market on foot of the marketing authorisation. The parent patent enjoyed a presumption of validity. There is nothing to suggest that any profits generated were in any way tainted or unjustly obtained. There were no gains unjustly made at the expense of the taxpayer.

85. The validity of the parent patent was challenged before the Opposition Division of the EPO and on appealed before the Technical Board of Appeal of the EPO. Each held that the patent should be revoked. However, this does not mean that the monopoly protection enjoyed by the rightsholder until the parent patent was revoked was in any way illegal. On the contrary, that would be inconsistent with the principle of the presumption of validity which every patent enjoys. What occurred in relation to the parent patent is in no way unusual; it is part and parcel of the way patents may, depending on the individual circumstances, be granted, exploited, enforced, challenged, and revoked.

86. Secondly, and equally importantly, the 873 patent is separate from the parent patent and what the appellants described as *"perceived dissatisfaction"* with what happened in the case of the parent patent cannot provide a valid basis for denying protection to the 873 patent. This would be to deny the separate rights enjoyed by each patent and the presumption of validity applying to each individual patent. It would also fail to give effect to Article 9 of the

Enforcement Directive, which specifically obliges Member States to ensure that interlocutory injunctions are available to prevent the imminent infringement of IP rights. Therefore, the profits earned by Biogen based upon the parent patent have simply no relevance to the issue whether the appellants are entitled to an injunction to restrain an infringement of the 873 patent. In my judgment the trial judge erred in principle in having regard to them and in weighing them as he did in determining the balance of justice on this application.

87. The trial judge cited, and the respondents referred to, no authority for the proposition that the public interest in the availability of cheaper generic drugs can override the rights of a patent holder in advance of a determination that the claim is invalid. This is hardly surprising as the proposition is contrary to principle. Such a proposition would inevitably mean that an injunction to restrain the launch of a generic product during the period a patent is registered will be refused; it would amount in effect to a derogation from Article 9 of the Enforcement Directive and would be incompatible with the judgment of the CJEU in *Phoenix*. It finds no support in the Patents Act, and counsel for the respondents advanced no basis for the proposition in his submissions to the court. It is also inconsistent with the reasoning in *Merck Sharpe & Dohme* where O'Donnell J. rejected arguments which would almost inevitably lead to either the granting or refusal of an injunction on the basis that *a priori* reasons did not represent the law, as they failed to reflect the essential flexibility of injunctive relief.

88. The trial judge referred to the decision of the Supreme Court in *Merck Sharpe & Dohme* and of the High Court in *Gilead Sciences Incorporated v Teva BV* [2019] IEHC 683 as supporting the proposition that he could have regard to the public interest in the introduction of generic drugs in determining the balance of justice in the case. He referred to para. 13 of *Merck Sharpe & Dohme* (quoted in para. 25 above) and concluded that

O'Donnell J. saw *"no issue"* in having regard to the public interest when considering the grant of interlocutory injunctions. I cannot agree with the trial judge's reading of this paragraph. In that passage the Chief Justice was commenting on the two competing interests in patent law and patent extension law, the second of which was the public interest in reducing the costs of drugs. He was not, at that part of the judgment, considering the factors to be weighed and considered by a court asked to grant an interlocutory injunction restraining an imminent infringement of a patent and so this reference does not support the conclusion of the trial judge.

89. *Gilead* concerned an application to revoke an SPC and McDonald J. considered the SPC Regulation (Regulation (EC) 469/2009 of the European Parliament and Council concerning the supplementary protection certificate for medicinal products)**.** He noted that recital 9 records that the duration of the SPC should be such as to provide adequate effective protection for the holder of the patent. At para. 70 he continued:-

> *"70. It is important however, to keep in mind that, as Recital 10 makes clear, the SPC Regulation also addresses the interests of public health. As the more recent case-law of the CJEU highlights, the public interest in promoting pharmaceutical research has to be balanced against the interests of public health more generally. For example, there is a competing public interest in ensuring the availability of drugs at a reasonable price. Recital 10 is in the following terms:-*
>
> > *"All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product."*

90. McDonald J. observed that the SPC Regulation balanced the public interest in promoting pharmaceutical research against the interests of public health generally in the context of determining the right to a rights extension by way of SPC. This observation is not relevant to the issues to be considered on an application for an injunction to restrain infringement of presumptively valid IP rights and it does not support the proposition that, in considering the balance of justice, the court can consider the public interest; as held by the trial judge in para. 78 of his judgment.

91. Thirdly, there was in fact no evidence that Biogen ever sought to restrain threatened or actual infringements of the parent patent or that there were, during the period of the registration of the parent patent, generic manufacturers anxious to enter the market but who were constrained from doing so by reason of the existence of the parent patent. In other words, there was no factual evidence underpinning the trial judge's criticism of the earnings of Biogen on foot of an *"unlawful monopoly at the expense of the taxpayer."*

92. Accordingly, it was not appropriate to weigh in the balance of justice the erroneous conclusion that *"Biogen has already had seven years of windfall revenue from its unlawful monopoly in Tecfidera®"* or the fact that the likely period of the injunction, which he estimated at between 12 and 18 months would be considerably less than *"the period of unlawful monopoly already granted to Biogen."* (para. 63*).*

Strong case for invalidity of the 873 patent

93. The second main basis for the decision of the High Court was the conclusion that the case for the invalidity of the 873 patent was strong and, according to the trial judge, therefore met the threshold referred to by the Supreme Court at para. 63. I respectfully disagree with this conclusion of the trial judge based upon the evidence (or the lack thereof) before him.

94. First, while the trial judge acknowledged the importance of the decision of the EPO to grant the 873 patent, he failed to give it adequate weight when he carried out his assessment of the case for invalidity. As was pointed out by the appellants, this was the only decision which addressed the merits of the claims of the patent, it was made by the Examining Division of the EPO, the expert body authorised under the EPC to do so, and it upheld the validity of the application by granting the patent. Further, this decision was made with full knowledge of the fact that the parent patent had been revoked, the grounds for same, and the fact that this was an application for a divisional patent. In addition, while not comparable to the procedure before the Opposition Division of the EPO, the Examining Division had received submissions of opposition to the grant of the divisional patent which raised the very issues relied upon by the respondents in these proceedings to assert that they have a strong case for invalidity. The awareness of the examiners of the issues raised by the application was further enhanced by the fact that one of the members of the panel which granted the 873 patent had been a member of the panel which held that the parent patent was invalid. The fact that the decision to grant the patent was short in no way detracts from the validity of the decision or in any way suggests that it should not be afforded due weight as a decision made with both knowledge of the claims and of the objections on the merits of the claim for registration.

95. Second, there was no independent expert evidence to support the respondents' assertion that they had a strong case for invalidity so that they should not be restrained from launching the generic. The trial judge relied upon the evidence of Dr. Ortel to reach his tentative conclusion that the respondents had met the threshold test. No doubt Dr. Ortel has great expertise in this area, and I would not wish this judgment to be read in any way to the contrary, but, as the respondents' German lawyer, he cannot provide independent expert testimony to this court as he is not an independent expert witness. In addition, part of his

case amounts to an unedifying *ad hominem* criticism of the members of the Examining Division who granted the 873 patent, which is of no assistance to this court, and does not, to my mind, overcome the obstacle to his thesis presented by that decision. It is also of note that he goes so far as to say that he disagrees with the EPO Guidelines in relation to the distinction between the formulae *"comprising"* and *"consisting of"*, a matter which is central to one of the arguments as to the validity of the 873 patent and accordingly a matter upon which expert testimony will be required. There was no affidavit or even report from an independent expert who could provide the evidence necessary to support a case that the 873 patent is invalid. As I have already stated, it is not simply a matter of reading across from the parent patent to the 873 patent. At the trial of these proceedings, if the respondents are to establish the invalidity of the 873 patent, they will do so based upon expert testimony as to how a reader skilled in the art would understand the claims in the patent and why it is invalid *inter alia* for obviousness and/or lack of novelty and/or added matter, as is asserted. If they wish to establish that they have a strong case for invalidity in order to resist the injunction sought, this requires that there be evidence as to invalidity and this in turn must be independent expert evidence. Absent such evidence, a court cannot be satisfied that the threshold has been met.

96. I do not in any way wish to prejudge the outcome of the trial on the merits in these proceedings. Suffice to say, in the words of O'Donnell J., the respondents' case has not been shown to have that degree of strength which would outweigh the factors in favour of the grant of an injunction.

97. The same applies to the respondents' reliance on the decisions from other courts. The court was not referred to any decision of a court of a Member State on the substance of the allegation that the 873 patent is invalid. The only decision on the merits is the decision of the EPO to grant the 873 patent. This is the decision of the expert body charged under the

EPC to decide whether to grant a patent and whether to revoke a patent which has been granted and, as such, the decision must carry weight. The other judgments referred to in the High Court and later on appeal were all interlocutory decisions. In the first place the court should be cautious when considering interlocutory decisions as the tests for the grant of interlocutory relief differ between jurisdictions. Furthermore, an Irish court may have little or no information as to the evidence adduced in the court of the Member State. Evidence which might result in the withholding of injunctive relief in one jurisdiction might not meet the threshold to justify the refusal of relief in this jurisdiction when the presumption of the validity of the patent and the provisions of Article 9 are considered. When the case was before the High Court, three courts had ruled on applications for injunctions. Courts in Germany and France had refused to grant injunctions while in Sweden one had been granted. By the time the appeal was heard, a court in the Czech Republic had granted an injunction and one in Spain had granted partial relief, while courts in Belgium, Estonia and Austria had refused injunctions. Thus, the decisions of the courts of Member States are not consistent one way or the other. Counsel for the respondents urged the court to follow the decision of the German Patent Court based on the cogency of the reasoning and the authority of this admittedly expert court. I do not in any way wish to detract from what was said in that regard, but the fact remains that it is difficult for this court to place great weight on the decision when it is not clear what evidence was before the German court (though there seems to have been some expert evidence), what arguments were advanced, and where a test different to that in Ireland is applicable.[2]

98. In *Merck Sharpe & Dohme*, O'Donnell J. said at para. 63 that where the balance of convenience may be finely balanced it may be appropriate to have regard, even on a preliminary basis, to the strengths of the rival arguments as to validity. He went on to say

[2] It appears that the threshold test is whether the patent is *"likely"* to be invalid and thus different to the assessment to be conducted by this court.

that if there had been *"successive determinations"* in the generic manufacturer's favour of a similar challenge in other jurisdictions, this might weigh against the grant of an injunction. It seems to me that O'Donnell J. was not referring to the outcome of interlocutory applications. He was considering the question of the strength of the argument as to invalidity and therefore the reference to successive determinations of a similar challenge must be to decisions on the validity of the patent on grounds similar to those relied upon in the proceedings before the court. In this case there are no such decisions. There are only interlocutory decisions. Further, the decisions are not consistent. In some instances, injunctions were granted and in other cases they were not. The phrase *"successive determinations"* suggests that something more consistent, though not necessarily unanimous, is required than is apparent from the information furnished to this court.

99. Accordingly, I am not satisfied that the threshold for the court to consider the strength of the arguments on validity/invalidity is met on the facts in this case. It follows that this is not a factor upon which the trial judge ought to have relied in his decision to refuse the injunction sought and it does not displace the presumption of validity in the application for interlocutory relief.

100. The appellants appealed the trial judge's finding that damages would be an adequate remedy for both of the appellants, but not the finding that they would adequately compensate the respondents if the patent is ultimately revoked but in the meantime the respondents were restrained from launching the generic. They say that there is no difference between their position in this case and that of the plaintiff in *Merck Sharpe & Dohme*. I agree. In that case O'Donnell J. concluded (para. 61) that damages would not adequately compensate either party in the event that they lost the injunction application but succeeded at trial. The trial judge has not adequately explained why he reached the opposite conclusion when there were no material differences in the facts. In my judgment, as there was no material difference, he

ought to have reached the same conclusion as the Supreme Court on the issue of the adequacy of damages to compensate the appellants if they ultimately succeeded at trial, but the respondents had launched the generic in the interim.

101. For these reasons I am of the view that the trial judge erred in his determination that these *"unusual features"* outweighed the presumptive validity of the 873 patent. Accordingly, the presumptive validity of the patent was properly determinative of the balance of justice on all the facts in this case, contrary to the trial judge's conclusion at para. 66, and an injunction ought to have been granted.

102. In my opinion the trial judge was correct to discharge the order of Owens J. of 2 August 2022. O'Moore J. granted the appellants an interim order and gave liberty to effect short service of the motion for interlocutory relief to the next sitting day of the Court. The clear intention of all concerned was that the respondents would be heard – or at the very least be afforded an opportunity to be heard – before a court would make an interlocutory order. The justice of the case clearly required that the respondents be heard on this issue which was of such importance to them. On the uncontested facts, the respondents first became aware of the application after Owens J. had made his order on the morning of 2 August 2022 through no fault of theirs (save possibly their refusal to correspond with the appellants and thereby identify a person or firm who could have been notified of the making of the order on 29 July and the return date of 2 August 2022). In the ordinary way, had the respondents been aware of the application in advance, they would have attended court and applied for an adjournment to afford them the opportunity to file replying affidavits, in which case almost inevitably, the interim injunction would have been continued until further order and the application for an interlocutory injunction adjourned. While the appellants cannot be faulted for the service actually effected (save possibly for the slight delay), that does not mean that justice still did not require that the respondents be afforded a genuine opportunity to be heard before the

court made an interlocutory order. Once the error which occurred became apparent and the respondents made it clear that they wished to oppose the grant of an injunction, the only way this could be achieved, and the justice of the case met, was by doing precisely what the trial judge did: discharge the interlocutory injunction which had been obtained in the absence of the respondents, and hear the application *de novo inter partes*. The rights of the appellants were in no way impaired by this approach and to have taken any other course would have been to deny the respondents the opportunity to be heard on a matter of great importance to them.

Conclusion

103. The trial judge erred in having regard to the benefits which accrued to the appellants from the parent patent at the expense of the taxpayer prior to its revocation when determining that they were not entitled to an injunction to restrain an imminent breach of the divisional patent, the 873 patent. The monopoly enjoyed prior to the revocation of the parent patent was not unlawful and the profits generated were not tainted with impropriety.

104. The profits derived from the exploitation of a registered patent which is subsequently revoked is not a matter to which a court may have regard when considering an application to restrain infringement of a different patent. In so doing the High Court failed to give effect to the separate rights enjoyed under each patent and the presumption of validity which applies in favour of each patent until revoked.

105. The trial judge erred in concluding that the public interest in cheaper drugs can override the rights of the patent holder in advance of a determination that the claim is invalid and that this was a decisive factor against the granting of an injunction.

106. The trial judge erred in tentatively concluding that the respondents' case for the invalidity of the 873 patent was strong and accordingly was a factor which justified the court in refusing to restrain the respondents from launching the generic. He did so in the absence

of independent expert evidence which could support his conclusion. It was not sufficient to rely upon the opinion of the respondents' expert lawyer. In reaching his conclusion he failed to give appropriate weight to the decision of the Examining Division of the EPO to grant the 873 patent.

107. The decisions of the courts of other Member States did not afford a basis to refuse the appellants relief. There were no judgments on the substance of the claim of invalidity. Furthermore, the decisions variously granted and refused interlocutory relief and could not be said to be *"successive determinations"* in the respondents' favour. Accordingly, the outcomes of the interlocutory applications in other Member States ought not to have been weighed against the grant of an injunction to restrain the imminent infringement of the 873 patent.

108. There were no material differences between the facts in this case and those in *Merck Sharpe & Dohme* which would justify the High Court in reaching the opposite conclusion to the Supreme Court on the question whether the parties could be adequately compensated by damages if they lost on the application for an injunction but succeeded at trial. The High Court erred in so doing.

109. The trial judge was correct to hold that the presumption of the validity of the 873 patent was determinative in favour of the grant of an injunction on the facts in this case, but he fell into error in concluding that this was outweighed by the *"unusual factors"* to which he erroneously had regard.

110. The trial judge was correct to discharge the injunction granted on 2 August 2022 in the absence of the respondents and to rehear the application for an interlocutory injunction, as any other course would have inflicted a grave injustice on the respondents with no corresponding detriment to the appellants.

111. For these reasons I would allow the appeal in relation to refusal of an injunction restraining the infringement of the 873 patent, but I would refuse the appeal in respect of the discharge of the injunction of the 2 August 2022. The matter will be listed for a short hearing on the form of the order and costs.

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