THE HIGH COURT

COMMERCIAL

[2022] IEHC 592

Record No. 2022/3782P

BETWEEN

BIOGEN MA INC.

AND

BIOGEN INTERNATIONAL GMBH

PLAINTIFFS

AND

LABORATORIOS LESVI S.L

AND

NEURAXPHARM IRELAND LIMITED

DEFENDANTS

JUDGMENT OF Mr. Justice Twomey delivered on the 26th day of October, 2022

INTRODUCTION

1. Should the public interest (in this instance, saving the taxpayer money) weigh in the balance of justice when a court is determining a dispute between two private parties, and, in particular, whether to grant an interlocutory injunction to one of those parties?

2. In this case, an interlocutory injunction is being sought in a patent dispute about a drug which is used to treat multiple sclerosis ("MS") and in particular to prevent the sale of a generic

drug. The public interest arises because the owner and marketing company of the patented drug at issue (the plaintiffs, together referred to as ("Biogen")) seek an injunction, pending the trial (at which the validity of the patent at issue will be decided). The injunction is being sought against the owner and marketing company of a competing generic drug (the defendants, together referred to as ("Neuraxpharm")).

3. If this injunction is granted, it will prevent the sale of the cheaper generic drug in Ireland and cost the HSE/taxpayer *circa* €8 million in the period of up to 18 months between now and the trial date.

4. This dispute between two large international pharmaceutical companies relates to the launch of a generic drug in Ireland to compete with a drug called Tecfidera. Like most patent disputes, it is a dispute about the money which is capable of being generated by the holder of a State-backed monopoly to supply a product/service based on the patent. In this case, the amount of money at issue is very significant, since Tecfidera had worldwide sales of $1.95 billion in 2021.

5. Biogen seeks to prevent the launch of the generic drug (Dimethyl Fumarate Neuraxpharm) by Neuraxpharm on the grounds that it infringes the underlying patent for Tecfidera, i.e. patent EP (IE) 2 653 873 (the "873 Patent"). The launch of the generic was originally planned for 1st August, 2022, but it was halted by the grant of an interim injunction on the 29th July, 2022.

6. However, Neuraxpharm claims that this 873 Patent underlying Tecfidera is invalid on the grounds that the parent patent of the 873 Patent, i.e. patent EP 2 137 537 (the "537 Patent") has itself been revoked on the basis, *inter alia*, that it did not involve an inventive step.

7. Furthermore, since Tecfidera is reimbursed in the amount of €1,030.80 per 240 mg dose by the HSE, while a similar amount of the generic has been agreed to be reimbursed by the HSE at €418.64 per 240 mg dose, Neuraxpharm claims that preventing the launch of its generic

drug will cost the taxpayer €5.5 million per annum. On this basis, it estimates that if an injunction is granted preventing the sale of the generic until the trial is heard in 12-18 months' time, the taxpayer will miss the opportunity to save *circa* €8 million.

8. The primary issue therefore which this Court has to resolve is whether an interlocutory injunction should be granted to Biogen preventing the sale of the generic drug in Ireland pending the trial of the action, which trial will determine whether in fact Biogen's patent is invalid, as alleged by Neuraxpharm.

PRELIMINARY ISSUE

9. However, this primary issue would not need to be addressed if this Court were to refuse to discharge the interlocutory injunction, which was granted to Biogen in August of this year and so is already in place. Accordingly, this Court must first deal with a preliminary issue, which is whether the interlocutory injunction, preventing the sale of the generic, which was granted during the court vacation (on 2nd August, 2022), should be discharged, on the grounds that it was granted in the absence of Neuraxpharm and so without hearing its side of the case (even though notice of the hearing had been served on Neuraxpharm in accordance with the relevant court order).

10. If the interlocutory injunction is discharged, then this Court will deal *de novo* with the question of whether Biogen is entitled to prevent the sale of the generic pending the trial, but now with the benefit of hearing from both sides.

Should existing interlocutory injunction be discharged?

11. The background to this preliminary issue is that an *ex parte* interim injunction was granted by O'Moore J. to Biogen on the morning of Friday 29th July, 2022, the last day of the legal term before the long vacation. The application for interlocutory relief was made

returnable to the next business day, which was during the vacation, i.e. Tuesday, 2nd August, 2022, the day after the Monday bank holiday.

12. The first and second defendants are part of the Neuraxpharm group of companies and O'Moore J. provided for notice of his order to be served on them by email (the first defendant is based in Barcelona and second defendant is based in Ireland), to clientes@neurapharm.com, dpo@neuraxpharm.com and CRO@fod.ie. The first two email addresses were obtained by Biogen from the Neuraxpharm group websites. The CRO@fod.ie email address was the address provided on the CRO B1C Annual Return form of the second defendant. According to the terms of O'Moore J.'s order, the email notices were to be served, within hours of the hearing, i.e. by 2pm of Friday, 29th July, 2022.

13. The very tight time return date for the interlocutory injunction, i.e. the next business day in Ireland, and the consequent very tight deadline for the delivery of the emails, is illustrated by the fact that even Biogen itself, the party with notice of the injunction, failed to serve the notices inside the timeframe set by the court. This is because the emails were served on the defendants some 53 minutes after the 2pm deadline.

14. On Tuesday 2nd August, the morning of the return date, there was no appearance on behalf of the defendants and Owens J. granted the interlocutory application. No criticism is made by the defendants of Owens J.'s decision in this regard, since he was not aware of why the defendants were not present. However, this Court has been provided with sworn evidence, which has not been disputed by Biogen that due to the bank holiday weekend and the use of customer facing email addresses, which were not consistently monitored, the lawyers in Neuraxpharm did not become aware of the Tuesday morning interlocutory hearing until Tuesday afternoon, which was obviously too late for them to appear in court.

15. At the hearing before Owens J., lawyers for Biogen suggested that any order granting the interlocutory injunction provide for liberty to apply to the defendants on 48 hours' notice

to the plaintiffs. Owens J. instead provided for 72 hours' notice in the order, presumably because he felt that, even though Biogen had suggested 48 hours' notice, a more reasonable period of notice (for Biogen, in light of the fact that Biogen would have to defend its obtaining of an interlocutory injunction), was 72 hours. The defendants duly exercised the right granted to them by Owens J., to seek the discharge of the interlocutory injunction in their absence, which they are now doing before this Court.

16. Undoubtedly, the lawyers for Biogen suggested to Owens J., that the defendants have liberty to apply, because the defendants were not represented at the hearing which granted the interlocutory injunction which was very detrimental to their interests as it was of significant commercial value and was likely to last for a period of 12-18 months. Therefore, it seems clear that, in making this suggestion, Biogen (or certainly its lawyers) felt that it was in the interests of justice that the defendants should be entitled to come back into court at any time, by simply giving 48/72 hours' notice to Biogen, in order to seek the discharge of the injunction which was obtained in their absence.

17. It also seems clear to this Court that the lawyers for Biogen, in suggesting the insertion into the order of liberty to apply, on the part of Neuraxpharm, were quite correctly discharging their overriding duty to the court to see that justice was being properly administered – overriding, that is, any duty to their client, Biogen.

18. In those circumstances, it seems ironic that their client, Biogen, is now instructing those same lawyers to contest the entitlement of the defendants to come into court to prevent the very application (to discharge the interlocutory injunction obtained in their absence), which their lawyers felt they should be entitled to make (in the interests of the proper administration of justice).

19. However, as strange as that may seem, that is the very position adopted by Biogen at this hearing. It has been described by Neuraxpharm as Biogen being opportunistic in seeking

to retain the 'windfall' benefit of obtaining an interlocutory injunction on an unopposed basis. While Biogen may be perfectly entitled to take this approach, it does appear to this Court to be a particularly unappealing one in all the circumstances.

20. Before considering why this is the case, it is relevant to note that it is not disputed by the parties that this Court has the jurisdiction to discharge an interlocutory order in the interests of justice (see for example *Irish Bank Resolution Corporation Ltd (in special liquidation) v. Quinn* [2015] IECA 84 at para. 62). It seems to this Court that this is particularly the case where an order has been granted at a court hearing in the absence of the party affected by the order, in this case Neuraxpharm, which has very significant financial consequences for a period of *circa* 18 months.

Why Neuraxpharm did not appear at the first interlocutory hearing

21. Uncontroverted sworn evidence was provided on behalf of the defendants explaining their absence from the hearing before Owens J. The defendants aver quite simply that they only became aware on Tuesday afternoon of the fact that the hearing of the application for an interlocutory injunction was to be, and was duly, held on Tuesday morning, because the email addresses to which the notices were sent were customer facing and not consistently monitored. In this regard, it is also to be noted that Biogen sent an email to info@neuraxpharm.de, which it got from a Neuraxpharm website. Neuraxpharm acknowledges that it received an email at info@neuraxpharm.com (which appears to be referring to this email). However, this email was also customer facing and not consistently monitored. In addition, on the afternoon of 29th July, 2022, hard copy notices were hand-delivered to the registered office of the second defendant in Dublin. However, these were delivered to an employee of a different company, Uniphar, that happened to share the registered office with the second defendant.

Notice of a hearing on the next business day

22. These averments regarding how and why Neuraxpharm were not at the hearing seem to this Court to be entirely plausible. First, this is because these notices, which were received by email addresses which are not constantly monitored, were received on a Friday afternoon about a hearing to be held on the next business day (Tuesday), in the case of the second defendant (since it is based in Ireland and the Monday was a bank holiday).

23. In the case of the first defendant, the notices were about a hearing to be held the second next business day in a foreign country (since this defendant is based abroad). In this regard, it is to be noted that the court rules grant defendants who are based abroad significantly more leeway regarding time periods, obviously in order to facilitate them getting local legal representation and advice from abroad e.g. the Plenary Summons in this case provides for the first defendant, who is based abroad, to have five weeks to enter an appearance in contrast to the second defendant, based here, who has eight days.

24. In addition, although the first defendant is based abroad, it seems likely that a key factor in O'Moore J. choosing a very short return date for the interlocutory injunction (the next business day) was that its sister company, the second defendant, is based in Ireland. Accordingly, a key consideration for this Court, in considering this discharge application, is the fact that the second defendant, based in Ireland, was being notified of a return date which was exceptionally short, namely the next business day.

Notice to be served on last day of term and a bank holiday weekend

25. In these circumstances, Biogen must have known that it was at least a possibility that the legal personnel in Neuraxpharm would not be aware of the hearing in time. Quite simply, this was because the emails were being sent to a general email address obtained from the company's website on the afternoon of the last day of term when many lawyers have already begun or were beginning their holidays. However, it was not just the last day of term, but it was also the afternoon of the August bank holiday, when some personnel might leave early.

Added to this was the fact that an unusually short return date was provided for, namely the next business day, Tuesday, 2nd August.

Short return date likely to have been granted for the benefit of Neuraxpharm

26. In this regard, no criticism was made by the defendants of O'Moore J. in relation to the order granted. In fact, the defendants argued that the very short return date was undoubtedly chosen by O'Moore J. in order to ensure that the defendants could seek to discharge a very damaging injunction to its business, which had been obtained in their absence, at the earliest possible moment. It was not granted so that Neuraxpharm might be caught on the hop over the bank holiday weekend or indeed so that Biogen might get the windfall of an interlocutory injunction lasting 18 months and so a huge financial benefit to it and a huge detriment to Neuraxpharm, in its absence.

27. In these circumstances, it would be ironic if the effect of the very short return date (chosen by O'Moore J. undoubtedly for Neuraxpharm's benefit) would be to leave Neuraxpharm in the position that it was subject, not just an to *interim* injunction obtained from O'Moore J. in their absence, but also an *interlocutory* injunction obtained in their absence from Owens J. (simply because they had missed the very short return date by a few hours). Yet this is the effect of Biogen's decision to contest the application by Neuraxpharm to discharge the interlocutory injunction granted by Owens J. Biogen is seeking to have the benefit of this very valuable injunction, which is detrimental to Neuraxpharm's business, without a court ever hearing Neuraxpharm's side of the story.

No tactical reason for Neuraxpharm to miss the hearing

28. Not only is it entirely plausible that Neuraxpharm did not become aware of the court hearing until it was too late, but also, there would appear to be no logical reason why Neuraxpharm would, if it had been aware of the hearing, not have sought to attend same and seek an adjournment to allow it to defend the application. In other words, there appears to be

no tactical advantage to Neuraxpharm coming into court now to seek the discharge of an interlocutory injunction, when this could have been avoided simply by the attendance of their lawyers on 2nd August to seek an adjournment, which no doubt, would have been granted, to enable it to put in the affidavits and legal submissions which have since been provided to this Court.

29. In this regard, it seems to this Court that it would be unjust if Biogen were to be the ones benefiting from the very short return date granted by O'Moore J., undoubtedly to benefit Neuraxpharm, by it obtaining an interlocutory injunction for *circa* 18 months, without having to deal with any opposing arguments in court.

But it was 'bad form' of Neuraxpharm to ignore pre-litigation letters?

30. This Court does not accept Biogen's argument that the fact that Neuraxpharm failed to reply to three pre-litigation letters sent by Biogen on the 5th May (from Herbert Smith Freehills), 24th June, and 20th July, 2022 (from McCann Fitzgerald), in which Biogen threatened to issue proceedings, is sufficient for this Court to exercise its discretion against the discharge of the interlocutory injunction.

31. In this regard, Biogen argues that if Neuraxpharm had responded to these pre-litigation letters, it would have provided Biogen with the names of solicitors in Ireland upon whom proceedings could have been served. This would, Biogen argues, have obviated the need to serve the notices on the defendants using emails addresses found on Neuraxpharm websites.

32. However, this Court does not accept this argument since there is no obligation upon a company which intends to launch a generic drug to respond to *in terrorem* letters from patent holders. Indeed, this claim, that it was 'bad form' of Neuraxpharm not to reply to these letters (even though there was no legal obligation upon it to do so), is a double-edged sword. This is because that same argument could be used against Biogen, when it issued the Plenary Summons on 28th July, 2022. It must have known that it was going to seek an *ex parte* injunction the

following day. Accordingly, it could equally be said that it was 'bad form' of Biogen not to attempt, on the 28th July, to notify Neuraxpharm that proceedings had commenced, rather than waiting until after it had obtained the interim injunction. It is quite conceivable that if Biogen had done so, lawyers would have been present in court on the Tuesday 2nd August to seek the adjournment of the application (to enable the preparation of affidavits and submissions that are now before this Court). This is the danger of relying, not on the breach of legal obligations to justify the exercise of this Court's discretion, but rather on whether something was 'bad form' or not.

33. For all these reasons, this Court believes that it is in the interests of justice, to discharge the interlocutory injunction granted in this case. It does so because it seems to this Court, as a general principle, that where an injunction, which is likely to last for 18 months and be of significant commercial effect, is obtained against a party, when that party was not present, then that party should be afforded an opportunity to have its side of the story heard in court, unless it has been established that it was aware, or should have been aware of the hearing, and then negligently or deliberately decided not to attend the injunction hearing.

34. This Court will now consider, having heard both sides of the argument (unlike Moore J. or Owens J.) whether Biogen is entitled to an interlocutory injunction preventing Neuraxpharm from selling its generic drug in Ireland, which would have the effect of extending the interim injunction which was granted by O'Moore J. on an *ex parte* basis.

BACKGROUND TO SUBSTANTIVE APPLICATION

35. On 29th May, 2013, the 537 Patent (also, the "Parent Patent") came into effect. This was the underlying patent for Tecfidera, which was duly authorised as a medicinal product for the treatment of MS on 30th January, 2014. From the 1st March, 2015, Tecfidera was capable of being prescribed in Ireland under what is known as the High Tech Scheme. The High Tech Scheme provides for the supply and dispensing of high-tech drugs, whereby the HSE purchases

the drug and supplies it to pharmacies, which are then paid a patient care reimbursement fee. In this way, Tecfidera is available to patients at no cost, or at a heavily subsidised cost, which the HSE bears.

36. It is relevant to note that the 873 Patent, which is allegedly being infringed by Neuraxpharm (and so is the basis for the interim injunction), was only granted by the Examining Division of the European Patent Office ("EPO") on the 20th July, 2022 and so just 9 days prior to the grant of the interim injunction by O'Moore J.

37. It is important to note that his 873 Patent is a divisional application of the Parent Patent and so the 873 Patent is also referred to herein as the "Divisional Patent". This Divisional Patent expires on 7th February, 2028 and so it grants Biogen a monopoly over the sale of Tecfidera for a period of almost five and a half years from now.

The Parent Patent is invalid

38. However what Neuraxpharm says is of crucial significance in this case is the fact that on 13th June, 2016 the Parent Patent was revoked by the Opposition Division of the EPO. The Opposition Division found, *inter alia*, that the Parent Patent did not involve any inventive step.

39. Almost 6 years later, on 20th January, 2022, the Technical Board of Appeal affirmed this revocation of the Parent Patent. It did so on the ground of added matters. It is to be noted that there was no need for the Technical Board of Appeal to revoke the patent on any other grounds dealt with by the Opposition Division, such as the fact that the Parent Patent lacks an inventive step. This decision of the Technical Board of Appeal is final. Thus, two independent bodies have found that the Parent Patent, which until 20th July, 2022, was the patent underlying Tecfidera, should not have been granted.

Taxpayer pays significant sums to Biogen on basis of unlawful monopoly in Tecfidera

40. This means that since 1st March, 2015 until 20th July, 2022 in Ireland, Biogen had an unlawful monopoly in Tecfidera at, what is likely to have been, a significant cost to the

taxpayer. In this regard, uncontroverted submissions were made by Neuraxpharm that the current cost of the Biogen monopoly in Tecfidera is €5.5 million per annum, since this is the saving which the HSE would make each year if there was no such monopoly (and Neuraxpharm's generic drug was instead available to patients).

41. No figures were provided to this Court for the cost to the taxpayer of this unlawful monopoly for the period March 2015 - July 2022. Therefore, it cannot be assumed that there would have been a saving of €38.5 million (7 x €5.5 million) to the taxpayer if Biogen had not succeeded in obtaining an invalid patent. However, whatever the precise figure, 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 *just* and so it is a matter which, although not dispositive of this application, can weigh in the balance when deciding what amounts to *justice* for Biogen in this case.

The law in relation to interlocutory injunctions

42. There is no dispute between the parties regarding the law applicable to the grant of interlocutory injunctions. Both parties place particular reliance on the importance of the recent Supreme Court decision in *Merck Sharpe and Dohme v. Clonmel Healthcare* [2019] IESC 65.

43. It is clear from this decision that for Biogen to be granted an interlocutory injunction, it must establish that:

- if it was to succeed at the trial, a permanent injunction, in the same form sought pending the trial, might be granted by the trial judge;
- that there is a fair issue to be tried;
- if so, that the balance of justice (but more traditionally referred to as the balance of convenience) favours the grant of an injunction pending the trial and, in this regard, the most important element is usually the question of the adequacy of damages.

Likelihood of permanent injunction and fair issue to be tried?

44. There was no real dispute between the parties regarding the first and second parts of the test for an interlocutory injunction. It is clear that there is a fair issue to be tried regarding whether the defendants have infringed the Divisional Patent and the connected issue of whether the Divisional Patent is valid. It is also clear that if Biogen were to succeed at that trial and establish that the Divisional Patent is valid, that it would obtain a permanent injunction against Neurxapharm.

The 'adequacy of damages' part of the balance of justice test

45. As regards the adequacy of damages element of the balance of justice, Biogen claims that damages would not be an adequate remedy for it because of the difficulties in assessing its damages (if it turns out the 873 Patent is valid, but this Court wrongly refused the injunction).

46. In this regard, Biogen points out that there are other generic companies interested in entering the market in the event of, what Biogen describes as, a 'free for all', if its monopoly in Tecfidera comes to an end (by the refusal of the injunction). Biogen claims that this entry by other generic companies will make it difficult for a future damages' hearing to establish the extent to which Neuraxpharm is liable for Biogen's loss. Similarly, Biogen points to the difficulty of assessing damages arising from the price depression which it says will apply to the cost of Tecfidera when a generic enters the market. Biogen also points, in particular, to the difficulty with restoring the price of Tecfidera after the trial (assuming the 873 Patent is held to be valid) and to which O'Donnell J. referred as one of the factors in favour of the grant of injunctions in patent cases - at para. 18 of *Merck.*

47. For its part, Neuraxpharm claims that its damages would be more difficult to assess (if the injunction were wrongly granted), than Biogen's would be (if the injunction were wrongly refused), and that this factor favours the refusal of the injunction. This is because Neuraxpharm

claims that it is a brand-new entrant to the market and therefore if the injunction is wrongly granted (because the 873 Patent ends up being held by the trial judge to be invalid), it will be difficult to assess what Neuraxpharm's market share would have been if it had not been (wrongly) prevented from entering the market.

48. In contrast, it points out that Biogen has a clear record of its current sales and therefore it will be easy to assess the loss to it if the generic drug is allowed into the market (and it subsequently transpires that it should not have been because the 873 Patent is held to be valid).

49. Neuraxpharm also argues that if it is prevented from entering the market it will lose its first mover advantage which may be difficult to quantify (which was recognised by O'Donnell J. at para. 56 of *Merck* as something to which weight should be given).

50. In considering both sides' claims regarding the inadequacy of damages, it is important to bear in mind that in this case one is dealing with two very large international commercial entities. It seems clear that whichever party wins at the trial, there is no question but that the other party will be in a financial position to meet a damages award if it is found that the injunction was incorrectly granted or refused.

51. Indeed, as noted by O'Donnell J. in *Merck* at para. 36 there will be many cases where there is some element of unquantifiable damage and where both parties can allege some irreparable harm. In fact, it seems to this Court that this is exactly what is happening here, with two corporate clients coming to court with high-powered legal teams with ingenious and persuasive arguments as to why damages would not be adequate for their side.

Robust scepticism of claims that damages are not an adequate remedy

52. However, in all these circumstances, the passage from *Merck* which seems most relevant to this case, but which was not relied upon by either party, is the point made by O'Donnell J. (at para. 65) that '*courts should be robustly sceptical of the claim that damages are not an adequate remedy'.*

53. Applying that scepticism here, this Court is of the view that in reality there is little or nothing between the parties regarding the adequacy of damages and that for both parties it will be *difficult* to calculate precisely the exact amount of financial harm suffered by them. However, it will *not be impossible* for a court at a future date to give a reasonable estimate of the damages suffered. Accordingly, for both parties, damages will be an adequate remedy if it turns out the injunction was wrongly refused or wrongly granted at this interlocutory stage.

The rest of the balance of justice

54. It is clear from *Merck* that the question of the adequacy of damages is to be considered by a court as part of the balance of justice, *albeit* that it is the most important part in some cases.

55. Since the adequacy of damages is not dispositive of this case, this Court must now consider the other circumstances of the case which are relevant to the balance of justice. In this regard, it is relevant to note that at para. 64 in *Merck*, O'Donnell J. observes that an interlocutory injunction is a flexible remedy and the balance is often a fine one, when deciding whether to grant or refuse an injunction, which is affected by the circumstances of the particular case.

56. This is a case where there are strong arguments in favour of the grant (namely that Tecfidera is currently subject to a legal monopoly, *albeit* one that was only a few days in existence when the interim injunction was granted) and against the grant (namely that the Parent Patent of the Divisional Patent underlying Tecfidera has been revoked and also that in seeking the injunction to protect/extend its monopoly over Tecfidera, Biogen, has benefited from an unlawful monopoly for several years).

57. In this regard, it is also clear from para. 63 of *Merck* that where there is a fine balance between the parties, as in this case, that '*it may be appropriate to have regard, even on a*

preliminary basis, to the strength of the rival arguments'. It is for this reason that this Court has regard hereunder, to, *inter alia*, the merits of the case.

Tipping the fine balance in favour of refusing the injunction

58. The following are the circumstances which this Court believes tip the fine balance, to which O'Donnell J. refers, in favour of refusing the injunction, even though the starting position is that Biogen has a Divisional Patent that has a presumption of validity and, as is clear from *Merck* at para. 63, the arguments regarding its invalidity need to be strong before it could weigh against the grant of the injunction.

59. It is important to note that, in reaching this conclusion, this Court is cognisant of the presumption of validity which applies to a patent. However, it feels that the special and unusual circumstances of this case justify this presumption of validity not taking precedence over those other factors, set out below, which are weighed in the balance when considering the balance of justice:

Biogen has had an unlawful monopoly in Tecfidera for seven years

60. By far the strongest factor is one which is perhaps an unusual feature of this case. Crucially it is one that is not open to dispute (unlike some of the arguments that might go either way at the trial). This is the fact that Biogen has had seven years' monopoly in Tecfidera to which it was not entitled.

61. In this regard, it is to be observed that when the courts are considering the various steps which are used to determine whether to grant an interlocutory injunction, the term *balance of justice* is sometimes used instead of *balance of convenience* (see for example, at para. 35 of *Merck*). It seems to this Court that the term *balance of justice* is particularly appropriate in this case, and indeed perhaps more generally, since it more accurately focuses a court's mind to the task in hand when determining whether to grant an interlocutory injunction. This is because the task for the court is to do justice, in particular between the parties (and, as noted hereunder,

to a lesser degree perhaps, to the public interest). This is clear from the judgment of O'Donnell J. at para. 64, where he notes that the fundamental objective is to minimise injustice.

62. The term balance of justice also highlights the fact that another way to consider whether to grant an interlocutory injunction is to ask which outcome is likely to lead to the least risk of injustice to the parties, since as noted by Clarke J. in *Okunade v. Minister for Justice* [2012] 3 I.R 152 at para. 9.5 in relation to interlocutory injunctions:

> *"[The] court is being asked, on the basis of limited information and limited argument, to put in place a temporary regime pending trial in the full knowledge that the court does not know what the result of the trial will be. It seems to me that, recognising that a risk of injustice is an inevitability in those circumstances, the underlying principle must be that the court should put in place a regime which minimises the overall risk of injustice*".

63. In this regard, in considering whether it would cause an injustice to Biogen to be refused an injunction, which will end its monopoly in Tecfidera, it seems to this Court that any such injustice is lessened by the fact that Biogen has already had seven years of windfall revenue from its unlawful monopoly in Tecfidera. It is also lessened by the fact that the likely period of the injunction, of 12-18 months, is considerably less than the period of unlawful monopoly already granted to Biogen, of seven years.

Divisional Patent is a derivative of invalid Parent Patent

64. The second factor is also an objective fact which cannot be disputed (at the trial or at this interlocutory stage) and that is that the Parent Patent has been definitively held to be invalid and one of the grounds of invalidity is that the Parent Patent lacks an inventive step. This is important because the Divisional Patent, upon which Tecfidera now relies for its monopoly, is clearly, by its very nature, derivative of, and a subset of, the Parent Patent. In this regard, it is relevant to note that Neuraxpharm has opposed the grant of the Divisional Patent at the EPO

and that it will claim in these proceedings (as a counterclaim to the injunction) that the Divisional Patent is invalid.

65. Accordingly, this is not a case where this is a standalone patent which is presumed to be valid and there are no objective arguments against that presumption. While this Court cannot at this stage make a finding that the Divisional Patent is invalid, this Court is entitled to reach a '*tentative view of the merits*' of the case, when determining the balance of justice (per O'Donnell J. at para. 63 of *Merck*).

Case for invalidity of Divisional Patent is strong

66. In this regard, this Court concludes, *albeit* on a tentative basis, that Neuraxpharm's case for invalidity is strong. This is because:

The Parent Patent, which protected Tecfidera for the past seven years in Ireland, is invalid.

The Divisional Patent which now protects Tecfidera is a derivative of that invalid Parent Patent, which Parent Patent has been found to lack an inventive step.

Dr. Ingo Ortel ("Dr. Ortel"), the patent attorney for Neuraxpharm, averred that the only difference between the Divisional Patent and the Parent Patent is the use of the word *'comprising'* instead of '*consisting of'*, as illustrated hereunder:

873 patent - Claim 1	537 patent - Claim 1
A pharmaceutical composition for use in the treatment of multiple sclerosis, said composition **comprising**: dimethyl fumarate or monomethyl fumarate, and one or more pharmaceutically safe drug carriers, wherein the composition is to be administered orally to a patient in need of treatment for multiple sclerosis and wherein the dose of fumar acid dimethyl ester or fumar acid monomethyl ester to be administered is 480 mg per day. (Emphasis added)	A pharmaceutical composition for use in the treatment of multiple sclerosis, said composition **consisting of:** dimethyl fumarate or monomethyl fumarate, and one or more pharmaceutically safe drug carriers, wherein the composition is to be administered orally to a patient in need of treatment for multiple sclerosis and wherein the dose of fumar acid dimethyl ester or fumar acid monomethyl ester to be administered is 480 mg per day. (Emphasis added)

At para. 4.20 of the *Guidelines for Examination in the European Patent Office*, it is stated that the term *'comprising'* is to be interpreted as meaning that it '*includes those features, but that it does not exclude the presence of other features'.* On the other hand, these Guidelines state that the term '*consist of*' means that '*no further features are present in the apparatus/method/product'.* What the foregoing table illustrates is that the only difference between the Divisional Patent and the Parent Patent is that the Divisional Patent uses broader language and so suggests that other features may be present in the patent. However, Dr. Ortel avers that if the narrower patent (the Parent Patent) is not based on an inventive step, then this applies *a fortiori* to the broader patent. Similarly, he observes that the minor difference in wording between the Parent Patent and Divisional Patent does not affect the Opposition Division's reasoning which led to the revocation of the Parent Patent. While 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.

<u>However the Examining Division considered these arguments</u>

Notwithstanding these issues, it is of course the case that the Examining Division of the EPO granted the Divisional Patent. The reasons the Examining Division gave for discounting the views of third parties, that the Divisional Patent should not be granted because the Parent Patent was invalid, are brief and are stated as follows:

> "The decision T1773/16 concerning the parent file relates to a different set of claims, more particularly they differ in that they are limited by the expression "consisting of".
>
> The present set of claims is drafted with the term comprising and therefore, not limited to *one sole active ingredient* discussed by T1773/16 as originating a selection.

> Therefore, the conclusions reached by the respective [Board of Appeal] do not apply to the present case. The examining division considers that claim 1 is not the result of a selection from two lists and complies with the requirements of Art. 123 (2) EPC.
>
> The arguments provided in the TIPAs in relation to Art. 56 EPC relate to the parent application. The present divisional application is a new application, independent from the parent. The arguments provided by the [Opposition Division]in relation to the parent have been considered and found that are not applicable to the present divisional."

<u>There is also a presumption that the Divisional Patent is valid</u>

In addition to this, Biogen also relies on the decision of the CJEU in Case C-44/21 *Phoenix Contact GmbH & Co. KG v. Harting Deutschland GmbH & Co. KG,* in which at para. 41 it is stated 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*."

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.

However, it is important to bear in mind that a presumption of validity, while persuasive, is simply that, a presumption, and in this case, it is the cumulative effect of all the factors in the balance of justice which leads this Court to its conclusion that the balance of justice favours the refusal of the injunction.

<u>Neuraxpharm did not 'clear the way' before planning to launch the generic drug</u>

Biogen claim that the injunction should be granted since Neuraxpharm sought to launch the generic in Ireland on 1st August, 2022, yet it failed to 'clear the way' in this jurisdiction by commencing invalidity proceedings against the Divisional Patent and prosecuting them

to a conclusion. Biogen relies on para. 62 of *Merck* to say that weight should be given to the failure to 'clear the way' in the determination of interlocutory injunction applications. However, this factor is of less significance in this case. This is because Neuraxpharm had already cleared the way in relation to the Parent Patent by successfully obtaining determinations of invalidity against the Parent Patent before both the Opposition Division and the Technical Board of Appeals. Thus, in circumstances where there are strong arguments, that the Divisional Patent suffers from the same invalidity as the Parent Patent, it seems to this Court that a claim that Neuraxpharm should have cleared the way, is, in effect, a claim that it should have cleared the way a second time, in relation to a patent that had only come into existence 12 days prior to its launch of the generic. This is not a particularly compelling factor in favour of granting an injunction in this case. This is particularly so where Dr. Ortel makes the point that a divisional application can be filed at the EPO at any time during the life of the Parent Patent, which opens the possibility of applicants filing divisional applications for strategic reasons to have a pending application even after the revocation of a parent patent.

Judgments in other jurisdictions which have rebutted the presumption in this case

67. It is relevant to note that, there have been three cases in other European countries in which Biogen sought an injunction preventing Neuraxpharm selling its generic drug after both the revocation of the Parent Patent and the grant of the Divisional Patent. It is a further factor in the balance of justice in favour of refusing the injunction (*albeit* not dispositive on its own) that, in two out of those three cases an injunction was granted despite the presumption of validity. The first case was in Sweden, the second was in Germany and the third was in France (and this later case was brought to the Court's attention, with the consent of both parties, after the hearing concluded).

68. The decision in Sweden in the case of *Biogen International GmbH v. Neuraxpharm Sweden AB* Annex 99, Case No. PMT 10739-22 was made by the Stockholm District Court on the 19th September, 2022 and granted Biogen the injunction on the grounds that there '*are probable grounds for the continued existence of the exclusive right conferred by the patent'.* In many ways this is not that surprising in light of the presumption of validity, to which the court in that case referred.

69. However, what might be regarded as *prima facie* surprising is the fact that the German Court and the French Court, despite this presumption of validity applying to the Divisional Patent, both refused an injunction to Biogen. The Düsseldorf Regional Court in *Biogen MA Inc. v. Neuraxpharm Arzneimittel GmbH* 4b O 54/22 held on the 22nd September, 2022 that it considered it:

> *"[M]ore likely in the present case that the parent for revocation will be revoked for lack of inventive step than it will withstand the attack on the validity of the patent."*

Accordingly, the German Court refused the injunction.

70. In France, in *France SAS and Biogen MA Inc. v. Mylan Ireland Limited and SAS Viatris Sante* N° RG 22/55799 - N° Portalis 352J-W-B7G-CXST V, the Paris Judicial Tribunal held on 6th October, 2022 that:

> "*[T]here is no need for an interim injunction in view of the serious plea that calls into question the apparent validity of the patent on which the claims of Biogen MA and Biogen France are based".*

71. It is important to note that these decisions, although of some relevance, are not crucial factors in this Court's decision. This is because they do not deal with the validity of the patent, as envisaged by O'Donnell J. at para. 63 of *Merck,* when referring to the fact that a factor, in determining interlocutory injunction applications, is whether the patent holder had lost validity

challenges in other jurisdictions. Instead these decisions deal with the grant of an injunction. In addition, although this Court is dealing with the grant of an injunction, the test for granting an injunction in these jurisdictions is not the same as in Ireland. 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 Divisional Patent, while a court in one EU country has granted such an injunction.

Biogen not seeking to rely on Divisional Patent in the UK

72. It is also of some relevance to the balance of justice (*albeit* that on its own it could not be said to be a decisive factor), that the Divisional Patent is no longer being relied upon by Biogen in the United Kingdom. The current monopoly over Tecfidera runs until February 2024 in the UK, which is 16 months from now. However, the monopoly which the Divisional Patent grants Biogen runs until February 2028, which is almost five and half years from now. For this reason, Neuraxpharm claims that if Biogen truly believed that there was no chance of the Divisional Patent being invalid, it would be defending the Divisional Patent in the UK, rather than allowing generic drugs to compete in that market shortly, particularly when it is seeking an injunction in Ireland to prevent such competition for five and a half years.

73. Biogen's reply to this claim is not entirely convincing, since it states that Biogen's decision in this regard was *'based on a number of considerations'*. However, Biogen then goes on to just mention one of those reasons, namely the fact that Biogen will continues to benefit from protection up to February, 2024. However, this fails to address the fact that by not defending its monopoly in the UK, beyond 2024, until 2028, it is losing four years of the monopoly for no apparent reason, which is curious in relation to a patent that it claims is valid.

Considerable sums recouped to date from Tecfidera by Biogen

74. Although not a strong factor on its own, in considering the balance of justice it is also relevant to note that uncontroverted sworn evidence was provided on behalf of Neuraxpharm that Biogen has more than recouped its investment in Tecfidera based on the fact that its revenue in 2021 from this drug was $1.95 billion.

The public interest/taxpayers' interests

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, 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. 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)

79. Of course, it is important to note that there has not been a determination of invalidity of the Divisional Patent, but rather a determination of invalidity of the Parent Patent, in this case. For this reason, this comment is not directly referable to the case at hand. However, what is clear is that O'Donnell J. sees no issue in having regard to the public interest when considering the grant of interlocutory injunctions and furthermore that there is a legitimate public interest in reducing the cost to the taxpayer of the costs of drugs.

80. The importance of the public interest generally in these types of patented drug cases is also clear from the judgment of McDonald J. in *Gilead Sciences Inc v. Teva BV* [2019] IEHC 683 at para. 70, *albeit* that that case concerned the revocation of a SPC:

> "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**." (Emphasis added)

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).

83. In this regard, it is worth considering the two likely outcomes of this Court's decision on the injunction.

84. If this Court is proven wrong to have refused this interlocutory injunction (because the trial judge determines that the Divisional Patent is in fact valid), the taxpayer will have nonetheless saved *circa* €8 million for the 12-18 month period of the interlocutory injunction. Bearing in mind the *injustice* of the taxpayer having overpaid for a drug based on an unlawful monopoly for the previous seven years, favouring Neuraxpharm in this way (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. This is because crucially, if this Court is proven wrong to

have refused the injunction, Biogen will be entitled to recover from Neuraxpharm, and not the taxpayer, this loss of €8 million (which the taxpayer will have gained). It is also important to note that this contingency, of Neuraxpharm having to pay Biogen's loss, is a contingency which Neuraxpharm is happy to undertake in order to get the interim injunction lifted. It is not something which is being imposed upon Neuraxpharm because it would benefit the taxpayer.

85. Obviously, if this Court is proven right to have refused the interlocutory injunction (because the trial judge determines that the Divisional Patent is invalid), then the taxpayer will not have missed the opportunity to save *circa* €8 million, which it would have missed if this Court had (wrongly) granted the interlocutory injunction.

86. It is however important to emphasise that while it is of some limited relevance, the fact that the *taxpayer will benefit* from the refusal of the injunction is not a decisive factor in this case. 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.

CONCLUSION

87. For all the foregoing reasons, this Court concludes that on the balance of justice, this interlocutory injunction should be refused and so the interim injunction should be lifted.

88. This Court orders the parties to engage with each other to see if agreement can be reached regarding all outstanding matters without the need for further court time, with the terms of any draft court order to be provided to the Registrar. In case it is necessary for this Court to deal with final orders, this case will be provisionally put in for mention a week from the date of delivery of this judgment at 10.45 am (with liberty to the parties to notify the Registrar, in the event of such listing being unnecessary).