THE HIGH COURT

[2021] IEHC 814

[2021 No. 2527 P]

BETWEEN

NOVARTIS PHARMA AG

PLAINTIFF

AND

ELI LILLY NEDERLANDS B.V.

AND

ELI LILLY KINSALE LIMITED

AND BY ORDER

ELI LILLY AND COMPANY (IRELAND) LIMITED

AND

ELI LILLY AND COMPANY LIMITED

DEFENDANT

JUDGMENT OF Mr. Justice Twomey delivered on the 21st day of December, 2021

SUMMARY

1. This case considers, *inter alia*, whether the current shortage of judges in the High Court affects the approach of a court to an application to modularise a trial, where that modularisation has the potential to save up to four weeks of very valuable and scarce court time.

2. This is a case dealing with a dispute between two multinational pharma companies regarding products with which persons with psoriasis may be familiar, i.e. *Cosentyx*, which is manufactured by the plaintiff ("Novartis") and *Taltz*, which is manufactured by the defendant, ("Eli Lilly"), the party seeking the modularisation.

3. The substantive proceedings, which it is proposed be modularised, involve two sets of proceedings relating to European patent (IE) 2 784 084 (the "Patent") owned by Novartis. The first set of proceedings is a revocation action (the "revocation action") taken by Eli Lilly against Novartis on the 13th April, 2021 in relation to the Patent, in which Eli Lilly claims, *inter alia*, that the Patent now owned by Novartis should not have been granted as it lacks novelty.

4. The second set of proceedings are patent infringement proceedings (the "infringement action") taken by Novartis against Eli Lilly on the 15th April, 2021 in relation to the Eli Lilly's competing product, *Taltz*, which Novartis alleges breaches its Patent.

5. Eli Lilly claims, as a defence to the infringement action, that Novartis' acquisition of the Patent and its alleged use by Novartis to seek to prevent competition from Eli Lilly constitutes an abuse of a dominant position in breach of competition law (the "competition defence"). In this regard, Eli Lilly claims that Novartis has a dominant position in the market for products targeted at the treatment of psoriasis where a high degree of efficacy and speed is required. Eli Lilly also relies on these same competition law issues to support its counterclaim in the infringement action.

The modularisation sought by Eli Lilly

6. Eli Lilly wants this Court to split the trial into two modules, with the first module addressing whether Eli Lilly's product, *Taltz*, and/or ixekizumab, falls within the scope of the claims of the Patent, i.e. the infringement action. This module would also deal with issues questioning the validity of the Patent in the revocation action and issues regarding Novartis's application for a supplementary protection certificate for the Patent. Damages would be dealt with in the second module.

7. Novartis agrees with Eli Lilly that the infringement and revocation actions should be dealt with in the first module and damages in the second module.

8. However, the main point of dispute is Eli Lilly's proposal that the second module, rather than the first module, should deal with the competition defence and the remedies to be granted, including in particular any injunctive relief to be granted against Eli Lilly, if Novartis were to be successful.

9. For ease of reference in this judgment, Novartis' preferred option will be referred to as a 'unitary trial' (*albeit* that Novartis agrees that damages will be dealt with separately in the second module). Eli Lilly's proposal will be referred to as a 'modularised trial' (i.e. with the competition defence and injunction issues dealt with in the second module, as well as damages).

Saving of costs for parties and court time, by modularising the trial?

10. If Eli Lilly were to win either on the infringement action or the revocation action in the first module, then it would not have to rely on its competition defence. It is because of this possibility of not having to deal with the competition defence, that Eli Lilly says that it should be part of the second module, particularly as it says that the competition defence will take between 2 ½ weeks and 4 weeks. Thus, Eli Lilly says that by putting the competition defence into the second module, while it is not *guaranteed* to save time and money (i.e. if Eli Lilly *loses* the infringement and revocation actions), it nonetheless has the clear potential to save a considerable amount of legal costs and management time in the interests of the parties and in the interest of saving court time, which is in the public interest.

11. For its part, Novartis makes the point that any remedies cannot be dealt with until after the question of whether Eli Lilly has a competition defence has been determined. Accordingly, the entitlement of Novartis to the remedy of an injunction can only be decided *after* the competition defence has been determined. Thus, deferring the competition defence to the second module has the effect of deferring its possibility of getting an injunction to the second module. This is the tactical reason, it claims, that Eli Lilly is seeking to have the competition defence dealt with in the second module.

Relevance of the expiry of the Patent

12. Novartis says that there is a clear tactical advantage to Eli Lilly taking this approach because the Patent is due to expire on 2nd June, 2024.

13. Accordingly, Novartis says that the interval between Eli Lilly's proposed first and second module, and in particular the possibility of Eli Lilly being able to delay the second module

by appealing the first module, means that the real effect, of putting the competition defence (and injunction) into the second module, is that the Patent will have expired by the time a judgment is delivered in relation to Eli Lilly's second module.

14. This, Novartis claims, will thereby deprive Novartis of the opportunity to apply for an injunction (assuming, of course, that it wins the litigation) and therefore deprives it of a very significant remedy in patent infringement cases.

Public interest is now more acute and favours the ordering of the modularisation

15. As noted hereunder, this Court concludes that there is a public interest in potentially saving 2 ½ weeks, at least, and possibly up to 4 weeks, of extremely valuable and scarce court time, and that this factor very much favours the modularisation of the trial as suggested by Eli Lilly.

16. This public interest in saving on court time, wherever possible, is particularly strong at present, since the *2021 EU Justice Scoreboard* illustrates in stark fashion (at p. 28) that Ireland is, literally, at the bottom of the table of 27 countries for the number of judges per 100,000 inhabitants, with less than 5 judges per 100,000 compared to say over 40 judges per 100,000 in Slovenia (the country at the top of the table).

17. The effect on the public interest of this shortage of judges is starkly illustrated by the fact that of the six serious criminal trials (including rape trials) listed in the Central Criminal Court to open on 8th November, 2021, just one got on for hearing (see the *Irish Times*, 12 November 2021 at p. 4).

18. In view of the acute pressure on court time, it seems to this Court that while heretofore potential savings of two weeks or more of court time justified decisions to modularise trials, it is appropriate for courts now to consider modularisations of trials, when the potential saving of court time is less than two weeks.

19. Indeed, were it not for the particular circumstances of this case, where a patent is due to expire, this Court would have little hesitation in ordering the modularisation of the trial in order to potentially save at least 2 ½ weeks of scarce court time.

BACKGROUND

20. As is clear from the foregoing summary, the key issue in this application is that the Patent, which is directed towards antibodies that act as antagonists to a protein that is implicated in immunity related diseases like psoriasis, is due to expire on the 2nd June, 2024. Novartis is concerned that if there is a modular trial, judgment on the injunction remedy will only issue after that date. Novartis is therefore concerned that it will lose the opportunity to apply for an injunction against Eli Lilly in the event that Eli Lilly is found to have infringed Novartis' Patent.

21. In contrast, Novartis claims that if there is a unitary trial, all matters will have been heard by the High Court with judgment delivered prior to the expiry of the Patent, thus enabling Novartis to seek the injunction, assuming it is successful in the litigation.

22. For its part, Eli Lilly accepts that, if the litigation is heard in a modular trial, the Patent will definitely have expired by the time judgement is delivered. However, it claims that even if the dispute is heard in a unitary trial, it is very unlikely that the judgment will be delivered in time (particularly if there is an appeal). In these circumstances, Eli Lilly claims that the Court should order a modular trial in order to potentially save the parties time and money and to potentially save court time.

23. Furthermore, it claims that the reason that Novartis will be deprived of the opportunity to apply for an injunction by the effluxion of time is not as a result of any modularisation, but rather because Novartis acquired the Patent late in its life. In addition, Eli Lilly states that at the time it acquired the Patent, Novartis was aware that there were validity issues surrounding the Patent.

24. In this regard, Novartis entered into an 'Asset Purchase, License, and Settlement Agreement' dated 23rd April, 2020 with Genentech Inc. (the original holder of the Patent). The Patent was then assigned to Novartis by Genentech Inc. on 25th September, 2020. The parent of this Patent had, however, been held to be invalid in the High Court of England & Wales on 14th February, 2020 and a final order revoking the Patent was made in November 2020. Accordingly, Eli Lilly says that Novartis was aware of issues around the Patent's validity at the time of its purchase agreement and its assignment. None of this is denied by Novartis.

25. Eli Lilly further points out that, prior to Novartis's acquisition of the Patent, from Genentech Inc., Novartis itself had objected to the grant of the European patent, from which the Patent is derived, in the European Patent Office. This objection was made on the basis that the European patent was already being asserted against Eli Lilly's product *Taltz* in national proceedings beyond the scope of any valid monopoly that could be claimed for it. It is also the case that Novartis objected to the Patent on grounds of invalidity, prior to its acquisition of the Patent from Genentech Inc.

26. Against this background, the law applicable to modularising trials will be considered.

THE LAW APPLICABLE TO MODULARISING TRIALS

27. There is agreement between the parties in relation to the relevant law regarding modularising trials, which is, in any case, well settled. It is not proposed to set out in detail the case law to which this court was referred, i.e. *Cork Plastics Manufacturing v. Ineos Compound UK Ltd. & Flopast Ltd. v. Cork Plastics* [2008] IEHC 93 ("Cork Plastics"), *McCann v. Desmond* [2010] 4 I.R 554 ("*McCann*"), *Weavering Macro Fixed Income Fund Ltd. (in liquidation) v. PNC Global Investment Servicing (Europe) Ltd*. [2012] 4 I.R 681 and *James Elliott Construction Ltd. v. Lagan* [2016] IEHC 599 ("*James Elliot*").

28. The following principles regarding modularising trials, which are relevant to this case, can be extracted from this case law:

    i. The default position in relation to litigation is that there should be a unitary trial.

ii. The onus is on the party seeking a departure from the default position to persuade the court that there are sufficient reasons to order a modular trial.

iii. Where proceedings are complex and the trial is likely to be lengthy and there is the possibility of a considerable saving of court time and parties' costs, then it is appropriate for the court to consider modularisation.

iv. The key consideration is the fair administration of justice and in particular the absence of prejudice for the party objecting to the modularisation. In this regard, a court should not order the modularisation of a trial if it creates a risk of prejudice to the other party sufficient to justify the refusal of the order.

v. Where the Court is not satisfied that the application for modularisation is brought in good faith so that it is likely to benefit both parties to the litigation, but for some ulterior benefit to the applicant, then it should be refused.

ANALYSIS

29. The details of this case will now be analysed on the basis of the foregoing five principles.

(I) Starting position is that there should be a unitary trial

30. Firstly, since the default position in relation to litigation is that there should be a unitary trial, and in light of the agreement between the parties regarding damages being heard in the second module, the starting position, in this case, is that all other matters should be heard in the first module. This reflects Novartis's position in this application, i.e. the unitary trial approach.

(II) Onus on Eli Lilly to displace presumption of unitary trial

31. Secondly, it is clear that the onus is on Eli Lilly, as the party seeking a departure from the default position, to establish to the satisfaction of this Court that it is appropriate to order the modularisation of the trial, i.e. that the second module should include the competition defence and the injunction issue, as well as damages.

(III)(a) Are proceedings sufficiently complex to consider modularisation?

32. The first part of the third step in this analysis is to consider whether the proceedings are sufficiently complex, such as to justify the engagement of this Court's jurisdiction to consider modularisation of the trial?

33. In this instance, it seems clear to this Court that the competition defence is complex since it will require evidence in relation to the relevant product market, including evidence regarding the substitutability of products, the alleged existence of a dominant position and the alleged abuse of that position.

34. As evidence of this complexity, it is to be noted that in the Defence filed by Eli Lilly there are eight pages of pleadings in relation to the competition defence. Similarly, in Replies to Particulars by Eli Lilly there are nine pages which refer to the competition defence. Furthermore, in the Reply and Defence to Counterclaim filed by Novartis there are nine pages dealing with the competition defence.

35. While in its written submissions, Novartis sought to argue that the competition defence was not complex, in its oral submissions, no real attempt was made by Novartis to deny that the competition law aspects of the trial are complex. This Court believes that such an argument is difficult to make when one has regard to the pleadings. The most that Novartis said in this regard at the hearing was that if the Court accepts the complexity of the proceedings, the Court must then consider whether there are any countervailing issues or prejudice that would militate against a modular trial.

36. In all these circumstances, this Court has little hesitation in concluding that the proceedings are sufficiently complex to consider modularisation.

(III)(b) Are the proceedings sufficiently lengthy to consider modularisation?

37. The next part of the third step is whether the proposed module is likely to be lengthy, such that *if* there is going to be a saving of court time, it amounts to a sufficient saving of parties' costs and time, as well as court time, so as to justify this Court in considering modularisation.

38. In this instance, it is clear that if the competition defence is put into the second module, it is possible that some court time would be saved in relation to that issue. This is for the simple reason that if, in the first module, the Court found that Eli Lilly was correct that there was no infringement by Eli Lilly of the Patent, or that Eli Lilly was correct, that the Patent should be revoked, then it would be unnecessary for Eli Lilly to have to argue in the second module that it has a defence to the infringement proceedings on the grounds that Novartis abused its dominant position.

39. In these circumstances there would clearly be a saving of *some* court time.

40. As regards the length of time which the competition defence will take, Ms. Laura Scott ("Ms Scott"), on behalf of Eli Lilly, exhibited a letter dated 24th September, 2021 (in her first affidavit dated 13th October, 2021) from Eli Lilly's solicitors. In that letter it is estimated that the modularisation of the trial would involve at least 4 weeks for module two, i.e. the competition defence and damages. That letter also estimated that the rest of the trial in module one would take between 4 and 6 weeks.

41. Further information was provided at the hearing regarding the amount of court time likely to be involved in dealing with the competition defence. Eli Lilly made oral submissions that the competition defence in module two will require at least one expert witness/clinician on each side in relation to defining the product market, but that it may require two such witnesses, as Novartis has made references to dermatology as well as allergy and clinical immunology in its pleadings.

42. Eli Lilly also submitted that a number of witnesses as to fact will be required for the second module. First, it submitted that one witness would be required regarding the open negotiations between Novartis and Eli Lilly over a licence based on international sales. It also claims that another witness will be required from the marketing side of Eli Lilly regarding its product, Taltz, in order to establish the relevant product market. It further

submitted that another independent witness in relation to the percentage of market share of the parties will be required, as well as an economic expert regarding product market definition and dominance.

43. On the basis of these several witnesses, and on the basis of the complexity of the issues at stake, Eli Lilly submitted, at various stages during the hearing, that the competition defence would take 10, 12 or 14 days. Thus, in light of its affidavit evidence and these submissions, Eli Lilly seems to be claiming that between 2 ½ weeks (10 days) and 4 weeks (16 days) of court time will be required for the competition defence – based on four days of hearings a week.

44. It is clear from the case law that the estimated time a subsequent module will take (which may be unnecessary, as a result of the outcome of a previous module, and thus be time saved by the parties and the court) is an important factor in this Court determining whether it is appropriate to consider a modularisation of the trial.

45. Yet, to assist the Court in this regard, Novartis, unlike Eli Lilly, did not, in its submissions or on affidavit, provide the Court with an estimate of the amount of time that it felt the competition defence would take. Instead, it simply disagreed with the time suggested by Eli Lilly and sought to undermine Eli Lilly's estimates by highlighting the fact that Eli Lilly seemed to jump from 10 to 12 to 14 days in its submissions on the one hand and have a reference to 4 weeks/16 days in its affidavit on the other hand.

46. However, this is not a valid criticism, in this Court's view, since predicting the amount of time that a trial will take is not an exact science. In the absence of any estimate on the part of Novartis, this Court concludes that the appropriate way to proceed is to assume that the competition defence will take at least 10 days/ 2 ½ weeks of court time, as this was the minimum amount of time estimated by Eli Lilly and where no contrary estimate was provided by Novartis.

47. It seems to this Court that a period of 10 days for a module, that might not have to proceed, can comfortably be described as sufficiently lengthy to consider modularisation, since by any standard a trial of 10 days in a civil action in the High Court would not be regarded as a short trial. In this regard, it is to be noted that only short trials are permitted on circuit in personal injury cases (with longer trials heard in Dublin), which is taken to mean trials of three days or less.

48. However, this still leaves the question of whether all or substantially all of this amount of time could be potentially saved by modularisation, which is the next issue.

(III)(c) Will this lengthy amount of court time be saved by modularisation?

49. Having concluded that the competition defence is likely to take at least 10 days and that this is sufficiently lengthy and complex to consider modularisation, this Court must now consider whether this amount of court time will actually be saved by modularisation, such as to engage the jurisdiction of this Court to modularise the trial, or is there an overlap, such that modularising the trial might actually increase the time a trial takes?

50. In this regard, it is relevant to note that Eli Lilly submitted that there is no overlap between the witnesses and expert evidence to be provided in the first module (in relation to infringement and revocation) and the witnesses and expert evidence to be provided in the second module (in relation to market share and related competition law issues).

51. Eli Lilly submitted that this was because there is a clear distinction between the science-based patent evidence to be provided by 'scientific doctors' in relation to the Patent (and its alleged infringement and revocation) on the one hand, and the 'treating doctor' evidence to be provided in relation to market share for the competition defence on the other hand. This was not disputed by Novartis in its oral submissions to any extent. In its written submissions, Novartis claimed that there was *'potential'* overlap with respect to common fact evidence and witnesses. However, it did not provide any support for this submission. In this regard, Mr. Gerard Kelly ("Mr. Kelly") avers on behalf of Novartis at para. 10 of his affidavit that:

> "The distinction between what would be required in terms of Court time and costs in pursuing a competition counterclaim (as opposed to a competition defence) is not understood as they are inextricably linked in nature in requiring the same questions to be assessed and will require the same evidence regarding market definition and dominance to be heard, for example, together with the same legal submissions around alleged abuse. As a result, a hearing on the competition aspects still appears likely in any event and I would respectfully suggest should not be used as a tactic to delay the determination of relief in these proceedings, something which clearly suits the Defendants for the reasons outlined in the rest of my Affidavit."

52. This averment appears to this Court to be the primary basis upon which Novartis claims that there would not be a significant saving of time arising from modularisation. However, there is nothing in this averment which indicates any overlap between the evidence of witnesses in the infringement/revocation actions and the competition defence.

53. In these circumstances, it seems clear to this Court that if the competition defence was to take at least 10 days, that, as there is no significant overlap between the evidence and witnesses in the two modules, if Eli Lilly were to win on the infringement action or the revocation action in the first module, there would in fact be a saving of court time of *circa* 10 days/ 2 ½ weeks.

54. Having determined therefore that a lengthy amount of time could be saved by modularisation, does this engage this Court's jurisdiction to consider modularisation?

55. In the *James Elliott* case, at para. 28, Costello J. determined that a saving of 'less than 3 weeks', was sufficient to engage the court's jurisdiction to modularise the trial.

56. More significantly for present purposes where there is a potential saving of 2 ½ weeks, is the case of *Cork Plastics*, where Clarke J., as he then was, determined, at para. 3.4, that a saving of '*two weeks'* was sufficient to engage the jurisdiction of the court to consider modularising the trial.

Would a period of less than two weeks engage the jurisdiction to modularise?

57. However, it seems to this Court that even if the period of time in this case was less than two weeks, this is not a bar to the engagement of this Court's jurisdiction to modularise a trial. This is because there is no suggestion in any of the case law opened to this Court that just because a saving of two weeks was *sufficient* in the Cork Plastics case, that this period of time is the *minimum* time-saving which must be achieved, before a court will consider modularising a trial.

58. Rather it is clear that the factors in the cases to date, which have engaged the jurisdiction to modularise a trial, and the factors which have justified an order to that effect, were not intended to be exhaustive. This is clear from para. 26 of Costello J.'s judgement in *James Elliott:*

> "The authorities relied upon by the parties discuss a number of factors to be taken into account by a court considering an application such as this. *These were not intended to be exhaustive lists of the matters* which a court should consider to the exclusion of others. It would appear that some of the points raised by the defendants were raised in the previous cases but that the defendants also raise points which either had not been raised or did not apply in those earlier cases." (Emphasis added)

59. For this reason, it seems to this Court that it is conceivable that one could have a trial where the first module is relatively straightforward and may take say, three or four days, while a complex and lengthy competition defence, like in this case, might take a week. In those circumstances it seems to this Court that a court should not refuse to consider whether to modularise the trial, simply because in the cases heretofore the amount of time saved was at least two weeks or more.

60. This is because, in considering whether to modularise a trial, one is not only dealing with costs-savings to the parties, but one is also dealing with the public interest of a saving of court time for the benefit of other litigants who are waiting to have their cases heard.

61. This public interest is particularly relevant at present, since as noted above, the shortage of judges in this country is particularly acute at present and there have been well-publicised delays of very serious trials because of this shortage. For this reason, this Court believes that even a saving of less than two weeks (and perhaps one week or less in certain circumstances) in court hearing time is sufficiently long to enable a court to consider whether, in the public interest, it would be appropriate to modularise the trial.

62. Thus, in relation to this final part of the third step in the analysis, this Court concludes that a potential saving in this case of 2 ½ weeks of court time is comfortably sufficient to engage this Court's jurisdiction to consider whether to modularise the trial on the facts of this particular case.

63. Thus, the conditions are satisfied for this Court to order modularisation, subject to the fourth step, namely whether Novartis is prejudiced by such an order.

(IV)(a) Is there a possible prejudice to Novartis which might prevent modularisation?

64. In relation to the issue of whether modularisation might prejudice the party opposing the order, Clarke J., as he then was, in *Cork Plastics* stated at para 3.13 that:

> "Finally, it is important to note that the courts should place significant weight on any *real suggestion that true prejudice (rather than a perceived tactical prejudice) might occur by the absence of a unitary trial.* If there were established to be a real risk that the courts view on earlier modules might legitimately be influenced by evidence which would more properly arise in a later module, or conclusions to be reached in relation to such evidence, then it would be difficult to envisage that the court could countenance a modular trial. Obviously the extent to which it can be said that any such risk exists needs to be realistically assessed." (Emphasis added)

65. Thus, when this Court is determining whether it is 'just' to modularise a trial for the purposes of Order 63A Rule 5, on the application of one party to a trial, this Court must consider whether ordering a modular trial '*might*' prejudice the other party, in this case, Novartis.

66. This is the first part of the fourth step in the analysis and it was on this issue that Novartis concentrated practically all its oral submissions in resisting Eli Lilly's application for a modular trial.

67. It is clear from the case law that there is not an exhaustive list of factors to be taken into account in determining whether it is just to order modularisation, since the circumstances of each case must be considered. This is because prejudice can arise in different ways for parties to litigation. Here, it concerns the opportunity of Novartis to apply for an injunction.

Will Novartis be deprived of opportunity to apply for injunction if a modular trial?

68. In this case, the particular circumstances in which prejudice is alleged to arise are that the Patent will expire on 2nd June, 2024 and if the judgement on the infringement/revocation/competition defence is not delivered prior to that date, such as to enable Novartis to apply for an injunction prior to that date (assuming it wins), then Novartis will have missed its opportunity to seek an injunction to prevent Eli Lilly infringing its Patent.

69. As previously noted, Eli Lilly believes that whether the trial is a modular or unitary trial, Novartis is unlikely to have the opportunity to seek an injunction before the expiry of the Patent. In reply to this claim, Novartis points out that, while it disagrees with Eli Lilly in relation to the effect of a unitary trial on its opportunity to apply for an injunction, it is in complete agreement with Eli Lilly that if the trial is modular, Novartis will be deprived of the possibility of applying for an injunction.

70. Because there is agreement between the parties that if there is a modular trial the Patent will have expired before judgment issues, this is precisely why Novartis says that Eli Lilly should not be granted the order for modularisation.

71. Furthermore, Novartis claims that seeking the modularisation is a tactical ploy by Eli Lilly to ensure that Novartis never gets an injunction against Eli Lilly for its alleged breach of Novartis' Patent.

72. In this regard, Novartis provided on affidavit estimates of the timeframe for the completion of a unitary trial and a modular trial. For the unitary trial, it estimates that a High Court judgment could be delivered in quarter one of 2023 which is a year or more *before* the expiry of the Patent in June 2024. For a modular trial, it estimates that a High Court judgment would be handed down in quarter four of 2024 which is some months *after* the expiry of the Patent.

73. In its oral submissions, Eli Lilly made it clear that it believes that Novartis' time estimates for a unitary trial are '*very very optimistic'* and that it is '*very unlikely'* that judgment will issue after a unitary trial before the expiry of the Patent, particularly if there is an appeal.

74. It is impossible for this Court to choose between, what appear to be, equally plausible guestimates (particularly, in view of the uncertainty in predicting how long litigation will take, bearing in mind how litigants' tactics can affect the timeframe). In these circumstances, and where the onus is on Eli Lilly, it seems to this Court that Eli Lilly has failed to provide this Court with sufficient cogent evidence to conclude that on the balance of probabilities its predicted timeframe is more likely to come true than Novartis' predicted timeframe. Of course, this is not the same as saying that this Court concludes that Novartis is correct. Rather this Court must bear in mind that the onus is on Eli Lilly to convince the Court that its suggested timeframe is more likely than Novartis' timeframe, which it has failed to do.

75. *If* such evidence existed, then this Court would able to conclude, on the balance of probabilities, that there is nothing to be gained by having a unitary trial, while on the other hand there exists a potential saving to the courts (and the parties) of at least 10 days of court time if a modular trial was to take place.

76. This Court is left in a situation where the two positions regarding the timeframes are equally possible, but crucially, that if Novartis is correct (which is as likely as Eli Lilly being correct), then Novartis would definitely be deprived of the opportunity to apply for an injunction if this Court were to grant the modularisation. This is because the one thing both parties agree on is that a definitive outcome of modularisation is the loss by Novartis of the opportunity to apply for an injunction.

77. In these circumstances, and bearing in mind that the onus is on Eli Lilly to justify departing from the default unitary trial, and that this Court has only to conclude that prejudice *'might'* be suffered by the party resisting the application, this Court concludes that if it were to order modularisation, it would be definitively depriving Novartis of even the possibility of applying for an injunction. This cannot be said if a unitary trial is ordered.

78. It seems to this Court that this amounts to a prejudice which may be suffered by Novartis by ordering a modularisation of the trial and so the next question is whether this prejudice is sufficient to justify the refusal of the order.

(IV)(b)..Is the prejudice sufficient to prevent the modularisation of the trial?

79. The next part of the fourth step in the analysis is whether the prejudice which may be suffered by the party opposing the modularisation is such that a court should exercise its discretion to refuse modularisation.

80. In this regard, Eli Lilly has argued that any such loss of the opportunity to apply for an injunction is not in fact a true prejudice and so not a sufficient prejudice to prevent modularisation. This is because Eli Lilly claims that the loss by Novartis of that opportunity is in fact caused, not by the modularisation of the trial, but by Novartis itself. This is because, Eli Lilly claims that it was Novartis which decided to purchase a patent very late in its life and whose validity was subject to challenge. Novartis, it says, should therefore have moved quickly in bringing the infringement proceedings, which would have avoided this potential/actual loss of the opportunity to apply for an injunction.

Prejudice caused by Novartis itself?

81. In this regard, at para. 44 of Ms. Scott's first affidavit dated 13th October, 2021 she avers on behalf of Eli Lilly that:

> "[…] Novartis owned the patent for nearly 8 months (and had entered into an "Asset Purchase, Licence and Settlement Agreement" dated 23 April 2020 in respect of the assignment of the patent nearly 5 months prior to its assignment by way of an agreement entitled "Delayed Patent Assignment" dated 25 September 2020) before it asserted the Patent in these proceedings such that keeping it from injunctive relief, if such were indicated, for a further period allowing determination of the proposed module 1 does not seem unjust."

82. However, Mr. Kelly has suggested at para. 30 of his affidavit dated 22nd October, 2021 that the reason for the delay referred to by Ms. Scott was because during this period the parties were engaged in open licensing discussions.

83. In addition, as regards the length of the delay, while not insignificant, it could not be said to be excessive, particularly when one bears in mind that a reason has been provided for some of the delay.

84. It is also relevant that, given that some part of the delay is excused by the fact that there were negotiations during that period for a license, the amount of culpable delay is only a matter of months. Novartis claims that this is less than the 1 ½ year delay Eli Lilly is seeking to impose upon it. This is because in Mr. Kelly's affidavit at para. 29, he claims on behalf of Novartis that a judgment will issue in quarter 1 of 2023 if there is a unitary trial, but in quarter 4 of 2024 if there is a modular trial, and so he claims that a delay of over 1 ½ years is being sought by Eli Lilly.

85. In all these circumstances, this Court cannot see how it can conclude that it would be just that the appropriate response of this Court to a claim that Novartis should have instituted proceedings several months sooner, is for this Court to make an order that ensures that Novartis is denied even the possibility of the remedy of injunction.

The prejudice to Novartis v. the prejudice to Eli Lilly

86. Furthermore, it would not, in this Court's view, be an appropriate exercise of its discretion, to deny Novartis the possibility of a remedy because it had not instituted proceedings several months sooner, particularly when the only prejudice to Eli Lilly, if this Court does not order modularisation, is that it had to argue its competition defence unnecessarily in a unitary trial, i.e. (a) the potentially unnecessary legal costs it incurs and (b) the potential wasted management time it incurs, in so doing

87. In this regard, the foregoing prejudice to Eli Lilly is significantly less than the prejudice to Novartis of losing the opportunity to apply for a remedy. It is also the case that Eli Lilly's prejudice can be reduced and/or alleviated. This is because as regards (a) the legal costs, this prejudice to Eli Lilly is eliminated by an award of costs against Novartis (and there is no suggestion that Novartis would not be able to meet such an award). As regards (b) the loss of management time, this prejudice to Eli Lilly could be alleviated, to some degree at least, by Eli Lilly complying with either of two undertakings sought by Novartis to enable the competition defence to be heard in the second module.

88. This possible alleviation of Eli Lilly's prejudice regarding loss of management time arises because, as noted hereunder, it appears to be the case that Novartis is happy to consent to the competition defence being heard in second module, and so to the saving of Eli Lilly's management time and costs, if Eli Lilly provides an undertaking to Novartis. This is an undertaking to be given by Eli Lilly consenting to an injunction if Eli Lilly loses the first module, or an undertaking that Eli Lilly would proceed expeditiously with the second module, even if there was an appeal by Eli Lilly of the first module.

Prejudice caused by circumstances?

89. Eli Lilly also submitted that the unavailability of any injunction remedy is a function of the circumstances, namely the decision by Novartis to acquire the Patent late in its life and so is not a true or sufficient prejudice.

90. However, it is this Court's view that simply because the owner of a patent purchased a patent late in the life of the patent, which will lead to *unavoidable* prejudice if the patent expires prior to judgment, does not justify further *avoidable* prejudice being suffered by that owner, at the behest of an alleged infringer of the Patent by obtaining a modular trial. Thus, this Court does not accept that Novartis is not suffering a true or sufficient prejudice in this case arising from these circumstances, since avoidable prejudice (of potentially being deprived of the remedy of an injunction) is, in this Court's view, true prejudice.

Not a true prejudice because SPC will grant extra five years' protection to Patent?

91. It was also submitted by Eli Lilly that the potential prejudice to be suffered by Novartis is not a true prejudice, since Novartis has applied for a Supplementary Protection Certificate

("SPC") in respect of the Patent, which if granted, would give the Patent a further five years of protection. On this basis, Eli Lilly points out that there would be no expiry of the Patent and so no loss of the opportunity to apply for an injunction caused by the effluxion of time.

92. However, there is no guarantee that the SPC will be granted. Thus, just because Novartis has *applied* for an SPC does not mean that prejudice *'might'* not occur, and as previously noted, this is all that is required for a Court to refuse modularisation (assuming that the prejudice is sufficiently significant).

93. In any case, the strength of this argument by Eli Lilly is somewhat weakened by the fact that Eli Lilly believes that Novartis is not, in any case, entitled to a SPC. This is evidenced by Eli Lilly's counterclaim to the infringement action, since therein it is seeking a declaration that Novartis is not entitled to the a SPC in relation to the Patent.

Conclusion regarding whether prejudice should prevent modularisation

94. In conclusion therefore, regarding this fourth step of the analysis, it is this Court's view that the loss by Novartis of the opportunity to apply for a significant remedy, such as an injunction, is a sufficient reason for this Court to refuse the modularisation application in this case.

95. Such a loss is, at the very least, the equivalent of instances of prejudice which have been found in other cases to justify a refusal of modularisation. For example, in *James Elliott*, a split of the trial between liability and quantum was refused. This was because the defendant wished to attack the credibility of the plaintiff's witness evidence. However, if only evidence regarding liability, and not quantum, was available to be attacked in the proposed first module, then it was claimed by the defendant that he would be prejudiced in his efforts to undermine the plaintiff. This was accepted by Costello J. as sufficient prejudice to prevent the modularisation of the trial.

96. Indeed, in the present case it is relevant to note that in its oral submissions, no attempt was made by Eli Lilly to suggest that the loss of the opportunity to apply for the remedy of injunction was not a *significant* prejudice, since it sought instead to claim that it was not a true prejudice, as, *inter alia,* Novartis was itself the cause of the prejudice by its delay (which has not been accepted by this Court).

97. That is the end of this application and it is not necessary for this Court to consider the fifth step in the analysis to see if modularisation should be ordered. However, for the sake of completeness, this Court will do so.

(V) Is application brought in good faith for both parties' benefit?

98. The fifth and final step in this analysis is to consider whether Eli Lilly has brought this application for modularisation in good faith so that it is likely to benefit both Eli Lilly and Novartis?

99. In the *McCann* case, Charleton J. observed at para. 6 that:

> "Where the court was not satisfied that an application was brought in good faith so that it was likely to be of benefit to both parties, but was instead sought so that discovery of an issue to the embarrassment of the plaintiff or defendant was avoided, then such an order should be refused." (Emphasis Added)

100. This Court does not believe that the point made by Charleton J. is restricted to applications brought for discovery of an issue embarrassing to a litigant. Rather it seems clear to this Court that the point being made is of more general application, so that if an application were made to modularise a trial, *not* for the benefit of both parties (i.e. to save the parties' legal costs and management time), but for some ulterior benefit for one party only, this would justify the refusal of the application.

101. This Court would also observe that the reference to '*good faith'* by Charleton J. is not, in this Court's view, a reference to any wrongdoing or *mala fides* on the part of the applicant for a modular trial, but simply a reference to an application which was brought, not for the primary purpose of saving legal costs and management time on the part of the parties (and court time in the public interest), but rather for a tactical advantage or ulterior benefit.

Loss of opportunity to apply for injunction is not for the benefit of Novartis

102. In this regard, it is relevant to note that there is little doubt that if this Court were to grant the modularisation application, it is accepted by both parties that Novartis would be denied the opportunity to apply for an injunction. There is no such guarantee if there is a unitary trial. Thus, there is a very clear tactical advantage to Eli Lilly in having the trial modularised. In this regard, it is to be noted that the Supreme Court has recognised the potential importance of injunctions in the field of patents in *Merck Sharpe & Dohme Corporation v. Clonmel Healthcare Limited* [2020] 2 I.R 1. This is because therein the Supreme Court rejected any suggestion of there being a general principle, *albeit* at the interlocutory stage rather than at final hearing stage, that an injunction should not be available to the owner of a patent on the grounds that damages are an adequate remedy (at para. 49 *et seq*).

103. For these reasons, it could be said that it is clearly not of benefit to Novartis that it be deprived of the opportunity to apply for an injunction. Thus, it could be said that in this regard the modularisation application is not brought for the benefit of both parties. This is because, while there may be cost/time saving for both parties, it is common case that Novartis will definitively be deprived of the injunction remedy, if the modularisation is granted.

Reduction in relative importance of the costs-saving reasons for modularisation

104. In considering whether the primary purpose of Eli Lilly's application is for the costs/time which it will save, or the tactical advantage to it of not being injuncted, it is relevant that the costs-saving benefit to Eli Lilly was significantly reduced by its oral submission that it was prepared, in the interests of getting the modularisation it seeks, to prepare the competition defence in the second module all the way to readiness for hearing, including

the making of discovery. It submitted that this was the price that it was willing to pay for the modularisation it seeks.

105. In such circumstances, while there would still be *some* costs and time saving to Eli Lilly in not having to proceed with the actual hearing on the competition defence in the first module for which it would be fully prepared (if it won in the first module), the costs and time saving to Eli Lilly would be very significantly reduced.

106. By Eli Lilly agreeing to do all the litigation preparatory work for the competition defence, save for the actual hearing, this increases the importance to Eli Lilly of the 'avoiding the injunction reason', relative to the 'costs saving reason', for the modularisation application.

Two opportunities to reduce tactical advantage not taken up by Eli Lilly

107. As this Court is considering whether the costs/time saving was the most important factor in Eli Lilly's application for modularisation, rather than the tactical advantage which will accrue to it, it is relevant to note that Eli Lilly had an opportunity to indicate that the tactical advantage is of no relevance to its application for modularisation, which opportunity Eli Lilly declined to take.

108. This is because a proposal was made by Novartis that it would agree to the modularisation and the saving of costs and management time (and of course the saving of court time in the public interest), but this was not accepted by Eli Lilly. This proposal was made in Mr. Kelly's affidavit dated 22nd October, 2021 when at para. 19 he stated:

> "In essence what the Defendants are contending for in the motion herein is a pushing out of the ultimate awarding of relief to a point after the determination of the competition defence and counterclaim in Module 2. They are perfectly entitled to have as many strings to their bow when it comes to defending the Plaintiff's claims for infringement, but deferring the ultimate determination in the manner which the Defendants propose would be manifestly unjust. Other than a refusal to entertain the Defendant's proposal, *the only other conceivable way in which justice could be served would be if the Defendants, while arguing for their form of modularisation, accepted that if Module 1 went against them at first instance they would consent to an interlocutory injunction being put in place pending the determination of their deferred competition defence* and counterclaim. I can confirm that the Plaintiff would be prepared to offer the usual cross undertaking as to damages in that event." (Emphasis added)

109. A proposal with similar effect appears to have been suggested by Novartis in correspondence, namely that it might agree to the modularisation if it got an undertaking from Eli Lilly that Eli Lilly would not delay the trial of the competition defence in the second module, if Eli Lilly was to appeal the first module judgment. This is because by letter dated 1st October, 2021 from Novartis' solicitor to Eli Lilly's solicitors, it is stated, *inter alia*:

> "In order for us to take our client's instructions, you might please confirm that your client, subject to the Court, will provide us with a written undertaking that it will not delay the second trial in the event that your client is dissatisfied with the outcome of the first trial, and in the event that your client loses. In other words*, your client will agree to proceed with the hearing of module 2, on an expedited case manged basis notwithstanding the status of any appeal* that your client might file against the outcome of the module 1 trial." (Emphasis added)

110. However, neither of these options were pursued or taken up by Eli Lilly, notwithstanding that, if such undertakings had been given, they would have eliminated/reduced any tactical advantage to Eli Lilly of avoiding an injunction.

111. Thus, it seems clear that Eli Lilly was not willing to forgo the tactical advantage of insulating itself from an injunction. Yet at the very same time, Eli Lilly is willing to forgo to a very large degree the costs and time saving benefits of modularisation, thereby maintaining the relative importance of the tactical advantage as a reason for modularisation.

112. For all these reasons, this Court concludes, that while Eli Lilly has given the saving of costs/time and saving of court time as the reasons for modularising the trial (which is accepted will occur and will benefit both parties) it seems to this Court that on the balance of probabilities, a more important reason for Eli Lilly in bringing the application was the benefit which would accrue to it of avoiding the threat of an injunction.

113. This Court interprets the requirement in *McCann* of bad faith and a likely benefit to both parties as being satisfied (a) if the primary reason for the application for modularisation is, not for the benefit of both parties, but for the tactical or other benefit of the applicant and/or disadvantage of the other party and (b) where the benefit to both parties, and in particular the party opposing the applicant, is not such as to eliminate, or sufficiently ameliorate, any such tactical advantage/disadvantage to it.

114. It is this Court's view that the test in *McCann* is satisfied in this case. Firstly because this Court has concluded that on the balance of probabilities the primary reason for the application was not for the benefit of both parties but rather for the tactical advantage accruing to Eli Lilly. Secondly, the tactical disadvantage to Novartis of losing the opportunity to apply for an injunction could not be said to be sufficiently ameliorated by any saving of legal costs or management time which will accrue to it. It is important to emphasise that this Court is not saying that Eli Lilly did not make this application for costs and time-saving reasons and for the public interest of saving court-time. Indeed, in other circumstances, as noted above, there would be a very strong public interest in granting the application made by Eli Lilly. Rather this Court is saying that on the balance of probabilities, the primary purpose in making the application is the tactical advantage of avoiding a possible injunction application – this is because of the considerable benefit (relative to any saving on legal costs), to a company selling a product that allegedly breaches a patent, of insulating itself from an injunction.

115. It also should be emphasised that while this Court is concluding that the threshold for refusing an application, as set down by Charleton J., is satisfied, this Court is not using the term 'bad faith' to describe Eli Lilly's application. This is because this Court interprets Charleton J.'s test as not requiring *mala fides* or wrongdoing on the part of an applicant, but rather as encompassing a situation where, while there may be costs/time saving for the parties and the saving of court time, the other benefits, in this case of avoiding a possible injunction, are greater and so, on the balance of probabilities, are deemed to constitute the primary reason for the application. In addition of course, applications such as these which have the prospect of saving court time in the public interest are not to be discouraged.

116. Accordingly, under this fifth step of the analysis, this Court would also refuse the modularisation application.

CONCLUSION

117. In all of the foregoing circumstances, this Court would conclude by first saying that it believes that it is very clearly in the public interest that *at least* 2 ½ weeks, but perhaps 4 weeks or more (on Eli Lilly's case) of extremely valuable court time could potentially be saved in this case.

118. This amount of court time will be saved if the competition defence is heard in the second module, rather than in the first module (and assuming Eli Lilly were to win the infringement or revocation action).

119. If there was no prejudice to Novartis, this Court would have no hesitation in ordering the modularisation sought, as it is in the public interest and indeed in the interests of saving legal costs and management time for both parties.

120. However, there is a prejudice to Novartis which is significant, since it is the possible loss of the opportunity to seek an injunction to prevent the sale of infringing products by Eli Lilly (if Novartis were to win the litigation).

121. Accordingly, this Court refuses to order the modularisation of the trial as sought by Eli Lilly.

122. However, it remains the case that if Eli Lilly was prepared to give the undertaking sought by Novartis (to consent to an interlocutory injunction, if it lost the proposed first module), this would achieve two things which should facilitate the modularisation.

123. First it would eliminate the prejudice to Novartis, of possibly losing the opportunity to apply for an injunction. Secondly, it would eliminate the requirement for Eli Lilly to incur the considerable costs of discovery etc. in being fully prepared for hearing module two, immediately after module one finishes (which it is prepared to do to obtain the modularisation). These legal costs and management time would then end up being saved by Eli Lilly (and Novartis), as well as court time in the public interest, if Eli Lilly ends up winning in module one.

124. It also seems to be the case that if Eli Lilly was prepared to give an undertaking, not to use its perceived tactical advantage (of appealing module one in order to delay module two), that this also should facilitate modularisation – i.e. by Eli Lilly undertaking to have module two heard in an expedited fashion, notwithstanding any appeal by Eli Lilly of module one.

125. This second undertaking would not however appear to eliminate the requirement on Eli Lilly to incur the legal costs and management time in discovery etc., which would end up being unnecessary if it won module one. However, it would save on the costs and time involved in proceeding with the actual hearing of module two, and perhaps more significantly valuable court time in the public interest.

126. However, this is not a matter for the Court as these are all matters for Eli Lilly. Now that Eli Lilly has obtained this Court's judgment that the potential prejudice to Novartis does not justify modularising the trial, these issues of how best to proceed are matters exclusively for Eli Lilly to consider along with other factors and considerations of which this Court may not be aware.

127. Insofar as final orders are concerned, this Court would ask 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. In case it is necessary for this Court to deal with final orders, this case will be provisionally put in for mention on Thursday 13th January, 2021, at 10.45 am (with liberty to the parties to notify the Registrar, in the event of such listing being unnecessary).