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Case No: HP-2019-000041

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

Royal Courts of Justice, Rolls Building
Fetter Lane, London, EC4A 1NL

Date: 02/06/2020

Before :

MR JUSTICE BIRSS

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Between :

TEVA UK LIMITED	**Claimant**
- and -	
CHIESI FARMACEUTICI SpA	**Defendant**

- -
- -

Thomas Mitcheson QC , **Daniel Piccinin** and **Stuart Baran** (instructed by **Pinsent Masons LLP**) for the **Claimant**
Charlotte May QC, **Sarah Ford QC** and **Anna Edwards-Stuart** (instructed by **Bristows LLP**) for the **Defendant**

Hearing date: 18th May 2020

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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MR JUSTICE BIRSS

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Mr Justice Birss :

1. In this action the claimant (Teva) seeks to revoke three patents held by the defendant (Chiesi). The patents are EP (UK) 2 146 704, EP (UK) 3 034 073, and EP (UK) 2 010 190. The claims essentially relate to a combination of beclomethasone and formoterol in an inhaler (DPI or MDI). The claims of 704 and 073 relate to the use of this product in rescue treatment for acute episodes of asthma attacks, when needed, as a complement to the maintenance treatment of asthma with the same medicament. The claims of 190 relate to the combination with certain excipients in an MDI, essentially for use for the prevention or treatment of severe broncho-pulmonary disease (either asthma or COPD).

2. The defendant has a product called FOSTAIR. Its name outside the UK is FOSTER. The product is protected by these patents amongst others. These patents are due to expire in 2027/28. Data exclusivity for the defendant's product expired in 2012.

3. The action commenced in October 2019. In its Defence and Counterclaim served in December 2019 the defendant counterclaimed for infringement of all three patents on a *quia timet* basis, on the footing that the claimant threatens and intends to infringe. The case is listed for trial in October 2020, to be heard at the same time as a parallel claim between Lupin Healthcare (UK) Ltd and Chiesi.

4. The defendant pressed the claimant for disclosure or a product description in relation to its product alleged to infringe. The claimant's response was to apply to strike out the infringement claim. The strike out is brought primarily on the ground that the pleaded case has no real prospect of success. The claimant contends there is no evidence it threatens or intends to commit an infringing act and that no sufficient support for that allegation is pleaded in the Particulars of Infringement. Therefore the infringement claim should be struck out. This is the first major issue I have to decide.

5. The claimant has an alternative ground for the strike out – based on abuse of process; and the claimant also submits that even if the infringement claim should not be struck out, it should be stayed, for reasons relating to competition law.

6. Also relevant is that the claimant has offered an undertaking to give the defendant 14 days' notice of any launch of a product. The precise period of 14 days is negotiable to a limited pragmatic extent. However the claimant is not by that pragmatic approach contemplating a significantly longer period such as 2 months' notice. The 14 days' notice is only meant to be sufficient time to allow the defendant, if advised, to bring an urgent claim for an interim injunction.

7. The claimant also submits that competition law plays a part in the analysis, particularly as a result of the recent judgment of the CJEU in the Paroxetine litigation (Case C-307/18 ***Generics (UK) and ors (Paroxetine)*** ECLI:EU:C:2020:52; January 2020). The point relates to the information which the claimant says the defendant says the claimant must disclose to the defendant if the infringement claim goes ahead. It is submitted that this disclosure, even if ordered by the court, would amount to a concerted practice contrary under Art 101(1) TFEU (and the equivalent provisions of the Competition Act). There may be a defence of necessity under the ancillary restraint doctrine (the doctrine is described in ***Sainsbury's v Mastercard*** [2018]

EWCA Civ 1536 at paragraph 58), but that would not justify disclosure now, only later. The competition law point is the other major issue I have to decide. For this purpose there is no difference between the position under Art 101 TFEU and the Competition Act.

8. The defendant contends that the infringement claim has a real prospect of success and should not be struck out. The defendant also denies that competition law has any bearing on the issues to be decided. A stay is also resisted. The defendant has also applied for disclosure relating to infringement. It is common ground that if the infringement claim is to go to trial along with validity in October, then some form of disclosure should be given. There may be issues of detail but they can be resolved if necessary when this judgment is handed down.

9. I propose to address the strike out in its own terms first. Then, if necessary I will consider the competition law submissions.

10. The evidence consists of witness statements from the solicitors acting for the parties. One thing is worth making clear at this stage. An important aspect of the way the claimant has put its case so far is that it has taken care to make no statement either way about its intentions. Occasionally in argument one might think that counsel was making a submission about what the claimant actually intended but that was not what was meant and nothing said at the hearing was a statement on the claimant's behalf about its intentions.

11. Arguments about the basis for *quia timet* infringement actions come up from time to time in patent cases. The legal test is whether the relevant party threatens and intends to commit the act alleged to infringe. It is also important to have in mind that this is an application to strike out. That means that the question is not whether the pleaded material proves that the claimant threatens and/or intends to infringe, but only whether, based on the material pleaded, there is a real prospect of success of establishing that at trial.

12. I had to grapple with how the legal test is applied in ***MSD v Teva*** (efavirenz) both at the interim stage (a strike out and interim injunction) at [2012] EWHC 627 (Pat) and at trial [2013] EWHC 1958 (Pat). That involved a review of the authorities. I applied that summary of the law from the trial judgment in ***MSD v Teva*** at the trial in ***Actavis v ICOS*** (tadalafil) [2016] EWHC 1955 (Pat) (that case went on appeal but not on this point). The summary of the law in ***Actavis v ICOS*** was followed by Arnold J in ***Generics (UK) v Sandoz*** (G-CSF) [2017] EWHC 2276 (Pat).

13. It is sufficient to start by setting out the conclusion reached at paragraph 56 of ***MSD v Teva*** (trial):

> "The principle I derive from these authorities is that the question the court is asking in every case is whether, viewed in all the relevant circumstances, there was a sufficiently strong probability that an injunction would be required to prevent the harm to the claimant to justify bringing the proceedings. ..."

14. Counsel for the claimant made various submissions which appeared to seek to qualify or add to this in various ways, emphasising statements in other cases about whether

there was a risk of grave irreparable harm or an imminent threat. I do not accept that those qualifications should be added to the statement of the legal principle, at least as it applies in a patent case. Many of the statements derive from cases in the law of nuisance, in which the circumstances relating to the grant or refusal of final injunctions is different. The cases often deal with factors relating to interim injunctions and final injunctions at the same time, but that is not the issue before me.

15. Counsel for the claimant also argued that there was or should be a legal principle in patent cases that a *quia timet* action cannot proceed with no relevant marketing authorisation pleaded. It is a prerequisite. Counsel for the defendant did not agree. The claimant's case on that is primarily based on some things I said in ***Actavis v ICOS*** but is also said to follow from a consideration of the authorities in other jurisdictions. I will deal with ***Actavis v ICOS*** first. The two passages relied on are at paragraphs 353 and 356 of that judgment.

16. At paragraph 353 of ***Actavis v ICOS*** I said:

> "353. Viewed objectively today, the UK market for tadalafil is large and valuable. It is obvious that a generic company would wish to sell tadalafil once the SPC has expired. Actavis and Mylan have applied for and are obtaining marketing authorisations for their generic tadalafil products. That is an expensive and time consuming process. Viewed objectively, it only makes sense if they are planning to sell tadalafil sometime. The 181 patent (and, I will assume, 092) are potential obstacles. Bringing proceedings to revoke them is not proof of an intention to sell but it also supports the inference based primarily on the marketing authorisation."

17. And at paragraph 356 of ***Actavis v ICOS*** I said:

> "356. The flaw in the logic of the question posed by Actavis and Mylan is that the inference on which this quia timet infringement action is based does not derive solely or even predominantly from the fact they have sought to clear the way by applying to revoke patents. It derives from the marketing authorisation process. Furthermore, while there is a cost and trouble associated with product and process descriptions, that only arises because there is an issue on infringement. The companies are entitled not to admit infringement, but in that case infringement is in issue and should be sorted out in advance just as much as validity. The logic of clearing the way covers both infringement and validity."

18. Taken out of context, these passages do appear to lend support for the claimant's view of the law, however in my judgment read in context they do not do so. To deal with this issue properly it is necessary to take a step back.

19. The present case arises in circumstances referred to as "clearing the way". An incumbent company has a medicinal product established on the market said to be protected by a patent with some time to run. Data exclusivity has expired or is

expiring fairly soon and in any case before the patent expires. A generic rival is thinking of entering the market. There are two legal barriers to entry. One is that rival needs a marketing authorisation. The other is or may be the patent.

20. The marketing authorisation for the rival cannot be granted until data exclusivity has expired. Marketing authorisations are applied for in advance. The application is not public but the grant of a marketing authorisation is public. The time between application and grant varies but very generally, the shortest time is likely to be some months and it can take a couple of years. The marketing authorisation will be specific to a particular form of product and particular indications (uses) and so on. So the rival has to get a marketing authorisation and once it is obtained, that is a matter of public record. The incumbent will notice immediately.

21. The marketing authorisation is a much stronger practical barrier than the patent. No pharmaceutical company will sell a medicinal product without a marketing authorisation, whereas a pharmaceutical company may decide to launch "at risk" in relation to the patent. So if the rival launches at risk, an application for an interlocutory injunction is likely to follow, which if granted will delay market entry while the patent issues are sorted out, even though the rival now has a marketing authorisation. Occasionally rivals try to pull off a surreptitious launch at risk, in other words a well planned launch but without any warning. This has led to emergency injunctions granted over the weekend.

22. However in this jurisdiction it is well established that a rival in these circumstances ought to clear the way in advance – in other words bring court proceedings such as an action for patent revocation and/or declarations of non-infringement well before the rival's launch on the market. The rival has no duty in law owed to anyone to clear the way, rather the courts have established that a failure to clear the way can be taken into account on an application by the incumbent for an interlocutory injunction to restrain the rival's sales pending resolution of the patent dispute. In many cases it is a strong or even decisive factor. Part of the point is that the rival will have been in a position to bring the claim in advance so as to clear the way in an orderly fashion. There are no barriers relating to standing which would prevent a rival from bringing a suitable claim to clear the way. The Patents Act specifically provides that any person may start either kind of action. There is a pre-requisite for a declaration action in that particulars of the product concerned have to be given to the patentee in advance but that is no barrier since, assuming they are provided and assuming the patentee does not respond, the claim can be brought. The particulars can be provided on a confidential basis.

23. Patent disputes are best decided with both validity and infringement before the court at the same time. This is not just for the sake of procedural economy, it is also important so as to ensure that the claims are construed the same way when deciding both issues. Indeed in reality there is only one question – which is whether the activity the rival wishes to undertake is lawful or not having regard to the incumbent's patent rights.

24. What happens if the rival brings a revocation action but no claim for a declaration? That may be because no point is being taken on infringement at all, in which case that can be explained. However the problem for the patentee is that if the issue of infringement is outstanding then a decision on validity will not resolve the dispute,

assuming the patentee wins on validity. It will do so of course if the patentee loses, but that is only one possible outcome. There is also the possibility that broad claims will fall but narrower claims might be found to be valid. If the issue of infringement is unresolved even after a patent has been found to have valid claims then the possibility of a launch at risk, possibly surreptitiously, remains. The way has not been cleared. Therefore in such a case the patentee may wish to counterclaim for infringement, to avoid these risks and ensure that validity and infringement are decided at the same time for the reasons already explained.

25. The starting point for such a claim is usually the simple inference from the fact they have brought revocation proceedings, that the rival presumably intends to infringe by launching a product within the period before expiry of the patent. That is a perfectly sensible inference to draw. Otherwise why do this at all? The simple inference might be rebutted by evidence that the claim was brought for another reason, e.g. to do with events abroad or something to do with licensing, but if that is the reason, it can be given.

26. Before me the claimant contends that because the law permits anyone to bring a revocation claim, it therefore follows that what I have called the simple inference cannot be drawn at all. I do not agree. The one does not follow from the other.

27. I can now turn to ***Actavis v ICOS***. What happened there is explained from paragraph 346 of the judgment onwards. The rivals had started a revocation claim only, with no claim for a declaration of non-infringement. The patentee counterclaimed for infringement on a *quia timet* basis, based on a threat and intention to infringe. The court held that the patent was valid. The findings also meant that the rival's products would, if sold, infringe the relevant claims (paragraph 346). So there would have been no purpose in a proceeding for a declaration of non-infringement anyway.

28. ***Actavis v ICOS*** was not concerned with what was sufficient to establish a real prospect of success, it was about whether to grant an injunction at trial, the question being treated as depending on whether a threat and intention to infringe had been established. What I have called the simple inference was the starting point and was not in dispute. The point was more sophisticated, namely that the rivals' intention was said to have been only to sell after successfully revoking the patent. In other words, the rivals had a positive case that they did have an intention to launch a product within the period ostensibly covered by the patent, but it was a contingent intention dependent on revoking the patent. They said they had no intention to launch at risk. Therefore, the court having found that the patent was valid and that their product would infringe, no injunction should be granted. The distinction being drawn was between an intention to sell in the period before expiry, which they did have albeit only on a contingent basis, and an intention to commit an infringement of a valid patent, which they said they did not have.

29. The judgment, applying the legal test from ***MSD v Teva***, was that in all the circumstances there was a sufficiently strong probability that an injunction would be required to prevent the rivals from infringing to justify the counterclaim and an injunction to follow. The point being made in the two passages cited above was concerned with deciding that question. It is a different question altogether from the one in the present case.

30. I am quite sure that there is no legal principle of the kind advanced by the claimant that a *quia timet* action cannot even be advanced without a marketing authorisation being pleaded. It cannot be derived from ***Actavis v ICOS***. Moreover I note that in ***Generics v Sandoz*** [2017] EWHC 2276 (Pat) in which Arnold J gave permission to allow a *quia timet* infringement claim to be added by amendment, there was no marketing authorisation in place at the time the decision was made.

31. It is important to be clear about timing. To commence a *quia timet* action in the first place the patentee has to show it has at that initial stage a real prospect of establishing that at trial – which may be months or years in the future – there is a sufficiently strong probability that an injunction would be required to prevent harm to the claimant occurring after trial. The question is not concerned with whether the rival may about to launch the product at the start of the action. So the fact there is no marketing authorisation in place when the claim form is issued, or otherwise when action begins, is not relevant. It is the existence of a threat and intention to start selling product sometime within the lifetime of the patent which justifies a *quia timet* infringement action. The material available at the start of the action may well not justify an interlocutory injunction at that early stage but that is not the question. A different question may be what to do if at trial, no marketing authorisation has been granted. That may or may not indicate that there will never be a launch in future, but it is a matter for trial.

32. As for the other jurisdictions, I dealt with that in ***MSD v Teva***. There is no suggestion the position has changed since then. The difficulty is that each case has to be decided on its own facts. I do not believe that different principles from the ones I have derived can be drawn from those cases.

The Particulars of Infringement

33. Four points are pleaded in the Particulars of Infringement to support the defendant's case. The four points are: the issue of the revocation proceedings, the expiry dates of the patents, the issue of equivalent revocation proceedings in Ireland where the claimant has a manufacturing facility which supplies the UK, and an exchange of correspondence. In that correspondence the defendant's solicitors made the point that it must be implicit in what the claimant had done so far that it intends to launch generic product in the UK in future. They sought an undertaking to provide two months' notice of launch as well as information about the claimant's launch plans and product details including whether it had applied for a marketing authorisation. The response was an offer of two weeks' notice of launch, but no further information on the grounds it is confidential.

34. I start with the same simple inference mentioned already. In this case the earliest expiry date for the patents is in 2027. The inference from the fact that the claimant has issued proceedings to revoke the patents is that the claimant intends to sell a product protected by the patent before 2027. It is not irrebuttable, but that is not the question at this stage. To fulfil that intention, the claimant will need to obtain a marketing authorisation. But all we know now is that the claimant does not have a marketing authorisation today. The claimant may already have applied. But in any event it follows from the simple inference that the claimant intends to launch before 2027, that it also intends to obtain a suitable marketing authorisation in that time frame. The absence of a marketing authorisation today does not mean that there is no

real prospect at trial of establishing a threat and intention to infringe. The claimant may have obtained a marketing authorisation by then.

35. If the claimant had wished to say that it did not intend to launch unless it succeeded in revoking the patent, then it had a clear opportunity to do so in the exchange of correspondence. It did not. It is a reasonable inference from the claimant's response in the present circumstances that the claimant wishes to reserve for itself the ability to choose to launch at risk using a product protected by the patents even if the patent(s) are found valid. The offer of two weeks' notice does not allow the question of infringement to be decided in advance of launch. Again all this may be rebutted by evidence, but this is a strike out application.

36. Another possibility is that in fact the claimant's launch plans are so inchoate that it does not yet have a concrete product in mind. The timing makes it unlikely, given how long it usually takes to develop products and obtain a marketing authorisation. Nevertheless it could be true, in which case it can be established.

37. In my judgment the defendant's pleaded case has a real prospect of success at trial. Subject to the competition law points, I would not strike it out. I am not persuaded that the third point, about the Irish case, would save the defendant if the other three points were not enough.

38. The claimant contends that there is an important principle at stake as to whether it should be forced to divulge its plans absent a properly pleaded case, particularly when the only basis for demanding the information is what the claimant calls its reasonable refusal to provide it. I will address the competition law points next. Aside from that, I do not accept this characterisation of the circumstances. If a claim is properly pleaded, as I have decided this is, then a party to civil proceedings does not have an unfettered right to keep relevant information to itself.

Abuse

39. There was a suggestion of a free standing abuse of process argument being advanced on the footing that the true motive of the defendant in bringing the infringement counterclaim was a collateral one, namely to have the claimant's launch plans disclosed to it. In my judgment this is hopeless.

40. In terms of the law I was referred to Bridge LJ in ***Goldsmith v Sperrings*** [1977] 1 W.L.R. 478 at p503F. He said:

> "…when a litigant sues to redress a grievance, no object which he may seek to obtain can be condemned as a collateral advantage if it is reasonably related to the provision of some form of redress for that grievance. On the other hand, if it can be shown that a litigant is pursuing an ulterior purpose unrelated to the subject matter of the litigation and that, but for his ulterior purpose, he would not have commenced proceedings at all, that is an abuse of process. These two cases are plain; but there is, I think, a difficult area in between …"

41. I was also referred to ***Wallis v Valentine*** [2003] E.M.L.R. 8, CA at paragraphs 31-32 (Sir Murray Stuart-Smith) in which he agreed with passages in the judgment of Simon Brown LJ in ***Broxton v McClelland*** [1995] E.M.L.R. 485, pp497-498. These

judgments stand for the proposition that the institution of proceedings with an ulterior motive is not of itself enough to constitute an abuse: an action is only abusive if the Court's processes are being misused to achieve something not properly available to the claimant in the course of properly conducted proceedings.

42. Finally the judgment of Teare J in ***JSC BTA Bank v Ablyazov (No. 6)*** [2011] 1 W.L.R. 2996 at paragraph 22(iii)-(iv) was referred to. This is to establish that even if a claimant has two purposes for commencing proceedings, one legitimate and the other sufficiently collateral as to be illegitimate, the commencement of proceedings will not be an abuse of process if one of the purposes is legitimate.

43. No doubt the defendant, as someone selling the patented product, would very much like to know what a rival's plans were. That applies in most patent cases. But it is quite another thing to infer that the true reason a patentee has brought a claim for infringement is not for its own sake, but is in order to find out the rival's plans. Even assuming that really is one of the defendant's motives, I am quite satisfied that the defendant has another purpose in bringing the infringement claim, namely to sue the claimant for infringement and obtain appropriate remedies such as an injunction if the claim is made out. Also relevant is the fact that it was not the defendant which started the proceedings. The infringement claim is a counterclaim to an action started by the claimant. Applying the legal principles identified, the infringement claim is not an abuse.

44. Moreover the claimant's overt acts have already made a partial disclosure of its intentions by bringing the revocation claim. It can avoid disclosing any further commercial plans altogether by undertaking not to sell a product covered by any patent found valid. If it wishes to do something different from that then there is a legal issue which ought to be resolved. The defendant is entitled to seek to resolve it in these proceedings.

Competition law

45. The recent ***Paroxetine*** judgment of the CJEU was a preliminary ruling on a reference from from the Competition Appeal Tribunal and relates to the issue called "pay for delay". That happens when a generic rival and a patentee settle a patent dispute in which the patentee effectively pays the generic rival to keep off the market. According to Mr Vidal of Pinsent Masons, the claimant now genuinely fears a serious risk of liability in EU and UK law if it were to provide the confidential information about its plans to the defendant. The possibility of a reference was mentioned. The claimant said it was not seeking one now, but the point might have to be referred in future.

46. The claimant's argument is in stages. The first stage is that in the light of the CJEU ***Paroxetine*** judgment the claimant and the defendant would be likely to be regarded as competitors for the analysis. The second stage is said to be that there is a very real risk that the provision of the requested information would be found to infringe Art 101(1) TFEU. The third stage (really a negative) relates to the issue of ancillary restraint.

47. The defendant does not accept the claimant's submissions.

48. Taking the first point. I agree the claimant and defendant can be regarded as potential competitors. However, as the defendant submitted, this is not something which one can say only became clear as a result of ***Paroxetine***. The test for potential competition has been set out for some time and the CJEU's judgment on this (paragraphs 42-44) applies well established competition law principles.

49. Turning to the second point, Art 101 TFEU prohibits restrictions on competition which arise from agreements between undertakings, decisions between associations of undertakings, and concerted practices. To avoid repeating that phrase, it is convenient to summarise what is prohibited as some form of collusion between undertakings. Without some form of collusion these provisions do not apply at all. The defendant submitted that there is no collusion of any sort in these circumstances. The defendant referred to the Commission's Horizontal Cooperation Guidelines at paragraph 60 which provide:

> "Concerted practice
>
> 60. Information exchange can only be addressed under Article 101 if it establishes or is part of an agreement, a concerted practice or a decision by an association of undertakings. The existence of an agreement, a concerted practice or decision by an association of undertakings does not prejudge whether the agreement, concerted practice or decision by an association of undertakings gives rise to a restriction of competition within the meaning of Article 101(1). In line with the case-law of the Court of Justice of the European Union, the concept of a concerted practice refers to a form of coordination between undertakings by which, without it having reached the stage where an agreement properly so called has been concluded, practical cooperation between them is knowingly substituted for the risks of competition."

50. The defendant also referred to the ***T-Mobile*** case (Case 8/08) to emphasise that at a minimum, to engage Art 101, it needed to be shown that practical cooperation between the parties was being knowingly substituted for the risks of competition. The defendant argued that there was no suggestion of that in this case, submitting that if disclosure of information relevant to these proceedings is directed by a court order, then clearly there is no agreement or concerted practice, nor could it be described as falling within that minimum level characterised in ***T Mobile***.

51. The claimant submitted that these provisions did apply or at least there was a real risk that they did, because it was the provision of information itself which amounted to collusion.

52. The claimant is right that the provision of information between undertakings can itself amount to the requisite form of collusion required by Art 101. That is clear from the first sentence of the Commission Guidelines which makes the point that information exchange can engage Art 101 if it "establishes" a concerted practice (etc.). In other words Art 101 can be engaged if the exchange itself is the concerted practice. However that does not mean that the provision of information which, on the relevant hypothesis, would be ordered in this case, must necessarily amount to a form of

collusion. That sort of exchange of information may simply not engage Art 101 at all. Assuming it is not part of some other collusion, the exchange will only engage Art 101 if it is an example of practical cooperation between the parties being substituted for the risks of competition, knowingly or not.

53. The information in this case is necessary disclosure in patent litigation. Although the point comes up again (below), it is worth pointing out at this stage that the purpose of the patent system is to stimulate innovation, which itself is pro-competitive. Resolving disputes between potential competitors about patent validity and infringement are part of that system and this sort of litigation, conducted properly, is inherently pro-competitive, irrespective of whether the result leads to a patent being upheld or not. The CAT dealt with this in its judgment ([2018] CAT 4) which led to the reference in ***Paroxetine***, as follows:

> "(3) In our view, an outcome of the litigation whereby the patent was upheld and the generic company found to infringe is not to be regarded as less competitive than an outcome the other way, since the purpose of the patent system is to stimulate innovation, which promotes dynamic competition. A court determination that a patent is valid and infringed therefore cannot properly be regarded as a "negative" result for consumers even if it means that they will continue to pay higher prices or the patented goods. Such determinations are a necessary means of ensuring that patent-holders receive the proper rewards for their innovations."
>
> [paragraph 321 (3)]

54. I respectfully agree. Moreover the disclosure to one party of relevant information in the control of the other party, is part and parcel of such litigation and that is something recognised in EU law (see e.g. Article 6 (1) of the Directive 2004/48/EC).

55. It is sometimes suggested that litigants use litigation as a front for something else. (There is no suggestion of that in this case.) I can see that if the litigation was a sham, designed to facilitate anti-competitive information exchange, then that would amount to collusion and would be a very different matter, but it is nothing to do with the present case.

56. I find that there is nothing here which could conceivably amount to any form of collusion, aside from the exchange of information itself. As to the provision of information itself, an exchange pursuant to the disclosure obligations and case management orders which are made in properly constituted patent litigation, even though it is an exchange of information between competitors or potential competitors, does not meet the minimum threshold to amount to a form of collusion prohibited by Art 101 TFEU. It is not an instance of practical cooperation between the parties working as a substitute for the risks of competition. I reject the second point.

57. The third point is ancillary restraint. The defendant advances it as an alternative to the issue I have just dealt with, but I will address it anyway. The principle can be taken from the ***Sainsbury's*** case at paragraph 58:

> "58. Although it is not expressly stated in the wording of article 101(1)TFEU, it is well established in European Union law that a provision of an agreement which has the effect of restricting competition does not constitute an infringement if it is objectively necessary for the implementation of the "main operation" of the agreement, provided that the main operation does not itself infringe article 101(1)TFEU."

58. The defendant submits that this principle would apply if, contrary to its primary case, the provision of information ordered by the court in these proceedings would amount to collusion which had the effect of restricting competition. The submission is as follows. First intellectual property rights enjoy a high level of protection in the internal market (see e.g. Case C-307/18 ***Generics UK*** at paragraph 41). Second the possibility for generic rivals to enter the market 'at risk' and potentially face infringement actions brought by the incumbent is an expression of potential competition in the pharmaceutical sector (see Case T-472/13 ***Lundbeck*** at paragraphs 96, and 128-129). Third this sort of patent litigation is pro-competitive (see the CAT's ***Paroxetine*** decision above). Therefore the proceedings of which the information exchange is a part, do not infringe Art 101. The disclosure of the information is objectively necessary in order for that litigation to take place and so, even though the disclosure involves providing commercially sensitive information, that does not constitute an infringement contrary to Article 101 TFEU.

59. The claimant did not dispute the first three points, but submitted that the test of necessity needed to be examined more fully. The submission was that it was not necessary for the information to be provided now because the issue of infringement may only need to be decided once a decision has been made about validity. Therefore if this ancillary restraint defence applied, it justified a stay of the infringement counterclaim until validity had been resolved.

60. I do not agree. For the reasons already given above, the right thing to do is resolve infringement and validity at the same time. A patent case which has both issues decided together is the right way to resolve most patent disputes, including this one. It is not anti-competitive to resolve this patent case that way. The question then is whether the disclosure is objectively necessary to that, pro-competitive, exercise. It is.

61. Accordingly I reject the claimant's case based on competition law. The order requiring disclosure, which would follow if the infringement claim proceeds, does not turn those proceedings into something contrary to Art 101, nor would the order for disclosure itself amount to something contrary to Art 101. Moreover consideration of Article 101 does not justify a stay of the infringement claim pending resolution of the validity dispute.

A stay in any event

62. As well as the submission about ancillary restraint, the claimant had a general submission that the infringement claim should be stayed since it was prepared to offer 14 days' notice of a launch. I can address that now that the other issues are dealt with. The offer of 14 days' notice is designed to show that the claimant is not trying to engage in a surreptitious launch, which has been criticised in the past. I accept that.

However it is no substitute for resolving any issues of infringement, on their merits, at the trial in October.

63. A different situation would be one in which a party came to court and explained that they simply did not have a fully specified product which could be the subject of adjudication. In that case no doubt some other course would be adopted. I expect it was considerations of that kind which led to the defendant asking the claimant for two months' notice, amongst other things. That offer seems to me to have been a sensible attempt at a compromise, bearing in mind that it is likely that a company in the position of the claimant would in fact have a finalised product formulation many months in advance of launch. However it was rejected.

64. I am not satisfied a stay of the infringement claim is warranted.

Conclusion

65. The infringement claim will not be struck out. It has a real prospect of success. It will not be stayed. Since it will continue, disclosure will be required from the claimant. There is no reason not to make the order.