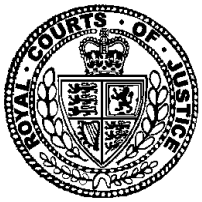

Neutral Citation Number: [2022] EWCA Civ 775

Appeal No. CA-2020-000835
Claim No. HP-2022-000006

IN THE COURT OF APPEAL
(CIVIL DIVISION)
IN THE HIGH COURT OF JUSTICE
ON APPEAL FROM THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

Royal Courts of Justice
Strand, London
WC2A 2LL

Wednesday, 25th May 2022

Before:
LORD JUSTICE BIRSS

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Between:

(1) NOVARTIS AG **(2) NOVARTIS PHARMACEUTICALS UK LIMITED**	**Appellants / Claimants**
- and -	
(1) TEVA UK LIMITED **(2) DR. REDDY'S LABORATORIES (UK) LIMITED** **(3) GLENMARK PHARMACEUTICALS EUROPE LIMITED** **(4) TILLOMED LABORATORIES LIMITED** **(5) ZENVITA PHARMA UK LIMITED** **(6) ARISTO PHARMA GMBH** **(7) VIATRIS UK HEALTHCARE LIMITED**	**Respondents / Defendants**

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MISS CHARLOTTE MAY QC, MR. HENRY EDWARDS and **MR. EDMUND EUSTACE** (instructed by **Bristows LLP**) appeared for the **Appellants/Claimants.**
MR. THOMAS HINCHLIFFE QC (instructed by **Pinsent Masons LLP** and by **Lambert Hornby Ltd**) appeared for the **First, Second** and **Seventh Respondents/Defendants.**
MR. THOMAS MITCHESON QC (instructed by **Taylor Wessing LLP**) appeared for the **Third Respondent/Defendant.**
MR. WILLIAM DUNCAN (instructed by **Mishcon de Reya LLP**) appeared for the **Fifth Respondent/Defendant.**

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Approved Judgment

Transcript of the Stenograph Notes of Marten Walsh Cherer Ltd.,
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LORD JUSTICE BIRSS :

1. This is an application for permission to appeal from the decision of Roth J, given on 26th April 2022, [2022] EWHC 995 (Ch), in which he refused to grant an interim injunction. The case is a patent dispute about a drug called fingolimod for the treatment of a form of multiple sclerosis called relapse remitting multiple sclerosis (RRMS). The brand name for this drug is Gilenya. The patent is EP 2 959 894. It is a divisional of a parent application filed in 2007, claiming priority from 2006.

2. The claim is brought by the patentee Novartis against a number of generic pharmaceutical companies as defendants. The defendants have already or intend immediately to launch generic fingolimod for the treatment of RRMS in the United Kingdom. Subject to a point below, there was no debate about whether the product would infringe the granted claims. The issue is validity. The defendants contend that the claims are or would be invalid. The trial has been fixed for October 2022, i.e. in about five months' time.

3. The application for interim relief was refused and the judge's reasons are contained in his judgment. The judge refused permission to appeal but in the meantime he granted a brief injunction to hold the ring while the patentee sought permission from this court.

4. I received the application on paper last week and directed that the matter be dealt with at a hearing today, with the brief injunction continuing over until this permission application is resolved.

The judgment

5. An unusual feature of this case is that although the machinery of the EPO means that the patent will inevitably be granted, the date of that grant under Article 97 of the EPC is in the future. Therefore today, and before the judge, the patent has not been granted. Novartis contended, and the judge accepted, that the court nevertheless had jurisdiction to grant an interim injunction despite the terms of section 69 of the Patents Act 1977, which only refer to a right to damages after publication. The judge decided that he had jurisdiction.

6. Having decided the jurisdiction point, the rest of the judgment follows the *American Cyanamid Co v Ethicon Ltd* [1975] AC 396 approach. Serious issue to be tried was not in dispute and the focus turned to the adequacy of damages and the balance of convenience. The judge decided that damages would be an adequate remedy for the patentee. That was for a number of reasons. First, the market is not like some familiar in pharmaceutical patent cases. The drug is not prescribed by GPs but only in secondary care, and the price is not determined by the Drug Tariff. At present supply is via contracts and there is an NHS tendering process. In fact in the expectation of the drug going generic, tender processes began by the time the judgment was given.

7. The judge accepted Novartis's argument that with the number of generics entering market there would be marked price depression in the pre-tender sales but he did not consider it was likely that there would be a significant price spiral in the period up to trial, given the nature of the market, the distribution arrangements and the short time between then and the trial. The majority of sales would be under tenders with a known fixed price throughout the period. The patentee had no rational incentive to reduce its

price pending trial since it could resume supply of Gilenya if it wins the trial. The group could also supply generic material via its own generic arm, Sandoz.

8. The judge held that if the patent was upheld at trial, the NHS would not refuse to buy at the monopoly price at which Gilenya had previously been sold. In doing that, he was not accepting evidence to the contrary from Ms. Bride of Novartis.

9. The judge did not think the presence of the alternative drugs existing and anticipated to enter the market in the future made any real difference.

10. Overall, he accepted that the level of sales of Gilenya could not be accurately predicted after late 2022 and held that they were unlikely to increase from then and may gradually decline, but nevertheless he did not see that there was any sound basis to find that future sales would be materially affected by the temporary introduction of generic fingolimod for a period of months and then a return to the branded form only, assuming Novartis won the trial.

11. The other major aspect of the case below was an allegation by Novartis that there would be significant reputational damage from the generic entry to the market, particularly bearing in mind an unusual aspect of the market for Gilenya, which is a service for patients provided by Novartis called GilenyaConnect, and the impact of moving patients on to whatever corresponding service might be provided by other suppliers and potentially the effect of and on other drugs.

12. As I say, the judge decided that damages were an adequate remedy for the patentee and so no interim injunction should be granted. Nevertheless, he also went on to consider the rest of the *American Cyanamid* factors in case that conclusion was wrong. He decided he would refuse the injunction on that basis too.

13. Novartis seek permission to appeal on six grounds. Grounds 1, 2 and 3 relate to the judge's factual conclusions about what was likely to happen to prices.

14. Ground 1 is that having found there would be marked price depression, it was not open to the judge to reject the allegation that there would be a severe price spiral, because they are the same thing.

15. Ground 2 is that the judge was wrong to hold that the reduction in generic prices in that period did not matter because the larger they are, the less likely it will be for the patentee to restore its prices, and the evidence was that the price could go down as low as 5% of the monopoly price.

16. Ground 3 is that the judge was wrong to reject Ms. Bride's evidence that the NHS would be extremely reluctant to go back to monopoly price, especially if the generic price had got as low as 5%.

17. In my judgment, these grounds have no real prospect of success. The judge's task was to examine the evidence and he is not bound to accept it uncritically: see *Neurim v Generics* [2002] EWCA (Civ) 973, paragraph 15. The judge drew a clear distinction between the price drop, which he acknowledged, and a possible severe price spiral, and he gave sensible and convincing reasons why he was not satisfied that the severe price

spiral would occur in the relatively short period to trial: see judgment, paragraph 50. There is no real prospect of success in showing that that was an error.

18. Grounds 2 and 3 go together. The judge recognised that Novartis's evidence was about what was going to happen in the future, but the key thing was that the judge did not accept Novartis's case that they would be unable to restore the monopoly price. In my judgment, this is fundamental. Ms May submits that the judge applied the wrong test or the wrong standard in his finding in the judgment that "it cannot be assumed that the NHS will nevertheless refuse to pay the monopoly price" if the monopoly is restored after trial. However, I find that ground has no real prospect of success. The judge was not applying the wrong standard, he was evaluating the strength of the likelihood of something material happening in the future. He gave sensible reasons for his view that the risk was not material to his decision. The purchasers are sophisticated, the period of the injunction will be short, and the drug has been approved at the monopoly price and the seller has no rational reason to reduce its price in the meantime. That was plainly a conclusion that was open to him.

19. Ground 4 challenges the judge's conclusions that damages would be an adequate remedy for the claimants. The problem here for the patentee is that that conclusion, it seems to me, follows from the judge's earlier conclusions, particularly rejecting as a serious concern the inability of the patentee to restore sales at the monopoly price. If there was a serious risk of an inability to restore sales at that price, then I can see that damages probably would be an inadequate remedy for the patentee, but for the reasons already given in my judgment the judge was entitled to reach the conclusion he did.

20. Given that there is no real prospect of success on ground 4 either. It follows there is no real prospect of success of overturning the main basis on which the judge decided this case and there was no need to examine grounds 5 and 6.

21. The only remaining question is whether there is some other good reason for giving permission to appeal and, in my judgment, there is not. No point of principle arises on the assessment of the quantifiability of the loss in this case. There is not time between now and trial to review *American Cyanamid* in the Supreme Court, and the novel point of law about pre-grant injunctions is not a reason to give permission to appeal, if the injunction aspect of this case has no real prospect of success. I therefore refuse permission to appeal. That is my decision.

[Further Argument]

22. I now need to resolve what to do about the costs of this appeal. Mr. Hinchliffe for Teva submits -- and I imagine Mr. Mitcheson would probably support it, so I did not give him a chance to say anything -- that I should apply Practice Direction 52C, rule 20(2) which says, "If the court directs the respondent to file submissions or attend a hearing, it will normally award costs to the respondent if permission is refused." He submits that is what has happened and therefore I should award the respondents their costs. He also submits that even if that is not the rule, I should award the respondents their costs anyway on general principles. Miss May submits the rule does not apply because I did not direct that the respondents should attend.

23. In my judgment, this rule does not apply, because the order that I made last week gave the respondents the ability to come if they wished, but it did not require them do so, and, accordingly, that rule does not apply.

24. Looking at the matter overall, in my judgment, there is no reason why the costs of this application for permission to appeal should be treated any differently from what is normally done, and what is normally done (see rule 20(1)) is the court will not normally make a costs order in favour of a respondent who attends a hearing voluntarily, even if permission to appeal is refused, so I will make no order as to costs.

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