Neutral Citation Number: [2019] EWHC 92 (Pat)

Claim No: HP-2018-000035

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

Royal Courts of Justice
The Rolls Building
7 Rolls Buildings
London, EC4A 1NL

Date: Tuesday, 15th January 2019

Before:

MR. JUSTICE BIRSS

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Between:

(1) NOVARTIS PHARMACEUTICALS UK LIMITED **Claimants**
(2) NOVARTIS PHARMA AG
(a company incorporated in Switzerland)
(3) NOVARTIS INTERNATIONAL PHARMACEUTICAL AG
(a company incorporated in Switzerland)
- and -
DR. REDDY'S LABORATORIES (UK) LIMITED **Defendant**

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MR. THOMAS HINCHLIFFE QC and **MR. TIM AUSTEN** (instructed by **Kirkland & Ellis International LLP**) for the **Claimants**

MR. JAMES ABRAHAMS QC and **DR. GEOFFREY PRITCHARD** (instructed by **Innovate Legal**) for the **Defendant**

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Approved Judgment

Transcript of the Stenographic Notes of Marten Walsh Cherer Ltd.,
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MR. JUSTICE BIRSS:

1. This is an application for an interim injunction relating to European Patent UK number EP 2, 269, 603 entitled "Treatment of breast tumors with a rapamycin derivative in combination with exemestane". The patent's earliest claimed priority is from a British filing on 19th February 2001. It was granted following an application having been filed on 18th February 2002 and published under the PCT as WO 02/066019 on 29th August 2002. The grant is 20th May 2015. Claim 1 of the patent is in this form:

> "40-O-(2-hydroxyethyl)-rapamycin in combination with exemestane for use in the treatment of hormone receptor positive tumor, wherein in the hormone receptor positive tumor is a breast tumor."

2. The claim is an EPC 2000 product for use claim. The compound 40-O-(2-hydroxyethyl)-rapamycin is also known as everolimus. For convenience, when I refer to the breast cancer indication in this judgment, I mean the breast cancer indication referred to in claim 1. There is no need to always read out the reference to hormone receptor positive tumours.

3. The patentee is a member of the Novartis group. The defendant, Dr. Reddy's Laboratories (UK) Limited, have a marketing authorisation for everolimus. The authorisation is not what is called a skinny label. The authorisation includes use for the indication which is claimed in claim 1 and including in combination with exemestane. That marketing authorisation was obtained in the summer of 2018.

4. In June 2018, the Opposition Division of the European Patent Office heard and determined opposition proceedings brought by a number of generic pharmaceutical companies against the patent. The proceedings were brought on various grounds, including lack of novelty, lack of inventive step and added matter (contrary to Art 123(2) EPC). The written decision was given in September 2018. The Opposition Division held that claim 1 as granted, which was the main request before the OD, was invalid for added matter. The patentee has appealed and contends in its grounds of appeal that claim 1 is valid and that the decision is wrong.

5. Today approximately 90% of the UK market for the compound everolimus is for the breast cancer indication. The patentee Novartis sells everolimus under the name Afinitor for that indication. The marketing authorisation for Afinitor includes the use of everolimus in combination with exemestane.

6. The SPC for everolimus *per se* expires on 17th January 2019.

7. Dr. Reddy's' position on this application is that the patent is invalid for the reasons given by the Opposition Division. It intends to launch everolimus after 17th January and its case is that this would not be an infringement of the patent because the patent is invalid.

8. These proceedings were commenced by issue of a claim form on 7th December 2018. Validity is the sole point taken by the defendant in its Defence to the Particulars of Claim and Particulars of Infringement.

9. The Particulars of Infringement include allegations that claim 1 is infringed under section 60(1) and section 60(2) of the Patents Act 1977 by the sales of everolimus by Dr. Reddy's. That is in paragraph 3. The Defence admits paragraph 3, subject only to the point that the patent is invalid. Therefore the Defence has admitted infringement of sections 60(1) and (2), subject only to the allegation that the patent is invalid. In saying this, I reject the submission of counsel for Dr. Reddy's that the admission in the Defence was only that "one or more" of the ways in which the claimant put its case on infringement was admitted; so that only one way but not the other one way was actually admitted. That does not make much sense. In any case the admission in the Defence made sense since Dr. Reddy's does not have a skinny label but has a marketing authorisation for the full range of indications, including the one claimed by the claimant in this patent.

10. The sole attack on validity in the defendant's Grounds of Invalidity is based on added matter. The plea is that the combination claimed in claim 1 is not disclosed in the application as filed.

11. The patentee brought an application for interim injunction and the defendant responded with an application for summary judgment on its Counterclaim for revocation. The patentee filed a report of Professor Johnston, who is currently Professor of Breast Cancer Medicine and Consultant Medical Oncologist at the Royal Marsden Hospital in London. His opinion is that the claim is disclosed and there is no added matter. The defendant's stance on this application is that they accept Professor Johnston's evidence for the purposes of this hearing, but contend that when one examines the Professor's reasons for his view, those reasons in fact support the defendant's case.

12. I read the materials I was invited to read in advance of this hearing, including the skeleton arguments and the evidence. The evidence included the witness statements relating to the interim injunction which dealt with the commercial position on the market and the alleged effects of granting or refusing an injunction. They were witness statements of Amanda Youds of Novartis, a commercial marketing manager and Subir Kohli, who is Vice President, Head of Sales and Marketing at Dr. Reddy's. I also read Professor Johnston's expert report. I read the patent and application as filed. I reminded myself of the authorities and read the Opposition Division's decision.

13. When the hearing was called on, I explained to the parties that I had formed a provisional but clear view that there was no added matter and that therefore the patent was valid. I asked counsel if I should dismiss the Counterclaim and give judgment on the claim now. Counsel for Dr. Reddy's explained that although his client had applied for summary judgment, the patentee had not sought summary judgment the other way round and that while he was arguing his case based on accepting for the purposes of the hearing Professor Johnston's evidence, that did not mean there was not more he might wish to say at trial, particularly if his clients saw my reasons for the view I had expressed. He submitted I should not rule now that the patent was valid but he accepted, I should say rightly in my judgment, that if that did remain my view, it might well have a significant bearing on any question of an interim injunction.

14. I accepted counsel's submission that I should not give judgment on the claim right now, so I heard counsel for Dr. Reddy's on his case that the patent was invalid. After hearing counsel, I decided that there was no arguable case that the patent was invalid on the ground pleaded on the materials available to the court today. The reason for that will

be explained in more detail in a moment. But listening to the arguments, I formed the clear view that based on those arguments there was no added matter.

15. It was no part of Dr. Reddy's case before me that something else would emerge at trial that might change that. I will not prevent Dr. Reddy's from bringing forward at trial any facts, evidence or arguments they wish to in the light of this judgment. However at this stage I am not persuaded there is an arguable case that the patent is invalid. Therefore, given the state of the pleadings, there is no arguable case in favour of the defendant on the merits of the claim at all.

16. Since it is manifest on the commercial evidence that there is a real risk of unquantifiable loss to both sides if I either grant or refuse an injunction pending trial, it seems to me that I should therefore grant an interim injunction pending trial. If, which is not this case, there was no unquantifiable loss to the claimant but there would be unquantifiable loss to the defendant from such an injunction, then one might take a different view despite the lack of an arguable defence, but that is not the facts and counsel rightly did not suggest it was.

17. There is no need to examine the evidence on the balance of convenience in any depth at all. The evidence covers the familiar ground one sees in pharmaceutical patent cases of this kind. It addresses the risk of losses to the patentee caused by irrecoverable price depression once a generic product enters the market and the risk of unquantifiable loss to the defendant caused by an injunction such as the loss of a first mover advantage for a generic defendant entering what had hitherto been a market entirely covered by the patentee's monopoly.

18. It would be hard either way once one approach is taken (generic product launched or not) to recreate what the market would have been like if the other version of events had occurred, but as I say, given the circumstances as they are, there is no need to get into that evidence in any more depth. Since there is a real risk of unquantifiable harm either way, in my judgment, the right thing to do is to grant an interim injunction.

19. I will now turn to explain what my view is on added matter and then deal with some issues on the terms of the order.

Added matter

20. Added matter is prohibited by s76 of the Patents Act (Art 123(2) EPC). The law of added matter is summarised in *Nokia v IPCom* [2012] EWCA Civ 567. The passage cited is the judgment of Kitchin LJ. The law ends at paragraph 60 but the reference particularly cited to me was from paragraph 45 through to 50. It covers the well-known authorities of *Bonzel v Intervention* [1991] RPC 553, *Vector v Glatt* [2007] EWCA Civ 805, *Richardson-Vicks* [1995] RPC 568 and so on.

21. One of the important principles is that the approach to take is the approach as explained by Aldous J in *Bonzel* which is that one ascertains through the eyes of the skilled addressee what is disclosed both implicitly and explicitly in the application, does the same in respect of the patent and then compares the two disclosures and decides whether any subject matter relevant to the invention has been added whether by deletion or addition. Aldous J there made the point that the comparison is strict in the sense that

the subject matter will be added unless the matter is clearly and unambiguously disclosed in the application, either explicitly or implicitly.

22. The strictness of the comparison was also referred to by Kitchin J in *European Central Bank v Document Security Systems* [2007] EWHC 600 (Pat) which I take from paragraph 99 of the quote from paragraph 7 of the quote from *Vector v Glatt* quoted in *Nokia v IPCom*. That is an important aspect of the principle, as Mr. Abrahams submitted.

23. Another important point made by Mr. Abrahams which I accept is that the disclosure is different from coverage, in other words the fact that claims or text may cover something is not the same thing as whether they disclose it. The test for the purposes of added matter is to consider disclosure.

24. Another important point is the question of whether anyone has learned anything about the invention which they could not have learned from the unamended specification or the application. That was how Jacob J put it in *Richardson-Vicks* and is a good way of summarising in a pithy way what the test for added subject matter is.

25. A further point is to note that the purpose of the law preventing added subject matter is to ensure that the patentee cannot gain an unwarranted advantage. Two ways in which that could occur are referred to in paragraph 6 of *Vector v Glatt*. One is they could circumvent the "first-to-file" rule and in effect obtain an unwarranted priority date for something they had not invented at the time. The other one is that they could obtain a different monopoly from that which could be predicted or justified from what was originally filed. That prejudices legal certainty for third parties.

26. Another important principle to note, also identified by Kitchin J in *ECB v Document Security Systems*, is the warning against hindsight. One needs to take care when reading the application as filed not to read it with hindsight knowledge of what is in the patent. It is not the right approach to read the patent and then look for what is there in the application. When one is applying the added matter test, the reader of the application does not know what is written in the patent.

27. Finally, Dr. Reddy's also relied on the decision in *Dr. Reddy's v Eli Lilly* [2009] EWCA Civ 1362 and a principle described by the Court of Appeal in the context of lack of novelty but applicable to disclosure in general. This is at paragraph 23 through to paragraph 33 of the judgment. My very terse summary of the principle is that a generic disclosure of a class does not disclose an individualised member of that class. That is why in that case the compound olanzapine was novel despite a prior disclosure of a chemical formula with a 10^{19} compounds in it, or for that matter a formula with 86,000 compounds of a supposed preferred class, when in neither case was olanzapine mentioned specifically.

28. Dr. Reddy's also referred to the European Patent Office's case-law textbook in its current edition and to paragraph 1.4.2 of section II.E.1 about Article 123(2) EPC. This section is headed "Selection from two lists and deletion of elements from two lists". Mr. Abrahams referred to the first two paragraphs of that which deal with the principle which is applied in the EPO that selecting items from two lists means that a claim may contravene Article 123(2).

29. It is notable that there is no UK case that I am aware of, or to which I have had my attention drawn by either party, that puts the principle applicable in relation to added matter in quite the way it is described in paragraph 1.4.2 of the textbook. There is a danger of taking a rather too rigid approach if one looks at it in that way. The two list cases may well be examples of cases in which there is added matter. I am sure many of them are. But it seems to me that the better approach, at least in this jurisdiction, is to focus on the application of the legal test itself. I do not accept that, as a general statement, it is true that a teaching which consists of a combination of two individualised lists, in other words two lists of individualised members, necessarily means that that combination is now to be treated as an un-individualised generic disclosure. I do not believe that is what Dr. Reddy's submission of law was, but if it had been I would have rejected it. Every case has to be decided on its own particular facts and I turn to those facts.

30. There is it no dispute who the addressee of the patent would be. I do not believe anyone actually set it out, but it would be someone, I guess a clinician, or a clinician together with some other relevant skilled person interested in investigating the development of treatments for cancer and in particular the relevant breast cancer indication. As a matter of common general knowledge, no particular matter of common general knowledge has been drawn to my attention as being sufficiently relevant to be worth mentioning at this stage.

31. Taking the *Bonzel* approach, I will start briefly with the patent, recognising that I should not use hindsight when I look at the application. It can be done simply. Claim 1 of the patent plainly discloses, as well as covers, the combination of the use of everolimus in combination with exemestane as a treatment for the breast cancer indication. The real issue is what information is conveyed by the application as filed, again at the risk of repetition, read without hindsight.

32. I turn to that document. First of all, it is clear, reading the document as a whole, that the disclosure is for the use of rapamycin and derivatives of rapamycin for various indications. That is unquestionably a wide class of compounds and a wide disclosure in terms of their utility. I can refer to that as the R&D class for Rapamycin and Derivatives. However, it is also manifest, reading the text as a whole, that a particular compound, which is referred to in the application as Compound A, is singled out. It is at least a -- and in fact I would say "the" -- paradigm example of the compound to be used from the R&D class. There a number of *in vitro* and *in vivo* examples. They all relate to Compound A, at least as an example. Some of those examples relate to monotherapy and some to combination therapy. I recognise, with an eye on the issue I have to decide, that the specific combinations in those examples are not with exemestane or for that matter any aromatase inhibitor. (I will come back to what an aromatase inhibitor is in a minute).

33. The second point is that Compound A is in fact everolimus.

34. The third point is that it is plain as a matter of disclosure that Compound A is being disclosed as one of the particular compounds to use to put the disclosure as a whole into practice, that is the whole of the application. The person skilled in the art reading this document without hindsight would see Compound A in that way. There is no question of selecting Compound A from a list in relation to anything in this document.

35. Next, the application discloses the idea of monotherapy and also discloses the idea of combination therapy. Professor Johnston explains that combination therapy is familiar in cancer treatment. Whether that matters I am not sure. The combinations described in the patent are with various agents of different kinds. Again, applying what I have determined already, there is a clear and unambiguous disclosure of the idea of using Compound A as the rapamycin derivative in the various combinations disclosed. The combinations are very wide indeed.

36. Counsel for the defendant described them as stupendously wide and in a sense that is true. However there is it no evidence, and I am not satisfied, that the skilled person reading this document would be mesmerised by the width identified by the defendant. It is true that the application discloses many ideas and in a wide way. But I do not see why the reader would be distracted by that. If something is identified specifically in a document then it does not cease to be disclosed simply because elsewhere in the document there is more wide language.

37. Next, one of the combinations clearly in the document is to combine the R&D compounds with compounds called aromatase inhibitors. That combination is specifically called out in relation to the use to treat hormone receptor positive tumours in breast cancer, in other words the breast cancer indication claimed in claim 1 of the patent as granted. The passage is on page 6 and is set out below. To emphasise, there is a clear and unambiguous disclosure that the combination of the compounds of the R&D class as a whole with aromatase inhibitors could be used for the breast cancer indication. That indication is not the only disease that one might want to treat by combining the R&D compounds with an aromatase inhibitor, but is a clear teaching of an association between that class of agents, as agents in the combination, and that indication.

38. Furthermore the aromatase inhibitors and, for that matter, the other agents listed as being things that could be combined with the R&D compounds, are not being disclosed as alternatives to the administration of the R&D compounds themselves. The only function of the agents listed to be added as combinations in this document is for them to be combined with the R&D compounds.

39. The class aromatase inhibitors is only one of the classes of agents to be combined and it is itself disclosed in wide terms. There is a functional description and some specific sub-types. However, also explicit in the document is a reference (more than once but at this stage at the beginning of the document) to exemestane as one of the specific aromatase inhibitors. I gather from Professor Johnston's evidence that it was known anyway, but that does not matter.

40. Again, pausing there, the only purpose from the point of view of a skilled person reading that reference to exemestane itself or the aromatase inhibitors in general, as I think I have already said, is for them to be combined with the R&D compounds. That is expressly taught. Page 6 of the document, which defines the term "aromatase inhibitor", mentions a number of compounds, including exemestane and the trade mark under which exemestane is sold, along with the trade marks that certain other aromatase inhibitors are sold under. At the end of that paragraph it states:

> "A combination of the invention comprising a chemotherapeutic agent which is an aromatase inhibitor is particularly useful for

> the treatment of hormone receptor positive tumours, e.g. breast tumors."

41. Then, in the text, one turns to the examples. As mentioned already they all refer one way or the other to Compound A, that is to say, everolimus. Nevertheless none of those combinations involve a specific example of a combination with an aromatase inhibitor. What could be have called an "example" of a combined treatment at section C.2, which is under the heading "Clinical trials", is not really an example at all. It is really, as Mr. Abrahams put it, a proposal for doing clinical trials on a wide range of possible combinations. I think that is a fair description.

42. Then there is some general wording after the end of the examples. Starting at page 18, there is a reference to combining R&D compounds with co-agents. One of the classes referred to is aromatase inhibitors. As counsel pointed out, at page 19 at the top, a specific embodiment is disclosed with an aromatase inhibitor which is not exemestane. The aromatase inhibitor in that specific embodiment is a compound called letrozole.

43. At end of the document, various dosing regimes and dosing levels are described. At page 21, it starts with the dosing relating to the R&D compounds and then moves on to the co-agents. Near the end of the dosing relating to the R&D compounds is a reference to dosing for Compound A in particular. At the paragraph bridging pages 21 and 22, the co-agents are referred to for dosing and the second one on the list is exemestane. That comes after fadrozole and before formestane at the top of page 22.

44. It seems to me that, again at the risk of repetition, the person skilled in the art reading this document would see Compound A as one of the compounds to take forward. They might then choose, if they are interested in combinations, to select a combination. That could be said to involve a selection but the idea of selecting a combination with exemestane, in particular for the breast cancer indication, is clearly and unambiguously contemplated and disclosed in this document.

45. Looking at the document as a whole, it comes down to this. First, the document teaches the idea of combining R&D compounds with aromatase inhibitors to treat the breast cancer indication. It discloses exemestane as one of the aromatase inhibitors you might select to be in that combination for that indication. Second of all, it teaches Compound A (that is everolimus) as the paradigm rapamycin derivative to choose from the R&D compounds in general. It is not a question of selecting Compound A from a list or a lack of an individualised disclosure of Compound A. Therefore, it seems to me that there is disclosure of everolimus combined with exemestane to treat breast cancer. That is not new information. It is something that is disclosed in the document. It is not at all the only thing disclosed, but it is one of the things which is individualised by this document. It would be no undue advantage, in my judgment, to claim that combination.

46. For this reason, I disagree with the decision of the Opposition Division. Their decision appears to take an unduly technical approach which has lost sight of the disclosure of the document as a whole and has also lost sight of the prominence of Compound A in it.

47. Dr Reddy's submitted that Prof Johnston's reasons supported their case. The high point is the use by the professor of the word "covers" at one paragraph. It is not clear to me whether he meant cover in the sense that a claim can cover, but not disclose, something;

or whether he was using the word in a different sense of "deals with". But if even if it was the former sense, that does not mean added matter is present, it simply means the expert's evidence does not establish it is not present. In any event added matter is primarily a matter of construction rather than expert evidence.

48. At times in the course of argument, it sounded like part of Dr Reddy's case may involve some sort of squeeze based on plausibility or prior art. That may or may not be the case, but such an argument is not the case pleaded at the moment.

49. That is my decision on added subject matter.

Terms of the order

50. Turning to the terms of the order, the order sought is for an injunction pending trial, until the expiry of the patent or further order:

> "that the defendant must not make, dispose of, offer to dispose of, use, import and/or keep, whether for disposal or otherwise in the United Kingdom
>
> (a) Everolimus Dr. Reddy's the subject of Marketing Authorisations [*and certain numbers are given*]; and
>
> (b) any medicinal products comprising the active ingredient everolimus that are approved for *the treatment of hormone receptor positive, HER2/neu negative advanced breast cancer, in combination with exemestane, in post-menopausal women without symptomatic visceral disease after recurrence or progression, following a non-steroidal aromatase inhibitor* (the 'breast cancer indication') save for everolimus supplied by, or on behalf of, Novartis Pharmaceuticals (UK) Limited."
>
> I have italicised words in (b). They are what is defined by the term the breast cancer indication in that sub-paragraph.

51. Counsel for Dr. Reddy's submitted that there should be a number of carve-outs from that order. The first one is that it should permit Dr. Reddy's to sell everolimus for non-breast cancer indications. The point being made, of course, is that those sales for non-breast cancer indications would not infringe the claim. It was also suggested that the only infringement alleged was under section 60(2) of the Patents Act 1977 and that I should insert words, based on the wording of section 60(2), such as a proviso the products could be sold as long as it was not obvious to the defendant that the goods being sold were to be used for breast cancer. In other words, they could sell it if it was not obvious that the products were to be used for breast cancer.

52. Of course, an important principle is that, generally speaking, one does not grant any injunction, let alone an interim injunction, which prevents a party from doing what is clearly a lawful act. Another relevant principle, from authorities like *Staver v Digitext* [1985] FSR 512 and *Video Arts Ltd v Paget Industries* [1988] F.S.R. 501, is that interim injunction orders should be clear. These two principles can interact, especially at an interim stage. Interim injunctions can, and sometimes do, prevent not just acts which

may or may not be lawful which the court cannot resolve, but also some acts which would be lawful. That is done when preventing those lawful acts is the price for sufficient clarity in the terms of the injunction. Of course, the courts will not do that lightly, but clarity in an order holding the ring pending trial is itself an important principle. The last thing the court should be doing is granting an injunction which is unclear, which may lead to trouble of enforcement and the like in between the interim hearing and the trial.

53. In my judgment, the principle that a lawful activity should not be prevented may yield, in a proper case, to the principle of clarity for the purposes of holding the ring.

54. I also bear in mind that Dr. Reddy's have marketing authorisations, which are referred to in the terms of the order, which expressly authorise the use of the product for the relevant indication in the claim, including in combination with the relevant other ingredient. This is not a case relating to a skinny label.

55. In my judgment, the carve-out proposed by Dr. Reddy's just stores up trouble for the future. It would need a trial to find out if it had been contravened. I bear in mind particularly that on the evidence in the case, the breast cancer indication represents 90% of the UK market for everolimus. If the relevant indication for breast cancer, let alone breast cancer with the combination, was only a very small part of the market, this might very well be a completely different factor, but in a case in which that is what everolimus is almost all being used for, it seems to me that a carve-out of the kind suggested by Dr. Reddy's in this case would not be appropriate.

56. I proposed as an alternative that a term be placed by Dr. Reddy's in the contracts for sale of their goods which would prohibit use of those goods for the claimed indication. However I was told on instructions by Mr. Abrahams that there was no scope for inserting clauses of that kind in the contracts.

57. Dr. Reddy's offered to make it clear in a letter going with the contract that the sale was on the basis that the compound was not to be used in that way. In my judgment, that would not be good enough. For the reasons I gave at the hearing - it would not alter the terms of the contract for sale and, when the market is as it is, I do not believe that would give the patentee the appropriate protection.

58. There ought to be a clear line drawn between now and the trial, so the terms of the order in that respect will remain as they are. I recognise that in making that order, it will mean that I am restraining Dr. Reddy's from supplying some product which would be used lawfully for indications outside the claim.

59. Another point on carve-outs was that I should permit Dr. Reddy's to sell product aimed at clinical trials based on the terms of section 60(5)(i) of the Patents Act. That is the exception for clinical trials which are within Article 10 of Directive 2001/83 EC on medicinal products for human use and, in particular, bioequivalence studies. That point was not pleaded. Mr. Abrahams argued that the fact it was not pleaded did not matter because it was only relevant to the interim injunction. That is not correct. If it was something which Dr. Reddy's were seeking to say would not be an infringement then they ought to have pleaded it. So I will not put in a carve-out relating to that, but I will give Dr. Reddy's liberty to apply. If they do wish to supply something of that kind, they can come back to court or explain it to Novartis and the matter can be dealt with.

60. The third point that was taken was whether the cross-undertaking should also cover the Department of Health or the relevant NHS entities. Dr. Reddy's submitted that it should. There have been previous cases, of course, where things of that kind have been done.

61. I should say that the reason for this is as follows. Very often, when a generic compound is prevented on an interim basis from coming on the market by a patent of this kind, once the SPC for the original compound *per se* has expired, it is possible that the entity which loses the most, if it turns out that the interim injunction should not have been granted, is not so much the generic supplier itself but the Department of Health or the relevant NHS entities. That is because they are the entities who will be paying the price, which will necessarily be a higher price than it would have been if the market had been opened up. That is why it makes sense in some cases for the Department of Health to be joined for the purposes of the cross-undertaking.

62. However, the Department of Health is not before the court, nor any NHS Trust or other entity. Novartis invited me to make the order I made in *Actavis v Boehringer* in similar circumstances, where I gave liberty in to the Department of Health to seek to be joined on the cross-undertaking.

63. As I say, they are not here. Novartis explained that they had written a letter to the Department of Health on 9th January 2019 informing them about these proceedings and the fact they were seeking a preliminary injunction and would be coming to court for a one-day hearing in the period between 14th and 16th January.

64. Dr. Reddy's submitted that the letter was unlikely to have alerted the Department of Health sufficiently that one can take their non-appearance as an indication that they have no wish to be a party for the purpose of the cross-undertaking.

65. As I did in *Actavis v Boehringer*, I will not, at this stage, extend the cross-undertaking to cover the Department of Health since they are not here. I will give the Department of Health or, for that matter, the relevant NHS entities, liberty to apply to be joined in relation to the cross-undertaking. I do see that there is some force in counsel for Dr. Reddy's submission that the letter may not have been sufficient to alert the Department to this possibility. With the assistance of the parties, I will write a letter myself to the Department of Health and any other relevant entity to indicate that if they wish to take advantage of the permission to apply, they can do so, which is, of course, a matter for them.

66. Finally, I will say this. It is a matter which I did not mention to the parties, but occurs to me ought to be at least considered, and that is whether the court should be writing a letter to Boards of Appeal of the European Patent Office to invite them to expedite the opposition appeal proceedings having regard to the existence of national infringement proceedings. I will hear the parties on that. That is my judgment.

Costs

67. I now need to deal with an interim payment. I have decided I will send the costs off to a detailed assessment, as invited by Dr. Reddy's counsel. The reason fundamentally is the fairly high level of costs incurred, particularly by the claimants, but also to some extent by the defendants, on this application. A detailed assessment seems to me to be

a better approach, but it does not mean I should not order a payment on account or interim payment in the meantime.

68. I believe I am right in saying that the general principle to be applied is to order a reasonable sum, having regard to all the circumstances. No-one has said otherwise.

69. The total of the two Statements of Costs from the claimants comes to almost exactly £190,000, by my arithmetic. Mr. Abrahams invites me to award a sum equivalent to his client's total costs, which is approximately £79,000 or £80,000. That would be less than half the amount claimed. Mr. Hinchliffe submits that I should order a higher sum, particularly bearing in mind the work that his clients had to do and matters of that kind.

70. I will take the two figures together. Doing the best I can, it seems to me that a reasonable sum is £120,000. That is what the interim payment will be.

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