Neutral Citation Number: [2018] EWCA 1186 (Civ)

Case No: A3/2016/1993 & A3/2016/1994

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE
CHANCERY DIVISION, PATENTS COURT
MR JUSTICE HENRY CARR
[2016] EWHC 87 (Pat)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 23/05/2018

Before :

LADY JUSTICE ARDEN
LORD JUSTICE KITCHIN
and
LORD JUSTICE FLOYD

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Between :

REGENERON PHARMACEUTICALS, INC	**Appellant in Appeal No: A3/2016/1993** **Respondent in Appeal No: A3/2016/1994**
- and –	
(1) KYMAB LIMITED	**Respondent in Appeal No: A3/2016/1993** **Appellant in Appeal No: A3/2016/1994**
(2) NOVO NORDISK A/S	**Respondent in Appeal No: A3/2016/1993**

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Justin Turner QC with Joe Delaney and William Duncan (instructed by **Allen and Overy LLP**) for **Regeneron Pharmaceuticals, Inc**
Michael Tappin QC and James Whyte (instructed by **Powell Gilbert LLP**) for **Kymab Limited**

Hearing dates of the substantive appeal: 17- 20 October 2017

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APPROVED JUDGMENT ON FORM OF ORDER

Lord Justice Kitchin:

1. This is the judgment of the Court.

2. On 28 March 2018 we gave judgment upon the substantive appeal: [2018] EWCA Civ 671. The parties have not been able to agree a form of order, however. A number of issues remain in dispute. Pursuant to our directions, the parties have now filed evidence and further written submissions. We have considered that evidence and the further submissions and are satisfied that it is proportionate and appropriate to deal with the outstanding issues without a further oral hearing, and that we now do. We will address them in turn.

Permission to appeal

3. Kymab seeks permission to appeal to the Supreme Court. We are not persuaded that the appeal raises a point of law of general public importance. Permission to appeal is therefore refused.

Final injunction

4. It is accepted that it is appropriate to grant an injunction restraining Kymab from infringing either European Patent (UK) No 1 360 287 ("the 287 patent") or its divisional, European Patent (UK) No 2 264 163 ("the 163 patent"). There is also no dispute that this injunction should not prevent Kymab from doing any acts for the purpose of a medicinal product assessment within the meaning of s.60(6D)–(6E) of the Patents Act 1977 ("the 1977 Act"). This section provides that anything done in or for the purposes of a medicinal product assessment and which would otherwise constitute an infringement of a patent is to be regarded as done for experimental purposes relating to the subject matter of the invention of that patent and is therefore exempted from infringement under s.60(5)(b) of the 1977 Act.

5. The parties are also agreed that there should be an exemption from the scope of the injunction to allow Kymab to take steps to produce non-infringing mice and in that way to preserve a series of technical advances which are unrelated to the inventions of the patents in suit. Until recently, there was a dispute between the parties as to how this exemption should be framed. It now appears that this dispute has been resolved but in any event we are satisfied that it is appropriate to limit the injunction in the manner requested by Kymab in paragraph [10] of its further submissions dated 20 April 2018 so that it does not apply to:

> "any mouse being kept for the purpose of making a mouse which does not infringe European Patent (UK) No. EP 1,360, 287 and/or European Patent (UK) No. EP 2,264,163, provided that any infringing mice used or generated in such programme are not used save for such a purpose and at the end of such programme are destroyed or delivered up in accordance with paragraph [ ]."

Delivery up or destruction

6. Regeneron seeks an order for the delivery up or destruction of all "Products" (defined as mice, mouse embryonic stem cells or mouse eukaryotic cells) and "Antibodies" (defined as antibodies produced by the method of claim 2 of the 163 patent) the keeping of which would infringe the 287 patent or the 163 patent and which are in the possession or control of Kymab in the UK. It also seeks an order for the delivery up of all cells engineered to produce such Antibodies and which are in the possession or control of Kymab in the UK.

7. Kymab recognises that Regeneron is entitled to an order requiring it to destroy or deliver up all Products and Antibodies in its possession, custody or control in the UK and the keeping of which would infringe the 287 patent or the 163 patent, but has raised four issues on the form of order sought by Regeneron. First, it objects to an order for delivery up or destruction of "cells engineered to produce Antibodies". Secondly, it resists an order requiring it to deliver up any of its products to Regeneron on the basis that Regeneron may in this way learn aspects of its confidential information. Thirdly, it seeks an exemption for acts done for the purposes of a medicinal product assessment. Fourthly, it seeks an exemption for acts done for the purpose of producing non-infringing products.

8. Kymab's objection to an order requiring it to deliver up or destroy "cells engineered to produce Antibodies" is particularly focused on cells which do not contain the reverse chimeric locus but instead contain DNA coding for a human variable region linked to DNA coding for a human constant region. It points to claim 2 of the 163 patent which reads:

> "2. A method of making a human antibody comprising:
>
> (a) exposing a mouse of claim 1 to an antigenic stimulation, such that the mouse produces an antibody against the antigen;
>
> (b) isolating the DNA encoding the variable regions of the heavy and light chains of the antibody;
>
> (c) operably linking the DNA sequence encoding the variable regions of (b) to DNA encoding the human heavy and light chain constant regions in a cell capable of expressing active antibodies;
>
> (d) growing the cell under such conditions as to express the human antibody; and
>
> (e) recovering the antibody."

9. Kymab accepts that, in light of our judgment, its process of making therapeutic antibodies is a process in accordance with claim 2 and that the therapeutic antibodies produced are the direct products of that process. But, it continues, the cells in issue correspond to those produced in step (c) of claim 2 but are not patented products in relation to which the patent has been infringed, nor are they any article in which that product is inextricably comprised. The patents contain no claim to such cells. Further, the cells are not the direct product of the process of claim 2 or any other claim of the

163 patent or any claim of the 287 patent. Any such cell is simply an intermediate in the process which, on our findings, falls within claim 2.

10. Regeneron responds that these cells are used for producing infringing antibodies and serve no other purpose. It says they are, in effect, machines which produce infringing antibodies, and can replicate and so potentially produce infringing antibodies ad infinitum. It invites us to say that we have jurisdiction to make such an order and that this is an appropriate case in which to exercise it.

11. We accept Regeneron's submissions on this issue. The court has power to make an order for delivery up to render more effective the injunction preventing further infringement. Kymab has not suggested that these cells have any purpose other than making antibodies in accordance with claim 2 and we are satisfied it is both necessary and proportionate to make the order sought in support of the injunction to restrain further infringement.

12. We can deal with the second issue very shortly. Under the draft order, Kymab has an option between delivery up and destruction. Further, Regeneron has proposed that delivery up should be to a third party to be agreed (and that in the absence of agreement the parties should be at liberty to apply to a judge of the Patents Court). We think the form of wording proposed by Regeneron is adequate to meet Kymab's concerns and we accept it.

13. As for the third issue, Regeneron has no objection to Kymab keeping Antibodies for the purposes of a medicinal product assessment within the meaning of s.60(6D)-(6E) of the 1977 Act. However, Kymab contends and we accept that if the order for delivery up is to extend to cells engineered to produce antibodies (as we believe it should) then this exception must also extend to such cells. This exception to the order requiring delivery up or destruction will therefore read:

> "any cell engineered to produce antibodies or antibody being kept for the purpose of a medicinal product assessment within the meaning of s.60(6D)-(6E) Patents Act 1977".

14. We have addressed the final issue in considering the appropriate form of the injunction. We are satisfied that it is appropriate to permit Kymab to retain its mice in order to render them non-infringing. The delivery up provisions will not therefore apply to mice being kept for that purpose. We have set out the appropriate form of limitation at paragraph [5] above.

Disclosure

15. Regeneron seeks orders requiring Kymab to make extensive disclosure of what it describes as relevant Products and Antibodies (each as defined above). In broad terms, Regeneron seeks disclosure of the locations and holders of:

    i) Products that were made or kept by Kymab in infringement of the 287 patent or the 163 patent, or the progeny of such Products, being in either case products or progeny which are not in the UK but are still in Kymab's possession or control.

ii) Antibodies or cells engineered to produce Antibodies which are (a) derived from Products in the UK, or (b) derived from the Products or progeny referred to in (i) above and which are not in the UK but are within Kymab's possession or control, and in either case the making or keeping of which in the UK would infringe the 163 patent.

iii) (a) Products that were made or kept by Kymab in infringement of the 287 patent or the 163 patent but which are no longer in its possession or control, and (b) the progeny of such Products.

iv) Antibodies or cells engineered to produce Antibodies that are either (a) derived from products in the UK, or (b) derived from the Products (or their progeny) referred to in (iii) above, and in either case the making or keeping of which in the UK would infringe the 163 patent.

16. Regeneron says it needs all of this information in order to police its patent rights in the UK against those entities with infringing products in the jurisdiction at present and against those entities which may seek to import infringing products into the UK from abroad. It also seeks information to allow it to secure whatever relief it may be entitled to in foreign jurisdictions.

17. Kymab objects to the provision of any of this information on the basis that no orders for disclosure were sought by Regeneron in its prayer for relief. It also contends that it has provided a good deal of information already and points out that Regeneron is not seeking an order for delivery up of any products made in infringement of either the 287 patent or the 163 patent but which are now located abroad; and is not seeking an order for delivery up of any products which were not made in infringement of either of the patents but the keeping of which in the UK would infringe one or other of them. In these circumstances, Kymab continues, it is hard to see any basis for the disclosure sought. Indeed it fears that Regeneron's intention in seeking this relief is to allow it to contact Kymab's customers and collaborators, even if they are operating in a jurisdiction in which Regeneron has no patent rights, or even if they are carrying out acts, such as clinical trials, which do not amount to infringements in a jurisdiction in which Regeneron does have patent rights. In the alternative, it invites us to make more limited orders for disclosure.

18. We reject Kymab's pleading point. The court has jurisdiction to grant a remedy to which a claimant is entitled even if that remedy is not specified in the claim form. So we turn to the categories of disclosure that Regeneron seeks and address first, those categories summarised in paragraphs [15(i)] and [15(ii)] above.

19. We are not persuaded it is appropriate to make these orders. As Kymab says, it is entitled to keep mice and mouse cells in any jurisdiction where Regeneron has no relevant patent rights and Regeneron no longer seeks an order for their delivery up. Nor are we persuaded that the disclosure of this kind is necessary to prevent Kymab from importing any of these materials into the UK in breach of an injunction restraining infringement. We therefore see no reason why Kymab should be required to disclose where such mice or cells are kept, still less where the progeny of such mice or cells are kept. The position in relation to antibodies and cells engineered to produce antibodies is just the same. Neither of the orders sought is necessary for the protection of Regeneron's rights in the UK, and we are not persuaded it is appropriate

to grant relief in order to assist Regeneron to bring proceedings in any other jurisdiction.

20. We consider next the categories of disclosure summarised in paragraphs [15(iii) and (iv)] above. These correspond broadly to the first two categories of disclosure sought by Regeneron save that they now relate to materials which are not in Kymab's possession or control. We are not persuaded that it is appropriate to order such disclosure in order to allow Regeneron to bring proceedings against third parties in other jurisdictions. To the contrary, we think there is force in Kymab's concerns that Regeneron may seek to contact its collaborators even if they are operating in a territory where Regeneron has no relevant patent rights or their activities do not amount to an infringement in any territory where Regeneron does have such rights. In our judgment Regeneron has made out its case for disclosure here but only in so far as it concerns materials which it has disposed of in the UK. We consider that the form of order suggested by Kymab is appropriate. This limits disclosure to Products and Antibodies made or kept by Kymab in infringement of one or other of the patents in issue but which are no longer in its possession or control as a result of its disposal of them in the UK. Any wider order would not be just or proportionate.

21. We therefore decline to make the first two orders for disclosure that Regeneron seeks but so far as materials which are not in Kymab's possession or control are concerned, we will make the order proposed by Kymab. We would emphasise that this decision does not preclude Regeneron from applying for disclosure in support of an enquiry for damages or account of profits, however. Any such application will fall to be decided on its merits in the enquiry or account, as the case may be.

Scope of any enquiry as to damages

22. There was at one point an issue between the parties as to whether the scope of any enquiry as to damages should be specifically limited to damage arising from the offer to dispose and disposal by Kymab in the UK of HK, HL, HKL, TK and TL strains of Kymouse. It is not clear whether this issue is still live. In so far as it is, we are satisfied that it is a matter best dealt with by the judge on the enquiry who will have the benefit of our main judgment, the pleadings in the action and in the enquiry and fully developed submissions. It is therefore appropriate to make an order for the enquiry or account in the usual general terms with both sides having liberty to apply to a judge of the Patents Court for directions. Accordingly we will make orders to the effect that:

    i) there be an enquiry as to the damages suffered, or at Regeneron's option, an account of the profits made, by reason of Kymab's acts of infringement of European Patent (UK) No. EP 1,360,287 and European Patent (UK) No. EP 2,264,163; and

    ii) Regeneron and Kymab be at liberty to apply to the Patents Court for directions in respect of the account or enquiry.

Publication

23. Regeneron asks for an order that Kymab should take measures for the dissemination of our judgment on the appeal. In particular, it seeks an order requiring Kymab to

disseminate the judgment to its customers and collaborators and place a notice on the top of its webpage informing visitors to that webpage of the judgment and provide a hyperlink to it. It contends that this is justified to remedy the suggestion Kymab made that it was the first to disclose the solution to the problem addressed by the inventions the subject of the patents in suit, that is to say inserting human variable regions into the mouse genome while retaining the mouse constant regions. Here it points to Kymab's paper "*Complete humanization of the mouse immunoglobulin loci enables efficient antibody discovery*" by Lee, E-Chiang et al, published in the journal Nature Biotechnology in 2014, and the passage in that paper stating: "*We are unaware of any other peer reviewed publications describing mice with such hybrid immunoglobulin loci*". It continues that, having had its patents vindicated, it is right that this false impression be corrected. It also contends that the order is necessary to put right any misconceptions in the marketplace as to whether Kymab is entitled to sell its Kymice in the UK.

24. We have come to the conclusion that it is not appropriate to make an order requiring Kymab to publicise our judgment. We are concerned here with a specialised and relatively small public. We think it highly unlikely that workers in this field have not become aware of our decision and its effect, at least in broad terms, and we are wholly unpersuaded that the order sought is necessary to act as a deterrent to future infringers or to contribute to the awareness of the public at large. To the contrary, we have come to the conclusion that the order sought would serve no proper purpose. It would merely cause Kymab embarrassment.

Costs

25. The issues between the parties in relation to costs come under the following heads:

    i) Costs of the appeal.

    ii) Costs at first instance.

    iii) The amount of any interim payment or payments.

Costs of the appeal

26. Kymab and Regeneron agree that Kymab and Novo should be liable for the costs of the appeal (save for some costs occasioned by Regeneron's production of a replacement skeleton argument). Novo contends that it is only jointly responsible for 20% of Regeneron's costs of the validity appeal (Novo not having been a party to the infringement appeal), and that even this element of its costs liability should not be enforced against Novo unless Regeneron fails to recover its costs from Kymab.

27. Novo submits that an order making Novo jointly and severally liable for all the costs of the validity appeal would not do justice between the parties, as it would not reflect the differing interests of Kymab and Novo in the outcome of the appeal and hence their respective contribution to the proceedings. Whilst the success by Regeneron in the appeal would have a serious effect on the viability of Kymab's business, the same was not true for Novo, against whom the action had been discontinued shortly before trial. Although it is accepted that Novo was a party to the validity appeal and adopted Kymab's submissions, Regeneron's costs were "directly occasioned" by Kymab and

not Novo. Ms Clare Bennett, Novo's solicitor, argues that contesting the appeal "was of much greater benefit to Kymab than Novo", and that Novo's counterclaim "was only of academic interest". She also says "Novo had no interest in invalidating the Patents in the UK after Regeneron had discontinued its claim for infringement against Novo". Regeneron resists an order in the form suggested by Novo, arguing that commercial partners should be expected to agree indemnities between themselves, and not leave it to the court to work out their respective contributions to an adverse order for costs.

28. We do not accept Novo's argument. Although Regeneron's discontinuance of its claim against Novo came shortly before the commencement of the trial, Novo did not then discontinue its counterclaim, but continued to ask for revocation of the patents. Thereafter it resisted the appeal, albeit leaving the control of the appeal to Kymab. If the true position is that Novo had no interest in the validity or invalidity of the patents once the claim had been discontinued, it should have discontinued its counterclaim and, in all likelihood, would then have been awarded its costs of the validity issues, given that those issues were simply one aspect of its defence to the claim: see by analogy *Norprint v SPJ Labels* [1979] FSR 126. Instead Novo elected to pursue its counterclaim to judgment and then resist the appeal.

29. The normal order where an appeal succeeds against two respondents is for both respondents to be liable for the costs of the appeal. We do not think that in the circumstances of the present case we should make a different order. Whatever its reasons for doing so, Novo has continued to express an interest in revocation of the patents, both at first instance and on appeal. Regeneron has succeeded in defeating Novo's attack on the patents on appeal, and is entitled to receive its costs of doing so, jointly and severally from Novo and Kymab.

Costs at first instance

30. There are three issues which we are invited to decide under this heading:

    i) How the costs of the issue of sufficiency should be dealt with.

    ii) Novo's position in relation to costs at first instance.

    iii) Whether Novo should repay the previous interim award.

Cost below: sufficiency

31. It is accepted by Kymab that Regeneron is the overall winner of the litigation. Regeneron seeks its costs of all issues of validity and infringement, save for those costs of infringement which were incurred in its discontinued claim against Novo. Kymab's and Novo's position is that Regeneron should be deprived of its costs of the issue of insufficiency at first instance, and that Kymab and Novo should receive their costs of that issue.

32. The ground on which it is argued that Regeneron, although successful overall on the issue of validity after the appeal, should pay the costs of the issue of insufficiency in the court below, is that Regeneron succeeded in this court on the basis of arguments which were not advanced to Henry Carr J either at trial or even after his judgment was

handed down in draft. Accordingly, on the basis of the evidence and arguments which Henry Carr J was asked to consider, it must be taken to be accepted on the part of Regeneron that the judge was entitled to declare the patent invalid on this ground.

33. We accept that the arguments presented to this court on insufficiency were not presented in terms to the judge. On that basis we think it right to deprive Regeneron of its costs of that issue at first instance. We do not think it right, however, to take the further step of ordering Regeneron to pay Kymab's and Novo's costs of that issue, for the following reasons. First, we consider that there is a material difference for the purposes of costs between a case where a party succeeds in an appeal on the basis of fresh evidence, and one where it succeeds, as Regeneron did here, by deploying the existing evidence in a way which it failed to do before the judge. In the former case, the party could not have succeeded at first instance, whereas in the latter it could. Secondly, many of Kymab's pleaded grounds of insufficiency at trial failed. Thirdly, the impact of Kymab's and Novo's proposed order would be that Regeneron would suffer a deduction of 76% of its trial costs (i.e. twice the 38% contribution which insufficiency is said by Dr Gilbert for Kymab to have made to the costs), a result which we regard as unfair overall, given the very large number of issues on which Regeneron succeeded.

34. It is obviously preferable that we estimate a percentage deduction from the overall costs rather than direct an issue based assessment. Given that Regeneron's infringement costs are dwarfed by the validity costs, we consider that a reduction of Dr Gilbert's estimate of 38% of that amount is fair and reasonable. Accordingly we award Regeneron 62% of its costs below.

Costs below: Novo

35. The judge dealt with Novo's costs by paragraph 5 of his order:

> "[Regeneron] shall pay [Novo]:
>
> (a) its costs of [Regeneron's] discontinued claim for infringement of the Patents, and
>
> (b) 90% of its costs of its counterclaim for revocation."

36. Regeneron does not suggest that paragraph 5(a) of the judge's order should be set aside, but an issue arises as to what is meant by it. Novo contends that paragraph 5(a) means that it should receive all its costs (i.e. infringement and validity issues) up to the date of discontinuance. The incremental costs of the counterclaim over and above those for defending the action on the twin bases of non-infringement and invalidity were minimal. It is implicit in Novo's argument that after the date of discontinuance Novo would receive 90% of its costs of the validity issues. Regeneron contends that the order only provided for Novo's costs of infringement issues (necessarily up to the date of discontinuance), validity issues (both before and after that date) being dealt with by paragraph 5(b).

37. To the extent that it matters, we prefer Regeneron's construction. Novo's counterclaim preceded the discontinuance, and it seems to us that the judge's percentage award only makes sense if it was intended to apply to all the costs of the

issue of validity, not just those which arose after discontinuance. We think, however, that it is a mistake to be drawn into a debate about construction of an order which was made in different circumstances, as costs are now at large given that we are making a different order from that made by the judge. Given that Novo elected to continue with its challenge to validity after discontinuance, it is fair that it should pay Regeneron's costs of the issues of validity both before and after discontinuance (subject to the 38% reduction). If Novo had wished to obtain a costs order in its favour on the issues of validity (for example because it believed that the validity of the patent was a truly academic question as far as it was concerned) it should have discontinued its counterclaim, and ceased to play any further part in the action.

38. Novo is nevertheless entitled to the costs of the issue of infringement.

Return of interim payments

39. As Regeneron is now the overall winner and the net recipient of orders for costs, we consider that the interim payments made by Regeneron on account of Kymab's and Novo's costs should be returned to Regeneron as provided for by sub-paragraphs 19(a) and (b) of Regeneron's draft order.

The amount of any interim payment or payments

40. In relation to the costs of the appeal it is necessary to apportion between validity (in which Kymab and Novo participated) and infringement (in which only Kymab participated). Infringement occupied about 30% of the time taken by the appeal, and is exclusively Kymab's responsibility. Accordingly, dividing the remaining 70% equally between Kymab and Novo, results in a 65/35 split of the costs of the appeal.

41. On the validity costs below, Kymab contends that the interim payment should be split 50/50 between Kymab and Novo, Novo submits that it should not be required to make any interim payment and Regeneron is prepared to accept a split of 70/30 Kymab/Novo. Given the joint and several liability, we prefer Kymab's proposal.

42. We have rounded up the estimate for Novo's costs of the infringement issue from the figure of £91,500 given by Ms Dagg, for Regeneron, in her fifth witness statement at paragraph [55] to £100,000.

43. The sums involved are very large. Regeneron contend that the interim payment should be calculated at 65% of their estimated costs recovery, whereas Kymab and Novo submit that it should be 50%. We agree with Kymab and Novo that, in all the circumstances, the interim payment should be calculated at 50%.

	Total	Kymab	Novo
Regeneron's costs of the appeal (split 65/35 Kymab/Novo)	1,080,000	702,000	378,000

Deduct Kymab's costs in relation to replacement skeleton (for reasons given by Dr Gilbert in her ninth witness statement at paragraph [25])		(107,574)	
62% of Regeneron's validity costs below	2,672,200	1,336,100	1,336,100
Adjust for infringement costs below payable by Kymab or to Novo, respectively		117,000	(100,000)
Total		2,047,526	1,614,100
Interim payment at 50%		1,023,763	807,050

44. Accordingly we order an interim payment to Regeneron of £1,023,763 by Kymab and £807,050 by Novo. These sums are separate from and additional to the repayment of the interim payments on account ordered below.

Stay pending any further appeal, and the terms of any stay

45. Kymab seeks a stay of the injunction, the order for delivery up or destruction and the order for disclosure pending the resolution of an application to the Supreme Court for permission to appeal and, if permission is granted, the appeal. It offers two undertakings in return for the grant of that stay, namely that it will not, without the consent of Regeneron:

> "A. dispose of or remove from the jurisdiction any mice or cells made in infringement of European Patent (UK) No. 1,360, 287 or European Patent (UK) No. 2,264,163 or any antibodies made in accordance with claim 2 of European Patent (UK) No. 2,264,163 or any cells which produce antibodies made in accordance with claim 2 of European Patent (UK) No. 2,264,163.
>
> Save that nothing in this undertaking shall prevent Kymab from disposing of or exporting:
>
> (i) antibodies or mouse serum for the purposes of:
>
> (a) Kymab's collaborations funded by the Bill & Melinda Gates Foundation; or
>
> (b) Kymab's collaborations with the International AIDS Vaccine Initiative and Heptares Therapeutics Limited; or
>
> (ii) antibodies or mouse serum for the purposes of preparing for and conducting pre-clinical or clinical trials; or

> (iii) antibody producing CHO cells which may be sent to Kymab's manufacturing CRO Lonza (and which will remain under Kymab's control) solely for the purposes of manufacturing antibodies under GMP conditions for use in pre-clinical or clinical trials;
>
> B. enter into any collaboration or partnership (other than a collaboration funded by the Bill & Melinda Gates Foundation) that would involve the immunisation of mice in the UK made in infringement of European Patent (UK) No. 1,360,287 or European Patent (UK) No. 2,264,163."

46. Kymab explains that undertaking A is based upon the form of short-term order which we made upon handing down our judgment. But, it continues, further investigations have shown that the savings to it need to be extended. In particular those savings (i) now include mouse serum in addition to antibodies; (ii) extend to Kymab's collaborations with the International AIDS Vaccine Initiative ("IAVI") and Heptares Therapeutics Limited ("Heptares"); (iii) include pre-clinical trials in addition to clinical trials; and (iv) extend to the supply and export of antibody producing CHO cells to Kymab's contract manufacturer Lonza for the purpose of manufacturing antibodies for use in clinical and pre-clinical trials. As for savings A(i)(a) and B, Kymab says that these are necessary to allow it to pursue its existing and future collaborations with the Bill & Melinda Gates Foundation ("the Gates Foundation").

47. Kymab has also offered an undertaking that its parent, Kymab Group Ltd, will undertake to pay any damages and costs ordered to be paid by Kymab, should we consider it necessary.

48. Regeneron objects to some of the savings that Kymab seeks. It also submits that Kymab Group Ltd should indeed be required to give the undertaking to which we have referred and that Kymab should itself ring-fence a portion of its funds to cover the ongoing damage caused by its infringement. It argues that, without such a ring-fence, it is likely that neither Kymab nor Kymab Group Ltd will have the resources to meet an order for costs or damages in the event that Regeneron ultimately prevails and so any stay should be refused.

Kymab's undertakings

49. The first group of savings to the undertakings to which Regeneron objects are those in A(i)(a) and B allowing Kymab to pursue current and future collaborations funded by the Gates Foundation. Kymab has filed a body of evidence seeking to explain why these savings are necessary. For present purposes it is sufficient to refer to the evidence of Dr Chiswell, the CEO of Kymab. He has made a witness statement dated 6 April 2018 in which he sets out aspects of the important work which Kymab is currently carrying out with the benefit of this funding. It has three antibodies that are now in the clinical development stage and have the potential to treat, respectively, a range of inflammatory and auto-immune diseases; patients with metastatic solid tumours for whom there are no other therapeutic options; and anaemia.

50. Dr Chiswell continues that Kymab also has a series of antibodies in earlier stages of development which are also funded by the Gates Foundation. He explains that, with

the benefit of this funding, Kymab is working on two therapeutic antibody programs which target, respectively, the pertussis toxin and the malaria parasite. He also explains that Kymab is collaborating with a number of research institutes appointed by the Gates Foundation to develop novel antibody therapies for the developing world on a non-commercial basis. Such collaborations include a joint collaboration with the IAVI and the Scripps Research Institute relating to HIV and malaria; a collaboration with the Malaria Vaccine Initiative relating to malaria; and a joint collaboration with the Hospital for Sick Children in Toronto and the German Cancer Research Centre which again relates to malaria. He also says that Kymab is in the process of establishing a number of additional collaborations pursuant to its partnership with the Gates Foundation which include a collaboration with the US National Institutes of Health relating to HIV, influenza and respiratory syncytial virus and a collaboration with the University of Washington relating to malaria.

51. Regeneron points out that, under the exception in A(ii), Kymab is entitled to continue to supply antibodies pursuant to its collaborations with the Gates Foundation for clinical trials and explains that, insofar as Kymab wishes to pursue commercial activities beyond such trials, it objects. In particular, Regeneron continues, Kymab has not disclosed the extent to which its collaboration with the Gates Foundation deals with commercial matters in addition to humanitarian matters. It also says that Kymab has not disclosed its agreements with the Gates Foundation despite requests that it should do so. In all these circumstances it resists the savings sought by Kymab at A(i)(a) and in B.

52. Kymab acknowledges that it has not disclosed the agreements underpinning its relationship with the Gates Foundation but says they are confidential and commercially sensitive to both itself and to the Gates Foundation. It also relies upon a second witness statement of Dr Chiswell dated 11 April 2018 in which he explains that, while Kymab is free to sell the drugs which it develops using its technology in the developed world at commercial rates, even on the most optimistic timetable, Kymab does not expect any of its antibodies to obtain a marketing authorisation before 2024. Kymab has also made clear that, if required, it will undertake not to commercialise any of the products which it develops under its partnership with the Gates Foundation prior to the final determination of its appeal. To this last point Regeneron responds that such an undertaking would have little value because the patents have limited lifespans and Kymab's activities pending the final disposal of the appeal will allow it to develop a springboard which it can exploit after their expiry.

53. The second saving to which Regeneron objects is set out in A(i)(b) and concerns Kymab's collaboration with Heptares. Kymab has explained that the purpose of this collaboration is to identify and develop antibody therapeutics targeting G protein-coupled receptors which have the potential to treat a number of cancers for which there is currently no effective therapy. It also says that under this collaboration it needs to provide Heptares with antibodies so that Heptares can test them in its UK laboratories using a number of its own proprietary assays.

54. The general principles we must apply in considering whether to grant an injunction or accede to an application for a stay pending further appeal are well established. The court should exercise its discretion so as to arrange matters such that the appeal court is best able to do justice between the parties once the final appeal has been heard.

55. We are in no doubt that, if the injunction and the order for delivery up or destruction are not stayed pending the final determination of any appeal to the Supreme Court, Kymab will suffer serious loss and damage which will be extremely difficult to quantify. It has made a significant investment in terms of time, money and expertise over the last eight years in developing its technology, much of which has nothing to do with the inventions of the patents in suit. We also accept that the imposition of the final injunction would bring to an end or at least seriously disrupt the projects to which we have referred in which it is, by itself or in collaboration with others, seeking to develop antibodies for the treatment of a range of diseases, including diseases for which there is a significant unmet clinical need, sometimes in developing countries. These are powerful overarching factors in assessing where the balance of justice lies.

56. Secondly, we accept in light of the evidence before us that an injunction preventing Kymab from continuing its work in the UK under its various collaborations and partnerships would be likely to cause it serious reputational and financial harm. That work would have to be abandoned or seriously delayed, many experiments which are ongoing would have to be started from scratch elsewhere by Kymab's partners and there would be a very real risk that Kymab's ability to secure funding in the future would be put at risk. Kymab also submits and again we accept that the injunction would be likely to do serious damage to its research base because a number of its researchers would have to be made redundant. Kymab also has a legitimate concern that destruction of the Kymice would constitute a breach of its licence issued under the Animal (Scientific Procedures) Act 1986.

57. Thirdly, we are conscious of the concern expressed by Regeneron that Kymab has failed to disclose its agreements with the Gates Foundation with the result that both it and this court are left in a position of considerable uncertainty as to the scope of those agreements and the extent to which they permit Kymab to exploit commercially any antibodies which may be developed by Kymab on its own or together with its various collaborators. It is, however, clear that aspects of those agreements deal with commercial matters and that Kymab has a right to commercialise antibodies in the developed world. We also recognise the force of Regeneron's point that while Kymab may not at this time have any settled intention to commercialise any of the antibodies that it develops, that position could change after the expiry of the patents in issue in which case Kymab could use its infringing activities as a springboard.

58. Fourthly, we have also given careful consideration to the further concern expressed by Regeneron that it is in competition with Kymab in relation to certain targets and that the partnerships and collaborations that Kymab has entered into, particularly those funded by the Gates Foundation, represent significant lost opportunities for Regeneron.

59. Fifthly, we have nevertheless come to the conclusion that any risk that Regeneron will suffer irreparable harm arising from the third and fourth points to which we have referred above would be considerably ameliorated if we were (i) to accept Kymab's offer to undertake not to commercialise any product developed under its partnership with the Gates Foundation prior to the final determination of its appeal; and (ii) to limit the further collaborations permitted under B to those identified in the evidence, namely the proposed collaborations with the US National Institutes of Health in relation to HIV, influenza and respiratory syncytial virus, and with the University of Washington in relation to malaria. We would also give Regeneron liberty to apply to a

judge of the Patents Court (in the event Kymab's appeal is unsuccessful) for an injunction to restrain Kymab from securing any advantage from its infringing activities after the expiry of the patents. But we express no view as to the merits of any such application or whether there is jurisdiction to make such an order.

60. Sixthly and should it be required by Regeneron, Kymab has offered and we would accept a further undertaking to transfer to the Gates Foundation all rights that it has to any product developed using infringing Kymice prior to the expiry of the patents and as part of its partnership with the Gates Foundation, such that Kymab would not have the right to commercialise any such product even after the expiry of the patents.

61. Seventhly, we see little prospect of Regeneron suffering irreparable harm arising from Kymab's proposed activities with Heptares. As we have explained, the purpose of this collaboration is to identify and develop antibody therapeutics to treat certain cancers for which there is currently no effective therapy; all antibodies generated as part of this collaboration will be jointly owned by Kymab and Heptares; and Kymab only intends to provide to Heptares clinical candidate antibodies so that Heptares can test those antibodies in its own assays within the UK. Here there is no real prospect of any commercialisation taking place before the final disposal of Kymab's appeal. But again, were a stay to be granted, we would give Regeneron liberty to apply to a judge of the Patents Court (in the event Kymab's appeal is unsuccessful) for an injunction to restrain Kymab from securing any advantage from its infringing activities after the expiry of the patents. But here too we express no view as to the merits of any such application or whether there is jurisdiction to make such an order.

62. In all these circumstances and subject to the issue of Kymab's ability to meet an award of damages, we have come to the firm conclusion that the balance of justice favours a suspension of the injunction and order for delivery up on the basis and subject to the qualifications we have described.

Ability to pay

63. Regeneron has expressed very serious concerns about Kymab's ability to meet any order for the payment of damages. In that regard it relies upon the following matters and submissions. First, there has recently been a restructuring of Kymab's ownership and assets with the result that Kymab Group Ltd is now Kymab's parent; Kymab has assets of around £15 million and Kymab Group Ltd has assets of around £45 million.

64. Secondly, Kymab's recent accounts show current liabilities of around £72 million, and suggest that it is solvent only because it has a loan of around £80 million from Kymab Group Ltd.

65. Thirdly and even were Kymab Group Ltd to stand behind Kymab, there would be a real risk that Kymab would not be able to meet any award of damages upon an enquiry because it is currently spending in excess of £27 million per year on R&D; and there is no evidence that Kymab is likely to secure a further or alternative revenue stream.

66. Fourthly, Regeneron has offered its own technology to Novo for $120 million with further annual payments and royalties to follow, and it has struck deals worth hundreds of millions of dollars with other companies such as Sanofi-Aventis, Astellas

and AstraZeneca, and so there is a high chance that an award of damages would exceed £60 million.

67. Regeneron contends that, in light of the foregoing, justice demands that it should be a condition of any stay that Kymab should ring-fence some of its assets, for example by placing in escrow a substantial sum of money. It proposes that £60 million should be ring-fenced, alternatively that £30 million in cash and short-term deposits should be ring-fenced together with half of Kymab's future revenues from whatever source until the conclusion of the enquiry or account or further order in the meantime.

68. Kymab does not challenge Regeneron's assessment of its current financial position but contends that Regeneron has exaggerated the extent of any damage which it may suffer pending the outcome of its further appeal and that the order sought would cripple its business.

69. We are not persuaded that it is appropriate to impose the condition upon a stay of the injunction and order for delivery up that Regeneron seeks. Our reasons are these. First, we do not think that it would be appropriate to impose as a condition of a stay a requirement that Kymab provide security for damages arising from past infringements.

70. Secondly, we are not persuaded on the materials before us that the sum for which Regeneron offered its technology to Novo and the sums which it claims to have generated from deals it has struck with other pharma companies provide any guide to the losses which it is likely to suffer pending the determination of Kymab's appeal were a stay to be granted upon the terms which we have explained. There is no prospect of Kymab commercialising any product in that time and we think that any damage which Regeneron may suffer is likely to be of a very much more modest size.

71. Thirdly, Dr Chiswell has made a third statement dated 20 April 2018 in which he explains that Kymab has hitherto been very successful in raising large sums in investment from the Wellcome Trust and the Gates Foundation, among others, but fears that it may well be unable to raise any further investment funds pending the final decision on a further appeal. The result is that Kymab will need to rely on its operating capital to continue as a going concern. However, Dr Chiswell continues, the payment of £30 million into escrow would mean that Kymab would only have sufficient operating capital to run its business for a further 12 months and that it is likely that the business would need to be shut down entirely before the outcome of a further appeal is known.

72. We are satisfied that the concerns expressed by Dr Chiswell cannot be discounted. In our judgment there is a real prospect that the security condition sought by Regeneron would drive Kymab out of business, frustrate any further appeal and lead to a termination of the humanitarian work that Kymab is undertaking with the Gates Foundation, IAVI and the Scripps Research Institute among others.

73. Accordingly we decline to make the security sought by Regeneron a condition of granting the stay of the injunction and order for delivery up. However, we would make it a condition of any stay that Kymab Group Ltd undertakes (by counsel for Kymab being its counsel for this purpose) to the court to be jointly and severally

liable for the payment of any damages and costs which Kymab may be ordered to pay to Regeneron.

Stay of the order for disclosure

74. Kymab seeks a stay of the order for disclosure pending appeal. We have explained the limited order we intend to make by way of final relief at paragraph [20] above. In our judgment this order should be stayed pending the determination of Kymab's appeal.

Final order

75. The parties must as soon as possible draw up, agree and submit to this Court for its approval a final order embodying these rulings.