

IN THE HIGH COURT OF JUSTICE  
BUSINESS AND PROPERTY COURTS  
OF ENGLAND AND WALES

INTELLECTUAL PROPERTY (ChD)

PATENTS COURT

Before the Honourable Mr Justice Nugee

20 November 2018

BETWEEN:

**ELI LILLY AND COMPANY**

**(a company incorporated in the State of Indiana, USA)**

**Claimant/Part 20 Defendant**

**-and-**

**MERCK SHARP & DOHME CORP.**

**(a company incorporated in the State of New Jersey, USA)**

**Defendant/Part 20 Claimant**

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**ORDER FOR DIRECTIONS**

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UPON THE APPLICATION of the Claimant/Part 20 Defendant (the “**Claimant**”) by Notice dated 17 October 2018

AND UPON the court having ordered that the trial of this action be listed in a 5-day window from 4 November 2019, with an estimated length of 8 - 9 days excluding 1 day for writing closing submissions and a further 2 days of pre-reading

AND UPON hearing Counsel for the Claimant and Counsel for the Defendant/Part 20 Claimant (the “**Defendant**”)

AND UPON the parties’ legal advisors having advised the litigants of the existence of mediation as a possible means of resolving this claim and counterclaim

**IT IS ORDERED THAT**



Claim no. HP-2018-000014

HP-2018-000014

### **Service on the Comptroller**

1. The Claimant shall serve on the Comptroller: (a) the claim form; (b) any other relevant statement of case (including any amended statement of case); and (c) any accompanying documents of any claim for a remedy which would, if granted, affect an entry in any United Kingdom Patent Office register.

### **Proof of Documents**

2. Legible copies of the specification of the patent in suit and any patent specifications or other documents cited in the Grounds of Invalidity or Particulars of Infringement (save for the prior art referred to as Benson 2) may be used at trial without further proof thereof or of their contents.

### **Independently Valid Claims**

3. The Defendant shall no later than 21 December 2018 serve on the Claimant a notice stating which claims of the Patent (either as granted or proposed to be amended) the Defendant will assert at trial to be independently valid.

### **Construction**

4. Each party shall on or before 4pm on 11 January 2019 simultaneously serve on the other party a statement of case on construction as follows:

(1) The Defendant shall set out the constructions of each of claims 1 and 2 of the Patent for which it will contend at trial; and

(a) in relation to each of those constructions, set out whether it maintains that on such construction the Patent would be (i) valid; and (ii) infringed; and

(b) set out the hierarchy in which it will be contending for its constructions.

(2) The Claimant shall set out, in the event such claims are not ambiguous:

(a) the possible constructions that it will contend at trial might apply to claims 1 and 2 of the Patent;

(b) in relation to each of those possible constructions, what the consequences will be for its pleaded invalidity and non-infringement positions;

(c) to the extent that Lilly intends to advance a hierarchy of such constructions, the order in which they will be contending them.

### **Amendment**

5. If in these proceedings the Defendant intends to rely at trial upon any amendments to European Patent (UK) 1 931 710 (the "**Patent**") (conditional and/or unconditional) which mirror those it has as at the date of this Order submitted to the EPO in the co-pending EPO Opposition, or any other amendments on which it currently intends to rely by 21 December 2018, it shall make and serve on the Claimant and on the Comptroller an application to amend the Patent in compliance with CPR Rule 63.10 giving particulars of all such proposed amendments (the "**Application to Amend**") together with particulars of the grounds on which amendment is sought on or before 4pm on 21 December 2018.
6. The Application to Amend shall be heard as between the parties at the trial of this action.
7. Should the Claimant intend to oppose the Application to Amend, it shall serve a notice opposing it either within 14 days of the first appearance of its advertisement by the Comptroller General of Patents, Designs and Trade Marks or on or before four weeks after service of the Application to Amend, whichever is sooner.
8. The directions in this Order shall apply as between the parties to any application to amend the Patent, including with regards to any disclosure or evidence in the amendment application.
9. If anyone not a party to these proceedings opposes the Application to Amend, the Defendant will apply for further directions.

### **Notices to Admit Facts**

10. The parties shall serve any Notices to Admit Facts on or before 4pm 30 November 2018.
11. Each party shall, no later than 21 days after the date on which any such notice is served, state in writing whether or not it admits the facts stated in any Notice to Admit Facts.

### **Disclosure on Invalidity**

12. The Defendant shall on or before 4pm on 15 March 2019 make and serve on the Claimant a list in accordance with Form N265 of the documents in its possession, which came into existence within the period from 31 August 2003 to 27 May 2008 and record epitope analyses, binding affinity and neutralisation data of:

the antibodies in the Patent and US patent application 60/713,585 (the Patent's "**Priority Document**"), namely:

- (a) the antibodies designated 7G10, 6H12, 13F11, 13B5, 7E2, 13G1, 11C10, 30F11, 34E4, 6H4, 33D2, 33B12, 1E10, 20A9, 22E9, 29D5, 5B12, 9C9, 11B10, 10H11, 19E9, 10G8, 39G2, 35F12, 49A10, 34F9, 7D7, 3D7, 21A10 and 30E10 in the Patent (and in some cases, the Priority Document);
  - (b) the humanized antibodies designated hum6H12, hum7G10, hum10H11 and hum22E9 in the Patent (and in some cases, the Priority Document); and
  - (c) 26D10, 501, 29A2, 74 and 490, which are referred to in Tables 2 and 3 in the Priority Document.
13. The Claimant shall on or before 4pm on 15 March 2019 make and serve on the Defendant a list in accordance with Form N265 of the documents in its control which came into existence within the period from 31 August 2003 to 31 August 2007, and record epitope analyses, binding affinity and neutralisation data of any human IL-23p19 antibodies generated in the development programme referred to in paragraph 66 of the first witness statement of Andrew Hutchinson, save for such antibodies as are referred to in WO 2007/024846. Where epitope analysis data, binding affinity data and neutralisation data are recorded in a results document, such as a project report or similar, it shall not be necessary for the Claimant to list the source material from which they are drawn.

### **Disclosure on Infringement**

14. In lieu of disclosure on infringement, the Claimant shall provide a written description to the Defendant in accordance with paragraph 6.1 of CPR Practice Direction 63 on or before 4pm on 11 January 2019 setting out full particulars of mirikizumab in sufficient detail for the question of infringement of the Patent to be determined (the "**Claimant's PPD**").

15. The description served under paragraph 14 shall be accompanied by a signed written statement which shall:

(1) state that the person making the statement is personally acquainted with the facts to which the description relates;

(2) verify that the description is a true and complete description of the product; and

(3) contain an acknowledgement by the person making the statement that he/she may be required to attend court in order to be cross-examined on the contents of the description.

### **Inspection**

16. If either party wishes to inspect or have copies of such disclosed documents as are in the other party's control, it shall give notice in writing that it wishes to do so and such inspection shall be allowed at all reasonable times upon reasonable notice and any copies shall be provided within five working days of the request, either (a) in hard copy upon the undertaking of the party requesting the copies to pay the reasonable copying charges; or (b) by providing an electronic copy in a format agreed in advance between the parties.

### **Confidentiality**

17. The parties shall use their best endeavours to agree, by no later than the date that is two weeks before the exchange of the parties' disclosure lists under paragraphs 12 and 13 and the Claimant's PPD under paragraph 14, the terms of a confidentiality regime to cover any documents designated as confidential by the parties. In the absence of agreement, the parties may apply to the court. In any event any such regime may be varied by the court on the application of any party to the action.

### **Scope of Protection**

18. If the Defendant intends to allege that, should mirikizumab be held not to be within the literal meaning of the claims of the Patent alleged to be infringed, nevertheless mirikizumab is within the scope of protection of such claims, the Defendant shall, within 21 days of service of the Claimant's PPD provided in accordance with the foregoing paragraph, provide a statement of its case (including all facts and matters relied on) in support of the allegations (if made) that:

- (1) mirikizumab achieves substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent;
- (2) it would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the mirikizumab achieves substantially the same result as the invention, that it does so in substantially the same way as the invention; and
- (3) the skilled reader of the patent has concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention.

19. Within 21 days of service of the Statement of Case provided in accordance with the foregoing paragraph, the Claimant shall serve a Statement of Case in answer setting out its case in response.

**Notice of Models, etc.**

20. If any party wishes to rely at the trial of this claim upon any model or apparatus, that party shall on or before 4pm on 17 May 2019 give notice thereof to the other party; shall afford the other party an opportunity within seven days of the service of such notice (and thereafter upon reasonable notice) of inspecting the same and shall, if so requested, furnish the other party with copies or illustrations of such model or apparatus.
21. If a party wishes to rely upon any such materials in reply to any matter of which notice was given under paragraph 20, that party shall, within 21 days after the last inspection to be made in pursuance of paragraph 20, give to the other party a like notice and, if so requested within seven days of delivery of such notice, shall afford like opportunities of inspection which shall take place within seven days of such request; and shall, in like manner, furnish copies of any drawing or photograph and illustration of any such model or apparatus.
22. No further or other model or apparatus shall be relied upon in evidence by either party save with consent or by permission of the court.

**Experiments**

23. Where a party desires to establish any fact by experimental proof, including an experiment conducted for the purposes of litigation or otherwise not being an experiment conducted in the normal course of research, that party shall on or before 4pm on 31 May 2019 serve on all the other party a notice stating the facts which it desires to establish and giving full particulars of the experiments proposed to establish them.
24. A party upon whom a notice is served under the preceding paragraph shall within 21 days, serve on the party serving the notice a notice stating in respect of each fact whether or not that party admits it.
25. Where any fact which a party wishes to establish by experimental proof is not admitted that party shall apply to the court for further directions in respect of such experiments.

#### **Technical Primer**

26. The parties shall use their best endeavours to agree a single technical primer setting out the basic undisputed technology relevant to the proceedings and shall do so by the following steps:
  - (1) on or before 4pm on 12 April 2019, the Claimant shall provide to the Defendant a draft technical primer, indicating which parts are considered to form part of the common general knowledge;
  - (2) on or before 4 weeks after the date in paragraph 26(1), the Defendant shall provide the Claimant with a revised draft of the Claimant's technical primer indicating its proposed amendments, and which parts are agreed to form part of the common general knowledge; and
  - (3) on or before 2 weeks after the date in paragraph 26(2), the Claimant shall provide the Defendant with a revised draft of its technical primer incorporating the Defendant's proposed amendments with which the Claimant agrees.

#### **Written Statements**

27. Each party shall on or before 4pm on 21 June 2019 serve on the other party signed written statements of the oral evidence which the party serving the statement intends to lead on any issues of fact to be decided at the trial, such statements to stand as the evidence in chief of the witness unless the court otherwise directs.

28. Each party shall on or before 4pm on 19 July 2019 serve on the other party signed written statements of the oral evidence which it intends to lead at trial in answer to facts and matters raised in the witness statements served on it under paragraph 27 above.

### **Expert Reports**

29. Each party may call up to three expert witnesses to address technical matters relating to: (i) antibody production and engineering; (ii) epitope mapping and biophysical characterisation and crystallisation of antibodies; and (iii) the immunology and related biology of IL-23, provided that:
- (1) each party supplies the names of such experts to the other party and to the court on or before 4pm on 21 June 2019; and
  - (2) no later than 4pm on 9 August 2019 each party serves upon the other party a report of each such expert comprising the evidence which that expert intends to give at trial.
30. Each party shall, on or before 4 pm on 20 September 2019, serve on the other party any signed expert reports in reply to the expert reports of the other party served under paragraph 29.

### **Civil Evidence Act Notices**

31. Each party shall no later than 4pm on 21 June 2019 serve upon the other party Civil Evidence Act Notices in respect of those documents upon which they propose to rely at trial.

### **Admissibility of Evidence**

32. A party who objects to any statements of any witness being read by the judge prior to the hearing of the trial shall serve, within 21 days of receipt of the statement of the witness to whose evidence objection is taken, upon the other party a notice in writing to that effect setting out the grounds of the objection.

### **Non-compliance**



33. Where either party fails to comply with the directions relating to experiments or written evidence it shall not be entitled to adduce evidence to which such directions relate without agreement between the parties or the permission of the court.

### **Pre-trial Review**

34. There shall be a pre-trial review (“**PTR**”) on a date to be fixed on or about five weeks before trial, to be held before the judge who will hear the trial (to the extent possible). At the PTR the parties shall raise whether any further directions for the trial are necessary, including whether any directions are required for the taking of any evidence by video link.
35. Before the PTR the parties must discuss and, if possible agree a draft written timetable for the trial. The Claimant must file a copy of the draft timetable for the trial at least two days before the hearing of the PTR. Any parts of the timetable which are not agreed must be identified and a short explanation of the disagreement given.
36. Where possible the court will set a timetable for the trial unless it considers that it would not be appropriate to do so or appropriate to do so at a later time.
37. At the PTR the parties shall, if necessary for good reason, apply for a fixed starting date and provide the reasons therefore.

### **Trial Bundles, Detailed Timetable and Reading Guide**

38. The Claimant shall no later than 4pm on 9 September 2019 serve upon the Defendant a proposed trial bundle index. The Defendant shall provide any comments on the proposed trial index within seven days of service of the proposed trial bundle index. The Claimant shall no later than 20 September 2019 serve upon the Defendant one hard copy and one electronic copy of the bundles for use at trial.
39. The Claimant must file the trial bundle with the court no later than four days before the date fixed for the trial together with an agreed reading guide in accordance with paragraphs 9.2 – 9.3 of CPR Practice Direction 63.

### **Skeleton Arguments**

40. Each party shall lodge a single copy of its skeleton argument not less than two working days before the trial.

### **Costs Budgeting**

41. These proceedings are exempt from the costs budgeting provisions contained in section II of CPR Part 3 and Practice Direction 3E.

### **Liberty to Apply**

42. The parties are to be at liberty on three days' notice to apply for further directions and generally.
43. Any of the times mentioned herein may be varied by mutual consent or otherwise with permission of the court.

### **Costs**

44. The costs of the Case Management Conference are to be costs in the case.

### **Service**

45. The Claimant shall serve this order on the Defendant.

### **Service of the order**

The court has provided a sealed copy of this order to the serving party:

Simmons & Simmons LLP, CityPoint, One Ropemaker Street, London, EC2Y 9SS

Ref: IP/008291-00173/AEJH/SFP/BXXT