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Claim No. HP-2020-000019

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

The Rolls Building 7 Rolls Buildings Fetter Lane London EC4A 1NL

Date: 07/12/2020

Before:

MR. JUSTICE BIRSS

Between:

(1) REGENERON PHARMACEUTICALS, INC. (2) TEVA PHARMACEUTICAL INDUSTRIES LIMITED - and -RINAT NEUROSCIENCE CORP. <u>Defendant</u>

MR. ADRIAN SPECK QC and MR. THOMAS JONES (instructed by Bristows LLP) for the Claimants

MR. THOMAS MITCHESON QC and MR. JOE DELANEY (instructed by Marks & Clerk Law LLP) for the Defendant

Approved Judgment

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MR. JUSTICE BIRSS:

- 1. I have before me a case management conference in a patent action. It relates to three patents in the name of Rinat, which I gather is a company that was spun out of Genentech. One patent is EP (UK) 2,270,048. That patent was filed in 2003, claiming priority back to 2002 and its application was published in July 2004. There are then two other patents, which are divisionals, EP (UK) 2,305,711 and EP (UK) 1,871,416. They claim a priority date after the publication of the application for the previous patent. The patents all concern antibodies which have affinity for nerve growth factor, i.e. anti-NGF antagonists, used for the treatment of osteoarthritis in one way or another.
- 2. The '048 patent has a claim to using the antibodies to treat osteoarthritis pain. The later two patents, it would appear, are directed to uses of the same kind of antibody, that is an anti-NGF antagonist antibody. In the Swiss form claims they are claimed for the manufacture of medicaments for the treatment of what appear to be symptoms of osteoarthritis. Whether these latter patents are valid or not in those circumstances remains to be seen. It is, however, a well-known difficulty in this area seeing applications for later patents based on symptoms of an earlier disease. It raises questions about inherency and how the Swiss form second medical use and EPC 2000 claims work in those circumstances. That is not a matter I need to resolve today.
- 3. The particular matter I need to resolve is this. The claimants, Regeneron and Teva together, are planning to market an antibody in this jurisdiction called fasinumab. It will be for treating osteoarthritis. As currently constituted these proceedings consist of an application for revocation of the three patents by the claimants. There is a counterclaim for infringement brought by Rinat relating to the earlier patent, the '048 patent. However -- and this is the issue I am having to address -- no counterclaims for infringement relating to the later two patents have been brought.
- 4. Regeneron and Teva contend that I should make an order requiring Rinat to bring counterclaims for infringement of the later two patents at this stage or not at all. Their reasons are essentially as follows. They contend that Rinat now has sufficient information to bring such a counterclaim and the only reason the counterclaim is not being brought is tactical. It arises because although Regeneron is an opponent against at least one, if not two, of these patents in the EPO, Teva is not. Therefore until an infringement counterclaim is brought against Teva, Teva would not be able to join the EPO proceedings. Whereas Teva would have the right to do so if it was sued for infringement.
- 5. It is also submitted by Mr. Speck on behalf of the claimants, that, as a matter of good case management, if a counterclaim for infringement in these circumstances can be brought at this stage, it should be. Although in some cases it proves not to be possible, it will be much better in the overall scheme of things for all matters to be resolved in one go at one trial.
- 6. Mr. Mitcheson, who appears for Rinat, contends his client is not in a position to bring a counterclaim for infringement of the later two patents, that is the '711 and the '416 patents, because it does not yet have sufficient information on which to do so. The point is that, as things currently stand, there is no draft label available, that is to say marketing authorisation label. Nor, according to the defendant, is there sufficient

clinical data available from the claimants in order to allow the defendant to bring a claim. Therefore, it is contended by the defendant that I should not make the order sought by the claimants.

- 7. First of all, the overall principle I should apply is the overriding objective, which is to deal with cases justly and at proportionate cost. In my judgment, in cases of this kind it is clearly right that if all issues which might arise can be resolved in one go at trial, then that is preferable. Accordingly, there would be sound case management reasons for requiring infringement claims to be brought at this stage, if that is otherwise appropriate. However, of course, if it really is the case that the patentee cannot bring a claim because it does not have sufficient information to do so, then of course it is obviously right that the court should not be forcing someone to bring a claim it is not in a position to bring.
- 8. However, Mr. Speck says that on one particular point, there is no good reason at all why Rinat cannot bring a counterclaim. That relates to claim 24 of the '711 patent. He points out in the skeleton argument for Rinat, that Rinat say as follows:

"First, they [*the claimants*] have given an unqualified acceptance that their dealings in fasinumab in the UK would infringe claim 24 of EP 711. That being the case, there is now no issue in dispute between the parties which needs to be resolved at trial. If the validity of claim 24 of the EP 711 is upheld in the present action then, absent agreement by the Claimants not to infringe the claim, questions about relief can be addressed at a later stage."

- 9. Mr. Speck submits that the sentiment expressed in that paragraph is wrong. It demonstrates that Rinat does have a sufficient basis to bring a claim for infringement on claim 24, and, since it does, it should be required to do so now.
- 10. I agree. Without the claim for infringement there will be no relief for infringement. It is wrong to think such a claim can be brought afterwards. In my judgment, Rinat has enough information to bring a claim for infringement of claim 24. I reject the submission inherent in paragraph 41 that what is proposed there is an appropriate course. The position is, and should be, that a party in a position to bring a claim like that in a case like this should bring it. I will accordingly make the order sought by the claimants.
- 11. However that does not fully resolve all the issues because it does not address the question of what to do about the other claims. I should make it clear that the order I intend to make relates only to claim 24 because it is in a special category for the reasons I have explained.
- 12. I cannot require Rinat to bring a claim for infringement about any other claims. What I will suggest the way forward ought to be is the following. If Regeneron or Teva wish other claims to be put in issue, then they have the means at their disposal to do it. They can bring a application for a declaration of non-infringement based on draft labels or the like. Then, in those circumstances it may well be that it would be appropriate, if Rinat did not otherwise agree to do so, to again require infringement claims to be brought (assuming Rinat did not accept there was no infringement on the

basis of the information on which the declarations were sought). That would be on basis that the patentee did then have the information necessary to do so.

13. I rather think that this eventuality will not arise, but that is how that aspect of this dispute ought to be resolved in future. That is my decision.