**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| NOVARTIS PHARMACEUTICALS CORPORATION, | : | |
| Plaintiff, | : | |
| v. | : | C.A. No. 18-1043-LPS |
| ACCORD HEALTHCARE INC., et al., | : | |
| Defendants. | : | |

**MEMORANDUM ORDER**

Having considered the parties' briefing (D.I. 358, 458, 514) and having conducted an evidentiary hearing and heard oral argument on June 21, 2019, **IT IS HEREBY ORDERED THAT** Plaintiff's motion for a preliminary injunction (D.I. 357) is **GRANTED**.

**IT IS FURTHER ORDERED THAT** the parties shall submit a joint status report by Friday, June 28, 2019. That status report shall address, in addition to anything else the parties wish to raise, (a) whether the trial date should be accelerated; (b) how long the parties are likely to need for their trial presentations; (c) the amount of bond the Court should require Plaintiff to post; and (d) whether any discovery disputes remain ripe and require judicial attention.

The Court's decision to grant the preliminary injunction was, as stated as the conclusion of the hearing, for the following reasons:

> First I want to note I carefully considered all the materials that were in the record, including the voluminous record that you all created before today and, of course, everything that was cited in court today. That includes, but is not limited to, the various declarations of the witnesses, the deposition testimony, many documents, and the testimony that I got to hear live today.

The legal standards I think are not disputed, but let me just try to quickly note them for the record.

A preliminary injunction, of course, is an extraordinary remedy that should be granted only in limited circumstances. Deciding whether to grant a preliminary injunction requires consideration of whether the moving party can prove the following. A reasonable likelihood of success on the merits, irreparable harm if the injunction is not granted, a balance of hardship tipping in its favor, and the injunction's favorable impact on the public interest. Although the factors are not applied mechanically, a movant must establish the existence of both of the first two factors to be entitled to a preliminary injunction.

In the context of this suit, which is a patent infringement action, with respect to the likelihood of success on the merits, Novartis as the moving party must show both, one, it is likely to prove that the proposed generic product will infringe the asserted patent claim on which the motion is based, and, two, that defendants' challenges to the validity of the patent lack[] substantial merit.

Having applied that law to the facts as best as I could, my decision is to grant the motion for a preliminary injunction. Let me try to explain why.

First, turning to likelihood of success on the merits, I find that Novartis has met its burden to demonstrate a likelihood of success on the merits. Infringement is not contested for purposes of the preliminary injunction motion, so I need not address it any further. The issue, of course, is invalidity, and on invalidity, I have made a preliminary assessment as I'm required to do on defendants' three challenges. Anticipation by Kappos 2006, lack of adequate written description, and lack of enablement or utility.

At one level I think it is fair to say that there is a "substantial question of patentability." [But] I don't think that that is a fair description when that phrase is used in the manner that I understand it to be pertinent to the preliminary injunction analysis. That is, I don't think that defendants' invalidity contentions as argued here today are frivolous. If I were to permit summary judgment practice in this case, the defendants' invalidity defenses might very well survive a summary judgment motion. It's even possible, despite what I'm about to say, that defendants might prevail on one or more of their invalidity theories after trial, but having considered the evidence and the arguments before me at

this stage, my finding is that defendants are not at all likely to prevail at trial on invalidity.

That is, I am persuaded by Novartis that at trial, defendants will likely fail to persuade me by clear and convincing evidence that the asserted claims of the '405 patent are invalid due to anticipation by Kappos 2006, or due to lack of adequate written description, or due to lack of enablement and utility.

Having made that finding, I believe that plaintiff has done what the law requires it to do on likelihood of success on the merits when confronted with a challenge to the validity of its patent at the preliminary injunction stage. That's my understanding of what the Federal Circuit has told us is the legal standard at this stage. For instance, in the *Titan Tire* decision, 566 F.3d at page 1372, a 2009 decision,[1] the Federal Circuit told us that what the Court must do is "determine whether it is more likely than not that the patent challenger will be able to prove at trial by clear and convincing evidence that the patent is invalid." And, again, my finding for reasons I'm going to now try to explain is for the plaintiff, applying that standard.

Highly relevant to my finding on likelihood of success on the merits is that the defendants have proposed the wrong person of ordinary skill in the art, the wrong POSA. I am persuaded instead by plaintiff that the PTAB's definition of a POSA is correct here. It is a team that includes not just a clinician, but also a pharmacologist. I've been using a shorthand here, as I hope you will appreciate. As a formal matter, I'm adopting the specific definition of a POSA proposed by the plaintiff.

I've reached this conclusion for at least the following reasons. The patent contains parts that would be best understood by a pharmacologist even though the claims are principally directed to treatment and therefore to a clinician.

For instance, a pharmacologist is needed to understand the link between the EAE discussion of the specification and human dosing. Some of the prior art listed on the face of the patent and considered by the PTO is . . . pharmacological work relating to fingolimod. The invention as a whole is directed to a team which would necessarily include a pharmacologist for all the reasons that plaintiff has given, which are all well supported in the record.

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[1] *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1379 (Fed. Cir. 2009).

Defendants did not present any evidence from a pharmacologist or from the perspective of a pharmacologist. Therefore, they did not provide any evidence from the perspective of a POSA. Their expert, Dr. Hoffman, candidly admitted he doesn't know how a pharmacologist would interpret the patent. This alone I think is likely a sufficient basis to find that defendants are not likely to prevail on their invalidity challenges at trial. But I am not resting my decision solely or even principally on my finding regarding a POSA.

I will now turn to the three specific invalidity defenses that defendants have argued, and I find again that defendants are likely to fail on all three of them at trial.

First, anticipation by Kappos 2006.

In order for Kappos 2006 to anticipate the claims of the '405 patent, it must contain every element of the claims, either expressly or inherently. Also, Kappos 2006 must be enabled.

The Court agrees with Novartis that defendants are unlikely to persuade the Court at trial that Kappos 2006 discloses the '405 claim limitations of treatment and no loading dose.

First regarding treatment, Kappos 2006 is a test, not a method of treatment. At its publication date, the .5 milligram dose of fingolimod had never been used on a human MS patient. Nobody knew it would be an effective treatment, and no clinician would have prescribed it for an RRMS patient, including candidly defendants' clinical expert, Dr. Hoffman.

Kappos 2006 was a test. It was a hypothesis. It does not disclose and does not anticipate the treatment limitations of the asserted claims of the '405 patent.

This is reflected in a great deal of evidence about, for example, ethical concerns and even opposition to testing such a low dose on human RRMS patients, including Dr. Lublin's own hospital refusing to participate in the study and the unusual futility analysis required after six months of the test.

All of this would in one form or another have been part of what a POSA knew about fingolimod and would be part of why a POSA would read Kappos 2006 as something other than a method of treatment.

So that limitation is missing and that's enough to defeat the Kappos 2006 anticipation defense, but I also agree that Kappos 2006 also does not exclude an immediately preceding loading dose, which is an express limitation of the asserted claims of the '405 patent.

It is undisputed that Kappos 2006 is silent on the matter of a loading dose. I am persuaded on the present record that . . . Defendants will fail to persuade me at trial by clear and convincing evidence that a POSA, that is the properly defined POSA, which includes a pharmacologist, would read the one-page, approximately 600-word abstract as inherently and necessarily excluding a loading dose.

. . .

Given my conclusions on Kappos 2006 not containing all of the limitations of the asserted claims, I don't need to decide today if Kappos 2006 is enabling. All I would say on that is that my sense at the moment is that plaintiff's analogy to our *GSK* case is a persuasive comparison, and [D]efendants' efforts to distinguish *GSK*, which only came up today, appear likely to fail.[2]

Turning next to the written description defense. Under 35 U.S.C., Section 112, a patent must convey with reasonable clarity to a POSA that the inventor was in possession of the claimed invention at the time of the application.

The Court agrees with Novartis, that defendants are unlikely to persuade the Court at trial that the inventors of the '405 patent were not in possession of the claimed invention at the time of the application.

The properly defined POSA would read the '405 patent to have an adequate written description. That POSA is again a team that includes a pharmacologist, and I am persuaded, it is unlikely defendants will persuade me that a pharmacologist would fail to understand what the inventors invented and what the inventors were disclosing.

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[2] *See GlaxoSmithKline LLC v. Glenmark Pharm. Inc., USA*, 2017 WL 8944995 (D. Del. May 2, 2017), *report and recommendation adopted*, 2017 WL 2290141 (D. Del. May 25, 2017); *see also GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 313 F. Supp. 3d 582, 598 (D. Del. 2018).

Although not necessary, the parties today both introduced evidence of what the inventors themselves testified to, and this evidence on the whole supports plaintiff's view that the inventors had possession of their invention.

A patent does not need to tell the full story or really even any story about how the inventors came to their invention, and it need not state things that a POSA would already know, including the prior art. Much of the defendants' attack on the supposed lack of adequate written description is really legal irrelevancies, therefore.

And the third defense, turning to that, the lack of enablement or utility defense. Very little was said about this defense in court today. It is addressed a little bit in the briefing.

To be enabling, a specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. It must have utility as well.

Although not entirely clear, it may be in this context that defendants are arguing. "If Kappos does not disclose the absence of a loading dose, neither does the patent, and thus, Novartis did not describe any method supporting of possession of a claim." To the extent defendants are making that argument either in this or any other context, I find that plaintiff has adequately demonstrated, as the Patent Office similarly found, that when read in its full context, a person of skill does understand the patent to preclude a loading dose.

The Court is persuaded by the evidence that a POSA may well read an abstract differently than they read a patent. While far from dispositive, I think it's worth noting that the title of the patent includes, "treating RRMS" while the abstract is called "design of a randomized placebo-controlled study," and then it goes on, but that's the end of the part I'm quoting.

Lastly, defendants argue, "Novartis and its expert cannot point to any portion of the specification that contains actual information supporting the claimed utility in human patients." This I disagree with. It is contradicted and persuasively so by the testimony of Dr. Jusko. That is, that a pharmacologist would, in fact, understand how the EAE studies relate to the stated human doses.

So that takes care of likelihood of success on the merits. Turning next to irreparable harm.

Novartis has [met] its burden to show that there's a reasonable likelihood that in the absence of a preliminary injunction, one or more and up to six generics will undertake an [at-risk] launch in August of this year, and as a result, Novartis will suffer immediate and substantial harm that cannot be remedied by money damages even if Novartis ultimately prevails at trial and obtains a permanent injunction. These harms include the likely massive and immediate price erosion in the market for oral treatment of RRMS.

After what might be as long as a year of generic competition by the time we get to trial and I get a post-trial opinion done, Novartis will not be able to raise the price back to where it is now, or to where it would have been at that post-trial date in the absence of defendants' at-risk infringement.

Therefore, even assuming the amount of what would by that point . . . be the amount of past damages . . . could, with some difficulty, . . . be calculated, future damages beyond that date would also have to be calculated. That may be impossible. And then at that point, defendants will argue that they should not have to compensate Novartis for those future damages, i.e., the damages following the permanent injunction for the life of the patent.

Novartis has also proven that the relevant market will be condensed for [reasons] including issues relating to the requirement of FDO and the potential impact an at-risk launch might have on the availability of FDO.

I'm also persuaded that Novartis will suffer an irreparable injury to its goodwill from an at-risk launch for reasons including that to try to make itself whole [(or as whole as possible should it prevail at trial after an at-risk launch)], Novartis would have to raise Gilenya prices back to the pre-infringement level. [B]ut if Novartis tries to do that, Novartis would [(in this scenario[,] unfairly)], be widely criticized, thereby suffering irreparable harm to its goodwill.

. . . I'm not going to go into any further detail about the evidence on irreparable harm. We discussed most of that. That's highly confidential evidence and the courtroom was closed. I've considered all of that and I am largely persuaded by all of the arguments that the plaintiff has made on irreparable harm, but I'm

not going to go into further detail on that. Instead I will just discuss some of the defendants' arguments against irreparable harm.

Defendants' principal argument against finding irreparable harm is that Novartis has brought the harm on itself and that it has within its control the ability to mitigate or prevent these harms. I am not persuaded by these arguments. . . . [D]efendants did not unreasonably delay bringing suit on the '405 patent. Novartis did nothing inequitable in waiting to bring suit until after it received all of the many paragraph 4 certifications and after the IPR was completed, especially because the '405 patent was one that was never eligible to trigger a 30-month stay under the Hatch-Waxman Act and because pediatric exclusivity on the '229 patent protected Novartis from any potentially infringing competition until August of 2019.

Now, Novartis's course of action was not the only reasonable course of action. It may not even have been the most reasonable course of action.

For instance, it's far from clear to me that I would have necessarily stayed proceedings on the '405 patent during the pendency of the IPR if I had been asked, but I was never asked. But the important point for today is that there was nothing wrong with what Novartis did. Novartis's actions and failure to sue sooner do[] not undermine its showing of irreparable harm. I entirely disagree with defendants' contention that none of us should be here today.

I also do think that defendants may well have been able to force the issue of the validity of the '405 patent earlier through a declaratory action. It may be that it would have been dismissed for lack of standing. I don't have to decide that now. Again, nobody asked me. But I think it is pertinent that defendants did not try.

Defendants have also contended that Novartis itself believes the '405 patent is invalid and had planned for and prepared to deal with event[ual] generic competition.

I'm not persuaded that Novartis believes the '405 patent is invalid, or that this belief somehow explains how Novartis has approached litigating the '405 patent[.] [A]nd the fact that Novartis is preparing, as best as it can, to deal with legitimate generic competition when it arrives does not mean that Novartis

should be confronted with premature [(likely infringing)] generic competition.

That's all I have to say on irreparable harm.

Turning, finally, to balance of harms and the public interest. I find again that Novartis has met its burden. Both of these factors, too, favor the relief that I am granting.

Defendants stand to lose the opportunity to earn on the order of $50 million collectively by not being able to compete over approximately the next year whereas Novartis will irreparably lose a market in which they sell approximately $1.8 billion of drugs [each] year. To me, that balance clearly favors Novartis under the circumstances.

I also think that while consumers would, of course, benefit from lower prices, there may be a corresponding harm in this particular market given the possible adverse impact on FDO services.

Further, the public has an interest in protecting valid patent rights and in maintaining incentives for the massive investments required for drug development.

Under the circumstances here, I think the balance of harms and the public interest favor the relief I am granting. Therefore, and for those reasons, I am granting the motion for a preliminary [injunction].

June 24, 2019
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE