CIVIL CASE MANAGEMENT PLAN

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

Novartis Pharma AG,
Novartis Pharmaceuticals Corporation,
and Novartis Technology LLC,

VS No. **1:20-CV-690 (TJM/CFH)**

Regeneron Pharmaceuticals, Inc.

IT IS HEREBY ORDERED that, pursuant to Rule 16(b), Federal Rules of Civil Procedure, a status and scheduling conference will be held in this case before the Honorable **Christian F. Hummel**, United States Magistrate Judge on **August 18, 2021 at 10:30 A.M. in Albany**.

Counsel for all parties or individuals appearing pro se in the above-captioned action are directed to confer in accordance with Fed. R. Civ. P. 26(f) with respect to all of the agenda items listed below. That meeting must be attended in person or, if counsel for the parties are not located in the same city and do not agree to meet in person, then by telephone, and must be held at least **twenty-one (21) days** before the scheduled Rule 16 Conference. Following that Rule 26(f) meeting, a report of the results of that meeting, in the format set forth below, must be filed with the clerk within **fourteen (14) days** after the date of the Rule 26(f) meeting or not later than **ten (10) days** prior to the scheduled Rule 16 conference with the Court, whichever date is earlier. Matters which the Court will discuss at the status conference will include the following: (insert a separate subparagraph as necessary if parties disagree):

1) JOINDER OF PARTIES: Any application to join any person as a party to this action shall be made on or before the 15th day of September, 2021. Third party Vetter Pharma International GMBH ("Vetter") is currently a party to the case pending before the Southern District of New York ("SDNY"), *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG, Novartis Technology LLC, Novartis Pharmaceuticals Corporation, Vetter Pharma International GMBH*, Case No. 1:20-cv-05502-AJN ("SDNY Action"), and Vetter has requested that Regeneron's antitrust claims in the SDNY Action be transferred to this court. Thus, Vetter would need to be added as a party if the SDNY Action is transferred here.

2) AMENDMENT OF PLEADINGS: Any application to amend the pleadings to this action shall be made on or before the 15th day of September, 2021.

3) DISCOVERY:

Novartis's Position:

All fact and expert discovery in this action shall be completed by May 16, 2022, which is the close of all discovery in the related SDNY Action. Local Patent Rule 2.1(b)(1) specifically contemplates potential "modification of the obligations or deadlines set forth in these local patent rules to ensure that they are suitable for the circumstances of the particular case." Novartis submits that the unique circumstances of this case, including the discovery that took place in the companion International Trade Commission patent infringement Investigation *In the Matter of Certain Pre-filled Syringes for Intravitreal Injection and Components Thereof*, Investigation No. 337-TA-1207 (the "ITC Action") and the discovery that is taking place in the co-pending and related SDNY Action, make it appropriate to modify the local patent rule deadline for the close of discovery so that it is coordinated with discovery in the SDNY Action..

It should be noted that Novartis's proposed schedule is not "expedited" because of Regeneron's request for *inter partes review* as Regeneron contends. The Local Rules provide that the trial date should be within 18 months from the date the complaint is filed unless "the case is of such a complex nature that it cannot reasonably be trial ready" by then. Novartis submits that the unique circumstances here actually make this case much *less* complex than an ordinary patent case, and make trial within the presumptive 18 months entirely reasonable.

Regardless of the outcome of the ITC Action, this case was going to go forward because the ITC cannot award damages for patent infringement. As such, district court actions after ITC proceedings are commonplace, and, by statute, should not be delayed. As 28 U.S.C. § 1659(b) recognizes, a district court patent litigation following a parallel ITC proceeding, the exact situation we have here, should not start from scratch. The statute provides that the record from the ITC case "shall be transmitted to the district court and shall be admissible in the civil action, subject to such protective order as the district court determines necessary, to the extent permitted under the Federal Rules of Evidence and the Federal Rules of Civil Procedure." According to its legislative history, the purpose of the statute is to help "expedite" the district court case. *See* H.R. Rep. No. 103-826(I) at 142 (1994). Here, as explained below, discovery can proceed even more efficiently and expeditiously because of the related SDNY Action.[1]

[1] At several points in this submission Regeneron refers to the Staff attorney pre-hearing brief in the ITC Action as being somehow relevant to the schedule here. It is not. Regeneron's unsupported speculations aside, the Staff attorney's brief was not the reason for Novartis's decision to terminate the ITC Investigation. As Novartis stated in its motion to terminate the ITC Action, it "strongly believe[d] it would prevail on the merits in this investigation—indeed, the Administrative Law Judge recently granted Novartis's motion for partial summary determination that Regeneron directly infringed [the '631 patent]—[and] that the ['631 patent] is valid and that Regeneron cannot prove otherwise." Novartis's reason for terminating the Investigation and seeking to lift the stay in this action was based on the fact that the only remedy available at the ITC was an exclusion order and Novartis was concerned that the ITC would significantly delay the implementation of an exclusion order because of, among other things, the COVID pandemic. Moreover, as previously explained to the Court, the ITC

As a general matter, discovery in patent cases is related to three issues: infringement of the patent, affirmative defenses to infringement, and damages. As set forth below, full discovery on Regeneron's infringement of the patent in suit, Novartis's U.S. Patent No. 9,220,631 ("the '631 patent"), and on Regeneron's affirmative defenses other than inequitable conduct took place in the companion International Trade Commission patent infringement Investigation *In the Matter of Certain Pre-filled Syringes for Intravitreal Injection and Components Thereof*, Investigation No. 337-TA-1207 (the "ITC Action").

Regeneron's Infringement of the '631 Patent

This case is based on Regeneron's infringement of Novartis's '631 patent through its manufacture and sale of its EYLEA® pre-filled syringe product ("EYLEA PFS"). The same claim of infringement was at issue in the ITC Action. There should be no need for discovery on infringement in this case because full discovery on the issue of infringement took place in the ITC Action, and Regeneron conceded direct and/or indirect infringement of all the claims of the '631 patent that Novartis asserted. Indeed, Regeneron does not argue that additional discovery is needed on the issue of infringement. The only remaining related issue is the willfulness of Regeneron's infringement.

Regeneron's Affirmative Defenses and Counterclaim

Regeneron raised the same patent invalidity defenses in the ITC Action, that it does here, and the parties took full discovery on those defenses, including production of approximately 6 million pages of documents, taking of 18 fact depositions, and service of 58 interrogatories. The parties have reached a cross-use agreement by which the discovery from the ITC Action, including documents, deposition transcripts and interrogatory responses, can be used in this case.

Even if Regeneron's need for additional fact discovery from Novartis as set forth below is credited, it is limited to exploring supposed new theories on "conception, diligence and reduction to practice" and "enablement." There is no dispute, however, that document production, by far the most time-consuming part of fact discovery, was complete on these issues in the ITC Action and can be used in this case. With respect to third-party discovery, Regeneron conducted third-party discovery in the ITC Action, and there is no reason to think these third parties will be unwilling to enter into the same cross-use agreement for third-party

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staff attorney is simply a party to an ITC proceeding and its brief was nothing more than a party brief. The Administrative Law Judge ("ALJ") did not have to accept the Staff's positions on any issue, and, in fact, had already rejected some of the Staff attorney's positions on invalidity. The prehearing briefs to which Regeneron repeatedly refers was filed before the final evidentiary hearing, and the Staff attorney himself may well have changed his positions based on the evidence.

discovery that the parties have for party discovery. Any additional third-party discovery can easily be completed on the same schedule as the SDNY discovery.

In addition to its invalidity defenses, which, as noted above, were already the subject of full discovery in the ITC Action, the only other defense Regeneron raises in this case is unenforceability of the '631 patent based on alleged inequitable conduct, which is also the subject of its declaratory judgment counterclaim. But discovery on that defense and counterclaim is currently taking place in the co-pending SDNY Action, where Regeneron has asserted an antitrust claim based on the same alleged inequitable conduct (known as a "*Walker Process*" antitrust claim). As a predicate to succeeding on its *Walker Process* claim in the SDNY Action, Regeneron must prove the same inequitable conduct it has alleged as a defense here. Accordingly, this case presents a unique situation in which Regeneron is currently taking the *exact same* inequitable conduct discovery in the SDNY Action that it would be taking in this case. As with the ITC Action, there is a cross-use agreement in place so that the SDNY discovery can be used here. Regeneron's claim that discovery in the SDNY Action is "significantly advanced relative to this case" is simply not correct. Document production by the parties will be completed at the *same time* in both cases, since everything produced in the SDNY Action can be used as if produced in this case under the cross-use agreement. Both cases are ready for depositions to begin now. The most efficient and fair course for the parties and the witnesses would be coordinating those depositions so deponents need not be deposed multiple times.

Damages

Novartis agrees with Regeneron that damages discovery did not take place in the ITC Action, but submits that discovery on the issue can proceed efficiently within the discovery period proposed by Novartis, especially since discovery has already taken place with respect to infringement and Regeneron's affirmative defenses and counterclaim so would be the only subject for which discovery is necessary. Novartis will respond to interrogatories seeking its contentions on damages as soon as served by Regeneron.

In sum, there is no need for the parties here to engage in the time-consuming collection and production of documents on liability issues, as all relevant documents have already been collected and produced in the ITC and SDNY Actions. Similarly, as further detailed below, all potential witnesses that the parties would notice for deposition in this case on those issues have already been deposed on the same issues in the ITC Action or will be deposed on the same issues in the SDNY Action. As the Court is aware, Novartis filed a motion in SDNY over a year ago to stay that case or transfer it here because the SDNY antitrust claims should have been filed as compulsory counterclaims here, but there has as of yet been no ruling. As matters of both efficiency and fairness, both fact and expert discovery in the cases should be coordinated, and should not be cumulative or duplicative of each other.

Regeneron's Position:

This Court's Local Patent Rules state that these "rules ***apply to all*** civil actions filed in or transferred to this Court which allege infringement of a patent in a complaint, counterclaim,

cross-claim or third-party claim, or which seek a declaratory judgment that a patent is not infringed, is invalid or is unenforceable." L. Pat. R. 1.2. Novartis, however, has requested that the Court disregard the Local Patent Rules without providing a legitimate basis for doing so. Indeed, during the teleconference conducted by Magistrate Judge Hummel on June 11, 2021, the Court already rejected Novartis's request to expedite the case schedule, and instead explicitly informed the parties that discovery and the case schedule would proceed in accordance with the Local Patent Rules.

Nonetheless, Novartis's proposed schedule entirely disregards this Court's Local Patent Rules. Novartis has proposed eliminating claim construction in its entirety, substantially narrowing the discovery period, and setting an unrealistic trial date when the Local Patent Rules are clear that a trial date should not be scheduled until after the issuance of a claim construction order and completion of all discovery and motions. Novartis cannot plausibly argue that an expedited schedule is needed to avoid prejudice given that Novartis abandoned an opportunity to have its infringement claim tried at the ITC in April 2021. Instead, Novartis is proposing an expedited schedule to support its argument to the PTAB that the Board should deny Regeneron's request for *inter partes* Review of the 631 Patent without addressing the merits of Regeneron's IPR Petition. Recently, the PTAB has issued discretionary denials of IPR Petitions without considering the merits of the invalidity arguments on the ground that a co-pending district court case will proceed to trial before the PTAB will issue a final written decision. The PTAB, however, is unlikely to issue a discretionary denial if the district court trial is scheduled to take place after the PTAB's final written decision. Novartis's proposed schedule is a clear attempt to leverage the PTAB's discretionary denial practice to avoid an invalidity decision by the PTAB on the merits.[2]

The Court should reject Novartis's attempted gamesmanship. As explained below, this case requires extensive claim construction and discovery before proceeding to trial, which warrants adoption of the schedule set forth in the Local Patent Rules. Moreover, given that one objective third party (the ITC Staff) has already concluded that the 631 Patent is invalid as obvious, the Court should enter a schedule that provides adequate time for the PTAB to conduct a full review of the 631 Patent prior to any trial.

Claim Construction:

Regeneron submits that this case should proceed according to the normal case schedule set forth in the local patent rules. In contrast, Novartis's proposal to expedite the schedule improperly eliminates the claim construction process from the case schedule. The claim construction briefing and hearing before the ALJ in the ITC Investigation was limited to whether certain claim limitations were indefinite. Moreover, after the *Markman* hearing and during expert discovery in the ITC Investigation additional disputes regarding the scope and meaning of various claim limitations arose. First, there is a dispute concerning the full scope of the claimed silicone oil and force ranges, which was not resolved during the ITC Investigation because the ALJ never issued a claim construction decision. Second, there is a dispute

[2] If the PTAB grants Regeneron's IPR Petition against the 631 Patent, the Board would be required by statute to issue a Final Written Decision no later than October 28, 2022.

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