

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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REGENERON PHARMACEUTICALS, :  
INC., :

Plaintiff, :  
Counterclaim-Defendant, :

14 Civ. 1650 (KBF)

MEMORANDUM  
DECISION & ORDER

-v- :

MERUS B.V., :

Defendant, :  
Counterclaim-Plaintiff. :

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KATHERINE B. FORREST, District Judge:

The Court scheduled a bench trial on Merus’s claim of inequitable conduct to commence on June 8, 2015. On May 29, 2015, Regeneron filed a number of trial declarations including those from Drs. Smeland, Murphy, and Jones. Smeland and Murphy are accused of having violated their duty of candor. Those declarations made a number of affirmative statements relating to certain prior art references Merus asserts should have been disclosed to the United States Patent and Trademark Office (“PTO”) during patent prosecution (“Withheld References” or “WR”), other prior art, the scope and meaning of claims in the ‘018 patent and related applications, prosecution strategy for the ‘018 patent and related applications, and views as to the patentability of the ‘018 patent. According to the Court’s bench trial procedures, such trial declarations would ordinarily be accepted at trial as the witness’s direct trial testimony. These declarations led directly and

indirectly to a waiver of attorney-client privilege and identification of discovery misconduct.

For instance, by making affirmative statements in his declaration that during patent prosecution he viewed certain prior art or claim scope in a particular manner, Smeland was using his statements as a sword. A long-standing legal principle based on fairness prevents the selective disclosure of evidence as a sword while using the shield of the attorney-client privilege to prevent testing of those assertions. This classic sword/shield issue injected a serious fairness concern into the trial at the very outset.<sup>1</sup> The parties had been working towards trial for a significant period of time; clients had flown in from overseas, witnesses were ready to be called, the courtroom was loaded with boxes upon boxes of trial exhibits. The Court and parties addressed the sword/shield issue immediately.

First, Merus argued that the Smeland declaration waived privilege and raised various issues with respect to Regeneron's (and its patent counsel Foley Hoag LLP) privilege log.<sup>2</sup> That log, according to Merus, contained numerous entries that appeared to relate directly to topics as to which the declaration now waived any privilege. Regeneron represented that its log did not contain documents within the

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<sup>1</sup> On June 4, 2015, after waiving privilege with the submission of the declarations on May 29, 2015, Regeneron sought to voluntarily withdraw portions of the Smeland declaration. At that point, Regeneron could not put the genie back in the bottle. In any event, efforts to withdraw selected portions of the declaration did not change the fact that Smeland's declaration remained focused on his state of mind at the time of patent prosecution. For example, Regeneron sought to strike "and still believe today" from the fourth paragraph of the Smeland declaration: "I firmly believed – and still believe today – that Brüggermann, Taki, Zou and Wood were not material to patentability . . ." The remaining portions of the declaration still implicate waiver of the privilege.

<sup>2</sup> Regeneron has submitted logs from both its files and from Foley Hoag LLP. The term "log" as used herein refers to any and all of the logs Regeneron submitted.

scope of the waiver. The Court determined that while a waiver had occurred, it remained unclear whether the log in fact contained any documents which should have been produced. It was, for instance, possible that all documents that might be implicated by a waiver had previously been disclosed. The Court thereafter conducted an in camera review of documents as to which privilege was claimed. The log contained thousands of entries and the Court could realistically only review a sampling of several dozen that it chose randomly. That sampling appeared not only to confirm Merus's concerns but also to reveal additional serious discovery issues: a number of non-privileged documents related to topics at issue throughout the litigation had been withheld on the basis of privilege, and other documents that should have been produced pursuant to a February 25, 2015 order (ECF No. 272) regarding a prior waiver issue (the so-called "Jones Memo" issue) had not in fact been disclosed. The Court additionally determined that documents withheld on the basis of privilege appeared to relate to waived topics from, inter alia, the Smeland declaration. Documents as to the first categories included, inter alia, ones authored (in whole or part) by Murphy or in his files.

The Court raised concerns regarding these categories of documents in open court without disclosing the particular content of what it had found. It then provided the parties with a list of log entry numbers in a written order (ECF No. 373), and provided hard copies of a subset of the documents to Regeneron only. Trial had commenced by this point. Regeneron responded to the Court's concerns in a document which raised yet additional issues, as it contradicted what appeared to

be the plain meaning of certain documents. The Court does not have a degree in molecular biology and believed it could not itself adequately determine potential meaning and relevance without assistance. It was too late to begin an undoubtedly lengthy and expensive process of seeking out and retaining a special master without conflicts and having him or her learn enough about the technology to give a view to the Court. The Court instead laid out a deliberate process with the parties taking it – as the Court repeatedly stated – “step-by-step.” It was in this context, with these time pressures, that the Court suggested that one counsel for Merus review the documents under stringent guidelines. Regeneron did not object.

Merus’s designated counsel reviewed the Court’s printed-out sample of documents, after which the Court and parties had a further (sealed) discussion in the robing room. Based on the parties’ arguments as to whether the documents meant x or y, and based upon a recitation of how Regeneron had interpreted the prior Jones Memo order of the Court – which made no sense – the Court and parties continued to be faced with a serious situation.

It was at this point that the Court bifurcated the trial. The trial was supposed to concern Merus’s claim of inequitable conduct related to prior art references (WR) that Regeneron did not disclose to the PTO during patent prosecution, as well as other conduct during prosecution. The first determination which must be made in such a proceeding is the materiality of the information or conduct at issue. Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1291 (Fed Cir. 2011) (“in assessing the materiality of a withheld reference, the court

must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference”). The Court therefore bifurcated that inquiry from the second determination: whether Regeneron “misrepresented or omitted material information with the specific intent to deceive the PTO.” *Id.* at 1287. The Court’s rationale was that the first topic would be addressed by the experts and through documents, and the second (which involved testimony from Smeland and Murphy) was only necessary if the Court determined the first issue in Merus’s favor. The trial accordingly proceeded as to the materiality issue. Following the close of evidence on materiality, the parties submitted post-trial briefing on (1) materiality, and (2) whether, in the context of a clear waiver of privilege, the documents inappropriately withheld from discovery constituted misconduct requiring a remedy.

Given the possibility of a continued trial on the “intent” determination (the second half of the bifurcated trail), the Court committed to providing the parties with an expeditious decision on the first issue (though perhaps with the full written opinion to follow) and a decision as to whether the trial on the second issue would proceed. The instant decision recites the Court’s determinations as to both issues. A full written opinion which will constitute the appealable order shall follow. This decision is not final and is not an appealable order.

This lengthy history provides a prelude to the following determinations.

First, the Court finds that the withheld references are material under the standard set forth in Therasense, 649 F.3d 1276. The Court has not fully resolved the questions relating to the additional conduct (the alleged affirmative egregious misconduct involving the presentation to the PTO or the failure to reveal lack of enablement, or the unknown metes and bounds of the locus). However, the materiality of the WR is alone sufficient to require a determination as to whether a second trial as to intent shall occur, or whether the above-referenced events preclude that. As discussed below, under the circumstances here, a further trial shall not be scheduled.

As set forth above, there are three categories of documents at issue:

1. Non-privileged documents that were not produced and instead have resided throughout this case on the privilege log (e.g. numerous Excel spreadsheets with scientific test results, third party filings to the PTO, numerous fact statements by non-lawyers not seeking legal advice, etc.).
2. Previously privileged documents as to which Regeneron affirmatively waived the privilege and that this Court ordered be produced pursuant to its February 25, 2015 order. (ECF No. 272.)
3. Documents on the privilege log relating to precisely those topics waived by Regeneron on May 29, 2015 when it filed its trial declarations.

Failure to make full and adequate production of documents within the first two categories alone warrants serious sanction. The production failure is

undoubtedly larger than the few exemplars revealed by the Court's own review. Given the many thousands of documents on Regeneron's privilege log, the Court cannot know the full extent of the problem.

The third category of documents presents its own very serious issues. Having now had the benefit of full briefing, there is no doubt that there are many, many documents on the log that have never been produced and that are directly relevant to the topics as to which privilege has been waived. Indeed, it is deeply troubling that some of those documents contain statements directly contradictory to Smeland's sworn trial declaration.

The next and obvious question is "where do we go from here"? To allow into evidence at trial declarations from witnesses to whom these three categories of documents relate could only occur – in fairness – if there was a wholesale re-opening of discovery. As a first step, a top-to-bottom re-review of the Regeneron privilege log would be necessary followed by additional document production, fact depositions, and revised expert reports and depositions. Given the Court's concerns with Regeneron's process to date, the Court would require that any such process only occur with the direct oversight of a special master. It is clear that this process and the attendant discovery would consume substantial time and cost. It would also undoubtedly require further judicial resources. This is not a fair burden for Merus or this Court.

The Court has considered whether striking the trial declarations and precluding Smeland and Murphy from testifying at trial would be a sufficient

remedy. It would not, though such an order is a minimum starting point. Based on the considerations discussed below and as shall be set forth in its full written decision, simply striking the declarations and precluding trial testimony would not sufficiently address the many issues now in play:

First, the Court must bear in mind that the first two categories of documents themselves reveal a separate need for a re-review of the privilege log under the direction of a special master, production and of course depositions as needed;

Second, striking the declarations and preclusion of certain witnesses alone fails to remedy the substantial disruption and delay caused by Regeneron's conduct; and

Third, merely striking the declarations and precluding certain witnesses fails to recognize the pattern of conduct by Regeneron throughout this litigation. That conduct included, inter alia, a host of issues at the outset regarding infringement contentions, positions in relation to claim construction and positions and representations with regard to the Court's February 25 Order (the Jones Memo Order). The Court also understands that current trial counsel was not responsible for the preparation of the privilege log and was not counsel at the outset of this case when the first issued occurred (though they were counsel for the Jones Memo order). In all events, this pattern by Regeneron is just that – a pattern. It is troubling to say the least. Merely striking the declarations and precluding testimony treats the most recent issues as isolated and remediable – when they are



yet another step in a long pattern of litigation choices that have caused delay, inefficient use of resources, and diversion from the merits.

The Court has carefully considered the appropriate combination of remedies that best – but yet most narrowly – addresses where we find ourselves in this litigation today.

Under these unusual circumstances, it is appropriate to preclude the testimony of Smeland, Murphy and Jones. It is additionally appropriate to make an adverse inference as to the intent of Smeland and Murphy. Only this inference, which is “the single most reasonable inference able to be drawn from the evidence”, is sufficient to remedy the array of issues discussed above and to place the prejudiced party, Merus, in a position as near as possible to that which it would occupy in the absence of the misconduct. See *Therasense*, 649 F.3d at 1290 (quoting *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)); *Residential Funding Corp. v. DeGeorge Financial Corp.*, 306 F.3d 99, 108 (2002).

The application of these inferences to the Court’s prior finding of materiality appears to lead inexorably to one final determination: that Regeneron engaged in inequitable conduct in connection with the prosecution of the ‘018 Patent. Should the parties disagree that this inference requires such a finding, they shall make a submission on such position not later than **August 25, 2015**.

As a final matter, the Court notes the application by Regeneron to enjoin Merus counsel exposed to Regeneron documents on the log from undertaking

certain work and for certain other relief. This application is wholly without merit. First, this entire issue is of Regeneron's own making – not Merus's. The parties and Court together did what was certainly necessary to address an issue created solely by Regeneron. Merus will not be penalized for doing that which the Court required it to do. Second, lawyers are exposed to competitive and sensitive information all the time and well understand how it may be appropriately used or not; this situation calls upon a routine exercise of a lawyer's skills in this regard. Third, lawyers are frequently exposed to another party's privileged information – and inadvertent waiver (when it is inadvertent, unlike here) provisions in protective orders evince an understanding that lawyers are capable of, having once seen privileged material, not using it further. And finally, of course, exposure to the first two categories of documents was not exposure to privileged documents at all. That is the point. Those documents should have been produced long ago. As to the third category, there is a substantial argument that on the day the Smeland trial declaration was filed, the waiver was complete. That waiver was accompanied by discovery misconduct – namely the failure to have produced certain documents that would allow Merus to fairly evaluate Smeland's statements. These are two analytically distinct issues. The waiver could, then, itself provide a basis for disclosure of the documents at issue publicly (or under the normal restrictions of the Protective Order in place here, as appropriate). Such disclosure would eliminate any particular arguments regarding the Merus counsel who has seen those documents, as he will have seen no more than that which he and other counsel and

parties are otherwise entitled to see. In light of the remedies on the merits set forth above, the Court sees no need to order this additional relief.

The Court will issue a full written opinion on materiality and inequitable conduct as soon as practicable (but very likely not before mid to late September).

SO ORDERED.

Dated: New York, New York  
August 6, 2015

Handwritten signature of Katherine B. Forrest in black ink.

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KATHERINE B. FORREST  
United States District Judge