Morris James LLP

Kenneth L. Dorsney
302.888.6855
kdorsney@morrisjames.com

July 2, 2020

VIA CM/ECF AND HAND DELIVERY
The Honorable Leonard P. Stark
United States District Court for the District of Delaware
844 N. King Street
Wilmington, DE 19801

Re: *Bayer Healthcare LLC v. Apotex Inc., et al.*,
C.A. No. 16-1221-LPS (Consolidated)

Dear Chief Judge Stark:

Plaintiffs' Motion to Strike misses the mark. The predicate of their Motion is the misguided allegation that Apotex is somehow trying to shoehorn a new defense to the patent-in-suit. Not so. Apotex's primary invalidity argument is, and has been, that the asserted claims of the '107 patent are obvious—a POSA would have lowered the identified impurities to the claimed ranges with a reasonable expectation of success. In attempting to rebut that position, however, Plaintiffs went too far. Plaintiffs' expert, Dr. Myerson, testified at his deposition that it would require "extensive experimentation" to achieve the levels of impurities recited in the claims. In other words, the level of experimentation to practice the full scope of the claims would be undue.[1] Not once did Dr. Myerson contradict his foregoing testimony. And, in taking such an extreme position, testified that the specification does not enable the asserted claims. Apotex is not taking liberties in making this assertion. That was Dr. Myerson's testimony. Thus, far from Plaintiffs' allegation that Apotex is now springing a surprise, the truth is that the defense is borne solely from Plaintiffs' own expert – during literally the last deposition of expert discovery. To preclude Apotex the ability to rely upon such glaring admissions would be manifest prejudice.

I. Exclusion Is Not the Appropriate Remedy

The balance of the *Pennypack* factors weighs in favor of admissibility. As this Court has noted, "[i]t bears emphasis that exclusion of 'critical evidence,' . . . is an 'extreme sanction not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence.'" *E.g., B. Braun Melsungen AG v. Terumo Med. Corp.*, 749 F.

[1] Plaintiffs may argue that a claim cannot be both obvious and non-enabled. That is incorrect. The asserted claims recite a composition with an impurity level of 0.01% to 0.0001%. For this claim to be obvious, the prior art need only teach the POSA how to reach the upper limit of the claimed range with a reasonable expectation of success. Apotex's expert opines that it does. But to be enabled, the specification must teach the POSA how to practice the *full scope* of the claims, i.e., the entire range of 0.01% to 0.0001%, without undue experimentation. Plaintiffs' expert, Dr. Myerson, opined that it does not.

Supp. 2d 210, 221 (D. Del. 2010) (Stark, J.) Here, invalidity of the '107 patent is clearly critical to Apotex's defense as Apotex stipulated to infringement. Plaintiffs actually agree that this is a "factor that could in theory justify permitting Apotex to proceed with its non-enablement defense." (Opening Letter Brief at 2). Nevertheless, Plaintiffs argue that "Apotex's defense is doomed to failure" because "Apotex cannot rely on Dr. Myerson's testimony in its case-in-chief, because it is inadmissible hearsay." (Opening Letter Brief at 2 (citing *Kirk v. Raymark Indus., Inc.*, 61 F.3d 147 (3d Cir. 1995) and *Pfizer, Inc. v. Ranbaxy Labs., Ltd.*, 2005 WL 2296613 (D. Del. Sept. 20, 2005)). But *Kirk* and *Pfizer* are distinguishable.

For example, in *Kirk*, the testimony that the plaintiff sought to introduce at trial was from an expert that the defendant had used in a *prior* litigation and was not using in the current litigation. 61 F.3d 147, 163 (3d Cir. 1995). In *Pfizer*, the plaintiff sought to supplement its deposition designations by adding testimony from the defendant's experts for use in plaintiff's case-in-chief to prove infringement under the doctrine of equivalents. 2005 WL 2296613, at *2. In precluding plaintiff from offering deposition testimony of defendant's experts, the court found that plaintiff failed to make any showing that the defendant's experts had the authority to speak on behalf of the defendant. *Id.*[2] Here, in contrast, Apotex does not plan on calling Dr. Myerson to testify, or designating his testimony, in its case-in-chief at trial. And Plaintiffs have cited no legal precedent that would prohibit Apotex from establishing its defense through cross-examination of Dr. Myerson. That is not surprising, as Apotex is aware of none. More importantly though, there is now time for this issue to be adjudicated on the merits, alleviating any perceived prejudice to either party.

Plaintiffs claim they "would be prejudiced if Apotex can pursue its theory [because it] would require Bayer to conduct further fact discovery that it had no reason to pursue before Apotex belatedly raised its defense." (Opening Letter Brief at 3). Again, this defense arose from Plaintiffs' own expert's testimony. But regardless, Plaintiffs have admitted that such prejudice could easily be cured. For example, in a draft Status Report sent to Apotex on June 5, 2020, Plaintiffs stated that that they would be in a position to "produce any additional documents that Bayer may rely upon at trial in response to Apotex's new theory . . . ***by July 10, 2020***." (Ex. A, 6-5-2020 Draft Status Report at 1; *see also* D.I. 153 at 1 ("Bayer had proposed providing discovery now.")) Plaintiffs also argue that it would be especially burdensome to make additional witnesses available for deposition because "Bayer's potential fact witnesses reside in Germany and are not native English speakers . . . and may need to rely on interpreters to interview them and to facilitate their testimony." Yet in the same draft Status Report, Plaintiffs stated that they would make "fact witnesses available . . . in ***July or August 2020*** to provide deposition testimony." (Ex. A, 6-5-2020 Draft Status Report at 2).

[2] Additionally, in *Pfizer*, defendant filed a motion in *limine* to exclude plaintiff from raising the doctrine of equivalents at trial. In its Answer Brief, Pfizer stated that it will rely on the testimony of defendant's experts to establish equivalence. The Court denied defendant's motion. 2005 WL 2296613, at *1.

This is particularly important because of the posture of the case. When this issue first arose, the parties were three weeks away from trial in November of 2019. At that juncture, there simply was not time for discovery on this issue, which is why Apotex stated that it did "not intend to submit any of its own expert evidence" on the issue. (Ex. B to Opening Letter Brief). Bayer's and Apotex's experts simply would have addressed the non-enablement issues at trial. That trial date, of course, was pushed to June 2020. (D.I. 141). As Apotex previously noted, it was willing to proceed with trial in June 2020, but accommodated Plaintiffs' request to move it further (eventually to the currently scheduled September date)[3]. In light of these changes to the schedule, the parties now have the ability to cure any perceived prejudice by conducting limited fact and expert discovery related solely to this issue. That includes a full and fair opportunity for both sides to address Dr. Myerson's testimony. Plaintiffs' tenuous arguments would effectively allow the last testifying expert in expert discovery free reign to take positions contrary to the party's case, yet prevent reliance on those positions since they were not previously at issue. That cannot be. Had Apotex's expert raised the issue without prior notice, a motion to strike would make sense. But that is not what happened here. Plaintiffs' expert took an extreme position to try to make the patent less obvious. He went too far, and the parties should be permitted to address the issue on the merits.

As to the last *Pennypack*, Plaintiffs cannot possibly argue that Apotex had any bad faith or willfulness in not disclosing its defense until the day immediately after Dr. Myerson's deposition. As noted above, Apotex's theory stems directly from Dr. Myerson's deposition testimony regarding non-obviousness. Nor can Plaintiffs demonstrate that Apotex acted in flagrant disregard of a Court order or with willful deception. *Braun Melsungen*, 749 F. Supp. 2d at 221.

II. Dr. Myerson's Testimony Forms the Basis of Apotex's Non-Enablement Theory

Enablement requires that claim scope be no broader than the scope of a patent's teaching. *Idenix Pharm. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1154 (Fed. Cir. 2019). Here, each asserted claim requires "from 0.0001% to a maximum of 0.01%" impurities. At his deposition, Dr. Myerson testified that the examples disclose only "typically" achieving "less than 0.01%." (Ex. B, Myerson Rough Transcript[4] 240:2-242:13). Dr. Myerson conceded that the examples do not disclose levels as low as 0.0001%: "The data's not in there . . . The POSA would have to perform example 4 and determine if it was achieved." (*Id.* at 82:19-21; 82:11-13). But, directing one of skill in the art to simply "perform the example" and "do the analysis" is not an enabling disclosure. *See, e.g., Idenix Pharm.*, 941 F.3d at 1159 (affirming JMOL (Stark, J.) that claims were not enabled because, *inter alia*, plaintiff's witness testified "you don't know whether or not a nucleoside will have activity against HCV until you make it and test it"); *MorphoSys AG v. Janssen Biotech, Inc.*, 358 F. Supp. 3d 354, 372-74 (D. Del. 2019) (Stark, J.).

[3] Covid-19 is of course a more than valid reason for rescheduling trial. But, it remains true that the June 2020 trial could have occurred entirely remotely, just as it will in September.

[4] For consistency with Plaintiffs' Opening Letter Brief, Apotex cites to the rough transcript of Dr. Myerson. (Opening Letter Br. at 2).

Further, according to Dr. Myerson, reducing impurity levels 10-fold, "from 1000 ppm to 100 ppm (i.e., the highest level allowed in the asserted claims of the '107 patent) . . . would be difficult to achieve even with extensive experimentation." (Ex. C, Myerson Report ¶ 85). "Extensive experimentation," according to Dr. Myerson, "would require optimization involving a *wide variety of variables*." (*Id.* ¶ 87; Ex. B, Myerson Rough Transcript 77:10-17). This, of course, is Dr. Myerson's attempt to rebut Apotex's obviousness challenge. In so doing, Dr. Myerson walked Plaintiffs' into an enablement problem. Plaintiffs cannot feign surprise that Apotex would hold Dr. Myerson to his opinions when they undermine Plaintiffs' own position.

But there is more. When asked whether the '107 patent taught the POSA what variables needed to be optimized to reduce the impurity levels 100-fold, from 100 ppm (i.e., 0.01%, the upper limit in the claims) to 1 ppm (i.e., 0.0001%, the lower limit in the claims), Dr. Myerson testified: "No, it does not. . . . [I]t doesn't tell you how to achieve one [ppm] versus 100 [ppm]." (Ex. B, Myerson Rough Transcript 85:7-18; 86:3-10 (same); 86:14–87:7 (100-fold reduction would be harder to achieve than 10-fold)). Thus, Dr. Myerson confirmed that the POSA would not have been able to practice the full scope of the claims, *even with the benefit of the patent's disclosures*, without undue experimentation.

Contrary to Plaintiffs' assertion, the basis for Apotex's non-enablement theory is not merely that "the '107 patent fails to disclose expressly how to achieve impurity levels of 100 ppm versus 1 ppm." (Opening Letter Brief at 2). Rather, Apotex argues the specification has not enabled the values in the claimed range (something *that is* required). Indeed, Federal Circuit case law strongly supports Apotex's position that the '107 patent's specification must enable the entire claimed range. Two cases— *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1380–81 (Fed. Cir. 2012) and *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1364-65 (Fed. Cir. 2012)—are particularly instructive.

In *MagSil*, the plaintiff asserted infringement of claims to a semiconductor device that could change in resistance by "by at least 10% at room temperature." 687 F.3d at 1379. The district court construed the asserted claims to cover "resistance changes beyond 120% and up to infinity." *Id.* at 1381. Yet the asserted patent's specification taught "that the inventors' best efforts achieved a maximum change in resistance of only 11.8% at room temperature." *Id.* The Federal Circuit found the claims not enabled, holding that the patent's specification only enabled a "small subset of the claimed range." *Id.* at 1384. It "only disclose[d] enough information to achieve an 11.8% resistive change." *Id.* at 1383. Moreover, it disclosed no "working examples" of "resistive changes of 20%, 120%, 604%, or 1000%." *Id.* at 1382.

In *Alcon Research, Ltd. v. Apotex Inc.*, the patentee asserted infringement of various claims that contained drug concentration ranges, including one as wide as from 0.0001% to 5%. 687 F.3d at 1364-65. In arguing the validity of this claim, the patentee conceded it had not enabled the portion of the claimed range below a 0.001% concentration, but argued that the claim should be construed so that only the enabled portions of the range were covered. *Id.* at 1367-68. The Federal Circuit rejected this argument, stating that "[t]his is not how patent law works." *Id.* at 1368. A patentee claiming a concentration range could not "simply disavow the invalid portion and keep

the valid portion of the claim." *Id.* Rather, "[i]f everything up to 0.001% w/v is admittedly not enabled, then the entire claim is invalid." *Id.*

Here, as in *MagSil* and *Alcon v. Apotex*, Plaintiffs have claimed a range, but the specification does not enable the entire range, at least according to Dr. Myerson: "[I]t doesn't tell you how to achieve one [ppm] versus 100 [ppm]." (Ex. B, Myerson Rough Transcript 85:7-18; 86:3-10 (same); 86:14–87:7 (100-fold reduction would be harder to achieve than 10-fold)); *see Par Pharm., Inc. v. TWi Pharm., Inc.*, 120 F. Supp. 3d 468, 478 (D. Md.) (discussing *MagSil* and *Alcon*, and finding claimed range not enabled), aff'd, 624 F. App'x 756 (Fed. Cir. 2015).[5]

Plaintiffs created their own enablement problem. To divorce them from their own admissions would be unfair. "In cases involving unpredictable factors, such as most chemical reactions . . . the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). By relying on the purported unpredictability of the art to establish non-obviousness of the claimed range, Plaintiffs brought upon themselves "the peril of losing any claim that cannot be enabled across the full scope of its coverage." *MagSil*, 687 F.3d at 1381.[6] Plaintiffs are not prejudiced by this extreme position taken by their expert—Apotex is. That prejudice can be cured by allowing limited fact and expert discovery prior to trial.

For the foregoing reasons, Plaintiffs' motion to strike should be denied.

Respectfully,

Kenneth L. Dorsney

Kenneth L. Dorsney (I.D. #3726)

cc: All counsel of record (via e-filing and email)

---

[5] Plaintiffs argue that "Apotex's defense fails" because "Dr. Myerson had neither performed experiments, nor reviewed documents—such as materials from Bayer reflecting impurity levels achieved with the patent's method—pertinent to the questions of whether and how much experimentation would be required to practice the claims using that method." (Opening Letter Brief at 2). With trial now scheduled for September 2020 (as opposed to June 2020 under the earlier schedule), Dr. Myerson will have ample opportunity to perform experiments and review documents from Bayer. And as Plaintiffs stated in their draft Status Report, they are prepared to "produce any additional documents that Bayer may rely upon at trial in response to Apotex's new theory . . . ***by July 10, 2020***."

[6] Plaintiffs imply that Apotex's argument is merely that "if the asserted claims are non-obvious, they cannot possibly be enabled." (Opening Letter Brief at 3 (quoting *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1310 (Fed. Cir. 2015)). Not so. As explained above, Dr. Myerson confirmed that the POSA would not have been able to practice the full scope of the claims, *even with the benefit of the patent's disclosures*, without undue experimentation.