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VIA ECF & FEDEX

CONTAINS HIGHLY CONFIDENTIAL MATERIAL PURSUANT TO DISCOVERY CONFIDENTIALITY ORDER

The Honorable Susan D. Wigenton, U.S.D.J.
United States District Court
Martin Luther King, Jr. Federal Building
50 Walnut Street, Room 5060
Newark, New Jersey 07102

Re: *Celgene Corporation v. Natco Pharma Limited, et al.*
Civil Action No. 10-5197 (SDW)(MCA)

Dear Judge Wigenton:

This firm, together with Quinn Emanuel Urquhart & Sullivan, LLP, Jones Day, and Richard G. Greco PC, represents Plaintiff Celgene Corporation ("Celgene") in the above-referenced matter.[1] We write to request that Your Honor bifurcate and stay expert discovery pertaining to claims involving U.S. Patent Nos. 6,045,501, 6,315,720, 6,561,976, 6,541,977, 6,775,784, and 8,315,886, which cover methods of safely distributing and administering pharmaceutical products, for example, Risk Evaluation and Mitigation Strategies ("REMS") (collectively, the "REMS patents").[2]

Bifurcation makes sense for several reasons. *First*, it would promote judicial economy, and Defendants' (collectively, "Natco") should have no objection because they requested that Celgene limit the number of asserted claims. *See* D.I. 317, 325, 328, 334. Indeed, bifurcation would allow the parties to remove 101 claims from the current dispute and, as describe below, those claims may never need to be litigated. [redacted]

[1] This letter contains the same type of confidential material previously ordered sealed by the court (D.I. 198). Accordingly, it is being filed under seal in its entirety and publicly redacted.

[2] Celgene first raised the issue of bifurcation with Defendants during a telephonic meet and confer in June of this year. At that time, counsel for Defendants represented that Defendants did not agree to bifurcation. Celgene again raised the issue with Defendants in writing on August 22nd. After close of business on September 2nd, more than two months after Celgene initially raised the issue, Defendants confirmed that they do not agree to bifurcation of the REMS patents.

[redacted][3][redacted] Thus, litigating those claims now would result in a substantial misuse of the Court's and the parties' resources. For all of these reasons, and as described further below, the Court should grant Celgene's request.

A. Legal Standard

Rule 42(b) states that, "[f]or convenience, to avoid prejudice, or to expedite and economize, the court may order a separate trial of one or more separate issues, claims, crossclaims, counterclaims, or third-party claims." Fed. R. Civ. P. 42(b). The decision to bifurcate is within the Court's "broad discretion," and is made on a "case-by-case basis." *Ricoh Co. v. Katun Corp.*, No. 03-2612, 2005 WL 6965048, at *1 (D.N.J. Jul. 14, 2005); *see also Barr Lab., Inc. v. Abbott Lab.*, 978 F.2d 98, 115 (3d Cir. 1992). Due to their complexity, patent cases are routinely bifurcated to promote efficiency and simplify issues. 8 Moore's Fed. Prac. 3d § 42.24[3], at n.5; *Ricoh*, 2005 WL 6965048, at *1 ("In the context of patent cases, experienced judges use bifurcation and trifurcation both to simplify the issues [] and to maintain manageability.").

B. Background

This litigation involves eighteen patents covering various aspects of Celgene's Revlimid® product. The active ingredient in Revlimid® is lenalidomide. Lenalidomide may cause fetal harm when administered to a pregnant female at certain stages of gestation, or when a pregnant female is exposed via administration to a male. Accordingly, the FDA required a REMS for Revlimid® as a condition of approving the drug for marketing. The FDA will similarly not approve a generic version of Revlimid® without an acceptable REMS. *See* 21 U.S.C. § 355-1(i)(1)(B)(i)-(ii). The Revlimid® REMS is covered by the asserted claims of the REMS patents.

In 2010, Natco filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic version of Revlimid®. [redacted]

To gain FDA approval for its proposed generic product, Natco must either use the same REMS as Revlimid®, or certify to the FDA that: (1) the burden of using the same REMS outweighs the benefits; or (2) parts of the Revlimid® REMS are patented (or trade secrets) and

[3] Natco has stipulated that it will infringe the asserted claims of the REMS patents. D.I. 305.

Natco has been unable to obtain a license. *See* 21 U.S.C. § 355-1(i)(1)(B)(i)-(ii). [redacted]

C. Bifurcation Will Promote Judicial Economy and Reduce the Risk of Prejudice

Celgene requests bifurcation of trial on all claims related to the REMS patents, as well as a stay of expert discovery on those claims, [redacted] Under the current circumstances, Rule 42 strongly favors bifurcation.

First, bifurcation will promote judicial economy. Natco—by way of its request that the Court order Celgene to reduce the number of asserted claims—recognizes that removing the REMS patents from the current dispute will ease the burden on the Court and the parties, and will promote judicial economy. *See* D.I. 317. Indeed, bifurcation and stay of the REMS patents would eliminate the need to litigate disputes pertaining to 101 asserted patent claims. Depending on the outcome of the parties' claims regarding the other patents-in-suit, it may be unnecessary to address the REMS patents separately. Therefore, bifurcation will allow the case to move forward more efficiently.

Second, as alluded to above, litigation of the REMS patents may ultimately be unnecessary. [redacted] Further, there are other patents-in-suit that expire later than the REMS patents. If Celgene prevails on the later-expiring patents, litigation of the REMS would be moot. This again strongly favors of bifurcation.[4]

Third, bifurcation will minimize prejudice to the parties. [redacted]

[4] Another court in this district recently bifurcated and stayed proceedings concerning patents covering a REMS with the same single, shared REMS requirements as Revlimid. *See Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, No. 10-6108 (D.N.J March 24, 2014) (Salas, J.) (D.I. 316, D.I. 270, attached hereto as Exhibit C); Jazz Pharmaceuticals, Inc., *2013 Annual Report* 5 (2014), *available at* http://www.sec.gov/Archives/edgar/data/1232524/000123252414000012/jazz1231201310k.htm (last visited Sept. 3, 2014)

[redacted]

Expert discovery on the REMS patents will involve several experts who would not be involved in any of the other pending issues in this case. [redacted] *See, e.g., Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc.*, No. 07-5855, 2010 WL 2428561, at *16 (D.N.J. June 9, 2010) (finding that plaintiffs' unrebutted accusation of copying "weighs in favor of" non-obviousness). [redacted] *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1081-82 (Fed. Cir. 2012) ("Evidence that others tried but failed to develop a claimed invention may carry significant weight in an obviousness inquiry.") [redacted]

And as discussed above, if Natco truly believes that it is currently being required to litigate an unreasonable number of patent claims, bifurcating the REMS patents would at least partially address that concern.

[5] [redacted]

Finally, the same reasons that support bifurcation also support staying expert discovery on the REMS patents. *See Akzona Inc. v. E.I. Du Pont de Nemours & Co.*, 607 F. Supp. 227, 232 (D. Del. 1984) ("It is implicit in [Federal Rule] 42(b) that a trial judge who grants bifurcation has the power to limit discovery to issues relevant to the first trial."). The factual issues underlying the claims pertaining to the REMS patents are separate and distinct from those underlying the remaining patents-in-suit, which are directed to compounds, formulations, polymorphs, and methods of treating patients, not REMS. [redacted]

* * *

For the foregoing reasons, Celgene respectfully requests that the Court bifurcate the claims relating to the REMS patents.

Respectfully yours,

Charles M. Lizza

Exhibits
cc: The Honorable Madeline C. Arleo, U.S.M.J.
All counsel (via e-mail)

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