



Phone: 609-750-2646
Fax: 609-897-7286
Email: Orlofsky@Blankrome.com

July 14, 2015

VIA ECF

The Honorable Peter G. Sheridan, U.S.D.J.
United States District Court for the District of New Jersey
Clarkson S. Fisher Bldg. & U.S. Courthouse
402 East State Street, Room 7000
Trenton, NJ 08608

**Re: *United Therapeutics Corporation. v. Sandoz Inc.*
D.N.J. Case No.: 3:14-cv-05499-PGS-LHG**

Dear Judge Sheridan:

This firm, together with Wilson, Sonsini, Goodrich & Rosati and Boies, Schiller & Flexner LLP, represents United Therapeutics Corp. in this matter. The Scheduling Order (ECF No. 24) and Amended Scheduling Order (ECF No. 31) mandated that by June 3, 2015, the parties complete and file a Joint Claim Construction and Prehearing Statement, which would include each party's proposed constructions and an "identification of all ... intrinsic evidence [and] any extrinsic evidence" supporting their constructions. *See* Amended Scheduling Order at ¶13; Scheduling Order at ¶11(c). Those orders also mandated that parties further file and serve their opening claim construction briefs on July 7, 2015. *See* Amended Scheduling Order at ¶14. The Court thus mandated that the parties identify all intrinsic and any extrinsic evidence supporting their claim constructions prior to filing their opening claim construction briefs, consistent with L. Pat. R. 4.3(b) & 4.5(a).

Despite these orders and without explanation or a showing of good cause, in violation of Fed. R. Civ. P. 16(b)(4), Sandoz cited new extrinsic evidence in its opening claim construction brief¹ — thirty-four days after the deadline to identify such evidence.

¹ In total, Sandoz cited five new references not identified in the joint statement: (1) Remodulin Product Information, Sandoz-Trep 0004334 – 4347, *see* Defendant's Opening Claim Construction Brief ("Defendant's Br."), at 12, fn 6; Martin Decl., Ex. C; (2) *Treprostinil I*, Trial Tr. at 538:23-539:3, *see* Defendant's Br. at 12, fn 6; (3) excerpts from UTC's Infringement Contentions (3/23/15), *see* Defendant's Br. at 24, fn 10; (4) U.S. Patent No. 6,765,117, *see* Heathcock Decl. at ¶161; (5) Memorandum Decision & Order at 4-6, *Treprostinil I*, Civil Action No. 12-cv-1617 (D.N.J. June 25, 2013) (D.I. 95), *see* Defendant's Br. at 3.



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Additionally, in its brief, Sandoz cited only three out of the approximately 30 extrinsic evidence references it had disclosed in the Joint Statement. Sandoz's delay and misdirection prejudices UTC's ability to timely prepare for the rest of the claim construction process. Further, UTC lost the opportunity to use their opening brief to address Sandoz's arguments based on the new evidence, and also wasted its time and resources briefing arguments stemming from a large number of references ultimately not relied on by Sandoz.

The requirement in L. Pat. R. 4.3(b) and 4.5(a) that the parties identify all intrinsic and any extrinsic evidence well in advance of the opening claim construction briefs is part of the carefully ordered process that seeks to prevent precisely the prejudice that UTC suffers. These rules exist to further the goal of full, timely discovery, and provide all parties with adequate notice and information with which to litigate their cases. *Voxpath v. LG Electronics*, 2012 WL 5818143, No. 2:12-cv-952, at *7 (D.N.J. Nov. 14, 2012); *Rambus Inc. v. Hynix Semiconductor Inc.*, 569 F.Supp.2d 946, 980 (N.D. Cal. 2008).² Sandoz did not disclose that evidence until it was included in its brief, filed the same day as UTC's opening brief. Accordingly, Sandoz's late disclosure of new extrinsic evidence and misdirection regarding the evidence it did cite is improper and "not conducive to the orderly progress of this case." *See Rambus*, 569.F.Supp.2d at 981.

This is not the first time that Sandoz has violated these rules – despite the fact that Sandoz is a repeat New Jersey participant and surely knows about the precise requirements of the Local Rules. In its Preliminary Proposed Claim Constructions, Sandoz included two claim terms that were not timely disclosed, and also failed to provide a construction for a term previously identified for construction. Additionally, Sandoz filed its non-infringement contentions seventeen days late, requiring UTC to file its responsive contentions after the exchange of proposed claim terms – contrary to L. Pat. R. 4.1 and the original Scheduling Order (setting the deadline for responsive contentions prior to the exchange of terms). Thus, Sandoz's untimely disclosure and misdirection in its opening brief is simply the latest example of Sandoz's willingness to play "legal musical chairs" with the claim construction process. *See Rambus*, 569 F.Supp.2d at 980 (noting that similar actions constitute "a kind of legal musical chairs" that "thwart the very intention behind the patent local rules").

² "As the District of New Jersey has developed its Local Patent Rules through guidance from corresponding rules in the Northern District of California and the Eastern District of Texas...this Court has allowed for consideration of those districts' decisions." *Voxpath*, at n. 3.



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This Court has broad discretion to address the prejudice to UTC caused by Sandoz's failure to comply with the Local Rules and the Scheduling Orders, *see SanDisk Corp. v. Memorex Products, Inc.*, 415 F.3d 1278, 1292 (Fed. Cir. 2005) (holding the trial court's interpretation and enforcement of the local rules is entitled to deference), including the ability to exclude the portions of Sandoz's brief that rely on the improperly disclosed and utilized extrinsic evidence, along with the newly disclosed evidence itself, *see Shire LLC v. Amneal Pharmaceuticals, LLC*, No. CIV.A. 11-3781 SRC, 2013 WL 1932927, at *3 (D. N.J. May 7, 2013) (holding that the court has the authority to exclude evidence for failure to follow the procedural schedule). And this Court and courts in the Northern District of California have excluded evidence and briefing in similar situations. *See, e.g., Shire*, 2013 WL 1932927, at *7 (striking portions of a party's claim construction brief relying on improperly disclosed expert opinions); *SanDisk*, 415 F.3d at 1292 (finding no abuse of discretion in the trial court's exclusion of untimely claim construction arguments); *Nordic Naturals, Inc. v. J.R. Carlson Laboratories, Inc. v. Carlson Laboratories, Inc.*, No. C 07-2385 PJH, 2008 WL 2357312, at *11 (N.D. Cal. June 6, 2008) (striking an expert declaration where the expert was not previously disclosed). In the alternative, this Court has also cured prejudice stemming from improper disclosures of evidence during claim construction by granting the prejudiced party an extension on filing the reply brief, additional pages in the reply brief to respond to the improperly identified evidence, and the ability to introduce new rebuttal evidence. *See Genentech, Inc. v. Trustees of the University of Pennsylvania*, No. 10-CV-02037-LHK, 2011 WL 866599, at *2 (N.D. Cal. Mar. 10, 2011).

Accordingly, UTC respectfully requests that the Court strike the passages of Sandoz's opening claim construction brief that rely on the newly disclosed evidence as well as the new evidence itself. Additionally, UTC respectfully requests that the Court inform UTC should it require a formal motion to strike.

Respectfully submitted,

s/ Stephen M. Orlofsky

STEPHEN M. ORLOFSKY

cc: Counsel of Record (by ECF)