UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. FRESENIUS KABI USA, LLC, Defendant.	**CONFIDENTIAL: FILED UNDER SEAL PURSUANT TO OMNIBUS SEALING ORDER ENTERED ON 12/3/2015** Civil Action No. 3:14-cv-07869(MAS)(LHG) Civil Action No. 3:14-cv-08082(MAS)(LHG) Civil Action No. 3:15-cv-02631(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. ACCORD HEALTHCARE, INC., Defendant.	Civil Action No. 3:14-cv-08079(MAS)(LHG) Civil Action No. 3:15-cv-02520(MAS)(LGH)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. BPI LABS, LLC AND BELCHER PHARMACEUTICALS, LLC, Defendants.	Civil Action No. 3:14-cv-08081(MAS)(LHG) Civil Action No. 3:15-cv-02521(MAS)(LHG)

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. APOTEX CORP. AND APOTEX, INC., Defendants.	Civil Action No. 3:15-cv-00287(MAS)(LHG) Civil Action No. 3:15-cv-01835(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	Civil Action No. 3:15-cv-00289(MAS)(LHG) Civil Action No. 3:15-cv-01836(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. MYLAN LABORATORIES LTD., Defendant.	Civil Action No. 3:15-cv-00290(MAS)(LHG) Civil Action No. 3:15-cv-03392(MAS)(LHG)

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. ACTAVIS LLC, Defendant.	Civil Action No. 3:15-cv-00776(MAS)(LHG) Civil Action No. 3:15-cv-03107(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES, LTD., Defendants.	Civil Action No. 3:15-cv-02522(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. GLENMARK PHARMACEUTICALS, INC., USA and GLENMARK PHARMACEUTICALS LTD., Defendants.	Civil Action No. 15-cv-02523(MAS)(LHG)

DEFENDANTS' JOINT RESPONSIVE CLAIM CONSTRUCTION BRIEF

portion of the preamble that was added to overcome a rejection was the portion requiring "a patient with prostate cancer that has progressed during or after treatment with docetaxel," which Defendants agree is limiting. In contrast, in *Helsinn*, relied on by Sanofi, the preamble language found to be limiting was added to overcome an enablement rejection. *See* 2015 WL 1817109, at *8-*9.

Moreover, the statements from the prosecution history relied upon by Sanofi are referring to "unexpected results"[8] that applicants alleged were produced when the claimed method was carried out (*i.e.*, when cabazitaxel and a corticoid were administered to a prostate cancer patient), rather than to what the claims actually require. For example, the statement from the Examiner's Reasons for Allowance relied on by Sanofi (ECF No. 59 at 14 (citing ECF No. 59-2 at SA_JEV_0004765-66)) that "it is surprising and unexpected that the claimed combination of cabazitaxel and a corticoid are clinically effective in the treatment of prostate cancer that has progressed during or after treatment with docetaxel" does not indicate that "clinical effectiveness" or "treatment of prostate cancer" is a claim limitation. Rather, the Examiner was accepting applicants' proffered evidence that the claimed method (*i.e.*, carrying out the steps required by the body of the claim) was patentable because, in the Examiner's view, it allegedly showed "unexpected results"—namely, clinical effectiveness in the treatment of prostate cancer that has progressed during or after treatment with docetaxel.[9] However, that does

[8] One way that an applicant can establish that a patent claim is not obvious is by showing that the claimed subject matter may produce unexpected results in comparison to the closest prior art. *See Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014).

[9] Applicants did not compare the claimed subject matter to the closest prior art (the numerous prior art references describing the TROPIC study) or even disclose that prior art to the Examiner, and thus the Examiner's acceptance of applicants' proffered evidence of unexpected results is not probative of non-obviousness of the claims.

not mean that a purportedly "unexpected result" should be converted into an element required by the claims.[10]

Indeed, Sanofi's argument contradicts Federal Circuit law which mandates that while an "unexpected result" is a benefit that may sometimes result from carrying out claimed subject matter, that does not render the "unexpected result" a required element of the claims. *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006) (*en banc*). In *Purdue Pharma*, the district court interpreted the asserted claims to require the result of "acceptable pain control for 90% of patients over a four-fold dosage range" based on applicants' argument during prosecution that the claimed subject matter produced this unexpected result. *Id.* at 1135. The Federal Circuit reversed this claim interpretation, holding that the claims did not require this unexpected result. *Id.* at 1136 (finding that "property of, or a result of administering" did not function as claim limitation).

Likewise, in *McNeil-PPC, Inc. v. Perrigo Co.*, 443 F. Supp.2d 492, 505 (S.D.N.Y. 2006), the court refused to import into the claims an unexpected result that applicants relied upon during prosecution, stating:

> It is true that a patent applicant using unexpected results to show non-obviousness must provide data commensurate in scope with the claims which the evidence is offered to support. However, that does not mean that courts mechanically import limitations from the test results into the claims....Moreover, the Federal Circuit has held that claims allowed based on "surprising results" may be construed more broadly that the results themselves. ...
> The submission of extraordinary results that are narrower in scope than the claims does not, by itself, impose a limitation on the construction of the claims.

Id. (internal citations omitted).

[10] The only subject matter that the Examiner explicitly indicated is required by the claims is a "combination of cabazitaxel and a corticoid," which the Examiner did by referring to "the claimed combination of cabazitaxel and a corticoid." The Examiner did not refer to being "clinically effective" or the "treatment of prostate cancer" as "claimed" elements.

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