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Watson Laboratories, Inc.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**CELGENE CORPORATION,**

**Plaintiff,**

**v.**

**NATCO PHARMA LIMITED,  
ARROW INTERNATIONAL LIMITED,  
and WATSON LABORATORIES, INC.,**

**Defendants.**

**Civil Action No. 10-5197 (SDW)(MCA)**

**Hon. Susan D. Wigenton, U.S.D.J.  
Hon. Madeline C. Arleo, U.S.M.J.**

**(Filed Electronically)**

**JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT**

Plaintiff Celgene Corporation and Defendants Natco Pharma Limited, Arrow International Limited, and Watson Laboratories, Inc. (collectively, "Natco") hereby submit their Joint Claim Construction and Prehearing Statement in accordance with Local Patent Rule 4.3.

**I. BACKGROUND**

This case arises out of Natco's filing of ANDA No. 201452 with the U.S. Food and Drug Administration ("FDA"), which seeks approval to market a generic version of Celgene's Revlimid<sup>®</sup> product. The active ingredient in Revlimid<sup>®</sup> is lenalidomide. Plaintiffs allege, among other things, that Natco's submission of ANDA No. 201452 to the FDA constitutes infringement

of certain claims of United States Patent Nos. 5,635,517 (the “517 patent”), 6,045,501 (the “501 patent”), 6,281,230 (the “230 patent”), 6,315,720 (the “720 patent”), 6,555,554 (the “554 patent”), 6,561,976 (the “976 patent”), 6,561,977 (the “977 patent”), 6,755,784 (the “784 patent”), 7,119,106 (the “106 patent”), and 7,465,800 (the “800 patent”) owned by Celgene (collectively, “the patents-in-suit”) under 35 U.S.C. §271(e)(2). Natco alleges, among other things, that certain of the asserted claims are invalid, unenforceable, and/or not infringed.

Pursuant to Local Patent Rules 4.2(a)-(b), on June 7, 2011, the parties exchanged preliminary claim constructions and identified intrinsic as well as extrinsic evidence in support of their proposed Preliminary Constructions. Pursuant to Local Patent Rule 4.2(c), on June 24, 2011, the parties identified all intrinsic and extrinsic evidence that each party intends to rely upon to oppose any other party’s proposed construction. Pursuant to Local Patent Rule 4.2(d), on July 8, 2011, counsel for the parties met and conferred for the purposes of narrowing the issues and preparation of the Joint Claim Construction and Prehearing Statement.

## **II. CONSTRUCTION OF PATENT TERMS**

### **A. Agreed Upon Claim Constructions**

Pursuant to Local Patent Rule 4.3(a), the parties identify the following terms and phrases on which the parties agree

#### **UNITED STATES PATENT NO. 6,045,501**

Term	Definition
Teratogenic drug	“a drug that may disturb the normal growth and development of an embryo or fetus”

**UNITED STATES PATENT NO. 6,315,720**

Term	Definition
Consulted	“accessed and considered”
Teratogenic effect	“any effect that disturbs the normal growth and development of an embryo or fetus”

**UNITED STATES PATENT NO. 6,561,976**

Term	Definition
Teratogenic risks	“risks of disturbing the normal growth and development of an embryo or fetus”

**UNITED STATES PATENT NO. 7,465,800**

Term	Definition
Crystalline	“made up of crystals”

**B. Disputed Claim Terms**

Pursuant to Local Patent Rule 4.3(b), attached hereto as Exhibit A is a series of claim charts identifying the claim terms and phrases in dispute and the parties’ proposed constructions. Additionally, attached hereto as Exhibit B is a series of claim charts providing the evidence, including intrinsic and extrinsic evidence, that each party intends to rely on in support of its proposed constructions.

**C. Claim Terms Whose Construction Will Be Most Significant**

Pursuant to Local Patent Rule 4.3(c), the parties were unable to agree that there are any terms “whose construction will be most significant to the resolution of the case.” Likewise, the parties were unable to agree that there are any terms “whose construction will be case or claim dispositive or substantially conducive to promoting settlement.”

**D. Anticipated Length of Time Necessary for the Claim Construction Hearing**

Pursuant to Local Patent Rule 4.3(d), the parties anticipate that the Court will be able to conduct a hearing on the meaning of the disputed terms in less than one day.

**E. Identification of Witnesses For The Claim Construction Hearing**

Pursuant to Local Patent Rule 4.3(e), Celgene has identified Dr. Jerry Atwood, Ph.D. and Dr. Stephen R. Byrn, Ph.D., as potential experts for the claim construction hearing. Pursuant to Local Patent Rule 4.3(e), Natco has identified Dr. Robert Boeckman, Ph.D. and Dr. Mark Hollingsworth, Ph.D., as potential experts for the claim construction hearing. A summary of each expert's testimony is included in Exhibit B where appropriate.

Respectfully submitted,

July 18, 2011

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