



(6) The availability and timing of production of invention records (including inventor laboratory notebooks and analytical test results);

The availability and timing of production of ANDA product research and development documents;

The availability and timing of production of ANDA product samples;

The date of conception and the date of reduction to practice for each patent asserted in the action, if applicable;

Each inventor's availability for deposition in the matter;

Availability of foreign witnesses for deposition and foreign documents;

Whether there is a 30-month stay and if so, when it ends;

A date for substantial completion of document production and a method for determining compliance;

Any other issues or matters that a party believes are time sensitive.

## 2.2. Confidentiality.

Discovery cannot be withheld or delayed on the basis of confidentiality absent Court order. Pending entry of a confidentiality order, discovery and disclosures deemed confidential by a party shall be produced to the adverse party for outside counsel's Attorney's Eyes Only, solely for purposes of the pending case and shall not be disclosed to the client or any other person.

Within 14 days after the initial Scheduling Conference, (a) the parties shall present a consent confidentiality order, supported by a sufficient certification (or statement complying with 28 U.S.C. § 1746) under L. Civ. R. 5.3(b)(2), or (b) in the absence of consent, a party shall, supported by a sufficient certification, apply for entry of a confidentiality order under L. Civ. R. 5.3(b)(5) and L. Civ. R. 37.1(a)(1). The Court will decide those issues and enter the appropriate order, or the Court may enter the District's approved Confidentiality Order as set forth in Appendix S to these Rules if appropriate, in whole or in part.

With respect to all issues of discovery confidentiality, the parties shall comply with all terms of L. Civ. R. 5.3.

## 3. PATENT DISCLOSURES

### 3.3. Invalidation Contentions.

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(d) Any grounds of invalidity based on 35 U.S.C. § 101, indefiniteness under 35 U.S.C. § 112(b) or enablement or written description under 35 U.S.C. § 112(1) of any of the asserted claims including a detailed explanation of the bases for the asserted grounds.

3.4A Responses to Invalidity Contentions.

\* \* \* \*

(d) For each asserted grounds of invalidity under L.Pat.R.3.3(d), a detailed explanation of how the asserted claim complies with 35 U.S.C. §112; and

(e) The production or the making available for inspection and copying of any document or thing that the party intends to rely on in support of its Responses herein.

3.6. Disclosure Requirements for Patent Cases Arising Under 21 U.S.C. § 355 (commonly referred to as “the Hatch-Waxman Act”).

The following applies to all patents subject to a Paragraph IV certification in cases arising under 21 U.S.C. § 355 (commonly referred to as “the Hatch-Waxman Act”). This rule takes precedence over any conflicting provisions in L. Pat. R. 3.1 to 3.5 for all cases arising under 21 U.S.C. § 355.

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(c) Not more than 30 days after the initial Scheduling Conference, each party opposing an assertion of patent infringement shall provide to each party asserting patent infringement the written basis for its “Invalidity Contentions,” for any patents referred to in the opposing party's Paragraph IV Certification, which shall contain all disclosures required by L. Pat. R. 3.3.

(d) Any “Invalidity Contentions” disclosed under L. Pat. R. 3.6(c), shall be accompanied by the production of documents required under L. Pat. R. 3.4(b) and (c).

(e) Not more than 30 days after the initial Scheduling Conference, each party opposing an assertion of patent infringement shall provide to each party asserting patent infringement the written basis for its “Non-Infringement Contentions,” for any patents referred to in the opposing party's Paragraph IV Certification which shall include a claim chart identifying each claim at issue in the case and each limitation of each claim at issue. The claim chart shall specifically identify for each claim which claim limitation(s) is/(are) literally absent from each opposing party's allegedly infringing Abbreviated New Drug Application or New Drug Application.

4. CLAIM CONSTRUCTION PROCEEDINGS

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4.2. Exchange of Preliminary Claim Constructions and Extrinsic Evidence.

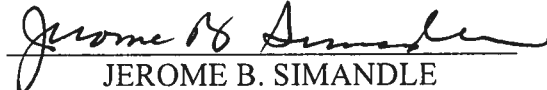
(a) Not later than 21 days after the exchange of the lists pursuant to L. Pat. R. 4.1, the parties shall simultaneously exchange preliminary proposed constructions of each term identified by any

party for claim construction, including constructions for each term for which “plain and ordinary” meaning is asserted. Each such “Preliminary Claim Construction” shall also, for each term which any party contends is governed by 35 U.S.C. § 112(6), identify the structure(s), act(s), or material(s) corresponding to that term's function.

It is FURTHER ORDERED these amendments are effective this date.

Date: *February 1, 2017*

FOR THE COURT:

  
JEROME B. SIMANDLE  
Chief Judge