

Local Patent Rules - Northern District of Ohio

**III. Patent Disclosures**

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

The following provision 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 provision takes precedence over any conflicting provisions in L. P. R. 3.1 to 3.8 for all cases arising under 21 U.S.C. § 355.

- (a) At or before the Case Management Conference, the Defendant(s) shall produce to Plaintiff(s) the entire Abbreviated New Drug Application or New Drug Application that is the basis of the case in question.
- (b) Not less than fifteen (15) calendar days after the Case Management Conference, the Defendant(s) shall provide to Plaintiff(s) written Invalidity Contentions, for any patents referred to in Defendant(s) Paragraph IV Certification. At a minimum, these Invalidity Contentions should include those items required by L. P. R. 3.5(a-d);
- (c) Any Invalidity Contentions disclosed under L. P. R. 3.9(b) shall be accompanied by the production of any document or thing that each Defendant intends to rely on to show invalidity. At a minimum, this disclosure should comply with L. P. R. 3.6(a).
- (d) Not less than thirty (30) calendar days after the Case Management Conference, the Defendant(s) shall provide to Plaintiff(s) the written basis for their Noninfringement Contentions for any patents referred to in Defendant(s) Paragraph IV Certification which shall include a claim chart as required by L. P. R. 3.3(a) 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) are literally absent from the Defendant(s) allegedly infringing Abbreviated New Drug Application or New Drug Application
- (e) Any Noninfringement Contentions disclosed under L. P. R. 3.9(d) shall be accompanied by the production of any document or thing that the Defendant(s) intend to rely on in defense against any infringement contentions by Plaintiff(s), including those items required by L. P. R. 3.4(a).
- (f) Not less than forty-five (45) calendar days after the disclosure of the Noninfringement Contentions as required by L. P. R. 3.9(d), Plaintiff(s) shall provide Defendant(s) with Infringement Contentions for all patents referred to in Defendant(s) Paragraph IV Certification, including, at a minimum, those items required by L. P. R. 3.1.
- (g) Any Infringement Contentions disclosed under L. P. R. 3.9(f) shall be accompanied by the production of documents required under L. P. R. 3.2.