

**DISCLOSURE REQUIREMENTS FOR PATENT CASES ARISING UNDER 21 U.S.C. § 355  
(COMMONLY REFERRED TO AS “THE HATCH-WAXMAN ACT”)**

The requirements of this Dist. Idaho Loc. Patent R. 3.6 apply 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 Dist. Idaho Loc. Patent R. 3.1 to 3.5 for all cases arising under 21 U.S.C. § 355.

- a) At or before the initial scheduling 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 more than 14 days after the initial scheduling conference, the Defendant(s) shall provide to Plaintiff(s) the written basis for their “Invalidity Contentions,” for any patents referred to in Defendant(s) Paragraph IV Certification which shall contain all disclosures required by Dist. Idaho Loc. Patent R. 3.3.
- c) Any “Invalidity Contentions” disclosed under Dist. Idaho Loc. Patent R. 3-6(b), shall be accompanied by the production of documents required under Dist. Idaho Loc. Patent R. 3.4.
- d) Not more than 14 days after the initial scheduling conference, the Defendant(s) shall provide to Plaintiff(s) the written basis for their “Non-Infringement Contentions,” for any patents referred to in Defendant(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) are literally absent from the Defendant(s) allegedly infringing Abbreviated New Drug Application or New Drug Application.
- e) Any “Non-Infringement Contentions” disclosed under Dist. Idaho Loc. Patent R. 3.6(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).
- f) Not more than 42 days after the disclosure of the “Non-Infringement Contentions” as required by Dist. Idaho Loc. Patent R. 3.6(d), Plaintiff(s) shall provide Defendant(s) with a “Disclosure of Asserted Claims and Infringement Contentions,” for all patents referred to in Defendant(s) Paragraph IV Certification, which shall contain all disclosures required by Dist. Idaho Loc. Patent R. 3.1.
- g) Any “Disclosure of Asserted Claims and Infringement Contentions” disclosed under Dist. Idaho Loc. Patent R. 3.6(f), shall be accompanied by the production of documents required under Dist. Idaho Loc. Patent R. 3.2.