

How Will H.R. 3309 (the "Innovation Act") Impact Pharmaceutical and Biotechnology Patent Cases?

BY [DAVID M. CONCA](#), [ERIC W. DITTMANN](#), & [SUKI C. PASQUET](#)

The Chairman of the House Judiciary Committee and a bipartisan group of U.S. Representatives introduced H.R. 3309, the Innovation Act, on October 23, 2013. Although its primary aims are to tweak certain provisions of the Leahy-Smith America Invents Act and to discourage frivolous lawsuits brought by certain patent assertion entities, H.R. 3309 contains several provisions that will impact pharmaceutical and biotechnology patent infringement cases, in particular those brought under the Hatch-Waxman Act.

A hearing on H.R. 3309 is scheduled for this morning – October 29, 2013 at 10:00 am.

The proposals in the Innovation Act most relevant to the pharmaceutical and biotechnology industry are summarized below:

- **Exemption from New Heightened Pleading Requirements** – H.R. 3309 will require all patentees to set forth in a patent infringement complaint, among other things, the specific patent claims alleged to be infringed as well as the specific "instrumentality" accused of patent infringement (by model number where available), along with an analysis of where each claim element can be found in the accused instrumentality, and to state whether the accused infringement is literal or under the doctrine of equivalents. H.R. 3309 Sec. 3(a) at §§ 281A(a)(1)-(10). These new pleading requirements are specifically exempted in infringement actions arising under 35 U.S.C. § 271(e)(2) – *i.e.*, Hatch-Waxman cases. H.R. 3309 Sec. 3(a) at § 281A(b).
- **Fee Shifting** – H.R. 3309 will permit a court to award fees and expenses to the prevailing party unless the non-prevailing party's position was "substantially justified" or there are exceptional circumstances that would make such fee shifting unjust. H.R. 3309 Sec. 3(b) at § 285(a). This provision significantly changes existing patent-related attorneys' fees law, which currently provides that attorneys' fees may be awarded to the prevailing party only in exceptional circumstances. 35 U.S.C. § 285. H.R. 3309 also states that a party that unilaterally extends to the other party a covenant not to sue will be deemed a non-prevailing party under this section, unless the offering party could have dismissed the case without a court order under Federal Civil Procedure Rule 41 (*i.e.*, before an answer or summary judgment motion was filed or by stipulation of all parties). H.R. 3309 Sec. 3(b) at § 285(c).
- **Discovery Limited Before Claim Construction** – H.R. 3309 will limit pre-claim construction discovery to "information necessary for the court to determine the meaning

of the terms used in the patent claim” in cases where the court determines that claim construction “is required.” H.R. 3309 Sec. 3(d) at § 299A(a). However, if the case needs to be resolved within a certain time period because it “will necessarily affect the rights of a party with respect to the patent,” such as in Hatch-Waxman cases – which are expressly exemplified in the bill – then the court may permit additional discovery “as necessary to ensure timely resolution of the action.” H.R. 3309 Sec. 3(d) at § 299A(b)(1). A court may also permit limited discovery “as necessary” to resolve “a motion properly raised by a party” before a claim construction ruling. H.R. 3309 Sec. 3(d) at § 299A(b)(2).

- **Exemption from New Patent Ownership Disclosure Requirements** – H.R. 3309 will require patentees to identify upon filing an initial complaint, the assignee of the patent(s) at issue, entities with the right to sublicense or enforce the patents, entities with a financial interest in the patent(s) at issue, or plaintiff and their respective ultimate parent entities. H.R. 3309 Sec. 4(a)(3) at (b)(1)(A)-(D). These new requirements are specifically exempted in infringement actions arising under 35 U.S.C. § 271(e)(2). H.R. 3309 Sec. 4(a)(3) at (b)(2).
- **Exemption from New Stay Provisions in Patent Actions Against Customers** – H.R. 3309 will require a court to grant a motion to stay certain patent cases brought against customers. H.R. 3309 Sec. 5(a) at § 296. This new requirement is specifically exempted in infringement actions arising under 35 U.S.C. § 271(e), which includes both Hatch-Waxman cases and cases brought pursuant to the Biologics Price Competition and Innovation Act, *i.e.*, 42 U.S.C. §§ 262 *et seq.* H.R. 3309 Sec. 5(a) at § 296(d).

H.R. 3309 contains several other notable provisions amending the patent laws, including:

- **Requirements and Limitations Regarding Document Discovery** – H.R. 3309 provides requirements that a party produce, at its own cost, “core documentary evidence,” such as documents concerning conception and reduction to practice, patent prosecution, licensing activity, and knowledge of the patent by the accused. H.R. 3309 Sec. 6(a)(2)(A), 6(a)(3)(D)(I)-(IX). The bill also staggers electronic discovery to occur after initial disclosures and core documentary evidence is disclosed. H.R. 3309 Sec. 6(a)(2)(B). H.R. 3309 further provides that “a party may not submit production requests to more than 5 custodians” unless the parties agree, and that the court may consider contested requests for “up to 5 additional custodians per producing party.” H.R. 3309 Sec. 6(a)(2)(B)(iii)-(iv).
- **Clarification of Claim Construction Standard in Post-Grant Proceedings** – H.R. 3309 requires the Patent Office to construe claims in post-grant and inter partes reviews in the same way “as such claim would be construed in a civil action to invalidate a patent” – namely using the “ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” H.R. 3309 Sec. 9(c).
- **Restrictions on Double Patenting** – H.R. 3309 codifies double patenting for first-to-file patents. H.R. 3309 Sec. 9(d).
- **Limitation on Patent Term Adjustment** – H.R. 3309 eliminates certain patent-term adjustment accruals. H.R. 3309 Sec. 9(a)(2)(C).
- **Clarification of Estoppel in Post-Grant Review** – H.R. 3309 revises the America Invents Act to provide estoppel only against claims in a later civil action that were

actually raised. H.R. 3309 Sec. 9(b). This would narrow the current America Invents Act's estoppel provision that included claims a challenger "reasonably could have raised."

The complete text of the bill can be found [here](#).

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings New York lawyers:

David M. Conca

1.212.318.6406

davidconca@paulhastings.com

Eric W. Dittmann

1.212.318.6689

ericdittmann@paulhastings.com