Pharmaceutical and Biotech Patent Law

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In this release, the authors update and expand Pharmaceutical and Biotech Patent Law with new discussion of many topics, including the following:

**Ineligible subject matter:** The Federal Circuit, in a case following the Supreme Court’s decision in *Prometheus*, found a claim to a method of comparing a sample prepared by “amplifying all or part of a BRCA1 gene” with the wild-type BRCA1 to identify any differences is patent ineligible subject matter because: (1) “[t]he number of comparisons is unlimited” and therefore this step constitutes an unpatentable abstract idea; and (2) the remaining steps of amplification and sequencing the sample are routine. See § 3:8.1[D][2].

**Conception:** In *Allergan, Inc. v. Apotex, Inc.*, the Federal Circuit provided extensive guidance on the need for corroborating evidence of conception for each element of a claimed invention. Where proof of conception is offered by the patentee to establish a prior date of invention, the patentee bears the burden of production to demonstrate an earlier date of conception. See § 4:1.2[A].

**Indefiniteness:** Federal Circuit case law on indefiniteness prior to *Nautilus Inc. v. Biosig Instruments, Inc.* may need to be re-evaluated in light of the Supreme Court’s 2014 decision. Section 5:7.2[B] now includes extensive new discussion of both Federal Circuit and Supreme Court decisions regarding the standard for indefiniteness.

**Written description—describing antibodies in terms of amino acid sequences:** In *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, the Federal Circuit upheld a jury verdict of invalidity for lack of written description of an antibody genus claim supported by disclosure of 300 antibodies. The court held that the patents need not describe the allegedly infringing antibody in exact terms, however, they “must at least describe some species representative of antibodies that are structurally similar” to the accused antibody. The court remarked that “[f]unctionally defined ge-
nus claims can be inherently vulnerable to invalidity challenge for lack of written description support.” See § 7:7.3[B][2].

**Patent certifications by ANDA or 505(b)(2) applicant:** See new section 8:1.3 for thorough explanation of the patent certification requirements for both ANDA applicants and applicants under 21 U.S.C. § 355(b)(2)(A) a section 505(b)(2), as well as the latest cases on the FDA’s authority to review and approve applications, such as *Takeda Pharm., U.S.A., Inc. v. Burwell*.

**Post-Phillips rules of claim construction—disavowal or disclaimer:** The Federal Circuit has “found disavowal or disclaimer [of claim scope] based on clear and unmistakable statements by the patentee that limit the claims,” including, in the 2015 case *Pacing Techs., LLC v. Garmin Int’l, Inc.*, the phrases “the present invention includes . . .,” “the present invention is . . .,” and “all embodiments of the present invention are . . .” See § 9:2.3[G].

**Infringement defenses—laches:** The defense of laches bars recovery for pre-suit infringement when the patent owner unreasonably delays filing suit to the prejudice of the accused infringer. In September 2015, the Federal Circuit issued its en banc decision in *SCA Hygiene Products v. First Quality Baby Products*, which confirmed in a 6-5 decision that laches remains a viable defense to a claim for legal damages resulting from patent infringement. See § 10:5.5[C].

**Biosimilars—litigation under the BPCIA:** As of June 2015, there have been relatively few reported decisions under the BPCIA. These decisions, however, have addressed important issues relating to biosimilar drug products, including subject matter jurisdiction over patent challenges raised by those seeking to make biosimilar drugs and whether a biosimilar applicant is required under the BPCIA to provide its application to the innovator company. A substantial new section 14:5 provides in-depth analysis of all of these key cases such as *Sandoz v. Amgen* (Enbrel®), *Celltrion v. Kennedy Trust, Hospira v. Janssen*, and *Amgen v. Sandoz* (Neupogen®).

The Table of Authorities and Index have also been updated.
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