This is your new 2019 edition

Pharmaceutical and Biotech Patent Law

by Arnold & Porter Kaye Scholer LLP

The experts at Arnold & Porter Kaye Scholer LLP have updated *Pharmaceutical and Biotech Patent Law* with new discussion of many topics, including the following:

Obviousness—"obvious to try": The Federal Circuit, in *In re Copaxone Consolidated Cases*, notes that it has "identified two categories of impermissible 'obvious to try' analyses that run afoul of *KSR* and § 103: when what was 'obvious to try' was (a) to vary all parameters or try every available option until one succeeds, where the prior art gave no indication of critical parameters and no direction as to which of many possibilities is likely to be successful; or (b) to explore a new technology or general approach in a seemingly promising field of experimentation, where the prior art gave only general guidance as to the particular form or method of achieving the claimed invention." See § 5:3.3[B][2], at note 272.2.

Obviousness—commercial success: The Federal Circuit has held that a patentee's evidence of commercial success may not be discounted merely because the owner possessed other patents that may have precluded its competitors from entering the market (*Merck Sharp & Dohme Corp. v. Hospira, Inc.*). See § 5:3.7[B][1], at note 373.1.

Written description: Among the purposes of the written description requirement is to establish conception and that the applicant actually invented the subject matter claimed. See § 5:4.2[A], at note 436.2.

Double patenting—safe harbor provision: According to the Federal Circuit in *In re Janssen Biotech, Inc.,* in order to fall within the scope of the safe harbor of section 121, a patent must have been "issued on" a divisional application: "[f]or a challenged patent to receive safe harbor protections, the application must be properly designated as a divisional application, at the very latest, by the time the challenged patent issues on that application." A patent "cannot retroactively become, for the purposes of § 121, a 'patent issued on' a divisional application after it already issued on a CIP application." See § 5:8.6[C], at note 898.8.

Antibodies—written description requirement: Formerly, applicants could satisfy the written description requirement for antibodies merely by describing the antigens to which they bind. However, the Federal Circuit rejected this approach in 2017 in *Amgen Inc. v. Sanofi.* The court criticized the old approach as "flout[ing] [the] basic legal principles of the written description requirement" by "allow[ing] patentees to claim antibodies

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by describing something that is not the invention, i.e., the antigen." See § 7:7.3[A][2], at note 952.1. See also § 7:7.3[A][3], at note 958.1.

Hatch-Waxman Act—infringement under section 271(e)(2): Amendments to an ANDA can constitute as an "act of infringement" under section 271(e)(2). In *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, the Federal Circuit held that the subsequent filing of a Paragraph IV certification directed at a patent that issued after the original ANDA application was filed, but before its FDA approval, constituted as an amendment to the ANDA and therefore an "act of infringement." See § 8:1.4[B][1], at note 105.1.

Biosimilars—*Amgen Inc. v. Sandoz Inc*. (Neupogen) litigation: On remand from the Supreme Court, the Federal Circuit held that Sandoz had not waived its defense that Amgen's state law claims were preempted by the Biologics Price Competition and Innovation Act, because Sandoz had pleaded the defense in its answer, notwithstanding that the issue was not argued in the district court. The court further held that the BPCIA preempted Amgen's state law claims under both field and conflict preemption principles, stating that "the preemption analysis here demonstrates that Amgen's state law claims conflict with the BPCIA and intrude upon a field, biosimilar patent litigation, that Congress reserved for the federal government." See § 14:5.3[C], at note 134.

The **Table of Authorities** and the **Index** have been updated for this edition.