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Pharmaceutical and Biotech Patent Law

by **Arnold & Porter Kaye Scholer LLP**

PLI is proud to present *Pharmaceutical and Biotech Patent Law* in a new casebound format, with 2017 updates fully integrated into this book. If you have previously purchased this title in binder format, please discard that book; future revisions will be casebound books.

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

On-sale bar: Offering its first interpretation of the on-sale bar in the AIA, the Federal Circuit found that where the existence of a sale was made known to the public, the sale constitutes prior art even if the public disclosure did not reveal the invention (*Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*). See § 5:2.3[C][1][a][i], at note 154.3.

Obviousness—long-felt need/failure of others: According to the Federal Circuit in *Millennium Pharmaceuticals, Inc. v. Sandoz Inc.*, “long-felt need” and “failure of others” are closely related but still conceptually distinct. “[E]vidence is particularly probative of obviousness when it demonstrates both that a demand existed for the patented invention, and that others tried but failed to satisfy that demand.” However, long-felt need may be established “without presenting evidence of failure of others.” See § 5:3.7[A], at note 352.3.

Indefiniteness: The discussion of indefiniteness is revised and expanded to take account of the continuing impact of the Supreme Court’s 2014 *Nautilus* decision, among others. Updated material addresses the evolution of the standard for indefiniteness; the standard of proof; and the standard of review. See §§ 5:7.2[B][1], [2], [4].

Inequitable conduct: Litigation misconduct which obfuscates prosecution misconduct can be considered in determining inequitable conduct, according to the Federal Circuit in *Regeneron Pharmaceuticals, Inc. v. Merus N.V.* See new § 5:9.5[E][6].

Antibodies—claim construction: In *UCB, Inc. v. Yeda Research & Development Co.*, the Federal Circuit held that the patentee was “estopped from including chimeric

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and humanized antibodies within the scope” of its claim to “[a] monoclonal antibody which specifically binds a human cytotoxin.” The court explained that the examiner had rejected amended claims to “rat, hamster and human antibodies and chimeras thereof” because they “were not supported in the specification” and that in response the patentee cancelled the claims. See new § 7:7.5[A].

Claim construction—conjunctions: The Federal Circuit has held that, when the specification or claim requires, “and” will be construed to mean “or.” However, when “the written description can be interpreted to support either construction,” the term “and” should be given its plain and ordinary meaning to mean “and” instead of “or.” See new § 9:3.3[C].

Infringement by equivalence: As the Federal Circuit notes, the “function, way, result” (FWR) test is not always suitable for certain claims, such as chemical compositions having many components, chemical compounds with many substituents, and those having a medical or biological use (*Mylan Institutional LLC v. Aurobindo Pharma Ltd.*). See § 10:3.2, at note 49.1.

Biologics Price Competition and Innovation Act: On June 12, 2017, the Supreme Court issued its first decision construing the BPCIA. In *Sandoz, Inc. v. Amgen, Inc.*, the Court addressed two key provisions. The first provision, section 262(l)(2)(A), provides that a biosimilar applicant “shall provide” to the reference product sponsor its biosimilar application and its manufacturing information within twenty days after the Food and Drug Administration (FDA) accepts the application. The Court held that the provision is not enforceable by injunctive relief under federal law, but remanded for a determination as to whether injunctive relief is available under state law. The second provision, section 262(l)(8)(A), provides that a biosimilar applicant “shall provide” to the reference product sponsor notice at least 180 days “before the date of the first commercial marketing of the biological product licensed under subsection (k) [the subsection directed to biosimilar applications].” The Court held that a biosimilar applicant may provide notice of commercial marketing before FDA approval of the biosimilar application. See new § 14:5.3[C].

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