This is your new 2020 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:

Treatment claims: The Federal Circuit held that a method of treating schizophrenia using iloperidone was directed to patent-eligible subject matter, because it taught "a specific method of treatment for specific patients using a specific *compound* at specific *doses* to achieve a specific *outcome*" based on the patient's genotype (*Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*). The court also upheld method of treatment claims insofar as they "require specific steps be taken in order to bring about a change in a subject, altering the subject's natural state" (*Natural Alternatives International, Inc. v. Creative Compounds, LLC*). See § 3:8.1[D][2][b], at note 74.32.

Written description—criticality factor: "In addition to predictability," the Federal Circuit has noted, the courts "have held that the criticality or importance of an unclaimed limitation to the invention can be relevant to the written description inquiry." In *In re Global IP Holdings LLC*, the Federal Circuit permitted issuance of a reissue application seeking to broaden claims so they no longer required having a metal tip with a tapered shape because the shape was not critical to overcoming prior art and "one skilled in the art would readily understand that in practicing the invention it is unimportant whether the tips are tapered." See § 5:4.2[B][2], at note 447.1.

Written description—functional genus: The risk of inadequate written description is "especially acute with genus claims that use functional language to define the boundaries of a claimed genus." A genus claim may be adequately described when a patentee has disclosed "[1] a representative number of species falling within the scope of the genus or [2] structural features common to the members of the genus"—but only if that permits the skilled artisan to "'visualize or recognize' the members of the genus." As the Federal Circuit indicated in *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, if a patentee identifies a genus of compounds that might possess the claimed functional properties, the patent must provide "blaze marks which single out particular" compounds in the genus. See new §§ 5:4.3[D]–[D][2].

Enablement—undue experimentation: In cases such as *Enzo Life Sciences v. Roche Molecular Systems, Inc.*, the Federal Circuit has invalidated functionally defined genus

(continued on reverse)

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claims for lack of enablement as a matter of law, because the specification merely taught trial-and-error testing of a large number of candidate compounds. It matters not that the species covered by the claim may, at the end of the day, turn out to be few in number, if a "large number" of candidates must first be tested to find them. See new § 5:5.8[C].

Obviousness—new methods of using old compounds: New methods of using old compounds include claims limiting their use to the treatment of new diseases, new dosing regimens, and combination treatments. In *In re Copaxone*, the Federal Circuit found claims to 40mg 3x/week obvious over prior dosing amounts of 20mg and 40mg, based on art that "encouraged POSITAs to pursue a less frequent than daily dosing regimen" and an "already-approved daily 20mg injection—120mg/week" regimen. The court explained that, in view of this motivation, "a POSITA had only a limited number of permutations of dose and frequency to explore that were not already disclosed in the prior art." The "already-approved" regimen was "120mg/week versus 140mg/week" in the claimed dose. "Although the universe of potential GA doses is theoretically unlimited, the universe of dosages in the prior art that had clinical support for being effective and safe consisted of only two doses: 20mg and 40mg. Even if there were multiple injection frequencies not yet tested in the prior art—1x, 2x, 3x a week etc.—these still represent a limited number of discrete permutations." See § 7:4.5, at note 604.3.

Hatch-Waxman Act—patent term restoration: 35 U.S.C. § 156 permits extension of only a single patent per regulatory review period for a product. According to the Federal Circuit in *Novartis AG v. Ezra Ventures LLC*, "nothing in the statute restricts the patent owner's choice for patent term extension among those patents whose terms have been partially consumed by the regulatory review process." See § 8:4.2[A], at note 429.1. Also, new Figure 8-3 shows the effect on patent terms of the Uruguay Round Agreements Act (URAA), which sought to harmonize the term of U.S. patents with foreign patents. See § 8:4.2[D].

Claim construction: In *Omega Patents, LLC v. CalAmp Corp*., the Federal Circuit explained that "[t]he court is not absolved of this duty to construe the actually disputed terms just because the specification of the patent defines the term. Even if the parties had agreed to the construction, the district court was still obligated to give that construction to the jury in its instructions." See § 9:1.2[A], at note 5.2.

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

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