Pharmaceutical and Biotech Patent Law

By Kaye Scholer LLP’s Patent Group

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

**Patentable subject matter:** The Supreme Court revisited the question of patentable subject matter in *Alice Corp. Pty. v. CLS Bank International*. Among other things, the Court noted that laws of nature and abstract ideas are basic tools of scientific and technological work, and “‘monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it,’ thereby thwarting the primary object of the patent laws.” See § 3:8.1[D], at note 74.10.

**Clones:** In *In re Roslin Institute (Edinburgh)*, the Federal Circuit relied on *Myriad* in holding that a genetic clone of an animal is equally as patent-ineligible as the original animal. Specifically, the Federal Circuit paralleled the Supreme Court’s *Myriad* conclusion—“that ‘isolated,’ naturally occurring DNA strands are not eligible for patent protection”—and concluded that the claimed invention “did not create or alter any of the genetic information’ of its claimed clones, ‘[n]or did [it] create or alter the genetic structure of [the] DNA’ used to make its clones.” See new § 3:8.2[C].

**Written description—unclaimed optional features:** The Federal Circuit, in *ScriptPro, LLC v. Innovation Associates*, noted that “[a] specification can adequately communicate to a skilled artisan that the patentee invented not just the combination of all identified features but combinations of only some of those features (subcombinations)—which may achieve stated purposes even without omitted features.” The court reversed a grant of summary judgment for lack of written description based on a specification that described a dispensing machine with sensors while claiming “a machine that need not have ‘sensors.’” See new § 5:4.3[G].

**Indefiniteness:** In 2014, in *Nautilus, Inc. v. Biosig Instruments, Inc.*, the Supreme Court adopted the “reasonable certainty” standard for measuring indefiniteness: “[W]e read § 112, ¶ 2 to require that a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.” Under the now-defunct Federal Circuit standard, claims were found indefinite only if they were “insolubly ambiguous, and no narrowing construction can properly be adopted.” See § 5:7.2[B], at note 755.2.

**Inventorship:** New discussion in chapter 4 provides an overview of how priority disputes have been eliminated under the America Invents Act, and how derivation proceedings in the PTO replace interferences, subjects discussed at length in the chapter. See new § 4:1.1[A]—[C].

(continued on reverse)

Chemical compounds—obviousness: In Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc., the Federal Circuit affirmed a district court bench trial verdict that claims to the compound entecavir, sold under the trademark Baraclude for the treatment of hepatitis B, was invalid as obvious over the prior art. In summing up its conclusion on the structural obviousness of entecavir based on the prior art, the Federal Circuit stated that “[u]pon selecting 2’-CDG as the lead compound, the steps of deciding which bond to modify and how to modify that bond ‘equate to a small, finite number of changes to try to [arrive at] the lead compound.’” Moreover, the evidence of unexpected properties, commercial success, and long-felt need did not overcome the strong evidence of obviousness. An illustration of the relevant molecular structures is included. See § 7:2.2[A][2][b][ii], at note 170.1.

Particle size claims—written description: The Federal Circuit affirmed a district court’s finding that a particle size claim construed to apply to raloxifene particles before and after formulation lacked written description because the specification only disclosed the size prior to formulation and did not disclose whether formulation changed the particle size (Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc.). See new § 7:2.8[C][2].

Method of treatment claims: In Abbvie Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust, the Federal Circuit construed a method of treatment involving “co-administering” of two pharmaceuticals to include three scenarios: (1) administering two drugs at the same time (concomitant administration); (2) adding treatment of drug B after treatment with drug A has already begun (adjunctive administration); and (3) adding treatment of drug A after treatment with drug B has already begun (adjunctive administration). See new § 7:4.4[B][3].

New chemical entity exclusivity—novel combinations: Reversing its previous position, the FDA has proposed that fixed-combination drugs should be eligible for new chemical entity (NCE) exclusivity if any of the active ingredients in the combination had not been previously approved. FDA has further proposed to implement its new policy prospectively, so that only those combination products that receive FDA approval after the proposal is finalized (after public comment) will be eligible for NCE exclusivity. See § 8:3.2[B][2], at note 385.1.

Extra exclusivity for certain new antibiotics: In the Generating Antibiotic Incentives Now (GAIN) Act, adopted as part of the 2012 FDA Safety and Innovation Act, Congress created an additional incentive to makers of important new antibiotics. Under new section 505E of the FD&C Act, an antibiotic that the Secretary of HHS has designated as a “qualified infectious disease agent” is entitled to five years of exclusivity beyond the period in which NCE exclusivity would otherwise expire. See new § 8:3.2[C].

“Divided” infringement of method claims: Can there be liability for infringement of a method claim where the recited steps are “divided” among more than one actor? In 2012, in Akamai Technologies, Inc. v. Limelight Networks, Inc., the en banc Federal Circuit held that a party could be held liable for inducing infringement under 35 U.S.C. § 271(b) in cases in which no one party performed, or controlled the performance of, all of the steps of a claimed method, but where a party knowingly induced others to practice the steps necessary for all of the steps to have been practiced. But in June 2014, the Supreme Court reversed and remanded that decision, holding that “there has simply been no infringement of the method . . . because the performance of all the patent’s steps is not attributable to any one person. . . . [W]here there has been no direct infringement, there can be no inducement of infringement.” See new § 10:2.6.

The Table of Authorities and the Index have also been updated.
FILING INSTRUCTIONS

Pharmaceutical and Biotech Patent Law

Release #7
(November 2014)

- Title page to li
- 3-1 to 8-111
- 10-1 to 10-30
- T-1 to I-63

- Title page to li
- 3-1 to 8-116
- 10-1 to 10-32
- T-1 to I-69