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BIOTECHNOLOGY PATENT LAW 2018 REVIEW

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I. INTRODUCTION

The year 2018 was a busy and exciting one for biotechnology patent law. The ownership odyssey of patents claiming mammalian CRISPR/Cas9 "gene editing" technology- perhaps the most important biotechnology invention since the polymerase chain reaction ("PCR") - was finally tested in Federal court. The Court of Appeals for the Federal Circuit ("CAFC") turned a distinctly cold shoulder to the Saint Regis Mohawk Tribe's invocation of tribal sovereign immunity to prevent *inter partes* review ("IPR") of its drug patents. And the United States Supreme Court ("Supreme Court") offered its views on the legitimacy of IPRs. In this article, we present a top ten list of the most important 2018 developments in biotechnology patent law. These top ten offer insights about both the current and future state of biotechnology patent law.

Choosing the top ten judicial decisions suffers from an inevitable degree of subjectivity. However, we believe the ten we have selected are among the most important decisions of the year in biotechnology patent law even if others might substitute a case or two for those on our list. Eight of the top ten decisions discussed in this article were delivered during the 2018 calendar year. Two constitute temporal anomalies, having been decided by the Supreme Court in 2017, but are included because of their great importance to biotechnology patent law.

We discuss the top ten biotechnology patent decisions below. They are not presented in any particular order. After consideration of individual judicial decisions, we conclude by suggesting what prospective impact these decisions may have on biotechnology patent law.

II. THE 2018 TOP TEN IN BIOTECHNOLOGY PATENT LAW

A. *Acorda Therapeutics, Inc. v. Roxane Laboratories, Inc.* (Fed. Cir. 2018)

(Panel: Circuit Judges Newman, Dyk, and Taranto; Opinion by Circuit Judge Taranto; dissenting opinion by Circuit Judge Newman)

Determining obviousness is always a reconstruction, imperfectly done, of a past that never was. The prior art is consulted and the question asked, would the worker of ordinary skill in the art *have been able* to achieve the claimed invention with a reasonable expectation of success? Of course, this question is posed against a backdrop of the ordinarily skilled worker *not* having achieved the invention; that accomplishment was

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attained by the named inventor(s). Nevertheless, the Supreme Court, since *Hotchkiss*, and the Patent Act, since 1952, have recognized that sometimes the answer to the question must be no, if only to ensure that the constitutional mandate that Congress only grant patents that will "promote the progress of . . . the useful arts" be satisfied.

In patent litigation, defendants have the motivation to cast the imperfect past in light most favorable to the claimed invention being obvious, and, to balance the rhetorical scales, they also bear the burden of establishing obviousness (as in all invalidity pleadings) by clear and convincing evidence. But what is clear and convincing to some is not to others, and the Federal Circuit's split decision affirming the District Court's obviousness determination in *Acorda Therapeutics, Inc. v. Roxane Labs., Inc*. illustrates the point -- and at the same time shows that even the "objective" indicia of nonobviousness identified by the Supreme Court in *Graham v. John Deere* do not always provide a reliable, fact-and historically based shield to a finding of non-obviousness.

The lawsuit arose when Roxane and co-Defendants Mylan Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc. each filed an Abbreviated New Drug Application (ANDA) for Acorda's multiple sclerosis drug Ampyra®, a formulation of 4-aminopyridine (4-AP) and sent Paragraph IV letters to Acorda (and co-Plaintiff Alkermes Pharma Ireland Ltd.) asserting that four Orange Book-listed patents (U.S. Patent Nos. 8,007,826; 8,663,685; 8,354,437; and 8,440,703) were invalid. As the Federal Circuit panel stated, there was one additional patent, U.S. Patent No. 5,540,938, owned by Elan Corp. plc and exclusively licensed to Acorda. That patent broadly claimed therapeutic formulations of 4-AP; Acorda's patents were for more narrow formulations having specific characteristics and properties that distinguished (undisputedly, for novelty purposes) these claims from the claims of the '938 patent.

For the purposes of the appeal all the asserted claims recited methods, dosing regimens, and sustained-release formulations for "methods of administering to a patient with multiple sclerosis a sustained-release 4-AP formulation (1) in a 10 mg dose twice daily, (2) at that stable dose for the entire treatment period of at least two weeks, (3) maintaining 4-AP serum levels of 15–35 ng/ml, (4) with walking improved." The parties treated the following claims as representative:

Asserted claim 7 (dependent on claim 6) of the '826 patent:

> 6. A dosing regimen method for providing a 4-aminopyridine at a therapeutically effective concentration in order to improve walking in a human with multiple sclerosis in need thereof, said method comprising:
>
> initiating administration of 4-aminopyridine by orally administering to said human a sustained release composition of 10 milligrams of 4-aminopyridine twice daily for a day without a prior period of 4-aminopyridine titration, and then,

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