Strafford

Presenting a live 90-minute webinar with interactive Q&A

Blocking Patents: Impact of Acorda Therapeutics on Obviousness Analysis

Non-Obviousness and Commercial Success, Cross Licensing, Searches

THURSDAY, JANUARY 31, 2019

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

Mark Kachner, Partner, **Knobbe Martens**, Los Angeles

Sarah A. Kagan, Attorney, **Banner & Witcoff**, Washington, D.C.

Kevin E. Noonan, Ph.D., Partner, **McDonnell Boehnen Hulbert & Berghoff**, Chicago

The audio portion of the conference may be accessed via the telephone or by using your computer's speakers. Please refer to the instructions emailed to registrants for additional information. If you have any questions, please contact **Customer Service at 1-800-926-7926 ext. 1**.

Tips for Optimal Quality

FOR LIVE EVENT ONLY

Sound Quality

If you are listening via your computer speakers, please note that the quality of your sound will vary depending on the speed and quality of your internet connection.

If the sound quality is not satisfactory, you may listen via the phone: dial **1-866-570-7602** and enter your PIN when prompted. Otherwise, please **send us a chat** or e-mail **sound@straffordpub.com** immediately so we can address the problem.

If you dialed in and have any difficulties during the call, press *0 for assistance.

Viewing Quality

To maximize your screen, press the F11 key on your keyboard. To exit full screen, press the F11 key again.

Continuing Education Credits

FOR LIVE EVENT ONLY

In order for us to process your continuing education credit, you must confirm your participation in this webinar by completing and submitting the Attendance Affirmation/Evaluation after the webinar.

A link to the Attendance Affirmation/Evaluation will be in the thank you email that you will receive immediately following the program.

For additional information about continuing education, call us at 1-800-926-7926 ext. 2.

Program Materials

FOR LIVE EVENT ONLY

If you have not printed the conference materials for this program, please complete the following steps:

- Click on the ^ symbol next to “Conference Materials” in the middle of the left-hand column on your screen.
- Click on the tab labeled “Handouts” that appears, and there you will see a PDF of the slides for today's program.
- Double click on the PDF and a separate page will open.
- Print the slides by clicking on the printer icon.

BANNER & WITCOFF, LTD.
INTELLECTUAL PROPERTY LAW

Acorda Therapeutics v. Roxane Laboratories—blocking patents

903 F.3d 1310 (Fed. Cir. 2018)

Sarah A. Kagan
skagan@bannerwitcoff.com

Blocking Patent-defined

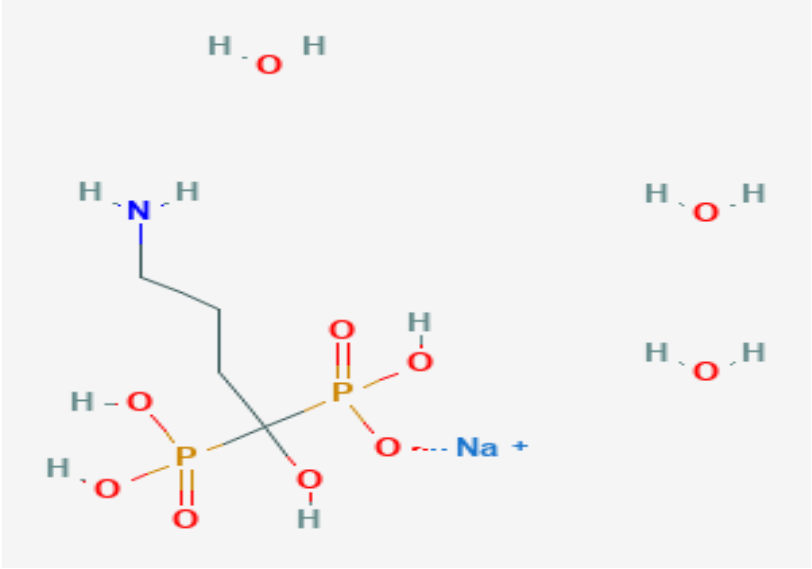
Blocking Patent-rationale

History of the Blocking Patent

- *Merck v. Teva* (Merck I) 2005
- *Galderma Laboratories v. Tolmar* 2013
- *Merck v. Hospira* (Merck II) 2017

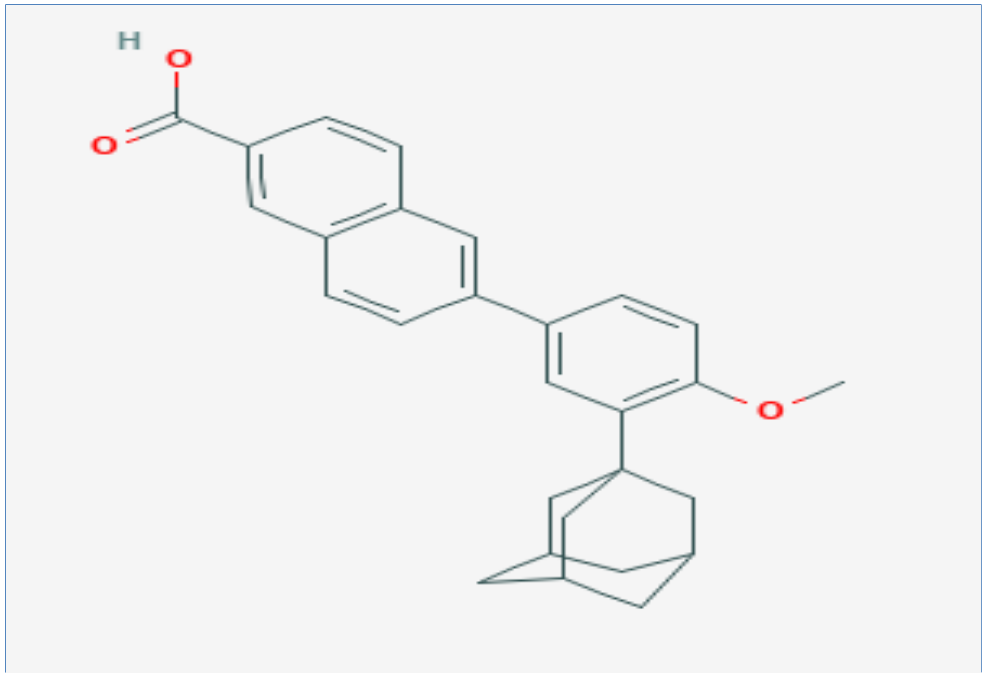
History of the Blocking Patent

Merck v. Teva 395 F.3d 1364 (Fed. Cir. 2005)



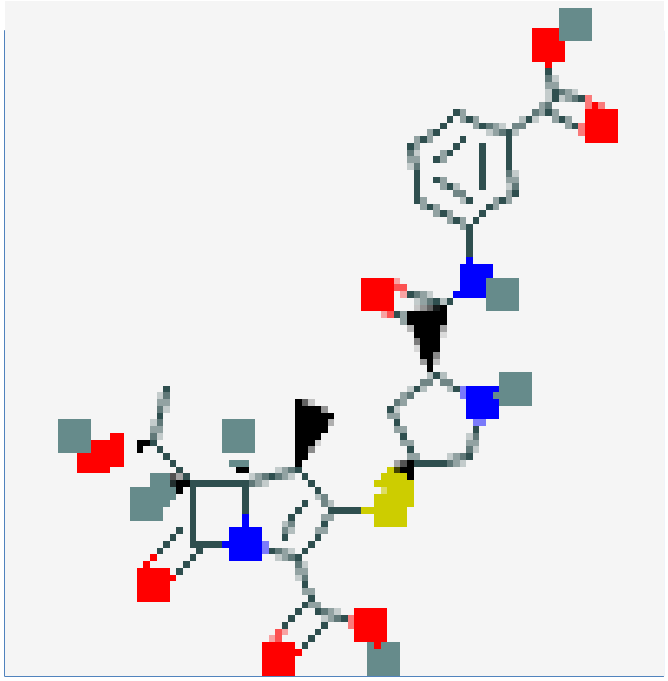
History of the Blocking Patent

Galderma Laboratories v. Tolmar, 737 F.3d 731 (Fed. Cir. 2013)



History of the Blocking Patent

Merck v. Hospira, 874 F.3d 724 (Fed. Cir. 2017)



Background

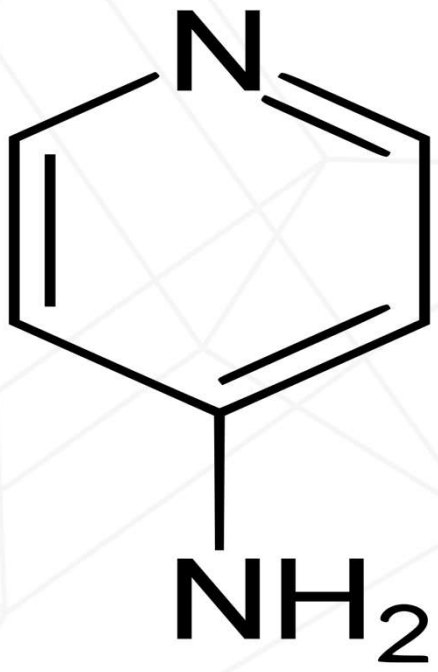
- Elan Corporation held U.S. Patent 5,540,938
- No FDA approved product related to it

Background—The Technology

MS characteristics

Background—The Technology

4-AP



Background—The Technology

Long history of drug, going back over one hundred years

Background—The Facts

Elan's work on 4-AP and MS

Background—The Facts

- Acorda's development of 4-AP for MS

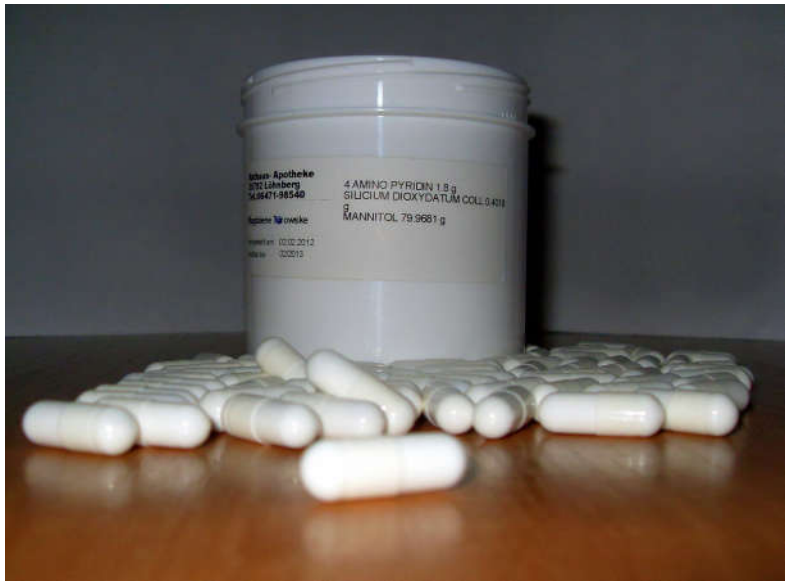
- U.S Patents 8007826, 8663685, 8354437, 8440703

Acorda Patent Claims

The court deals with the 4 patents collectively.

Background: Procedural History

- Acorda submitted NDA No. 022250 to the FDA
- Approved in 2010



Background—Procedural History

- Roxane, Mylan, and Teva submitted ANDAs
- Acorda filed §271(e) infringement suit

Background - Procedural History

- **35 U.S. Code § 271**
- (2) It shall be an act of infringement to submit—
  - (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

Background - Procedural History

- Challenged validity of Acorda patent claims under § 103
- Challenged validity of Elan patent claims under § 112, ¶ 1

Background - Procedural History

Bench trial :

- Elan patent not proven invalid
- Acorda patents invalid for obviousness

Background - Procedural History

- Lower court opinion:
  - Acorda's claimed subject matter obvious over prior art
  - Objective indicia of non-obviousness

Background - Procedural History

- Objective indicia of non-obviousness
  - All discounted

Background - Procedural History

District court order

- **FDA** cannot finally approve any of the defendants products before the Elan patent expires*
- **Defendants** enjoined from any infringing activity before Elan patent expiry

Federal Circuit Opinion

- Filed by J. Taranto
  - We'll skip over the entire 103/prior art
- Dissent filed by J. Newman

Federal Circuit Opinion

- Did the district court apply a **categorical rule** that a blocking patent defeats objective indicia of nonobviousness?
- Better to read it as "drawing conclusions [based] on the limited factual record created in this case."

Federal Circuit Opinion

Factors to be considered:

- Strength of blocking patent (validity)
- Willingness to research without license
- Availability of license to blocking patent
- Willingness to cross-license subservient patent

Federal Circuit Opinion

Economic factors

- Costliness of the research
- Risk of research failure
- Nature of possible improvements
- Scope of blocking patent vis-a-vis improvements
- Anticipated market for improvement

Federal Circuit Opinion

Economic factors (continued)

- Risk of losing the invention race
- Risk of unavailability of license
- Risk of unaffordability of license

Federal Circuit Opinion

Conclusions:

- A blocking patent diminishes possible rewards to non-owner/non-licensee
- Fact-specific inquiry on magnitude of deterrence
- Challenger always retains the burden of persuasion on obviousness

Federal Circuit Opinion

"A court may ultimately be left for its evaluation, with the solid premise of diminished incentives, plus some evidence (possibly weak or ambiguous) about the significance of the deterrence, together with a background sense of the general realities in the area at issue that can affect the weight to be given to the evidence in the specific case."

Federal Circuit Opinion

"District court did not err in viewing the blocking Elan patent, among other evidence, as… discount[ing] the weight of …evidence of"

- Commercial success
- Failure of others
- Long-felt but unmet need

Avoiding a Blocking Patent

- Avoid obtaining an exclusive license
- Take a covenant-not-to-sue
- Delay taking a license to dominating claims until subservient patent application filed
- What if you own a dominating patent and want to invent within that space?

Processing the Acorda Decision

- Can a blocking patent discount unexpected results?
- Unexpected results may be the key to avoiding blocking patent effect
- This was not a case of evergreening
- No prior grant of exclusivity from FDA
- Does blocking patent have any life outside of drugs?

www.bannerwitcoff.com

CHICAGO, IL
Ten South Wacker Drive
Suite 3000
Chicago, IL 6060
T 312.463.5000
F 312.463.5001

WASHINGTON, DC
1100 13th Street NW
Suite 1200
Washington, DC 20005
T 202.824.3000
F 202.824.3001

BOSTON, MA
28 State Street
Suite 1800
Boston, MA 02109
T 617.720.9600
F 617.720.9601

PORTLAND, OR
One World Trade Center
121 Southwest Salmon Street
11th Floor
Portland, OR 97204
T 503.425.6800
F 503.425.6801

BANNER & WITCOFF, LTD.®
INTELLECTUAL PROPERTY LAW

Judge Newman's Dissent in *Acorda v. Roxane Labs*

Kevin E. Noonan, Ph.D.
noonan@mbhb.com

January 31, 2019

McDonnell Boehnen Hulbert & Berghoff LLP

Judge Newman's dissent: background

- Why do we have "secondary considerations" (aka "objective indicia") in the first place
- Recall that determining obviousness is *always* a reconstruction of a past that never occurred
- What *would* the person of ordinary skill have been able to do with a reasonable expectation of success
- Against a backdrop of that person *not* having done any such thing

Judge Newman's dissent: background

- Supreme Court recognized this potential in *Graham v. John Deere*, saying

  > Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

- A grudging concession to imperfection

Judge Newman's dissent: background

- Learned Hand may have said it best:

  The test laid down [in 35 U.S.C. § 103] is indeed misty enough. It directs us to surmise what was the range of ingenuity of a person "having ordinary skill" in an "art" with which we are totally unfamiliar; and we do not see how such a standard can be applied at all except by recourse to the earlier work in the art, and to the general history of the means available at the time. To judge on our own that this or that new assemblage of old factors was, or was not, "obvious" is to substitute our ignorance for the acquaintance with the subject of those who were familiar with it. *Reiner v. I. Leon Co.*, 285 F.2d 501 (2d Cir. 1960)

Judge Newman's dissent: background

- Learned Hand may have said it best:

  Courts, made up of laymen as they must be, are likely either to underrate, or to overrate, the difficulties in making new and profitable discoveries in fields with which they cannot be familiar; and so far as it is available, they had best appraise the originality involved by the circumstance which preceded, attended and succeeded the appearance of the invention. *Safety Car Heat & Light Co. v. General Electric Co.*, 155 F.2d 937 (2d Cir. 1946).

Judge Newman's reasoning in *Acorda*

- Her concern: "the afflicted public," who were without this MS treatment in the prior art
- Most or all of the prior art cited showed extensive *failure of others*
- But district court and Federal Circuit majority glossed over in discussion of commercial success
- First basis for her dissent: the court using evidence of failure as prior art
- A rational distinction: while these results were certainly art they should have negated (or at least reduced) the expectation of success

Judge Newman's reasoning in *Acorda*

- Secondary considerations also an antidote to hindsight
- Here, almost all the prior art would have informed the skilled worker that effective dosages and administration regimes were accompanied by unacceptable side effects
- Not the case of single failure, but "*many* scientists in institutions studied and eventually abandoned 4-AP as a treatment prospect for multiple sclerosis"
- Judge Newman believes majority ignored implications of prior art failures in view of the patentee's successes

“Blocking” patent significance

- Majority’s discussion of prior art seemingly a classic case of failure of others – disregarded by majority in her view
- An anomaly: court majority recognizes the extensive prior art attempts at developing 4-AP based MS drug and at the same time discounts commercial success due to “blocking patent” (*i.e.*, little evidence that patent truly blocked)
- Ineffective nature of such blocking (in Judge Newman’s view) evidenced by attempts to develop drug

“Blocking” patent significance

- In Judge Newman’s view, “commercial success is measured against the products available for the same purpose, not against infringing copies of the patented product”
- Conventionally, in applying secondary considerations to the question of obviousness was not a direct comparison
- Majority thought existence of prior patent sufficient to overcome consideration of commercial success because blocking nature of patent provided alternative explanation

“Blocking” patent significance

- Majority are saying (for commercial success at least) a blocking patent can *prevent* others from having the success the patentee claims shows nonobviousness
- Judge Newman takes the question from the other side, wherein the existence of the prior patent would not have prevented experimentation (safe harbor) with a goal of developing a patentable, useful formulation
- The question is not why someone else didn’t develop the claimed formulation, but why didn’t they develop a competing one

Judge Newman's greater concern

- Proper role of secondary considerations
- Believes them to be equal to the rest of the *Graham* calculus
- Others on the court believe them to be merely a check, that can be overridden by a strong prima facie obviousness case
- Consequence: secondary considerations become secondary to judicial reconstruction (and hindsight risk) instead of providing the balance of objective contemplation of the history and context of the invention

Judge Newman's greater concern

- Judge Newman first voiced these concerns (post *KSR v. Teleflex Int'l*.) in *Pharmastem Therapeutics v. Viacell*; much stronger secondary considerations included commercial success, long-felt need, and recognition in the art, including testimonials from the Defendants
- Unrebutted secondary considerations should be enough to overcome obviousness determination as evidence of what if fact happened (rather than reconstruction)

Judge Newman's greater concern

- The objective indicia "may often be the most probative and cogent evidence in the record . . . . It is to be considered as part of all the evidence, *not just when the decisionmaker remains in doubt after reviewing the art*." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538–39 (Fed. Cir. 1983).

Knobbe Martens

Blocking Patents

Mark Kachner

Knobbe Martens

mark.kachner@knobbe.com

Majority Decision (applied to future litigation)

- "…the district court's opinion is best read **not as invoking a categorical rule**, but as drawing conclusions on the **limited factual record created in this case bearing on the effect of a blocking patent**." (emphasis added).
- "…a blocking patent may or may not deter innovation in the blocked space by commercially motivated potential innovators other than the owners or licensees of the blocked patent."

Majority Decision (applied to future litigation)

- Citing *Merck II*, the Court stated that "commercial success is 'a fact-specific inquiry' that may involve considering the operation of specific blocking patents on possible competition. But the mere existence or sheer number of blocking patents does not, **without more**, 'necessarily detract from evidence of commercial success of a product or process." (emphasis added).

Majority Decision (applied to future litigation)

- Key variables relevant to the calculus of the relevance of secondary consideration of nonobviousness:
  - Costliness of research
  - Risk of research failure
  - Nature of improvements that might arise from research
  - Whether such improvements will be entirely covered by blocking patent
  - Size of anticipated market opportunities
  - Costs of arriving at improvements and getting them to market
  - Risk of losing invention race to blocking-patent owner
  - Risk blocking-patent owner will refuse to grant reasonable license to improvement

Future Litigation considerations

- Majority states: "[t]here is no evidence that Elan sought to license the Elan patent to any entity other than Acorda, or that Acorda sought to sublicense the Elan patent, either of which would dilute the power of the blocking patent."
  - Consider introducing evidence that third-parties sought licenses to the blocking patent.
  - Develop evidence that one reason no third-party sought such a license was due to prior failure of others and low expectation of success given prior published research.

Future Litigation considerations

- Majority states: district court determined that third-party Sanofi-Aventis experimented with alternative to blocked compound, but likely did not use the blocked compound "due to blocking effect of the Elan patent."
  - Consider taking third-party discovery into why third-parties did not experiment with blocked compound.
    - Perceived small market opportunity.
    - Perceived difficult given prior failure of others.
    - Perceived lack of improvements to invention in blocked patent.

Future Litigation considerations

- Majority states: “Acorda notes that U.S. patents do not block sales outside the United States. That observation is relevant, but is not shown to be weighty in this case by any concrete evidence about the particular inventions at issue.”
  - Consider developing evidence about international market for the blocked drug, (e.g. in Acorda’s case – international population diagnosed with MS, international sales of patented drug, testimony that international market is sufficient incentive to invest despite exclusion from U.S. market during patent term).