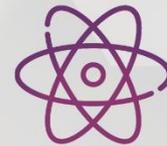
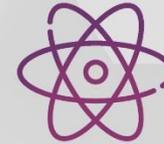


THE PRACTICAL IP FOR NATURAL SCIENCES WEBINAR SERIES



RESURGENCE

OF COMPETENT OPINIONS A LA HALO



THE PRACTICAL IP FOR NATURAL SCIENCES WEBINAR SERIES

MEET THE PRESENTER



Jim Nelson (J.D., Ph.D.)

- Registered Patent Attorney and Principal
- Over 40 years of IP experience in chemical, polymer, pharmaceutical, biotechnology, cosmetics and medical device fields.

Evolving Law Regarding Opinions

- History

- *Underwater Devices v. Morrison Knudsen*, 717F.2d 1380 (Fed. Cir. 1983)
 - §282, presumption of validity; §284 Triple Damages
 - Infer bad faith without an outside counsel opinion
- *Knorr-Bremse Systeme Fuer Nutzfahrzeuge v Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004)
 - 20 years later, validity respected, revert to usual view regarding inference of intentional infringement.
- *In re Seagate Technology*, 497 F.3d 1360 (Fed. Cir. 2007)
 - Two part objective test for “knowing” infringement
- *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 127 S.Ct. 2201 (579 U.S. ____)
(2016)
 - No objective recklessness std, reasonable but unsuccessful defense = no ↑ damage

Does Halo Change Evolution?

- For contributory and inducement – yes
 - Plaintiff must prove “knowing” infringement
 - Competent Opinion is significant evidence of good faith effort not to infringe valid patents, avoids willfulness charge.
- For direct infringement – yes
 - Post Halo cases indicate opinion before litigation is significant protection against charge of willfulness.

POST HALO SITUATION

- Commentators suggest that opinions prepared PRE-LITIGATION provide significant evidence of a defense against willfulness
 - See IP Watchdog, Sept 2017, Intellectual Property Magazine June 2017
 - Cases
 - *Greatbatch v. AVX Corp D. Del. Dec. 13, 2016*: timely obtained and reasonable reliance = complete defense against charge of willfulness even though defendant lost.
 - *Omega Patents LLC. V. Calamp Corp. M.D. Fla. April 5, 2017*, absence of formal opinion before litigation demonstrated that defendant had no knowledge of its patent invalidity defense at time of infringement; **RESULT**: increased damages awarded for willfulness.

Practical Results of Evolving Law on Opinions

- 1980's Hay Day for opinions, always needed outside counsel opinion
- About what?
 - Non-infringement, Invalidity regarding patent that arguably covers product
 - FTO Clearance, Survey
- 2004 Onward
 - Outside counsel opinions before litigation a very good idea
 - Inside counsel reasonable review okay; but need independent review
 - Patent owner still needs to show defendant knowledge of patent and willful disregard to get increased damages
 - Lack of opinion puts defendant in danger zone but does not necessarily lead to an automatic willfulness result.
 - BOTTOM LINE  GET AN OPINION BEFORE LITIGATION BEGINS

Practical Reasons for Opinions

- Wholly aside from threat of 3X damage, why get opinions
 - R&D Investment, time, effort, \$\$ expense, but blocked by 3rd party patents – not smart!
 - Run Freedom To Operate
 - Search, review, consider coverage of 3rd party patents
 - If find highly relevant patent, do deep dive into infringement analysis; consider design around
 - If find blocking patent with no design around possibility, do deep dive into validity analysis

Elements of an Opinion – High Level

- Kinds of opinions
 - Survey of relevant art, FTO, informal report directed toward further product development, formal non-infringement, formal Invalidity
 - Infringement Opinion of Plaintiff to satisfy Rule 11
 - Opinion of Plaintiff regarding patent validity
 - Analysis of patent – two parts – UNIVERSAL
 - Interpret claim language
 - Apply interpreted claims to product (infringement/non-infringement) or to prior art (validity/invalidity)
 - *Graver Tank & Mfg. v. Linde Air Products, 339 U.S. 605 (1950).*

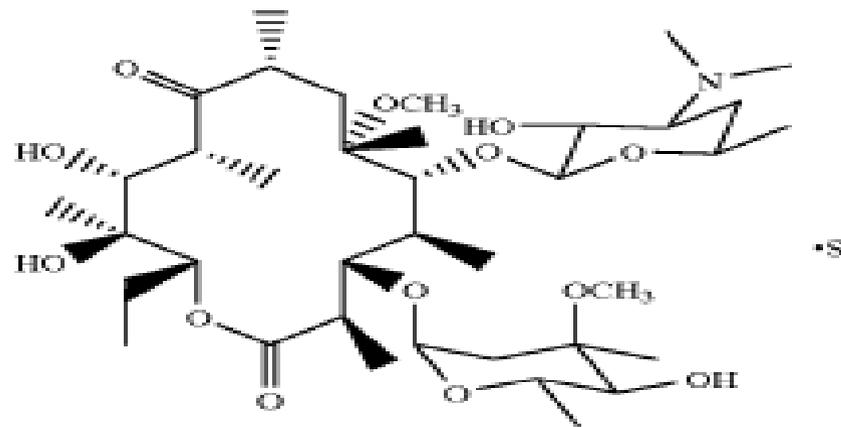
Interpretation of Claims

- Follows *Phillips v. AWH Corp.* 415 F.3d 1303 (Fed. Cir. 2005)
 - *Plain meaning to one of skill in the art based on words of claims, description in specification, prosecution history and cited prior art (not uncited art)*
 - *This is a court oriented interpretation based on the record*
 - At PTO such as in prosecution and in PTAB IPR's current rule is **BROADEST** reasonable interpretation
 - However, PTO has proposed a rule change to conform PTAB IPR rule with Court rule

Claim Term Interpretation is Tricky and Subtle

- Consider *Teva Pharmaceuticals v. Abbott Labs*, 301 F. Supp.2d 819 (N.D. Ill 2004)
- *Issue: what is ethanol in Claim of US patent 4,331,803*

1. An isolated crystalline antibiotic designated 6-O-methylerythromycin A form 0 solvate having the structure



wherein S is a solvating molecule selected from the group consisting of ethanol, isopropyl acetate, isopropanol and tetrahydrofuran.

Rules for Infringement Analysis

- Infringement analysis requires two parts
 - Literal and Doctrine of Equivalents: *Graver Tank*, cited above and *Markman v. Westview Instruments*, 52 F.3d 967 (Fed. Cir. 1995)
 - Literal Infringement Rule: All Elements Rule
 - Doctrine of Equivalents rule: All Limitations Rule
 - Intrinsic Evidence: specification, file history, cited prior art

Application of Rules

- Depth of analysis and explanation
 - Depends on context of opinion
 - Survey
 - FTO
 - Informal Report
 - Formal Opinion with Bells And Whistles
 - Need to address literal and DOE
 - Depth of explanation depends upon need for claim interpretation, nature of opinion and analytic distance between product and claim.

The FTO

- Goal: to provide responsible parties with assurance that product development will not be blocked
- Search of patent art
- Address relevant aspects of patents that possibly raise a question
- Deal with All Elements and All Limitations summarily or in depth as analytic distance between claim and product demand.

The Formal Opinion

- The need for a formal opinion considers the risk of suit, the litigiousness of the patent holder, the value of the product, prior evaluations
- Why have one?
 - From outside counsel
 - Shows good faith effort to avoid infringement
 - Substantial evidence of thoughtful product development – first FTO then FO.
 - Goes a long way toward Negating charge of willfulness and request for increased damages
- What is inside an FO?
 - The full two stage analysis
 - Claim term interpretation fully written out
 - All aspects of All Elements and All Limitations addressed in writing
 - Other approaches avoiding patent fully discussed: marking, written description, indefiniteness, laches, inequitable conduct, Lanham act, fair dealing, contract issues

Organization of The Formal Opinion

- Can be like Fed Cir opinion
- Section on Law
- Indicate who would be POSTA
- Incorporate case law into discussion of “walk the line” sections of analysis
- Provide formal claim term interpretation of terms that are not clear on face
- Can write interpretation and analysis as separate sections or together but explain how interpretation meets standard and how product does not fit interpreted term

Organization of the Formal Opinion

- Discuss Literal (All Elements) and DOE (All Limitations) sequentially
- Literal is straightforward once term interpretation is done
- DOE is always difficult: the penumbra between literal language and prior art. What is it and how far does it extend
- Use Fed. Cir. Law for scoping penumbra: FH estoppel, Claim amendment, FH argument, Common Sense, Scope of term interpretation
- Give detailed well reasoned analysis
- Above all, do not provide conclusory remarks alone.

QUESTIONS & DISCUSSION



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