# THE PRACTICAL IP FOR NATURAL SCIENCES WEBINAR SERIES

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# RESURGENCE

## OF COMPETENT OPINIONS A LA HALO

THE PRACTICAL IP FOR NATURAL SCIENCES WEBINAR SERIES

# MEET THE PRESENTER

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

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# 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?

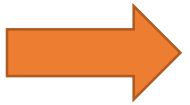
- For contributory and inducement – yes
  - Plaintiff must prove “knowing” infringement
  - Competent Opinion is significant evidence of good faith effort not to infringe valid patents, avoids willfulness charge.

- 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 <u>necessarily</u> 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 pty patents – not smart!
  - Run Freedom To Operate
  - Search, review, consider coverage of 3rd pty 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).*

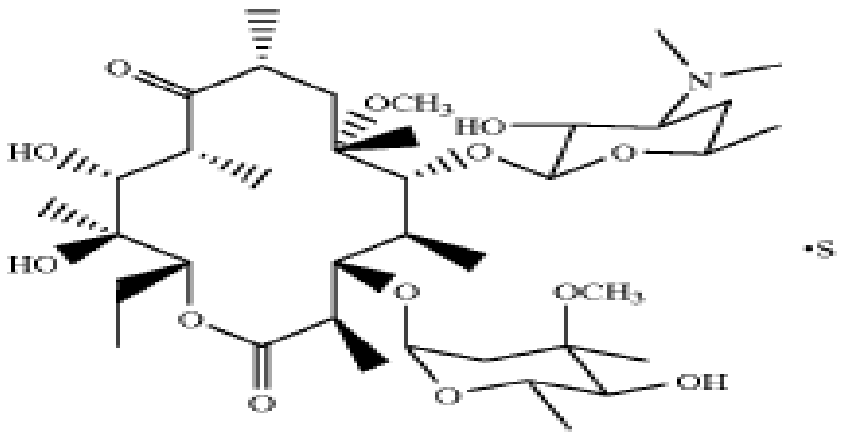
# Interpretation of Claims

- 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 antiobiotic 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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