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Hatch-Waxman Update: Recent Trends in DOE

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Bruce M. Wexler

Basic Concepts of DOE

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- **Fundamental components of the "invention"**
  - The arrangement of structures, materials, substances, etc. (*i.e.*, way);
  - The forces or principles of operation invoked by that arrangement (*i.e.*, function);
  - The useful outcome achieved (*i.e.*, results).

- **Function-Way-Result Test**
  - The accused product infringes if, on an element-by-element, it "performs substantially the same function in substantially the same way with substantially the same result."

Basic Concepts of DOE

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- **Key aspects of *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997)**
  - Equivalency determined against "the context of the patent, the prior art, and the particular circumstances of the case"
  - Consider "the purpose for which an ingredient is used in a patent, the qualities it has when combined with other ingredients, and the function which it is intended to perform"
  - The "perspective of a skilled practitioner" provides "content to, and limits on, the concept of 'equivalence'"
  - Consider interchangeability *at the time of infringement*; experiments by the accused infringer could be probative of known interchangeability
- **Equivalency is determined as a question of fact**

Philosophies Driving DOE

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- **"The nature of language makes it impossible to capture the essence of a thing in a patent application"**
  - Patent claim language "may not capture every nuance of the invention or describe with complete precision the range of novelty"

- **The infringer has the greater incentive to devote its efforts to studying the literal words to find unimportant and insubstantial changes that add nothing but avoid the literal language**

- **Protect against unforeseeable trivial changes**

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002)

Must Clear Threshold Legal Hurdles

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- **Prosecution History Estoppel**
  - Narrowing amendments or arguments made to satisfy patentability requirements bar the subject matter surrendered from being deemed equivalent
  - If no reason given for amendment, all equivalents are barred
  - Patentee bears burden of showing amendment was not for reasons related to patentability, or that amendment does not surrender particular equivalent
  - May rebut with arguments of unforeseeability, or at most tangential relationship between rationale underlying the amendment and the equivalent
    - *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1291-92 (Fed. Cir. 2010) (good case for tangential relationship between equivalent and amendment)

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002)

Must Clear Threshold Legal Hurdles

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- **Preclusion by Prior Art**
  - *Wilson Sporting Goods v. David Geoffrey & Assocs.,* 904 F.2d 677 (Fed. Cir. 1990)
- **Disclosed But Not Claimed**
  - But, disclosure in a context other than as an alternative to the claimed element is not dedication. *Pfizer, Inc. v. Teva Pharms. USA*, 429 F.3d 1364, 1379 (Fed. Cir. 2005)
- **Vitiation**
  - All Elements Rule: each element (or combination of elements) must find an equivalent in the accused product
    - Also need "particularized testimony and linking argument as to the insubstantiality of the differences"; DOE evidence also cannot simply be subsumed in plaintiff's case on literal infringement. *Amgen Inc. v. Hoffman-LaRoche*, 580 F.3d 1382 (Fed. Cir. 2009)
  - Subject matter "specifically excluded" from a claim, or the "antithesis" of a claim element, cannot be equivalent.
    - *Athletic Alternatives v. Prince Mfg.*, 73 F.3d 1573 (Fed. Cir. 1996); *Planet Bingo v. GameTech Int'l*, 472 F.3d 1338 (Fed Cir. 2006)

Federal Circuit DOE Decisions of Interest Upholding Infringement Under DOE

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- *Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151 (Fed. Cir. 2012)
  - Claimed product (Treximet®): bilayer tablet in which each layer had "substantially all" of each of two drugs that dissolved independently
    - "substantially all" construed to mean ≥ 90% of one drug and ≤ 10% of the second drug in each layer
  - Accused products had 100% of one drug and 15% of the second drug in one layer, and 85% of the second drug in the other layer; used granulation to insert more into the layer without detrimental effects
  - Equivalence in function of separate distinct layers of drug; way of formulating to create physical barriers; and result of separation to achieve independent dissolution
  - Expert testimony and FDA filings in ANDA showed equivalency
  - No direct testing comparing rates of dissolution of each ingredient in accused product versus literally claimed product

Federal Circuit DOE Decisions of Interest Upholding Infringement Under DOE

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- *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283 (Fed. Cir. 2010)
  - Claimed product (Mucinex®): an extended release product with an immediate release portion and an extended release portion where the C_{max} is "equivalent" to the C_{max} of an immediate release formulation dosed in a particular way; dependent claim added "at least" a certain AUC value
    - "equivalent" construed to refer to the FDA's 80-125% range
  - If commercial embodiment meets all the claim limitations, accused product can be compared to commercial embodiment to support a finding of infringement
  - Mere fact of FDA bioequivalence does not show infringement, but it can be coupled with evidence of PK and C_{max} values
  - DOE may apply to a claim reciting "at least" a numeric value
  - 3493.38 hr*ng/mL was insubstantially different from 3500
  - S/J of no DOE vacated

Federal Circuit DOE Decisions of Interest Upholding Infringement Under DOE

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- *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319 (Fed. Cir. 2009)
  - Claimed product: stent that had certain "corners," construed to mean "a place where two surfaces meet to form an angle"
  - Accused device had rounded edges or circular arcs, and expert testimony explained how they functioned as reference points, achieved the function at similar locations, with the same result
- *Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196 (Fed. Cir. 2007)
  - Claimed product (Biaxin XL®): Extended release antibiotic containing "a pharmaceutically acceptable polymer."
  - Accused product used glyceryl monostearate; functioned as a release controlling agent; equivalence in PI upheld
- *Pfizer v. Teva*, 429 F.3d 1364 (Fed. Cir. 2005)
  - MCC equivalent to "saccharide" where both inhibit hydrolysis

Federal Circuit DOE Decisions of Interest Upholding Infringement Under DOE

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- *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370 (Fed. Cir. 2006)
  - Claimed product (Diprivan®): IV formulation containing propofol and EDTA in an amount sufficient to prevent bacterial growth
  - Mayne's product contained calcium trisodium DTPA
  - Same function (retarding microbial growth in an o/w emulsion); same way (metal ion chelation); same result (retardation to extent required by test set forth in claims). Experts and FDA documents confirmed this.
  - Equivalence shown by accused infringer's choice of DTPA due to structural similarity to EDTA and belief properties would be the same; and its patent showing unforeseeability
  - Narrower definition of "way" rejected; argument that claiming EDTA rather than broader genus (polyaminocarboxylate) disclaimed materials within the genus (such as the accused DTPA) also rejected

Bruce M. Wexler

PAUL HASTINGS

Bruce M. Wexler

Partner, Litigation Department
75 East 55th Street
New York, NY 10022-3205

T: (212) 318-6020
brucewexler@paulhastings.com

- **Bruce M. Wexler** is a trial lawyer with extensive experience litigating patent cases, representing clients as lead counsel in cases involving multi-million and multi-billion dollar products. Recent representations include:
  - *Boehringer v. Mylan*: Argued and won a Federal Circuit appeal for client Boehringer Ingelheim. Mr. Wexler was hired to handle the appeal and obtained a reversal of a district court judgment of patent invalidity.
  - *Teva and Apotex v. Eisai*: Won dismissals of declaratory judgment actions asserting noninfringement of several patents owned by client Eisai.
  - *Boehringer v. Sandoz*: Argued and won a preliminary injunction preventing Sandoz from launching a generic version of Mirapex®, a leading drug for the treatment of Parkinson's disease.
  - *Eisai v. Teva*: Obtained a preliminary injunction against Teva's threatened launch of a generic version of the market leading Alzheimer's disease drug, Aricept®, having U.S. sales of almost $2 billion per year.
  - *Pfizer v. Teva*: Successfully tried a case for Pfizer defending its patent on Accupril®, an ACE inhibitor.
  - *Eisai v. Teva, Dr. Reddy's, Mylan*: Successfully tried a case for Eisai covering its patent for Aciphex®, an acid reflux drug with annual US sales in excess of $1 billion. Mr. Wexler previously won summary judgment for Eisai of patent validity.
- *IAM Magazine* refers to him as an "awesomely effective trial lawyer." *Chambers USA* calls Mr. Wexler a "litigation and trial expert at the firm," noting his ability to "explain complex situations clearly to enable informed decision-making," and "exceptional writing skills and strong technical ability." *The Financial Times* awarded his successful defense of the Aricept® drug franchise "standout" notice for innovative lawyering.
- Mr. Wexler is a former judicial law clerk of the U.S. Court of Appeals for the Federal Circuit, where he served under Chief Judge Glenn L. Archer, Jr. during his preparation of influential Federal Circuit opinions including *Markman v. Westview.*
- Mr. Wexler received his J.D. *magna cum laude* from New York University (Order of the Coif) and his B.S., *summa cum laude*, in physics from Rensselaer Polytechnic Institute, where he was a member of Sigma Pi Sigma honor society.

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20 OFFICES ACROSS ASIA, EUROPE, AND THE U.S.

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Our Offices

PAUL HASTINGS

NORTH AMERICA

Atlanta
1170 Peachtree Street, N.E.
Suite 100
Atlanta, GA 30309
t: +1.404.815.2400
f: +1.404.815.2424

Chicago
191 N. Wacker Drive
Thirtieth Floor
Chicago, IL 60606
t: +1.312.499.6000
f: +1.312.499.6100

Houston
1000 Louisiana Street
Suite 5400
Houston, TX 77002
t: +1.713.860.7300
f: +1.713.353.3100

Los Angeles
515 South Flower Street
Twenty-Fifth Floor
Los Angeles, CA 90071
t: +1.213.683.6000
f: +1.213.627.0705

New York
75 East 55th Street
New York, NY 10022
t: +1.212.318.6000
f: +1.212.319.4090

Orange County
695 Town Center Drive
Seventeenth Floor
Costa Mesa, CA 92626
t: +1.714.668.6200
f: +1.714.979.1921

Palo Alto
1117 S. California Avenue
Palo Alto, CA 94304
t: +1.650.320.1800
f: +1.650.320.1900

San Diego
4747 Executive Drive
Twelfth Floor
San Diego, CA 92121
t: +1.858.458.3000
f: +1.858.458.3005

San Francisco
55 Second Street
Twenty-Fourth Floor
San Francisco, CA 94105
t: +1.415.856.7000
f: +1.415.856.7100

Washington, D.C.
875 15th Street, N.W.
Washington, DC 20005
t: +1.202.551.1700
f: +1.202.551.1705

EUROPE

Brussels
Avenue Louise 480
1050 Brussels
Belgium
t: +32.2.641.7460
f: +32.2.641.7461

Frankfurt
Siesmayerstrasse 21
D-60323 Frankfurt am Main
Germany
t: +49.69.907485.0
f: +49.69.907485.499

London
Ten Bishops Square
Eighth Floor
London E1 6EG
United Kingdom
t: +44.20.3023.5100
f: +44.20.3023.5109

Milan
Via Rovello, 1
20121 Milano, Italy
t: +39.02.30414.000
f: +39.02.30414.005

Paris
96, boulevard Haussmann
75008 Paris, France
t: +33.1.42.99.04.50
f: +33.1.45.63.91.49

ASIA

Beijing
19/F Yintai Center Office Tower
2 Jianguomenwai Avenue
Chaoyang District
Beijing 100022, PRC
t: +86.10.8567.5300
f: +86.10.8567.5400

Hong Kong
21-22/F Bank of China Tower
1 Garden Road
Hong Kong
t: +852.2867.1288
f: +852.2526.2119

Seoul
33/F West Tower
Mirae Asset Center1
67, Suha-dong, Jung-gu,
Seoul, 100-210, Korea
t: +82.2.6321.3800
f: +82.2.6321.3900

Shanghai
35/F Park Place
1601 Nanjing West Road
Shanghai 200040, PRC
t: +86.21.6103.2900
f: +86.21.6103.2990

Tokyo
Ark Hills Sengokuyama Mori Tower
40th Floor, 1-9-10 Roppongi
Minato-ku, Tokyo 106-0032 Japan
t: +81.3.6229.6100
f: +81.3.6229.7100

For further information, you may visit our home page at www.paulhastings.com or email us at info@paulhastings.com