PRESENTATION TO

May 20, 2008

PATENT LAW UPDATE

by

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CLAIM CONSTRUCTION

- "The complexities of patent claim writing are notorious. There are few, if any, legal documents more difficult to craft, more fraught with pitfalls than patent applications; and patent claims are so universally challenging to the non-specialist, that this court has converted the judicial need to understand them into an unruly cottage industry called "claim construction."
  - Circuit Judge Newman dissenting in Energizer v. U.S. International Trade Commission, 2008 WL 1791980 (April 21, 2008).

CLAIM CONSTRUCTION
AND=OR

- Ortho-McNeil Pharms. Inc. v. Mylan Labs., Inc., 520 F.3d 1358 (Fed. Cir. 2008)
  - Ortho's patent claims topiramate (TOPOMAX®)
  - Claim 1: [A compound wherein]

    R1 is hydrogen or alkyl; **and**

    R2, R3, R4 **and** R5 are independently hydrogen or lower alkyl **and** R2 **and** R3 and/or R4 **and** R5 together may be a group of the following formula …wherein R6 and R7 are the same or different **and** are hydrogen, lower alkyl or are alkyl **and** are joined to form a … ring.

CLAIM CONSTRUCTION
AND=OR

- Ortho-McNeil (con't)
  - In topiramate, R2 and R3 and R4 and R5 together are a group of formula (II), wherein R6 and R7 are methyl.
  - Mylan argued "and" in the claim precludes the claim from encompassing topiramate.
    - First limitation: "R2, R3, R4, and R5 are independently hydrogen or lower alkyl"
    - Second limitation: "R2 and R3 and/or R4 and R5 together may be a group of formula (II)."
    - Both of these limitations must be met in order for a compound to infringe.
    - Both of these limitations are not met in topiramate.
      - None of the R2, R3, R4, and R5 subunits are hydrogen or lower alkyl because both R2 and R3 and R4 and R5 together are a group of formula (II).

CLAIM CONSTRUCTION
AND=OR

- Ortho-McNeil (con't)
  - DC: permanent injunction against Mylan and reset effective approval date for Mylan's ANDA
  - FC: Affirmed - claim 1 covers topiramate
    - "the claim language depicts two subsets of compounds, but does not require their simultaneous existence."
      - In one subset of compounds covered by claim 1, the groups R2, R3, R4, and R5 are independent of one another.
      - In a second subset of compounds covered by claim 1, the R2 through R5 groups are not independent, but rather R2 and R3 are together, and/or R4 and R5 are together, to form either one or two groups of formula (II).
      - Topiramate is an example of this type of compound. In it, R2 and R3 are arranged together in a group, as are R4 and R5.
      - "as used in this claim, 'and' conjoins mutually exclusive possibilities."
    - "Construing claim 1 to require a conjunctive meaning of 'and' would render several dependent claims meaningless."

CLAIM CONSTRUCTION
AND=OR

- Ortho-McNeil (con't)
  - FC: Affirmed - claim 1 covers topiramate
    - Specification uses "and" to link alternative chemical structures.
      - "R2, R3, R4 and R5 are independently hydrogen or lower alkyl and, when X is CH2, R4 and R5 may be alkene groups joined to form a benzene ring and when X is oxygen, R2 and R3 and/or R4 and R5 together may be a methylenedioxy group of the following formula II . . . .
      - "Without question, this passage within the specification shows use of the word 'and' to join alternatives."
    - "In the circumstances of this case, the use of 'and' to express alternatives was chosen and adequately expressed by the applicant."

CLAIM CONSTRUCTION: ORDINARY WORDS

- Chef America, Inc. v. Lamb-Weston, Inc., 358 F.3d 1371 (Fed. Cir. 2004)
  - •Claim process for baking dough by "heating the . . . dough **to** a temperature in the range of about 400 degrees F. to 850 degrees F."
  - • If dough were heated to the temperature specified in the claim, "it would be burned to a crisp."
  - • Expert declaration that one skilled in the art reading the claim would believe temperature range referred to temperature of oven, not dough.
  - • Patent gives two examples, each stating that the dough product is placed in a multi-layered convection oven and baked "at temperatures" or "at a temperature" of 680° F to 850° F.
  - • DC: Construed claim to mean temperature of dough -> no infringement.
  - • FC: Affirmed. "courts may not redraft claims."
    - • Could have chosen "**at** a temperature", but didn't.

SPECIFICATION AS GUIDE TO THE MEANING OF THE CLAIM TERMS

- Halliburton Energy Services, Inc. v. M-I LLC, 514 F.3d 1244 (Fed. Cir.), reh'g denied (March 2008)
  - Claim: "A method for conducting a drilling operation in a subterranean formation using a fragile gel drilling fluid[.]"
  - Specification defined "fragile gel" as:
    - a "gel" that is easily disrupted or thinned, and that liquifies or becomes less gel-like and more liquid-like under stress, ... but which quickly returns to a gel when the movement or other stress is alleviated or removed, ... The "fragileness" of the "fragile gels" of the present invention contributes to the unique and surprising behavior and advantages of the present invention. The gels are so "fragile" that it is believed that they may be disrupted by a mere pressure wave or a compression wave during drilling. They seem to break instantaneously when disturbed, ... with less pressure, force and time than known to be required to convert prior art fluids from a gel-like state into a flowable state.

SPECIFICATION AS GUIDE TO THE MEANING OF THE CLAIM TERMS

- Halliburton (con't)
  - DC: definition of "fragile gel" in the specification "was too subjective and unclear[.]"
  - FC: Affirmed.
    - "[N]either Halliburton's proposed definition nor any other possible construction resolves the ambiguity in the scope of the term "fragile gel[.]"
    - "Halliburton's failure to distinguish the fragileness of the drilling fluids of the invention from the close prior art … is fatal."
    - "By failing to identify the degree of the fragility of its invention, Halliburton's proposed definition would allow the claims to cover not only that which it invented that was superior to the prior art, but also all future improvements to the gel's fragility. While patentees are allowed to claim their inventions broadly, they must do so in a way that distinctly identifies the boundaries of their claims."

CLAIMS NOT LIMITED TO PREFERRED EMBODIMENT

- PSN Illinois, LLC v. Ivoclar Vivadent, Inc., -- F.3d --, 2008 WL 1946550 (Fed. Cir. May 06, 2008)
  - Invention: method of fabricating porcelain veneers for teeth.
  - Claim 1, the only independent claim, requires "eroding away said statue from said porcelain veneer restoration leaving said restoration **ready for mounting** on said tooth."
  - DC: summary judgment of non-infringement
    - Construed "ready for mounting" as "leaving the veneer restoration ready to be fitted to and cemented on a patient's tooth for which it was custom-made."
    - No finishing steps allowed after removal of statue.
    - The accused process could not infringe either literally or under the doctrine of equivalents because the veneer was not "ready for mounting" when removed from the investment material.
      - Sprue was removed and area was filled after removal.

CLAIMS NOT LIMITED TO PREFERRED EMBODIMENT

- PSN (con't)
  - FC: Affirmed, even though the district court construed the claim term "ready for mounting" too narrowly.
    - Although the "specification provides no explicit definition for "ready for mounting[,]" [n]evertheless, the specification illuminates the proper construction of the term. In the summary of the invention section, the specification teaches that some finishing steps may be performed after the statue is eroded[.]"
    - Description of preferred embodiment: "While still on the statute, the veneer casing may be subject to finishing treatment to improve the esthetics…The support provided by the statue with the casing still mounted while such treatment is conducted is a feature of this invention."

CLAIMS NOT LIMITED TO PREFERRED EMBODIMENT

- PSN (con't)
  - PSN cited Oatey for the proposition that "[a]t leas[t] where claims can reasonably [be] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment, absent probative evidence on the contrary."
  - FC: "This statement from Oatey is not applicable in this case, because as discussed above, the term 'ready for mounting' can and should be construed in a way that encompasses the preferred embodiment."
    - "Additionally, we note that Oatey is not a panacea, requiring all claims to cover all embodiments. … disclosed embodiments may be within the scope of other allowed but unasserted claims."
    - "during prosecution an applicant may have cancelled pending claims."
    - Unasserted or cancelled claims may provide "probative evidence" that an embodiments is not with scope of an asserted claim.
  - "a person of ordinary skill in the art would understand that a veneer was "ready for mounting" after statue removal even if some "finishing" operations still needed to be performed."
    - Color and shape must already be defined.

CLAIMS NOT LIMITED TO PREFERRED EMBODIMENT

- PSN (con't)
  - No literal infringement.
    - Because sprue must be removed after statue removal, the shape is not yet defined.
  - No infringement under the DOE because doing so would render the "ready for mounting" limitation meaningless."

CLAIMS SHOULD INCLUDE EMBODIMENTS IN THE SPECIFICATION

- Oatey Co. v. IPS Corp., 514 F.3d 1271 (Fed. Cir. 2008)
  - Invention: washing machine outlet boxes.
  - Claim: 1. A washing machine outlet box comprising a housing including a bottom wall, *first and second juxtaposed drain ports* in said bottom wall, and a common tailpiece for both of said drain ports extending from said bottom wall, ...
  - DC: Summary judgment of noninfringement.
    - Claims, correctly construed, exclude the embodiment shown in Figure 3.

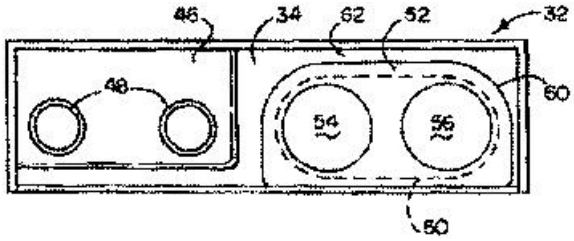


Fig. 2

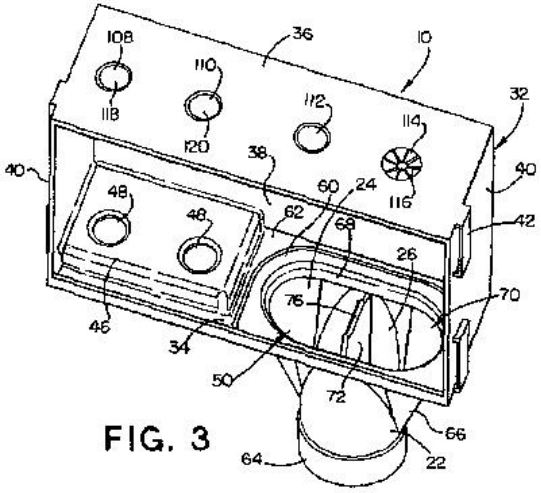


FIG. 3

CLAIMS SHOULD INCLUDE EMBODIMENTS IN THE SPECIFICATION

- Oatey (con't)
  - FC: Vacate and remand with modified claim construction.
    - IPS position: patent provides no definition and the ordinary meaning "requires separate and distinct ports . . . , and not merely a partition of an elongated opening [as depicted in Figure 3]."
    - "At least where claims can reasonably [be] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment, absent probative evidence to the contrary."
    - Here, the structure of Figure 3 was not disclaimed or subject to estoppel during prosecution.
    - "We conclude that the embodiment in Figure 3 was improperly excluded from the scope of claim 1. ... The recitation in claim 1 that the drain ports are in the bottom wall does not exclude the Figure 3 embodiment whereby the ports are formed using a dividing wall provided by the tailpiece. In Figure 3 the juxtaposed drain ports are defined by the perimeter of the oblong opening in conjunction with the dividing wall.

CLAIM CONSTRUCTION: RELIANCE ON ANOTHER CLAIM

- Monsanto v. Syngenta Seeds, Inc., 503 F.3d 1352 (Fed. Cir. 2007)
  - Claim 1 of '880 patent: 3-step process for generating an original RO fertile transgenic plant containing DNA that provides herbicide resistance.
  - Claim 4: A process comprising obtaining progeny from a fertile transgenic plant obtained by the process of claim 1 which comprise said DNA.
  - DC: No infringement.
    - Claim 4 is a dependent claim.
      - Adds fourth step of obtaining progeny.
    - Monsanto performed all of the steps of claim 1 prior to issuance of the patents. Performance of last step of claim 4 alone is not infringement.

CLAIM CONSTRUCTION: RELIANCE ON ANOTHER CLAIM

- Monsanto (con't)
  - FC: Affirmed.
    - Monsanto argued claim 4 was single-step process, not dependent claim.
      - Dependent language refers to novel starting material (fertile transgenic plant previously obtained using claim 1 process) of the new process in claim 4.
    - Determining dependency requires examination of new claim to see if refers to earlier claim and further limits that earlier claim.
    - "Claim 4 clearly references another claim, not simply a starting material. The claim might have used express language to clarify that it only invoked the product of the process in claim 1 as a starting material, but did not do so. Instead, the claim language reads claim 1 into claim 4."
    - Claim 4 "only stands if all three steps recited in claim 1 have been performed."

CLAIM CONSTRUCTION: RELIANCE ON ANOTHER CLAIM

- Monsanto (con't)
  - FC: Affirmed.
    - Rejected argument that claim 4 is product-by-process claim.
      - Even if claim 4 is a product-by-process claim, Syngenta would still have to perform the steps of the process of claim 1 to infringe.
      - "[c]laim 4 would only have meaning according to the incorporation of the limitations of claim 1."

CLAIM CONSTRUCTION: RELIANCE ON ANOTHER CLAIM

- Monsanto (con't)
  - FC: Affirmed.
    - Originally filed claim 30 (corresponds to claim 4) was "incontestably a dependent claim."
      - 30. The process of claim 23 *further comprising* (iv) obtaining progeny from said fertile transgenic plant of step (iii), which comprise said DNA." (emphasis added).
      - Upon amending that claim after prosecution closed, Monsanto explained that the claim amendments "[did] not introduce new matter and are allowable without further search or consideration."
      - Examiner accepted amendment as "directed to matters of form not affecting the scope of the invention."
    - "These two statements underscore that Monsanto did not change a four-step claim (original claim 30) into a single-step claim (claim 4) with its amendment.

DOUBLE PATENTING

- In re Metoprolol Succinate Litigation, 494 F.3d 1011 (Fed. Cir. 2007)
  - AZ's claim: metoprolol succinate (salt of metoprolol with succinic acid).
  - DC: Invalid based on double patenting with the '318 patent:
    - '318 claim" is directed to certain pharmaceutical compositions containing metoprolol succinate" and the '154 patent "broadly claims any pharmaceutical compositions containing metoprolol succinate,"
    - '154 patent is a genus of the species claimed by the '318 patent and not patentably distinct.

DOUBLE PATENTING

- Metoprolol Succinate Litigation (con't)
  - FC: Affirmed.
    - Two-part test: 1) construe claims and determines the differences; 2) determine whether the differences render the claims patentably distinct. A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.
    - "critical inquiry" remains whether later-filed claims define an obvious variation of the earlier-filed claims.
    - '154 claimed compound is an obvious variation of '318 claimed composition comprised of one compound of an enumerated list that includes the '154 claimed compound.

DOUBLE PATENTING

- Pfizer, Inc. v. Teva Pharms. USA, Inc., 518 F.3d 1353 (Fed. Cir. 2008)
  - Restriction requirement during prosecution
    - Compound claims (celecoxib) issued as '823 patent
    - Composition claims issued as '165 patent from divisional application
    - Method claims issued as '068 patent from CIP
  - DC: Infringement and not invalid for obviousness-type double patenting
    - § 121 protected the child patents (filed in response to restriction requirement) from being prior art against each other

DOUBLE PATENTING

- Pfizer (con't)
  - FC: Claims are invalid based on double patenting
    - § 121 explicitly refers to "divisional applications" only and patents issued on such applications
    - Purpose of § 121 was to eliminate the inequity from responding to the PTO's restriction requirement
      - "The need for the protection only existed when a divisional application was filed as a result of the restriction. If the section had included CIPs, which by definition contain new matter, the section might be read as providing the earlier priority date even as to the new matter, contrary to the usual rule that new matter is not entitled to the priority date of the original application. … If the drafters wanted to include CIPs within the protection afforded by section 121, they could have easily done so."
    - § 121 does not apply to the '068 patent and that the '165 patent may be used to invalidate the '068 patent

DOUBLE PATENTING

- Pfizer (con't)
  - FC: (con't)
    - Obviousness-type double patenting analysis:
      - construes "the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences."
      - Determine "whether those differences render the claims patentably distinct."
        - "A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim."
        - "claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use."
    - Double patenting is a question of law, which we review without deference.

DOUBLE PATENTING

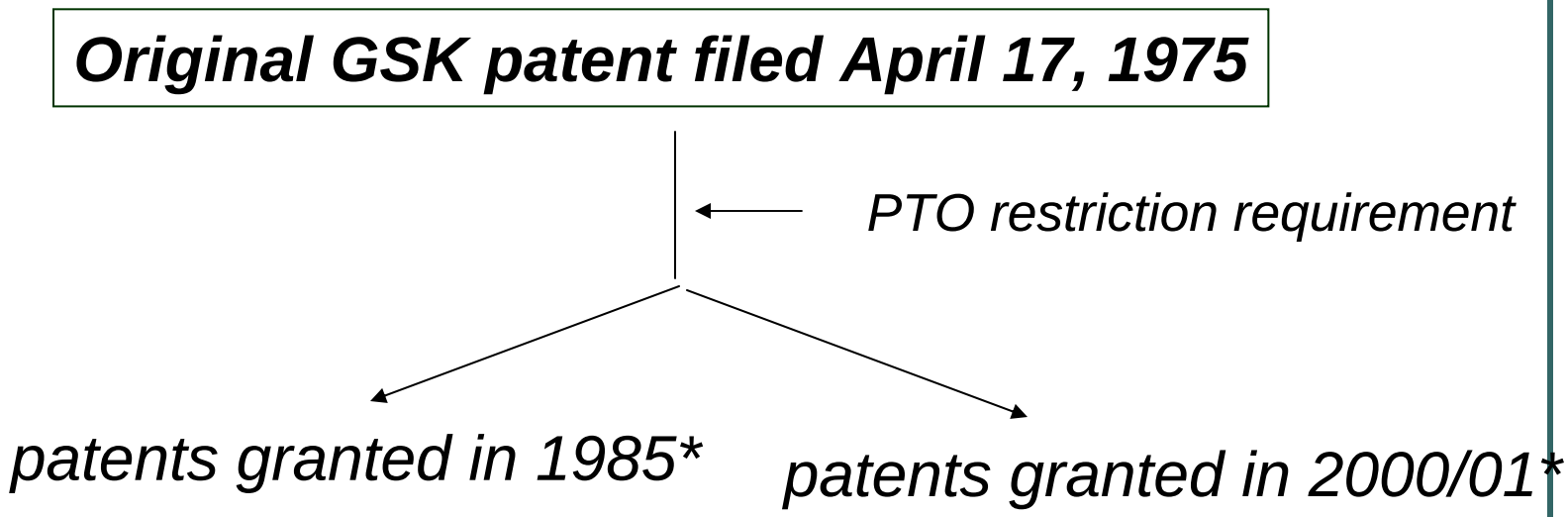
- Pfizer (con't)
  - FC: (con't)
    - relevant claims of the two patents are not patentably distinct
      - claims of the '068 patent merely recite methods of administering a "therapeutically-effective amount" of the compositions found the '165 patent.
      - the '068 patent merely claims a particular use described in the '165 patent of the claimed compositions of the '165 patent.
      - "The asserted claims of the '068 are therefore not patentably distinct over the claims of the '165 patent."

DOUBLE PATENTING

- Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373 (Fed.Cir.2003)
  - Infamous footnote
    - The distinctions between obviousness under 35 U.S.C. § 103 and nonstatutory double patenting include:
      - The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application;
      - Obviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not;
      - Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not.

DOUBLE PATENTING

- Geneva v. GSK (con't)



*No terminal disclaimers filed

DOUBLE PATENTING

- Geneva v. GSK (con't)
  - Patents relate to antibiotic clavulanic acid and its salts
    - 1985 patents
    - 2000/01 patents
  - During reexamination proceedings for the 2000/01 patents, PTO found common ancestry and a restriction requirement -> § 121 shield
  - DC: granted SJ that 2000/01 invalid due to double patenting
    - Original application did not show that the PTO issued a restriction requirement
    - No § 121 shield
    - One-way obviousness test because the applicant could have avoided the multiple filings

DOUBLE PATENTING

- Geneva v. GSK (con't)
  - Two issues
    - original application did not contain the "method of use claims" that later appeared
    - examiner did not issue a formal restriction requirement relating to the claims at issue in any document in the record

DOUBLE PATENTING

- Geneva v. GSK (con't)
  - § 121: "If two or more independent and distinct inventions are claimed in one application…
  - Judge Rader:
    - "This clause notes that the restriction requirement applies to a single application that formally claims two or more distinct inventions. This indicates that the earlier application must contain formally entered claims that are restricted and removed, and that claims to the second invention reappear in a separate divisional application after the restriction. The text of § 121 does not suggest that the original application merely needs to provide some support for claims that are first entered formally in the later divisional application."

DOUBLE PATENTING

- Geneva v. GSK (con't)
- FC: Affirmed
  - Not entitled to protection of § 121 where the principle of consonance is violated
    - "line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement must be maintained."
    - If the claims are changed "in material respects" from the claims subject to the restriction requirement, there is no consonance and § 121 will not provide any protection from a charge of double patenting
  - method of use claims were not entered in original application
    - if wanted benefit of § 121, applicants should have requested entry of the claims so that the PTO could issue a formal restriction requirement
    - prosecution history does not document a restriction requirement
  - "This record is deficient. Accordingly, § 121 does not shield the 2000/01 patents against the '720 patent."

DOUBLE PATENTING

- Geneva v. GSK (con't)
  - FC: (con't)
    - Interview Summary: "It was agreed that "simple beta-lactamase inhibition" composition claims, i.e., new claims 97 through 112, are proper in the present case but that method of use claims, that is a method of effecting beta-lactamase inhibition in humans and animals would not be proper in the present case and therefore an appropriate set of method of use claims corresponding to new claims 97 to 112 will be presented in Divisional Application, Serial No. 964,035."
    - Court found passage did not state that the examiner required restriction between those two sets of claims, nor did it state that any claims are patentably distinct

DOUBLE PATENTING

- Geneva v. GSK (con't)
  - FC: (con't)
    - 1985 patent claims are invalid for nonstatutory double patenting over the Crowley patent
      - claim subject matter that encompasses a substantial part of the subject matter of the Crowley claim
      - genus-species relationship makes the claims patentably indistinct, because the earlier species within the Crowley claim anticipates the later genus of the 1985 claims

DOUBLE PATENTING

- Geneva v. GSK (con't)
  - DC: Another 1985 patent invalid for nonstatutory double patenting over the Fleming patent
    - '720 patent claim differs only as a method of inhibiting beta-lactamase and in specifying the amount of compound necessary to inhibit the beta-lactamase
    - inhibiting beta-lactamase is an inherent property of potassium clavulanate, and therefore the Fleming claims anticipated the '720 claims.
  - FC: Affirmed. A person of ordinary skill in the art reviewing the disclosure of the Fleming patent would recognize a single use for potassium clavulanate, administration to patients to combat bacteria that produce beta-lactamase. The '720 patent simply claims that use as a method.

BEST MODE OF PRACTICING THE INVENTION: CAFC CASES NOW UP TO "8"

- **Failure to disclose preferred embodiment**
  - Northern Telecom, Inc. v. Datapoint Corp. (1990) (type of audio cassette)
  - Chemcast Corp. v. Arco Indus. (1990) (grommet material)
  - U.S. Gypsum Co. v. Nat'l Gypsum Co. (1996) (particular perlite)

- **Failure to disclose preference with material effect**
  - Spectra-Physics Inc. v. Coherent, Inc. (1987) (brazing material)
  - Dana Corp. (1988) (fluoride surface treatment)
  - Great Northern Corp. v. Henry Molded Products (1996) (diamond indentations)
  - Nobelpharma AB v. Implant Innovations (1998) (machining parameters)
  - Go Medical Industries Pty., Ltd. v. Inmed Corp. (2007) (catheters)

Discussion of Best Mode Law

- Best mode for the claimed invention must be satisfied at time of filing
  - Evaluated on claim-by-claim basis
- Specification must disclose the best mode of each inventor
- Two part test for compliance with best mode
  - Subjective test: did inventor(s) contemplate a mode for practicing an invention that was better than any other?
  - Objective test: is the disclosure in the specification sufficiency adequate to enable one skilled in the practice the best mode without undue experimentation?

BEST MODE OF PRACTICING THE INVENTION: FAILURE TO DISCLOSE PREFERENCE WITH MATERIAL EFFECT

- **Go Medical Industries Pty., Ltd. v. Inmed Corp. 471 F.3d 1264 (Fed. Cir. 2006)**
  - DC: granted summary judgment of invalidity as anticipated because Go was not entitled to claim the priority date of an earlier application
    - earlier patent application did not meet the requirements of 35 U.S.C. § 112
  - FC: Affirmed best mode violation.
    - Original 1979 application claims were drafted broadly to include a variety of medical instruments "for insertion into a body passage."
    - District court thus correctly concluded that Dr. O'Neil possessed a best mode—i.e., a sheath length of 1.5 cm.
    - 1979 application lacked sufficient disclosure to allow others to practice the best mode. Preferred length of 1.5 cm was not expressly disclosed. Dr. O'Neil even testified at his deposition that when drafting the 1979 application, he purposely "avoid[ed] any comment with relation to length" because he "was aware that numbers would become limiting themselves."
    - "[P]atent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue."
    - "one of ordinary skill would not know from reading the 1979 application that the preferred length between the stop member and the distal end of the sheath was 1.5 cm."

REMEMBER, CAFC INDICATED THAT TANGENTIALLY RELATED REBUTTAL IS "VERY NARROW"

- **Cross Medical Products Inc. v. Medtronic Sofamor Danek Inc., 480 F.3d 1335 (Fed. Cir. 2007)(per curiam), reh'g denied (2007)**
  - **"tangentially related" rebuttal is "very narrow."**
  - **"an amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim."**

REBUTTING FESTO PRESUMPTION

- Only three Federal Circuit cases have successfully invoked the tangential rebuttal, Primos Inc. v. Hunter's Specialties Inc. (2006); Insituform Tech. Inc. v. Cat Contracting Inc. (2004); and Regents of the University of California v. Dakocytomation California, Inc.(Fed. Cir. 2008).

REBUTTING FESTO PRESUMPTION

- Primos Inc. v. Hunter's Specialties Inc. 451 F.3d 841 (Fed. Cir. 2006), reh'g denied (2006)
  - "the amendment was merely tangential to the contested element in the accused device, and thus prosecution history estoppel does not apply to prevent the application of the doctrine of equivalents."
- Insituform Tech. Inc. v. Cat Contracting Inc. 385 F.3d 1360 (Fed. Cir. 2004)
  - ""there is no indication in the prosecution history of any relationship between the narrowing amendment and . . . the alleged equivalent in this case."

REBUTTING FESTO PRESUMPTION

- Regents of the University of California v. Dakocytomation California, Inc., 517 F.3d 1364 (Fed. Cir. 2008)
  - UC patents for methods of staining chromosomal DNA used to detect abnormalities associated with cancer and other disorders
  - DC: denied preliminary injunction and construed claims
    - patentees narrowed the scope of the "blocking nucleic acid" limitation during prosecution, therefore, appellants were barred from asserting that PNAs were an equivalent of a "blocking nucleic acid," and granted summary judgment of noninfringement under the doctrine of equivalents.

REBUTTING FESTO PRESUMPTION

- University of California v. Dakocytomation (con't)
  - FC partly overturned SJ of no infringement
    - "Because the prosecution history suggests that the patentees limited the claim to the blocking method at least in part to overcome the examiner's rejections, the patentees presumptively surrendered all equivalents of the 'blocking nucleic acid' limitation."
    - Patentees amended the claim in order to distinguish the invention over the prior art.
      - Prior art "did not concern targeting unique sequences, as does the claimed use of blocking nucleic acids. As such, the patentees argued that the invention would not have been obvious in view of the prior art because a person of ordinary skill would not have considered the use of blocking for the detection of unique sequences."

REBUTTING FESTO PRESUMPTION

- University of California v. Dakocytomation (con't)
  - FC partly overturned SJ of no infringement
    - "The prosecution history therefore reveals that in narrowing the claim to overcome the prior art rejections, the focus of the patentees' arguments centered on the method of blocking-not on the particular type of nucleic acid that could be used for blocking. Indeed, the "nucleic acid" limitation was never narrowed during prosecution and was not at issue in the office action rejecting the claims, the Examiner Interview Summary Record, or the patentees' remarks accompanying the amendment. Moreover, Dako does not dispute that none of the cited references concerned the type of nucleic acid that could perform the blocking, or mentioned the accused equivalent. We thus conclude that appellants have met their burden of showing that the amendment did not surrender the equivalent in question because the narrowing amendment was only tangential to the accused PNA equivalent, i.e., the peptide nucleic acid. Accordingly, the court erred in concluding that appellants are precluded by estoppel from asserting that Dako's products infringe under the doctrine of equivalents. Whether they do infringe is a question of fact for the trial court to consider on remand."

§ 101
"To Be or Not to Be"

- In re Bilski, 2008 WL 417680 (Fed. Cir. Feb. 15, 2008)
  - En banc hearing granted
  - Questions to be briefed:
    2) What standard should govern in determining whether a process is patent-eligible subject matter under section 101?
    3) Whether the claimed subject matter is not patent-eligible because it constitutes an abstract idea or mental process; when does a claim that contains both mental and physical steps create patent-eligible subject matter?
    4) Whether a method or process must result in a physical transformation of an article or be tied to a machine to be patent-eligible subject matter under section 101?
    5) Whether it is appropriate to reconsider State Street Bank & Trust Co. v. Signature Financial Group, Inc., … (Fed .Cir.1998), and AT & T Corp. v. Excel Communications, Inc., … (Fed.Cir.1999), in this case and, if so, whether those cases should be overruled in any respect?

§ 101
"To Be or Not to Be"

- In re Nuijten, 500 F.3d 1346 (Fed. Cir. 2007)
  - Claim on appeal: "A signal with embedded supplemental data…"
  - FC: Affirmed rejection.
    - "transitory forms of signal transmission such as radio broadcasts, electrical signals through a wire, and light pulses through a fiber-optic cable… are not directed to statutory subject matter."
    - "A transitory, propagating signal like Nuijten's is not a "process, machine, manufacture, or composition of matter." Those four categories define the explicit scope and reach of subject matter patentable under 35 U.S.C. § 101 ; thus, such a signal cannot be patentable subject matter."

§ 101
"To Be or Not to Be"

- In re Comisky, 499 F.3d 1365 (Fed. Cir. 2007)
  - Claim: "method for mandatory arbitration resolution regarding one or more unilateral documents comprising the steps of…"
  - FC: held that claims were "barred at the threshold by § 101" even though the subject of the appeal was not a § 101 rejection.
    - "mental processes-or processes of human thinking-standing alone are not patentable even if they have practical application."
    - "Comiskey's independent claims 1 and 32 seek to patent the use of human intelligence in and of itself. …Comiskey's independent claims 1 and 32 describe an allegedly novel way of requiring and conducting arbitration and are unpatentable."
    - "When an unpatentable mental process is combined with a machine, the combination may produce patentable subject matter, as the Supreme Court's decision in Diehr and our own decisions in State Street Bank and AT & T have confirmed. [citations omitted] While the mere use of the machine to collect data necessary for application of the mental process may not make the claim patentable subject matter, …, these claims in combining the use of machines with a mental process, claim patentable subject matter."

§ 102(b)

- Atlanta Attachment Co. v. Leggett & Platt, Inc., No. 07-1188 (Fed. Cir. February 21, 2008)
  - Invention: machine
  - DC: SJ of infringement
  - FC: Reversed.
    - Invention was on sale more than a year before patent filing.
    - Testing by Sealy Inc. on a prototype was not experimental use because Atlanta did not have control.
    - Atlanta presented Sealy with a commercial offer for sale and the protoype was reduced to practice.
  - ***Concurring opinion: post-Pfaff case law is confused and experimentation may have relevance to reductions to practice as well as to commercial offers for sale.***

Evaluation of Validity of Key Patents: Novelty and Obviousness

- Obviousness: Post-KSR era
  - Generally, more difficult to establish nonobviousness
    - Ordinarily "creative" skilled artisan
    - Use of known elements for known function to yield expected results
      - Look for evidence of unexpected benefit or result (e.g., synergism)
    - Obviousness to try: finite v. very large number of possibilities
    - Look for teachings away or disincentive to make a modification to arrive at claimed invention
  - KSR addressed motivation
  - Obviousness requires motivation and reasonable expectation of success
    - For "predictable" technologies (mechanical and electrical) could be easier to establish reasonable expectation
    - Chemistry and biology are well recognized as "unpredictable" technologies; reasonable expectation of success remains a viable argument in addressing obviousness issues

OBVIOUSNESS

- **KSR Intern. Co. v. Teleflex, Inc., 127 S.Ct. 1727 (2007)**
  - DC: claim invalid for obviousness under Graham and teaching-suggestion-motivation ("T-S-M") test
  - FC: Reversed. "T-S-M" analysis not strict enough.
  - At issue: Federal Circuit's ruling that a patent may not be found invalid for obviousness unless the prior art sets forth a "teaching, suggestion, or motivation" to combine the prior art teachings in the manner claimed in the patent.
  - USSC: Claim obvious. Reverse and remand.
    - Graham analysis reaffirmed.

OBVIOUSNESS

- **KSR (con't)**
  - USSC: "We begin by rejecting the rigid approach of the Court of Appeals. Throughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here. To be sure, Graham recognized the need for 'uniformity and definiteness.' Yet the principles laid down in Graham reaffirmed the 'functional approach' of Hotchkiss. To this end, Graham set forth a broad inquiry and invited courts, where appropriate, to look at any secondary considerations that would prove instructive." [internal citations omitted]

OBVIOUSNESS

- **KSR (con't)**
  - USSC: "Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents."

OBVIOUSNESS

- **KSR (con't)**
  - USSC: "The flaws in the analysis of the Court of Appeals relate for the most part to the court's narrow conception of the obviousness inquiry reflected in its application of the TSM test. In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under §103."

OBVIOUSNESS

- **KSR (con't)**
  - USSC: "[t]he analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." The Court of Appeals erred in "its assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem." "A person of ordinary skill is also a person of ordinary creativity, not an automaton."

OBVIOUSNESS

- **KSR (con't)**
  - USSC: "Obvious to try" may be sufficient.
    - "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely a product not of innovation but or ordinary skill and common sense."

OBVIOUSNESS

- **KSR (con't)**
  - USSC: Although "[a] factfinder should be aware . . . of the distortion caused by hindsight ...." "Rigid preventive rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it."

GRAHAM V. JOHN DEERE

- **Graham v. John Deere Co., 383 U.S. 1 (U.S. 1966)**
  - "[if] the difference between the subject matter sought to be patented and the prior art… would have been obvious at the time to a person skilled in the art, then the subject matter cannot be patented."
  - Satisfying § 103 is legal question with factual underpinnings:
    - the scope and content of the prior art;
    - differences between the prior art and the claims at issue; and
    - the level of ordinary skill in the pertinent art.
    - And "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., … may have relevancy."

OBVIOUSNESS

- PharmaStem Therapeutics Inc. v. ViaCell Inc., 491 F.3d 1342 (Fed. Cir. 2007)
  - •Two patents covering the collection, cryopreservation, and use of stem cells from umbilical cord blood
  - • "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so."
  - • Jury verdict: patents infringed and not invalid.
  - • DC: refused to overrule jury.
  - • FC: Reversed refusal and directed judgment of invalidity be entered.

OBVIOUSNESS

- **PharmaStem (con't)**
  - FC: (con't)
    - Reason to attempt to make the composition or device, or carry out the claimed process?
      - Yes, idea of using cord blood not new.
    - Reasonable expectation of success?
      - Pharmastem said no – declaration testimony that before the experiments leading to this patent, no one knew stem cells were in cord blood.
      - But specification represented that prior art disclosed stem cells in cord blood.

OBVIOUSNESS

- **PharmaStem (con't)**
  - FC: (con't)
    - "Given that the jury was legally required to find that that those of skill in the art would believe that cord blood contained … stem cells, the question before us is whether a reasonable jury could nonetheless have found the invention nonobvious. We conclude a reasonable jury could not have done so. While the inventors may have proved conclusively what was strongly suspected before…and while their work may have significantly advanced the state of the science …[the] experiments and the conclusions drawn from them were not inventive in nature. Instead, the inventors merely used routine research methods to prove what was already believed to be the case. Scientific confirmation of what was already believed to be true may be a valuable contribution, but it does not give rise to a patentable invention."

OBVIOUSNESS

- Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368 (Fed. Cir. 2006), reh'g denied (2007), on remand, June 19, 2007
  - Invention: clopidogrel bisulfate, enantiomeric active ingredient of Plavix®.
  - the prior art patent disclosed the racemate.
  - DC: Not obvious (and infringed and granted permanent injunction)
    - "mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole. Rather, a party alleging invalidity due to obviousness must articulate the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them."
    - "the prior art did not enable a person ordinary skill in the art to predict with a reasonable expectation of success whether one enantiomer would have better pharmaceutical properties than the racemate itself."

OBVIOUSNESS

- Sanofi (con't)
  - DC:
    - Pfizer v. Apotex (Fed. Cir. 2007) is distinguishable.
      - no structural features that would have guided sanofi chemists in avoiding or selecting any specific acid.
      - no prior art references specifically suggesting the properties of the enantiomer
      - "the unexpected success of the bisulfate salt of clopidogrel independently supports the conclusion of non-obviousness"

OBVIOUSNESS

- Sanofi (con't)
  - DC (con't):
    - Sanofi effectively rebutted a prima facie case of obviousness by "demonstrating that clopidogrel bisulfate – as a whole – possesses unexpected properties that could not have reasonably been viewed as a likely outcome of preparing the invention. …the wide range of possible outcomes and the relative unlikelihood that the resulting compound would exhibit the maximal increase in antiplatelet aggregation activity and the absence of neurotoxicity makes clopidogrel bisulfate non-obvious."

OBVIOUSNESS

- Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir. 2007), reh'g denied (May 21, 2007)
  - Invention: besylate salt of amlodipine (Norvasc®).
  - DC: Patent valid.
    - besylate salt of amlodipine was unexpectedly superior to the amlodipine salts of the prior art.
  - FC: Reversed.
    - Motivation to make amlodipine besylate from the prior art as a whole and from the nature of the problems encountered with the amlodipine maleate tablet formulations sought to be solved.

OBVIOUSNESS

- Pfizer (con't)
  - FC (con't):
    - One skilled in the art would have had a reasonable expectation of success.
    - No unexpectedly superior results
    - The basic compound was in the prior art
    - Salt: new way of delivering a known compound

OBVIOUSNESS

- Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350 (Fed. Cir. 2007)
  - Invention: pioglitazone marketed as diabetes drug, Actos®
    - Critical portion: the ethyl-substituted pyridyl ring.
  - Prior art TZD compound: a pyridyl ring with a methyl (CH) group attached to the 6-position of the ring.
  - DC: Not obvious.
    - Necessary to identify some reason that would have led a chemist to modify a known [even if structurally similar] compound in a particular manner to establish prima facie obviousness of a new claimed compound.

OBVIOUSNESS

- Takeda (con't)
  - FC: Affirmed.
    - Analyzed using four Graham factors
    - Situation was not one with "a finite number of identified, predictable solutions"
    - Alphapharm failed to show that a compound would have been selected as the lead compound and failed to show a reason existed to perform the necessary chemical modifications.
    - "[T]he prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation. Significantly, the closest prior art compound (compound b, the 6-methyl) exhibited negative properties that would have directed one of ordinary skill in the art away from that compound."
    - No reasonable expectation in the art that changing the positions of a substituent on a pyridyl ring would result in beneficial changes.
    - Pioglitazone exhibited unexpectedly superior properties over the prior art compound b.

OBVIOUSNESS

- Ortho-McNeil Pharms. Inc. v. Mylan Labs., Inc., 520 F.3d 1358 (Fed. Cir. 2008)
  - Ortho's patent claims topiramate (TOPOMAX®)
  - DC: claims not invalid for obviousness
  - FC: Affirmed
    - "this invention does not present a finite (and small in the context of the art) number of options easily traversed to show obviousness."
    - "the challenges of this inventive process would have prevented one of ordinary skill in this art from traversing the multiple obstacles to easily produce the invention in light of the evidence available at the time of invention."
    - Mylan's expert used hindsight – "Of course, this reasoning is always inappropriate for an obviousness test[.]"
    - "a flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis such as occurred in this case."
    - Objective evidence of nonobviousness supports conclusion.
      - "this evidence is not just a cumulative or confirmatory part of the obviousness calculus but constitutes independent evidence of nonobviousness.

MAY 3, 2007 USPTO MEMO RE EXAMINATION GUIDANCE POST-KSR

- No rigid application of “teaching-suggestion-motivation” test.
- “Therefore, in formulating a rejection under 35 USC § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.”

USPTO GUIDELINES

- "Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc," 72 Fed. Reg. 57,526 (Oct. 10, 2007)
  - Rationales and examples provided.
    - A. Combining prior art elements according to known methods to yield predictable results;
    - B. Simple substitution of one known element for another to obtain predictable results;
    - C. Use of known technique to improve similar devices (methods, or products) in the same way;
    - D. Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
    - E. ''Obvious to try''—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
    - F. Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;
    - G. Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

"CASE OR CONTROVERSY"

- MedImmune, Inc. v. Genentech, Inc., 127 S.Ct. 764, 166 L.Ed.2d 604 (2007)
  - Issue: Did the "actual controversy" requirement of the Declaratory Judgment Act require a patent licensee to terminate or be in breach of its license agreement before it can seek a declaratory judgment that the underlying patent is invalid, unenforceable, or not infringed?

"CASE OR CONTROVERSY"

- MedImmune (con't)
  - Facts: MedImmune-Genentech license agreement 1997
    - covered a then-pending patent application.
    - MedImmune to pay royalties on "licensed products."
    - December 2001, the application matured into the "Cabilly II" patent.
    - Genentech expressed expectation that MedImmune would pay royalties beginning March 1, 2002.
    - MedImmune paid royalties "under protest", believing that the Cabilly II patent was invalid, unenforceable, and not infringed.

"CASE OR CONTROVERSY"

- MedImmune (con't)
  - MedImmune filed DJ action
    - considered letter to be a clear threat to enforce the Cabilly II patent, terminate the 1997 license agreement, and sue for patent infringement if royalty payments not made.
  - DC: granted Genentech's motion to dismiss the DJ claims for lack of subject-matter jurisdiction.
    - Gen-Probe Inc. v. Vysis, Inc., 359 F.3d 1376 (2004): a patent licensee in good standing cannot establish an Article III case or controversy because the license agreement "obliterate[s] any reasonable apprehension" that the licensee will be sued for infringement.
  - FC: Affirmed.

"CASE OR CONTROVERSY"

- Medimmune (con't)
  - USSC: Reversed and remanded.
    - Aetna Life Ins. Co. v. Haworth, 57 S.Ct. 461 (1937): "case of actual controversy" in the [DJ] Act refers to the "Cases" and "Controversies" justiciable under Art. III.
    - Altvater v. Freeman, 63 S.Ct. 1115 (1943): licensee's failure to cease payment of royalties did not render nonjusticiable a dispute over validity.

"CASE OR CONTROVERSY"

- Medimmune (con't)
  - USSC (con't):
    - Federal Circuit's "reasonable-apprehension-of-suit test …conflicts with our decisions[.]"
    - Maryland Casualty Co. v. Pacific Coal & Oil Co., 61 S.Ct. 510 (1941): "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."
    - "[Medimmune] was not required, insofar as Article III is concerned, to break or terminate its 1997 license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed.

POST-MEDIMMUNE

- Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp., 482 F.3d 1330 (Fed. Cir. 2007), reh'g denied (June 20, 2007)
  - Facts:
    - Novartis listed 5 patents in Orange Book related to Famvir® (1 product patent, famciclovir, and 4 method of therapeutic use).
    - Novartis sued on product patent (pending in D. NJ).
    - Teva filed DJ of invalidity or noninfringement on remaining method patents.

POST-MEDIMMUNE

- Teva (con't)
  - DC: Dismissed Teva's DJ action for lack of subject matter jurisdiction.
    - relied on two-part declaratory judgment test for patent non-infringement .
      - ANDA DJ plaintiff must show both: (1) a "reasonable apprehension" of "imminent" suit by the patentee; and (2) activity constituting infringement or intent to infringe.
      - Teva could not show a "reasonable apprehension of imminent suit."

POST-MEDIMMUNE

- Teva (con't)
  - FC: Reversed, in light of Supreme Court's MedImmune decision.
    - Congress explicitly extended federal court DJ jurisdiction to ANDA paragraph IV disputes (35 U.S.C. § 271(e)(5)).
    - "In MedImmune, the Court re-affirmed the correct standard for determining a justiciable declaratory judgment action: 'Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'"
    - "We hold that under " all the circumstances" as found in this case, Teva has an injury-in-fact and therefore has a justiciable Article III controversy."

POST-MEDIMMUNE

- Teva (con't)
  - FC: (con't)
    - "While it is true that the suit on the [product] patent is a different 'case' than Teva's declaratory judgment action, Novartis created a present and actual " controversy" by choosing to sue under 35 U.S.C. § 271(e)(2)(A) on Teva's single act of infringement, thereby placing into actual dispute the soundness of Teva's ANDA and Teva's ability to secure approval of the ANDA. Thus, while Teva's declaratory judgment action and the pending [product patent] suit are different 'cases,' they arise from the same controversy created when Novartis listed its Famvir® patents in the Orange Book, Teva submitted its ANDA certifying all five Famvir® patents under paragraph IV, and Novartis sued Teva challenging the submission of Teva's ANDA…. In light of Novartis' pending suit on the same ANDA, this threat of litigation is a present injury creating a justiciable controversy.

POST-MEDIMMUNE

- **SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372 (Fed. Cir. 2007), reh'g denied (June 8, 2007)**
  - April 16, 2004 through Oct. 14, 2004 – cross-licensing discussions.
  - Aug. 27, 2004 meeting where ST's technical experts identified and discussed the specific claims of each patent and alleged that they were infringed by SanDisk. Also ST's vice-president stated: "ST has absolutely no plan whatsoever to sue SanDisk."
  - Oct. 15, 2004 SanDisk filed DJ.

POST-MEDIMMUNE

- **SanDisk (con't)**
  - DC: Dismissed SanDisk's DJ action for lack of subject matter jurisdiction.
    - SanDisk did not have an objectively reasonable apprehension of suit.
    - "SanDisk has presented no evidence that ST threatened it with litigation at any time during the parties' negotiations, nor has SanDisk shown other conduct by ST rising to a level sufficient to indicate an intent on the part of ST to initiate an infringement action."
    - the infringement analyses that ST presented to SanDisk did not constitute the requisite "express charges [of infringement] carrying with them the threat of enforcement."
    - totality of the circumstances did not evince an actual controversy because ST told SanDisk that it did not intend to sue SanDisk for infringement.
    - alternatively, even if it did have jurisdiction, court said it would exercise its discretion and decline to hear the case.

POST-MEDIMMUNE

- Sandisk (con't)
  - FC: Vacated and remanded
    - "The Supreme Court's opinion in MedImmune represents a rejection of our reasonable apprehension of suit test."
    - "Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do. … We hold only that where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights."

POST-MEDIMMUNE

- Sandisk (con't)
  - FC: (con't)
    - Facts establishing an Article III case or controversy supporting DJ jurisdiction:
      - ST sought license under its patents based on specific, identified activity by SanDisk.
      - During discussions, the experts liberally referred to SanDisk's present, ongoing infringement of ST's patents and the need for SanDisk to license those patents.
      - ST communicated to SanDisk that it had made a studied and determined infringement determination.

POST-MEDIMMUNE

- Sandisk (con't)
  - FC: (con't)
    - Facts establishing an Article III case or controversy supporting DJ jurisdiction:
      - SanDisk maintained that it could proceed in its conduct without the payment of royalties to ST.
      - These facts evince that the conditions of creating "a substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment" were fulfilled.
      - "SanDisk need not 'bet the farm,' so to speak, and risk a suit for infringement by cutting off licensing discussions and continuing in the identified activity before seeking a declaration of its legal rights."

POST-MEDIMMUNE

- Sandisk (con't)
  - FC: (con't)
    - What about statement that "ST has absolutely no plan whatsoever to sue SanDisk"?
    - "ST has engaged in a course of conduct that shows a preparedness and willingness to enforce its patent rights despite [its] statement. Having approached SanDisk, having made a studied and considered determination of infringement by SanDisk, having communicated that determination to SanDisk, and then saying that it does not intend to sue, ST is engaging in the kinds of ' extra-judicial patent enforcement with scare-the-customer-and-run tactics' that the Declaratory Judgment Act was intended to obviate."

POST-MEDIMMUNE

- Sandisk (con't)
  - FC: (con't)
    - DC's alternative grounds for dismissal: exercise of discretion.
    - FC: "Although the district court is given the discretion, in declaratory judgment actions, to dismiss the case, there are boundaries to that discretion."
    - "When there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity, in the usual circumstance the declaratory judgment is not subject to dismissal." Genentech v. Eli Lilly & Co., 998 F.2d 931, 937 (Fed.Cir.1993).

POST-MEDIMMUNE

- Sandisk (con't)
  - FC: (con't)
    - "Furthermore, the exercise of discretion must be supported by a sound basis for refusing to adjudicate an actual controversy."
    - In this case, alternative grounds noted in a footnote, without explanation.
    - "Given the change reflected in MedImmune …, we discern little basis for the district court's refusal to hear the case[.]"

POST-MEDIMMUNE

- Sony Electronics, Inc. v. Guardian Media Technologies, Ltd., 497 F.3d 1271 (Fed. Cir. 2007)
  - DJ actions filed
  - DC: dismissed for lack of subject matter jurisdiction
    - No expressly threat to sue.
    - No actions or correspondence amounted to an "implicit threat of immediate litigation."

POST-MEDIMMUNE

- Sony (con't)
  - FC: Vacate and remand to exercise discretion.
    - When DJ filed, actual controversy existed.
    - Guardian explicitly identified the allegedly infringing patents, the relevant claims of those patents, and the relevant allegedly infringing products. Accused identified the allegedly invalidating specific prior art references.
    - "[P]atentee's apparent continued willingness to engage in licensing negotiations does not prevent a plaintiff from maintaining a declaratory judgment suit."
    - district court used "reasonable apprehension of suit" test. "But that test, …, is the wrong test."

POST-MEDIMMUNE

- Sony (con't)
  - FC: Vacate and remand to exercise discretion.
    - District court concluded that appellants filed this litigation to improperly obtain a more favorable bargaining position in licensing negotiations, but that was not an abuse of discretion.
    - No affirmative evidence to suggest that appellants filed this suit in order to obtain a more favorable bargaining position or as an intimidation tactic in any ongoing license negotiations.
    - Not appropriate to draw any inference from appellants' decisions to file these lawsuits simultaneously.

INJUNCTIONS IN PATENT CASES

- **eBay v. MercExchange, 126 S.Ct. 1837 (USSC May, 15, 2006)**
  - Background
    - DC judgment of valid and infringed, awarded damages, but denied permanent injunction.
    - CAFC reversed in part, finding that District Court abused its discretion by denying permanent injunction.
      - "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances." 401 F.3d 1323, 1339 .
    - USSC vacated CAFC decision, CAFC remanded to district court for analysis consistent with 4-factor test (2006 WL 2036554 (July 6, 2006)(unpublished)).

INJUNCTIONS IN PATENT CASES

- **eBay (con't)**
  - USSC
    - Four-factor test for permanent injunction
      - irreparable injury;
      - remedies available at law are inadequate to compensate;
      - balance of hardships indicate warranted; and
      - public interest would not be disserved by a permanent injunction
    - Act of equitable discretion, reviewable on appeal for abuse of discretion.

INJUNCTIONS IN PATENT CASES

- **eBay (con't)**
  - USSC (con't):
    - "These familiar principles apply with equal force to disputes arising under the Patent Act. … Nothing in the Patent Act indicates that Congress intended such a departure. To the contrary, the Patent Act expressly provides that injunctions 'may' issue 'in accordance with the principles of equity.'"
    - "the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and … such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards."

INJUNCTIONS IN PATENT CASES

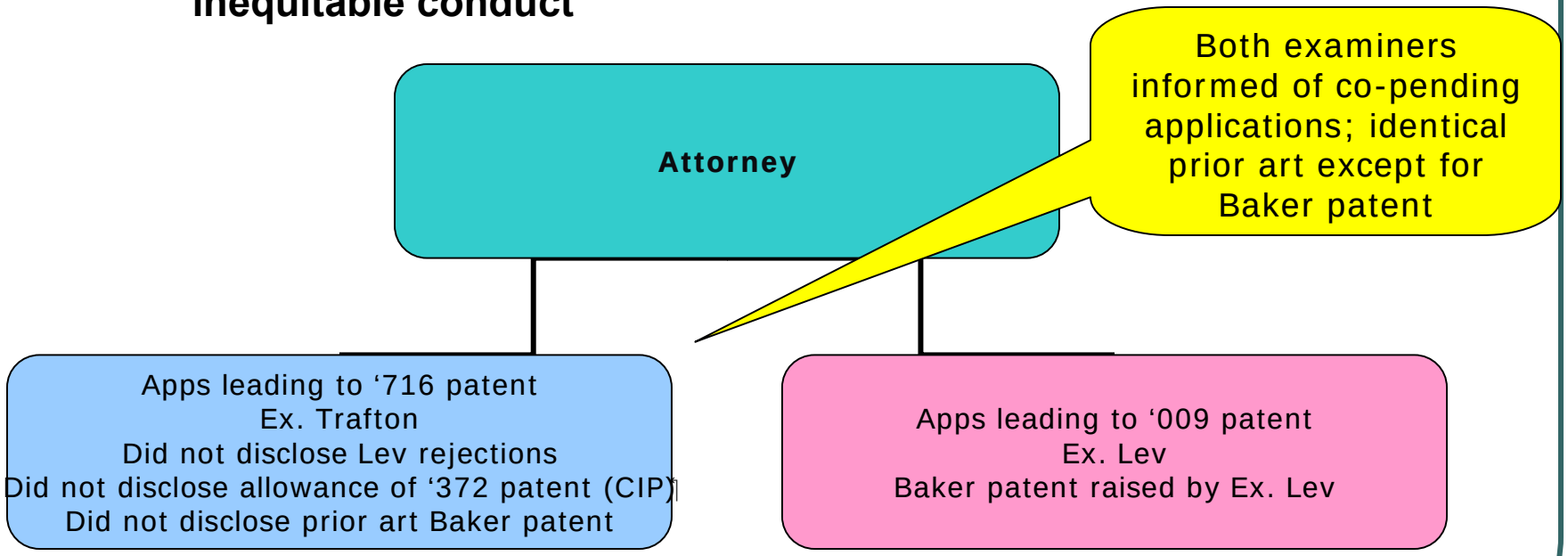
- **MercExchange, L.L.C. v. eBay, Inc., on remand, 2007 WL 2172587 (E.D. Va. July 27, 2007)**
  - **DC denied renewed motion for a permanent injunction against eBay.**
    - Patentee failed to show irreparable harm absent entry of an injunction.
    - Patentee is not practicing the patent, but rather is only trying to use the patent to extract royalties.
      - Patentee did not seek a preliminary injunction.
      - Patentee stated to the media that it only wanted a royalty.
    - Money damages would adequately compensate the patentee.
    - Equities did not demand the entry of a permanent injunction.
    - Award of enhanced damages would fairly compensate the patentee for the willfulness of the infringement.

INJUNCTIONS IN PATENT CASES

- **MercExchange v. eBay (con't)**
  - DC refused to stay case even though the PTO, on a subsequent reexamination, rejected all of the infringed claims.
    - eBay had not sought reexamination until after the jury returned its infringement verdict.
    - "to stay the post-trial proceedings … would create the incentive for adjudicated infringers to seek to circumvent an otherwise enforceable jury verdict by utilizing an alternate forum."
  - DC stayed further proceedings as to a second patent during the pendency of a reexamination since the circumstances were different for that patent.

NONDISCLOSURE OF PRIOR ART AND/OR PROCEEDINGS IN CO-PENDING APPLICATIONS

- **McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 2006 WL 1652518 (E.D. Calif. June 13, 2006)**
  - **DC: judgment declaring '716 patent unenforceable for inequitable conduct**



NONDISCLOSURE OF PRIOR ART AND/OR PROCEEDINGS IN CO-PENDING APPLICATIONS

- **Prior Art Baker patent disclosed in ‘009 but not ‘716.**
  - ***Material***
    - examiner's reliance on a prior art reference in ‘009.
    - limitations rejected also present in co-pending ‘716.
    - contradicts position Schumann took in prosecution of co-pending ‘716.

NONDISCLOSURE OF PRIOR ART AND/OR PROCEEDINGS IN CO-PENDING APPLICATIONS

- **Prior Art Baker patent disclosed in ‘009 but not ‘716**
  - ***Intent***
    - simultaneous withholding from one examiner while disclosing to another examiner supports an inference of deceptive intent.
    - no single “credible explanation” for failure to disclose the Baker patent to Examiner Trafton; no notes or records documenting that Schumann either reviewed Baker or made an affirmative decision that it was not material to the '716 prosecution.
    - “evidence overwhelmingly establishes that Mr. Schumann knew of the Baker patent, knew or should have known that it could be material to the '716 prosecution, and yet withheld that prior art from Examiner Trafton.”

NONDISCLOSURE OF PRIOR ART AND/OR PROCEEDINGS IN CO-PENDING APPLICATIONS

Rejections in '009 not disclosed in '716

- ***Materiality***
  - material rejections in one prosecution must be disclosed to the examiner in a copending case (Dayco, 329 F.3d 1358, 1368 (Fed.Cir.2003)).
  - MPEP § 2001.06(b): rejections are material if the rejected claims were "substantially similar" to the claims pending before Examiner.
  - "a reasonable examiner would find it important that (1) another examiner had rejected a claim limitation that he himself was considering, (2) that another examiner had done so based on prior art that was not before him, and (3) the applicant had acquiesced in the rejection and cancelled all claims that had been rejected based on that same prior art."
  - Also, contradicts Schumann's argument for patentability in the '716 prosecution.
  - disclosure of a copending application does not constitute disclosure of all information regarding that application.

NONDISCLOSURE OF PRIOR ART AND/OR PROCEEDINGS IN CO-PENDING APPLICATIONS

- **Rejections in '009 not disclosed in '716**
  - ***Intent***
    - Schumann was aware of the rejections.
    - inference arises from withholding information Schumann knew or should have known could be material to patentability.
    - "studied ignorance" "supports, rather than defeats, an inference of deceptive intent."

NONDISCLOSURE OF PRIOR ART AND/OR PROCEEDINGS IN CO-PENDING APPLICATIONS

- No disclosure of ‘372 patent in ‘716.
  - ***Materiality***
    - MPEP and Dayco: an applicant must disclose material “information ... as to copending United States applications....” MPEP § 2001.06(b).
    - allowed claims were “substantially similar” to the '716 claims.
    - conceivable that the '716 could have been rejected under the doctrine of obvious-type double patenting.
    - allowance was material and should have been disclosed.

NONDISCLOSURE OF PRIOR ART AND/OR PROCEEDINGS IN CO-PENDING APPLICATIONS

- No disclosure of ‘372 patent in ‘716.
  - ***Intent***
    - allowance was withheld with deceptive intent.
    - Schumann should have known that an allowance of identical claims might have been important to the '716 prosecution

NONDISCLOSURE OF PRIOR ART AND/OR PROCEEDINGS IN CO-PENDING APPLICATIONS

- *Equitable Balancing*
  - "A pattern of material nondisclosures, such as present here, weighs firmly in favor of unenforceability."
  - information "Schumann withheld from Examiner Trafton, both individually and as a whole, constitute matter a reasonable examiner would have been substantially likely to consider important while evaluating patentability of the '716 patent application, and there is no dispute that Mr. Schumann was aware of each piece of material information-the Baker patent, the '009 rejections, and the allowance of the '372 patent."

NONDISCLOSURE OF PRIOR ART AND/OR PROCEEDINGS IN CO-PENDING APPLICATIONS

- *Equitable Balancing (con't)*
  - circumstantial evidence here strongly supports an inference of deceptive intent
  - failure to provide a credible explanation for nondisclosures
  - "the court finds that each of the nondisclosures set forth above…individually would support judgment of unenforceability. For each, the showings of materiality and intent are high. … The record compels a finding that the '716 patent was procured through inequitable conduct, thereby rendering the '716 patent unenforceable."

NONDISCLOSURE OF PRIOR ART AND/OR PROCEEDINGS IN CO-PENDING APPLICATIONS

- **McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897 (Fed. Cir. 2007)**
  - FC: Affirmed McKesson's patent was unenforceable for inequitable conduct.
  - three McKesson "nondisclosures", individually and collectively, supported finding of inequitable conduct.
    1. another examiner discovered a prior patent during simultaneous examination of another application;
    2. rejections made in another application; and
    3. allowance of claims in another application that might have been a basis for a double patenting rejection.

NONDISCLOSURE OF PRIOR ART AND/OR PROCEEDINGS IN CO-PENDING APPLICATIONS

- McKesson (con't)
  - "[T]his [i]s not a case of mistake or negligence-the prosecuting attorney testified that he would make all the same nondisclosure decisions again if prosecuting the same applications today."
  - MPEP § 2001.06(b) (5th ed. rev.3, 1986): The individuals covered by 37 C.F.R. 1.56(a) have a duty to bring to the attention of the examiner ... information within their knowledge as to other copending United States applications which are "material to the examination" of the application in question.
  - MPEP § 2001.04 (5th ed. rev.3, 1986): "The term "information" is intended to be all encompassing[.]"

INEQUITABLE CONDUCT
HOW NOT TO PROSECUTE A PATENT

- Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223 (Fed. Cir. 2007)
  - Nilssen sued Osram for infringement of several patents pertaining to fluorescent light bulbs.
  - DC: all patents were unenforceable due to several independent findings of inequitable conduct.
  - FC: Affirmed on each of four separate instances of inequitable conduct.
    - Although Nilssen's defenses to inequitable conduct were "not per se unreasonable when considered in isolation[,]" in this case there was evidence of "repeated attempts to avoid playing fair and square with the patent system.]"
    - "Mistakes do happen, but inadvertence can carry an applicant only so far."

INEQUITABLE CONDUCT
HOW NOT TO PROSECUTE A PATENT

- Nilssen (con't)
  1. Improperly claiming ***small entity status*** (21 payments made)
     - "While a misrepresentation of small entity status is not strictly speaking [inequitable conduct] in the prosecution of the patent… it is not beyond the authority of a district court to hold a patent unenforceable for inequitable conduct in misrepresenting one's status as justifying small entity maintenance payments." (citing Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp., 351 F.3d 1139, 1146 (Fed.Cir.2003).
  2. Misclaiming ***priority dates*** during prosecution.
  3. Failing to disclose ***ongoing litigation*** to the examiner.
  4. Failing to disclose ***material prior art***.

NONDISCLOSURE OF NOTES DESCRIBING PRIOR ART

- **Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d 1229 (Fed. Cir. 2008)**
  - At issue: 4 Bayer patents relating to chimeric genes.
  - Bayer disclosed as prior art the "Barnes Abstract" and the "Barnes Poster" (presenting findings).
  - To overcome the Barnes reference, Bayer argued that Barnes failed to identify which Bt. toxin gene should be utilized and also fails to show that the fusion gene would work in plants.
  - Bayer did not disclose the notes taken by one of its employees, Dr. Celestina Mariani, regarding the Barnes Poster, nor the information contained in the notes.

NONDISCLOSURE OF NOTES DESCRIBING PRIOR ART

- **Monsanto Co. v. Bayer Bioscience N.V., (con't)**
  - DC: Unenforceable for inequitable conduct.
    - " [I]t is very obvious that the poster notes, if they were disclosed to the patent examiner, which they were not, would stand in sharp contradiction to the Bayer argument before the patent examiner."
    - "The Barnes notes by themselves withheld by Bayer from the PTO examiner, if disclosed, would establish a prima facie case of unpatentability of Bayer's claims under the '565 patent."

NONDISCLOSURE OF NOTES DESCRIBING PRIOR ART

- **Monsanto Co. v. Bayer Bioscience N.V., (con't)**
  - FC: Affirmed.
    - "Bayer's quotation of the sentence of the district court's opinion upon which it places primary reliance leaves out this important final clause of the sentence and, by failing to use ellipses, makes it appear that it has quoted the entire sentence. Such misquotation of text, whether inadvertent or purposeful, risks misleading this Court and cannot be of help to the client."
    - Undisputed evidence established that the arguments Bayer made to the Examiner to overcome the rejection based on the Barnes Abstract cannot be reconciled with the information about the Barnes Poster disclosed in the Mariani notes.
    - "The notes are therefore material under 37 C.F.R. § 1.56(2)(i). …There is a substantial likelihood that a reasonable examiner would have considered the Mariani notes important in deciding whether to allow the application to issue."

NONDISCLOSURE OF NOTES DESCRIBING PRIOR ART

- **Monsanto Co. v. Bayer Bioscience N.V., (con't)**
  - FC: Affirmed.
    - "We hold that the Mariani notes are material because they directly contradict arguments Bayer made to the PTO in support of patentability. We do not suggest that all internal documents of potential relevance must be submitted to the PTO as a matter of course. Rather, it is the particular circumstances that render the internal documents material in this case."
    - "That the Mariani notes may have required some explanation by Mariani to be fully understood does not alter their materiality. Rather, it is the information contained in them that makes the notes material and which Bayer, in light of its interpretation of the Barnes Abstract, had an obligation to communicate to the PTO. If an accompanying declaration by Mariani was necessary to make the notes legible, then the duty of candor would require disclosing both the notes and such a declaration."

NONDISCLOSURE OF NOTES DESCRIBING PRIOR ART

- **Monsanto Co. v. Bayer Bioscience N.V., (con't)**
  - FC: Affirmed.
    - Bayer's "attempts to establish subjective good faith sufficient to overcome the intent to mislead [were] not persuasive"
    - Meulemanns admitted that he was aware of the notes during the prosecution of the '565 patent, that he had discussed the content of the notes with Mariani, and that the notes would have been important to the Examiner if the notes contained reliable information.
    - Absent a credible reason for Meulemanns to have not understood the content of Mariani's notes after having discussed them with Mariani, the district court did not clearly err in inferring the requisite intent.
    - "Intent is easily inferred when, as here, an applicant makes arguments to the PTO that it knows, or obviously should have known, are false in light of information not before the examiner, and the applicant knowingly withholds that additional information."

INTENT TO DECEIVE

- **Aventis Pharma s.a. v. Amphastar Pharms., Inc., -- F.3d– (Fed. Cir. May 14, 2008)**
  - Patents are directed to a composition comprising low molecular weight heparins ("LMWHs").
    - Marketed as Lovenox®
  - Earlier Federal Circuit opinion held that the dosage of the prior art composition used in half-life comparisons with the patented composition was material information.
  - On remand, district court found intent to deceive.
  - FC: Affirmed patents unenforceable for inequitable conduct.

INTENT TO DECEIVE

- **<u>Aventis</u> (con't)**
  - Specification: the advantage of the claimed LMWHs as compared to heparin is that they exhibit a longer half-life, excellent bioavailability, higher rate of absorption, low clearance, resistance to degradation, increased residence time, and reduced sensitivity to serum factors.
  - Original claim 1:
    - A heterogeneous intimate admixture of sulfated heparinic polysaccharides, such sulfated polysaccharides having a weight average molecular weight less that that of heparin and which comprise from 9% to 20% of polysaccharide chains having a molecular weight less than 2,000 daltons and from 5% to 20% of polysaccharide chains having a molecular weight greater than 8,000 daltons, the ratio between the weight average molecular weight and the number average molecular weight thereof ranging from 1.3 to 1.6.

INTENT TO DECEIVE

- **Aventis (con't)**
  - Prior art reference EP '144
  - Aventis:
    - EP '144 does not expressly state that the mixture contains two types of polysaccharides, one with a MW less than 2,000 daltons and one with a MW greater than 8,000 daltons, nor does it state the number average/weight average MW ratio.
    - Evidence in the specification rebuts inherency, see Example 6.
      - Based on Example 6, the claimed LMWHs exhibit a significantly longer half-life than formulations prepared in accordance with EP '144.
    - Also no obviousness because EP '144 provides no suggestion to select the particular combination of oligosaccharide chains of specified lengths as claimed.

INTENT TO DECEIVE

- **Aventis (con't)**
  - In response to final rejection, amended claim:
    - A heterogeneous intimate admixture of sulfated heparinic polysaccharides, such sulfated polysaccharides having a weight average molecular weight less that that of heparin and said admixture comprising
      - from 9% to 20% of polysaccharide chains having a molecular weight less than 2,000 daltons
      - from 5% to 20% of polysaccharide chains having a molecular weight greater than 8,000 daltons, and
      - from 60-86% of polysaccharide chains having a molecular weight of between 2,000 and 8,000 daltons,
      - the ratio between the weight average molecular weight and the number average molecular weight thereof ranging from 1.3 to 1.6,
      - said admixture (i) exhibiting a bioavailability and antithrombotic activity greater than heparin and (ii) having an average molecular weight of between approximately 3,500 and 5,500 daltons.
    - "comprising" was changed to "consisting essentially of," before issuance.

INTENT TO DECEIVE

- **Aventis (con't)**
  - Uzan Declarations
    - claimed compounds have a longer half-life, compounds prepared in accordance with EP '144 fall outside the scope of the claims, and the compositions in EP '144 did not exhibit the unexpected properties of the claimed combination of MW chains.
    - half-life comparisons between the claimed compound and the EP '144 compound showing a statistically significant difference between the mean half-life for the claimed compound and that of the EP '144 compound.
    - Table III in which comparison data was recorded did not mention dosage.
  - Claims allowed.

INTENT TO DECEIVE

- **Aventis (con't)**
  - Aventis argued:
    - comparison of half-lives at different doses was reasonable because it was customary to compare the half-lives of different drugs at the "clinically relevant dose," i.e., the dose presenting the best efficacy-safety ratio, and the half-life comparisons were intended to show a difference in therapeutic properties, not a compositional difference;
    - comparison of half-lives at different doses was reasonable because half-lives are dose independent; and
    - failure to disclose was due merely to inadvertence.
  - DC on remand rejected arguments and held patents unenforceable due to inequitable conduct.

INTENT TO DECEIVE

- **Aventis (con't)**
  - On appeal, Aventis argued that Uzan's half-life comparisons were intended to show a difference in properties in response to the obviousness rejection under 35 U.S.C. § 103, not to demonstrate a compositional difference to address the anticipation rejection under 35 U.S.C. § 102
  - FC: Affirmed patents unenforceable.
    - The half-life comparisons were intended to address both the anticipation and obviousness rejections, and, to the extent that they were intended to address the anticipation rejection, the failure to disclose the dosage information evidenced intent to deceive.
    - Although the raw half-life data showed doses, "the data were provided in a very misleading way"

INTENT TO DECEIVE

- **Aventis (con't)**
  - Rader (dissent)
    - Negligence is not clear and convincing evidence of intent to deceive
    - "Dr. Uzan neglected to add the information. To make it clear, Dr. Uzan did not attempt to conceal data that were otherwise present. Rather he just submitted the study without adding to the disclosure. This omission, even if negligent, is hardly Kingsdown's culpable intent to deceive."
    - omissions and prosecution errors were committed by two individuals
    - "Dr. Uzan himself revealed the error. This candor is inconsistent with deceptive intent. He submitted all of the underlying data to the patent office with his second declaration on June 9, 1994. Thus, unlike the situation in Kingsdown, Dr. Uzan corrected the mistake before it resulted in an issued patent."
    - Before filing its infringement suit, Aventis filed a reissue application for the '618 patent. The patent reissued on June 14, 2005 with all of the original independent claims, but without example 6. The half-life data were apparently not even necessary for patentability."

NEW AUGUST 21, 2007 RULES: HIGHLY COMPLEX OR INCOMPREHENSIBLE?

- Imposes severe notification requirements on applicants with respect to certain "commonly owned," "within two months (any filing, priority or benefit dates)" applications and patents with at least one inventor in common.
- Imposes severe restrictions on numbers of claims in applications filed on or after Nov. 1, 2007 and some "No FAOM" applications filed before Nov 1, 2007.
  - Maximum of 25 claims, with no more than 5 independent claims.
- Impose severe restrictions on continuation applications.

GSK BRINGS PTO TO SCREECHING HALT

- Oct. 31, 2007: Judge Cacheris in the Eastern District of Virginia granted a preliminary injunction enjoining the PTO from implementing the Final Rules relating to, inter alia, the total number of requests for continued examination allowable, and the total number of claims that may be filed with the PTO.
  - Preliminary injunction granted.
    1) Likelihood of Success on the Merits: genuine possibility that GSK will succeed on issue of whether the Final Rules comport with the Patent Act and that Final Rules 78, 114, 75, and 265 exceed the plain language of Title 35 in limits the number of continuing applications.
    2) Irreparable harm to GSK if injunction is not granted: GSK will be unable to recover their losses if the Final Rules are ultimately determined to be invalid.
    3) Balance of hardships between the parties: although the hardship to the PTO is not nonexistent, the uncertainty and loss of investment suffered immediately by GSK tilts the balance of the hardships in their favor.
    4) Public interest: public interest is most served by continuing the status quo and granting the TRO.

GSK BRINGS PTO TO SCREECHING HALT

- April 1, 2008: Judge Cacheris granted GSK's motion for summary judgment and granted permanent injunction voiding the new rules.
  - "Final Rules are substantive in nature and exceed the scope of the USPTO's rulemaking authority under 35 U.S.C. § 2(b)(2)."
  - "the Court will grant summary judgment and void the Final Rules as "otherwise not in accordance with law" and "in excess of statutory jurisdiction [and] authority." 5 U.S.C. § 706(2).
  - 35 U.S.C. § 2(b)(2) empowers the USPTO to "establish regulations, not inconsistent with law," to "govern the conduct of proceedings in the Office," to "facilitate and expedite the processing of patent applications," and "govern the . . . conduct of agents, attorneys, or other persons representing applicants or other parties before the Office,"
    - "Section 2(b)(2) does not vest the USPTO with any general substantive rulemaking power."
    - "In addition, …the structure of Section 2(b)(2) makes it clear that the USPTO must engage in notice and comment rulemaking when promulgating rules it is otherwise empowered to make – namely, procedural rules."
    - "since 2005, Congress has debated and considered whether it should grant the USPTO substantive rulemaking authority but has declined to do so."

GSK BRINGS PTO TO SCREECHING HALT

- USPTO argued
  - "2+1 Rule and the 5/25 Rule fall within the reach of Section 2(b)(2) because they "govern the conduct of proceedings in the Office" by 'facilitat[ing] and expedit[ing]' the application process."
  - Final Rules constitute an exercise of "providing policy direction" to the Office, which the USPTO is permitted to do under 35 U.S.C. § 3(a)(2)(A).

- DC: "the balance of the case law in the Federal Circuit and the Supreme Court indicates that the [substantive-procedural] distinction exists,"
  - "Accordingly, the Court finds that Section 2(b)(2) does not permit the USPTO to promulgate substantive rules, and any rules that may be deemed substantive will be declared null and void."

GSK BRINGS PTO TO SCREECHING HALT

- USPTO's second argument:
  - if the substantive/procedural distinction matters, the Final Rules are only procedural in nature.

GSK BRINGS PTO TO SCREECHING HALT

- DC: "Despite the USPTO's arguments, the Court finds that the Final Rules are neither procedural rules nor rules relating to application processing that have substantive collateral consequences, but substantive rules that change existing law and alter the rights of applicants … under the Patent Act."
  - "The 2+1 Rule and the 5/25 Rule, … constitute a drastic departure from the terms of the Patent Act as they are presently understood."
    - Final Rule 78 and the hard limit it imposes changes existing law and deprives applicants of their valuable rights under 35 U.S.C. § 120 to an unlimited number of continuation and continuation-in-part applications as a matter of right. By so doing, it may also impact applicants' rights under Sections 102 and 103 and result in the denial of otherwise meritorious patents."
    - Final Rule 114 limiting RCEs based on application family is a clear departure from the plain language of 35 U.S.C. § 132, and significantly changes existing law and alters applicants' rights under 35 U.S.C. § 132 to an unlimited number of RCEs per application.
    - 5/25 Rule
      - Since 1938, the CCPA has consistently held that the Patent Act does not place any mechanical limits on the number of claims an applicant may file.
      - 5/25 Rule imposes a mechanical limit
      - the ESD requirement changes existing law and alters the rights of applicants under the current statutory scheme by shifting the examination burden away from the USPTO and onto applicants, and alters applicants' rights under Sections 102, 103, and 131.
      - "Applicants must now undertake new substantive responsibilities if they wish to file more than five independent or twenty-five total claims, which represents a significant departure from Section 112's rule of unlimited – though not unduly multiple – claims."

JUDGES

- Liptak, Adam, "In One Flaw, Questions on Validity of 46 Judges," The New York Times, May 6, 2008 (http://www.nytimes.com)
  - In 1999, the law changed so that the director of the Patent and Trademark Office (not the secretary of commerce), appoints APJ's.
  - According to John F. Duffy, Professor at the George Washington University Law School, there is a constitutional flaw in the new appointment process.
    - In particular, since 2000, 46 patent judges have been appointed by a government official without the constitutional power to do so.
    - "arguably invalidates every decision of the patent court decided by a three-judge panel that included at least one judge appointed after March 2000."

Thank You!

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