

Biotech Patent Prosecution Update

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Backdrop

Pressure points on PTO to get tough:

Item:

Council on Foreign Relations: 11/28/06

"Undue strengthening"

1. patents on forms of life, software
2. Bayh-Dole! Federal funds!
3. Fed. Circuit – not hostile enough – *e.g.*, *Madey v. Duke*
4. "lengthening" patent term 17  20

PTO should have "office of competition advocacy" to consider economic implications

Pressure points on PTO to get tough: (cont'd)

Item:

Brookings Institution: 12/4/06

Too many invalid patents

1. Get rid of the blanket presumption of validity – at least weaken
2. Tougher, optional more expensive exam by PTO
3. Extend presumption to reexamined or successfully litigated patents

Pressure points on PTO to get tough: (cont'd)

Items:

- Barner Speech at AIPLA
 - Increased number of cases taken by Supreme Court
- Apparent hostility to Federal Circuit
 - *KSR v. Teleflex* "gobbledygook"
 - Comments in dismissing *Metabolite*
- Recurrent suggestion for opposition procedure

Supreme Court Dismissal of *Metabolite*

Metabolite Laboratories v. Laboratory Corp. of America, decision by Fed. Cir. 2004 cert. granted, case dismissed, but gratuitous opinion rendered by Breyer, Stevens, Souter

Claim:

A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:

assaying a body fluid for an elevated level of total homocysteine; and

correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

Supreme Court Dismissal of *Metabolite* (cont'd)

They said:

If the Court were to uphold this vague claim, anyone could obtain a patent on any scientific correlation - - that there is a link between fact A and fact B - - merely by drafting a patent claiming no more than "test for fact A and correlate with fact B"... Claim 13 does no more than that. If it is upheld, CTI (Metabolite's licensor) would improperly gain a monopoly over a basic scientific fact rather than any novel invention of its own. The law is settled that no such claim should be allowed.

Supreme Court Dismissal of *Metabolite* (cont'd)

So: Screening tests would be suspect

A method to identify a compound to treat disease X which comprises determining whether a candidate compound binds to receptor Y whereby a candidate compound that binds receptor Y is identified as a compound useful to treat disease X.

Isn't this just the connection between X and Y?

Response by PTO – Proposed Rule Changes

1. Limitation on Continuations & Divisionals
2. Limitation on number of claims examined
3. Limitation on documents in IDS without further requirements

All overcomable by jumping through hoops.

Response by PTO – Proposed Rule Changes (cont'd)

Comments Submitted on CON/DIV

24 Bar associations and U.S. Department of Justice

65 Corporations and Universities

20 Law firms

228 Individuals

Comments on Claim Limitations

23 Bar associations & U.S. Justice & SBA

37 Businesses & Non-profits

10 Law firms

125 Individuals

Standards for Utility

Compounds *vs.* Methods of Use

Brana

(characterized
as utility)

Rasmusson

(characterized
as enablement)

But does this make sense?

Rasmusson Conundrum

How much evidence of efficacy must be available:

Time of filing? By later declaration?

In re Brana, 51 F3d 1650, 34 USPQ2d 1436

(Fed. Cir. 1995): declaration later, but there was no *prima facie* case by PTO

Rasmusson, et al., v. SmithKline Beecham, 413 F3d 1318,
75 USPQ2d 1297 – An interference
(Fed. Cir. 2005)

Casts some doubt

Rasmusson (cont'd)

Claim: Method to treat prostate cancer by administering finasteride.

In vitro activity: Inhibits enzyme “5 α R”
testosterone (T) \rightarrow dihydro testosterone (DHT)

DHT more potent than T as androgen

Other “5 α R” inhibitors – not selective – also bind
T receptor, so block T activity

Rasmusson (cont'd)

Nine continuations - first 1987
- last 1995

Prima facie case that skilled person would not accept assertion treatment works before 1995 application

- 5 α R inhibitors used were not selective
so could be inhibiting T, not DHT formation

Only after 8/94 is this made credible because third party reported at AUA meeting that finasteride works !

Rasmusson (cont'd)

Query – if evidence had been brought forward by *Rasmusson* after filing date (of which?) would that have entitled *Rasmusson* to all earlier dates?

Why should this (vs. 3rd party evidence) matter?

Rasmusson (cont'd)

Shift of burden of proof compared to *Brana* –
cites *In re Novak*, 306 F.2d 924, 134 USPQ 335
(CCPA 1962)

Precedent that *Brana* cannot change?

Slow release system for basic pharmaceuticals
through neutralization with carboxymethyl
dextran with some free carboxyl groups

In re Novak

- PTO found compound (acid + organic base) might not behave as individual components known to behave
- Court said: “when an applicant bases utility . . . On allegations of (this) sort . . ., unless one with ordinary skill in the art would accept those obligations as obviously valid and correct . . .” (the Examiner can ask for evidence).

Rasmusson (cont'd)

Does the prior art have to be enabling?

Rasmusson EP application published 10/5/88

SKB claims (1990 filing date) to essentially the same method are anticipated/made obvious by EP publication?

No requirement that prior disclosure show efficacy

Rasmusson (cont'd)

Holding: The EP 1988 publication is “enabled for purposes of anticipation”

Back to the Board: SKB anticipated?
Obvious?

Rasmusson 1995
Obvious?

Issue: does not enable using the invention.

Rasmusson (cont'd)

Impax Lab vs. Aventis (Fed. Cir. 2006)

Aventis' patent on riluzole to treat ALS anticipated by
earlier Aventis patents

"proof of efficacy not needed for enablement".

Utility / Enablement

Summary: For compounds utility standard not high

For method of use, "utility" standards very high

But compound claims are the more dominant.

Terminal Disclaimers and Extensions

Merck v. Hi-Tech now at Federal Circuit – can Merck extend a terminally disclaimed patent on glaucoma drug?

Put exclusion into TD

- Extensions for approval delays
- Extensions for PTO delays

Terminal Disclaimer Issue

Further, the owner does not disclaim any right to an extension of the term of any patent issuing from the instant application under 35 U.S.C. §§ 155-156 or adjustment of patent term pursuant to 35 U.S.C. § 154(b) or pursuant to any other subsequently enacted public law or act which provides for extension of term of a patent.

Other Thorns – How Careful do you Have to be writing those claims?

Phillips v. AWH Corp., 415 F3d 1303,
75 USPQ2d 1321 (Fed. Cir. *en banc* 2005)

No more dictionaries! Context counts.

Literal / dictionary *vs.* Contextual

Dictionary definition

Chef America v. Lamb-Weston, 358 F3d 1371,
69 USPQ2d 1857 (Fed. Cir. 2004)

Panel: Rader, Friedman, Schall

4,761,290

1. ... heating the resulting batter-coated dough to a temperature in the range of about 400° F. to 850° F. for a period of time ranging from about 10 seconds to 5 minutes to first set said batter and then subsequently melt said shortening flakes, whereby air cells are formed in said batter and the surface of said dough.

What does "to" mean?

Contextual definition

Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.,
347 F3d 1367, 68 USPQ2d 1857 (Fed. Cir. 2003)

Panel: Newman, Prost; Mayer dissenting

4,621,077

1. A method of treatment of urolithiasis and inhibiting bone reabsorption which consists of administering to a patient in need thereof an effective amount of 4-amino-1-hydroxybutane-1,1-biphosphonic acid.

Salts are included in this claim 1.

Contextual definition (cont'd)

North American Vaccine Inc. v. American Cyanamid Co.,
7 F3d 1571, 28 USPQ2d 1333 (Fed. Cir. 1993), cert. denied
114 S.Ct. 1645 (1994)

Panel: Lourie, Rader, Skelton

4,356,170

11. An antigenic-polysaccharide-protein conjugate wherein the polysaccharide and protein are covalently linked through a

CH₂-NH-protein

linkage to @terminal portion of the polysaccharide without significant crosslinking, said antigenic polysaccharide having a MW [molecular weight] above about 2,000.

"a" means just one

Whoops!

Pfizer, Inc. v. Ranbaxy, 457 F3d 1284 (Fed. Cir. 2006)

Make sure dependent claims are dependent.

Subject: Lipitor[®]

1. Atorvastatin or atorvastatin analog and pharmaceutically acceptable salts thereof
2. Compound of claim 1 which is atorvastatin
6. The hemicalcium salt of the compound of claim 2.

Claim 6 is invalid (§ 112, ¶ 4)

Inequitable Conduct

Ferring BV vs. Barr, 437 F3d 1181 (Fed Cir 2006)

Summary judgment upheld – inequitable conduct because interests of declarants concealed.

Purdue Pharma v. Endo, 438 F3d 1123 (Fed Cir 2006)

Remanded to find facts after upholding Summary Judgment for inequitable conduct in prior decision – implication "surprising" results were actually obtained

Pharmacia v. Par, 417 F3d 1369 (Fed Cir 2005)

Contradictory article not disclosed, no crossover to related application.

Procedural Background – *Ferring v. Barr*

Barr files ANDA with para. IV certification re: US 5,047,398

- non-infringement
- invalidity

Ferring & licensee Aventis filed suit §271(e)(2) SDNY
SJ: inequitable conduct – infringement not reached.

Ferring v. Barr (cont'd)

U.S. 5,047,398

Filed: 12/17/85 Issued: 9/10/91

Representative claim

6. A method for initiating antidiuresis comprising administering a gastrointestinally adsorbable, antidiuretically effective, amount of 1-deamino-8-D-arginine vasopressin to a human for absorption in the gastrointestinal tract of said human.

Ferring v. Barr (cont'd)

U.S. 3,497,491 as prior art

As anti-diuretic:

"1-deamino-8-D-arginine vasopressin" ... "may be used ... for the parenteral, peroral, intranasal, subcutaneous, intramuscular, or intravenous application."

Issue: meaning of peroral

Ferring v. Barr (cont'd)

- ◆ 4 declarations that "peroral" meant absorbed through the mouth
- ◆ rejected anyway
- ◆ BPAI reversed – new rejection: combination with a publication that this peptide is "slow to degrade"
- ◆ 5 declarations – combination does not suggest "gastrointestinal absorption"
- ◆ allowed

Ferring v. Barr (cont'd)

Problem: 4 of 5 declarants had connection with Ferring.
Disclosed only as to one of them (and this one was already known to the PTO).

Decision: Highly material

Actual evidence of intent to deceive (rare)
(Good review of law)

Declaratory evidence is never cumulative

Dissent by Newman

Purdue Pharma. vs. Endo

Claims: controlled release of oxycodone (OxyContin[®]) for pain require specified maximum and minimum plasma concentration at specified times after administration

"Surprisingly found" that only a 4-fold dosage range required in 90% of patients (as opposed to 8-fold range)

Purdue Pharma. vs. Endo (cont'd)

Procedural background:

- Endo files ANDA – para. IV certification
- Purdue sues on 3 Orange Book patents
- Bench trial SDNY – unenforceable and infringed
(because bioequivalent to Purdue)
- Fed. Cir. affirms
- Reheard and vacates/remands unenforceable finding and affirms infringement, but reverses claim construction

Purdue Pharma. vs. Endo (cont'd)

Issue: Implication of "surprisingly discovered"
4-fold vs. 8-fold range in 90% of patients
(more easily tolerated)

No specific assertion these were actual
results (vs. Hoffman-LaRoche)

Decision: Not high enough degree of materiality
automatically to find intent

Does not create a claim limitation
(no disavowal if not met)

Pharmacia v. Par

17-phenyl derivative of PGF for treating glaucoma

5,296,504 }
5,422,368 } both continuations of same patent

Terminally disclaimed with respect to each other.

Pharmacia v. Par (cont'd)

Procedural Background

- Par filed ANDA with para. IV certification
- Pharmacia sues (DCNJ) – Par admits infringement of both
 - Bench trial – asserts inequitable conduct
 - '504 OK and infringed
 - '368 unenforceable
- Fed. Cir. – affirmed

Pharmacia v. Par (cont'd)

Issue: Does the terminal disclaimer tie the patents so '504 is tainted also?

(one unenforceable claim in a patent renders all unenforceable)

Answer: No. (language of terminal disclaimer separates them)

Prosecution Issues

1. Pressure on PTO & negative attitude at the Supreme Court
2. PTO mantras & proposed rules
3. Utility & enablement / double-edged sword
4. Terminal disclaimers & extensions
5. Nitpicks on claim language
6. Inequitable conduct issues.