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Five Cases from the Last Two Years Likely to Have a Big Impact on Life Sciences IP

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October 25, 2019

Technical Minds. Legal Muscle.

V04 13954102 22OCT2019

Top Five Cases…

- #5: *Helsinn v Teva* (are public non enabling sales prior art ?)
- #4: *Amgen v Sanofi* (written description of antibody claims)
- #3: *U California v Broad* (obviousness *v*. enablement)
- #2: *Natural Alternatives v Creative Cpds* (eligibility of natural products)
- #1: *Vanda v Westward* (direct and induced "paper" infringement by ANDA applicants)

… and

- Emerging rules on the eligibility of method/process claims

#5: *Helsinn v Teva* (Sup. Ct. 2019)

Public, not enabling, sales are prior art - even after the AIA

- Post-AIA 35 U.S.C. §102(a)(1) (emphases added): A person shall be entitled to a patent unless . . . the *claimed* invention was …in public use, ~~or~~ on sale ~~in this country~~, *or otherwise available to the public before the effective filing date of the claimed invention.*
- Helsinn sold palonosetron 0.25 mg (the claimed invention) to MGI before the filing date
- Sales agreement was publicly announced, although no details of the dosage, 0.25 mg.
- *Pfaff v Wells* (S. Ct. 1998) requires two conditions for "on sale" 1) a sale or offer for sale and 2) invention ready for patenting
- Pre-AIA *Pfaff* case law has never required that a sale be enabling, only that it be public.
- The post-AIA phrase, "… or otherwise available to the public…" has not modified the *Pfaff* requirements.

4: *Amgen v Sanofi* (Fed. Cir. 2018)

The *Noelle* test for written description of antibodies *(a fully characterized antigen describes all antibodies)* has been gutted

- **Amgen claim**: An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following [15] residues: S153, I154, … or S381 … and wherein the monoclonal antibody blocks binding of PCSK9 to LDL[-]R.
- **CAFC**:
  - *Noelle* based on *dicta;* can't describe antibody by describing the antigen.
  - Correct test is *Regents v Lilly* (representative number of examples or structure-function relation)
  - Representativeness can be tested with after-arising embodiments and data.

3: *U California v Broad* (Fed. Cir. 2018)

The relation between obviousness and enablement is about to be tested

- **1st interference**: UC's earlier claims to CRISPR in any environment against Broad's later claims to CRISPR in eukaryotes
- **CAFC held,** no interference in fact: There was 103 motivation to do CRISPR in eukaryotes but no reasonable expectation of success (REofS)
- **2nd interference**: Later-allowed UC's claims to CRISPR in eukaryotes against the same Broad claims to CRISPR in eukaryotes
- **Broad has said**: Lack of REofS from the 103 ruling in 2018 forces conclusion that UC could not have a complete invention of CRISPR in eukaryotes without an actual reduction to practice
- **UC has said**: This confuses 103 standards(REofS) with 112 enablement (*i.e.*, *Wands* 112 unpredictability is *not* the same as 103 REofS)

2: *Natural Alternatives v Creative Cpds* (Fed. Cir. 2019)

Compositions containing natural products are not ineligible as a matter of law.

- **Claim 5 :** A composition [which is a dietary supplement or a sports drink] comprising: glycine; and… an amino acid selected from the group consisting of a beta-alanine [or derivatives]
- **CAFC** (Judge Moore): Claim is not ineligible solely on a motion to dismiss under Rule 12(c)
- **Patentee's proposed construction**: Beta-alanine addition to the human diet is not a natural food, it increases athletic performance, and is manufactured to be used over a period of time.
- Analogized to ***Chakrabarty*** (1980): A claim to a manufacture or composition of matter made from a natural product is not directed to the natural product where it has different characteristics and "the potential for significant utility."
- Distinguished ***Funk Brothers*** (1948): "… does not stand for proposition that any combination of ineligible subject matter is itself ineligible. The 'combination of bacterial species in *Funk* produce[d]... no enlargement of the range of their utility.' … Here… the claimed combination of glycine and beta-alanine *could have* synergistic effects allowing for outcomes that the individual components could not have."

1: *Vanda v Westward* (Fed. Cir. 2018)

Direct and induced "paper" infringement by ANDA applicant can be demonstrated by the proposed drug label

- **Claim:** Method of treating a patient comprising a) determining if the patient has CYP2D6 genotype and, if so, b) administering iloperidone at 12 mg/day or less.
- **CAFC**: "Drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, the ANDA itself dominates the analysis"
- "[Patentee] can satisfy its burden to prove the predicate direct infringement by showing that if the proposed ANDA product were marketed, it would infringe…The … proposed label "recommends" that physicians perform the claimed steps."

Emerging clarity on eligibility of method / process claims

- **Methods of testing without assessing are ineligible**
  - *Cleveland Clinic II* (2019) (Method of detecting MPO by a) obtaining sample and b) detecting MPO in the sample by immunoassay)
- **Methods of testing and assessing without significant post-assessment steps are also ineligible.**
  - *Athena v Mayo* (2019) (Method for diagnosing a disease related to Muscle Serine TK comprising detecting an epitope of MuSTK by radio-I immunoprecipitation, wherein its presence is indicative of the disease)
- **Methods of testing and assessing followed by significant post-assessment steps are eligible.**
  - *Endo Pharma v Teva Pharma* (2019) (Method of treating pain comprising a) providing oxymorphone, b) measuring creatinine clearance rate and, c) depending on the clearance rate, administering a given dose of oxymorphone)
- **Methods of directly treating a subject are not *per se* ineligible**
  - *Natural Alternatives v Creative Cpds* (2019) (Method of increasing anaerobic working capacity, comprising: a) providing, through a dietary supplement, an amount of beta-alanine sufficient to increase beta-alanylhistidine)

Emerging rules… (cont'd)

- **Methods of producing a tangible product are eligible**
  - *Rapid Litigation v CellZDirect* (2016) (Method of producing cryopreserved hepatocytes by double freezing and thawing)
- **A method of screening for drugs using non conventional tools has been held to be eligible.**
  - *AMP v USPTO v Myriad Genetics* (2012) (Method of screening by the use of eukaryotic cells transformed with the BRCA1 gene)
- **Even narrow claims that do not preempt a large field may be ineligible**
  - *Roche v Cepheid* (2018) (Method of detecting mycobacteria using very specific mutated primers)
- **Lack of eligibility may or may not be decided on a motion to dismiss, depending on the case's posture.**
  - Compare: *Athena v Mayo* (2019) (dismissed as ineligible on a 12(b)(6) motion, since no facts in dispute) with
  - *Natural Alternatives v Creative Cpds* (2019) (not dismissed on a 12(c) motion, since facts in dispute)
- **Claims based on a non obvious - even groundbreaking - invention may be ineligible**
  - *Myriad, Roslin, Ariosa v Sequenom*

Thank you!

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