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Top 10 Biotech / Pharma Cases In 2012

Bard Peripheral Vascular v. W.L. Gore & Assoc.

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Bard Peripheral Vascular v. W.L. Gore & Assoc.

- District Court: jury found patent was valid and willfully infringed; awarded lost profits, reasonable royalties; enhanced damages (two times the compensatory damages), attorneys' fees and non-taxable costs and ongoing royalty
- Federal Circuit initially affirmed the judgment of validity and willful infringement, as well as award of enhanced damages, attorneys' fees and costs, and an ongoing royalty
- Federal Circuit granted the petition for rehearing *en banc* and returned case to the original panel for reconsideration of the standard of review for willful infringement

Bard Peripheral Vascular v. W.L. Gore & Assoc.

- Federal Circuit held that the threshold determination of objective recklessness under the *Seagate* standard for willful infringement is a question of law to be decided by the trial court and subject to de novo review
  - where threshold determination of objective recklessness is dependent on purely legal questions (e.g., claim construction), determination should be made by the trial court
  - where threshold determination is based on fact questions (e.g., anticipation) or legal questions dependent on underlying facts (e.g., obviousness), ultimate determination should be made by the court, although the underlying fact questions may be sent to the jury

2012 WL 2149495 (Fed. Cir. June 14, 2012)

Exelixis v. Kappos

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Exelixis v. Kappos

- **Three Recent Decisions Address Impact of RCE on PTA**
- **Exelixis v. Kappos – (*Exelixis I*) E.D. Va. – Nov. 1, 2012 -** RCE filed after the 3-year application pendency date does not toll PTA
- **Novartis v. Kappos – D.D.C – Nov. 15, 2012 –** Adopts reasoning of *Exelixis I*
- **Exelixis v. Kappos (*Exelixis II*) E.D. Va. – Jan. 28, 2013 –** Rejects reasoning of *Exelixis I* – Filing of RCE tolls PTA, regardless when filed

Exelixis v. Kappos

- PTA – patent term adjustment
  - Time added to patent term to account for patent office and applicant delays in prosecution
- B Delay – Guarantee of no more than 3 year application pendency – PTA added for each day of additional pendency
  - Some exceptions, including if an RCE application filed during 3 year pendency
  - PTO took position that any time consumed by RCE is excluded from PTA, regardless of when RCE is filed

Exelixis v. Kappos

- Court in *Exelixs I* disagreed with PTO position
- Plain language of statute is clear and unambiguous
- Once the 3 year clock has run, PTA is to be awarded on a day to day basis, regardless of subsequent events
- The *Novartis* decision adopted the same reasoning

Exelixis v. Kappos

- District Court in *Exelixis II* disagreed with *Exelixis I* – "plain language" of statute produces "absurd results". Reasonable interpretation of statute supports conclusion that there is "no reason to treat RCEs differently based upon when they were filed

- PTO's regulation is reasonable conclusion as to proper construction of the statute (*Skidmore* deference)

- Once an RCE is filed, whether before or after 3 year clock has run, no further B-delay adjustment will be made to the patent term

Exelixis v. Kappos

- PTO appealed E*xelixis I* to Federal Circuit on Dec. 31, 2012
- If Exelixis I district court decision is upheld on appeal, could have significant impact on patent term
- Estimated that 10% of patents would be affected, and could add substantial PTA

Momenta Pharm. v. Amphastar

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Momenta Pharm. v. Amphastar

- H-W case regarding generic version of Lovenox® (enoxaparin)
- Momenta sued for infringement based on quality control batch
- Amphastar argued that its testing fell within the scope of the Hatch-Waxman safe harbor, 35 U.S.C. §271(e)(1)
- The trial court held that the safe harbor did not apply because it did not permit a generic manufacturer to continue in the otherwise infringing activity after obtaining FDA approval

Momenta Pharm. v. Amphastar

- Federal Circuit reversed and remanded
  - safe harbor not limited to submission of ANDA
  - statute applied to any use of a patented invention as long as the ***use was reasonably related to the development and submission of information under a federal law*** that regulated the manufacture, use, or sale of drugs
    - requirement to maintain records for FDA inspection satisfied the requirement that the uses be reasonably related to the development and submission of information to FDA

Appeal Nos. 2012-1062, -1103, -1104 (August 3, 2012)

Monsanto v. Bowman

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Monsanto v. Bowman

- Patent Exhaustion for “self-replicating” technologies”?
- Roundup Ready seeds, genetically altered to provide resistance to herbicide glyphosate (Roundup)
- Monsanto has patents covering the chimeric gene and plant cells including the gene
- Seeds self-replicate when planted as crops, and the genetic trait carries forward to each successive seed generation

Monsanto v. Bowman

- Monsanto requires that all sales of Roundup Ready seeds include a "Monsanto Technology Agreement"
  - Seed only for planting crop in a single season
  - Can't save any crop for replanting or supply to others
  - Farmer only licenses the seed for one crop season, does not own
- Agreement does permit selling crop to grain elevators as a commodity without restrictions on the subsequent sale of that seed
  - Commodity seed is a mixture of both Roundup Ready seeds and other seeds

Monsanto v. Bowman

- Bowman is a farmer who bought Monsanto seed and followed the terms of the Monsanto Agreement
- Bowman also bought commodity seed from a grain elevator for a “second crop” to avoid high price of Monsanto seed
- Much of the seed turned out to be Roundup Ready
- Bowman saved some of the crop for replanting and continued to purchase commodity seed
- Monsanto sued Bowman for patent infringement of the patent

Monsanto v. Bowman

- Bowman argued exhaustion of patent rights for the commodity seed that he bought –

  District Court found infringement, holding that the "first sale" exhaustion doctrine did not apply to the sale of soybeans that contained a patented trait by grain elevators or dealers to farmers, who then used them for planting

- The Federal Circuit affirmed the District Court, holding that "[a]pplying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder." Here, the grower has created a newly infringing article to which patent exhaustion does not apply

Monsanto v. Bowman

- Bowman had argued that under the Supreme Court *Quanta v. LGE* case, exhaustion applied to authorized sale of seeds as commodity and that downstream product of purchases from that commodity "substantially embodies" the same characteristics

- Supreme Court granted certiorari – Oct. 5 ,2012

  - Whether the Federal Circuit erred by (1) refusing to find patent exhaustion in patented seeds even after an authorized sale and by (2) creating an exception to the doctrine of patent exhaustion for self-replicating technologies?

Monsanto v. Bowman

- Oral argument held February 19, 2013
- Court's questioning suggested that it would uphold the Federal Circuit
- "Why in the world would anybody spend any money to try to improve the seed if as soon as they sold the first one anybody could grow more and have as many of those seeds as they want?" (Chief Justice Roberts)

Caraco v. Novo Nordisk

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Caraco v. Novo Nordisk

- Novo's Prandin® (repaglinide) was approved for three methods of treating Type II diabetes: monotherapy and two combination therapies
- Orange Book listed patent claimed only one of the combination therapies
- Caraco filed an ANDA – and Orange Book Use Code amended by Novo covered all approved uses – "treatment of type II diabetes"

Caraco v. Novo Nordisk

- Generic Caraco therefore was not able to “carve” out a non-infringing use, by a section viii statement
- Caraco attempted to use the statutory counterclaim provision to require the brand to correct its use code or delete patent information submitted by the brand, “on the ground that the patent does not claim … **an** approved method of using the drug”.

Caraco v. Novo Nordisk

- District Court granted Caraco summary judgment requiring Novo to reinstitute its former use code

- Federal Circuit reversed, reading the statute as requiring that the brand's patent does not claim *any* approved method of use. Since it does cover at least one here, the counterclaim was unavailable. In addition, statute does not reach "use codes", since they are not "patent information"

Caraco v. Novo Nordisk

- Supreme Court (Apr. 17, 2012): In a unanimous decision held:
- counterclaim statute can be used to reform overbroad Use Code to ensure that it does not foreclose generic marketing of non-infringing uses of the drug
- Construction of statute as a matter of statutory context
- Use codes do constitute "patent information"

FTC v. Watson

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FTC v. Watson

- Watson / Solvay settlement agreement for drug Androgel® (pay for delay)
- FTC sued Watson under Section 5 of the FTC Act, 15 U.S.C. § 45
- N.D. Ga dismissed FTC's claim for failure to state a claim:
  - reverse payments do not constitute anticompetitive behavior "so long as the terms of the settlement remain within the scope of the exclusionary potential of the patent, *i.e.*, do not provide for exclusion going beyond the patent's term or operate to exclude clearly noninfringing products, regardless of whether consideration flowed to the alleged infringer"

FTC v. Watson

- 11th Circuit affirmed (677 F.3d 1298)
  - "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."

FTC v. Watson

- Supreme Court granted certiorari on December 7, 2012
- Issue presented:
  - Whether reverse-payment agreements are *per se* lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held), or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held in *In re K-Dur Antitrust Litigation*)

In re K-Dur Antitrust Litigation (3d Cir. 2012)

- **The History:**
  - Schering settled with 2 ANDA filers who agreed to stay off market for certain time in exchange for payment/licensing terms
  - FTC action begun but dismissed by Administrative Law Judge
    - agreements included separate licensing terms that fell outside a simple "pay for delay" arrangement
  - FTC reversed the ALJ's determination
    - found "direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry" and that this agreement "unreasonably restrain[ed] commerce"
  - Schering appealed in the Eleventh Circuit, which reversed FTC

In re K-Dur Antitrust Litigation (3d Cir. 2012)

- **The Case:** antitrust actions filed by several private plaintiffs (drug wholesalers/retailers), which were consolidated in D. N.J.
  - **District Court:** granted summary judgment for the pharmaceutical defendants
  - **Third Circuit:** reversed and remanded holding that a fact finder should "treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade." This presumption can be rebutted by showing that the payment "(1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit."

In re Antor Media Corp.

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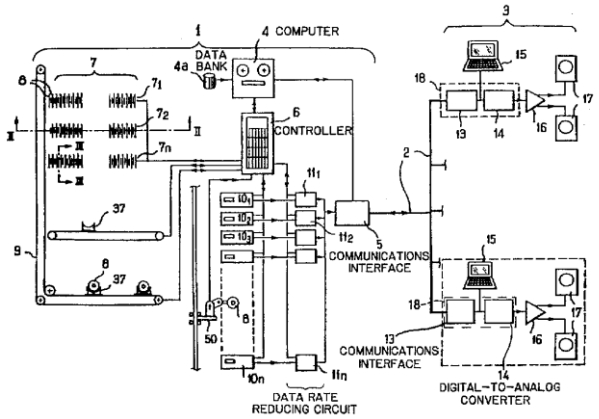
In re Antor Media Corp.



- The Federal Circuit "logically extends" the presumption of enablement to all prior printed publications, regardless of source of provenance (not only for prior patents and published patent applications)
  - citing *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003): "both claimed and unclaimed materials disclosed in a patent are presumptively enabling"

In re Antor Media Corp.

- During prosecution, Examiner can make a *prima facie* case of anticipation; the burden then shifts to applicant to submit rebuttal evidence of non-enablement

- Implications – non-patent literature includes unlimited speculation; although may be rebuttable, will increase costs and time for prosecution

Akamai Tech., Inc. v. Limelight Networks, Inc.
McKesson Tech., Inc. v. Epic Systems Corp.

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Akamai Tech., Inc. v. Limelight Networks, Inc. McKesson Tech., Inc. v. Epic Systems Corp.

- On August 31, 2012, the Federal Circuit issued one *en banc* decision that addressed two cases on the questions of joint/direct infringement

Akamai Tech., Inc. v. Limelight Networks, Inc.

- **Patent:** methods for delivering web content by placing content on a number of "replication servers" and having web browsers access the content by being directed to those server pages

- **Defendant:** didn't modify content providers' web pages; instead, instructed users how to do so

- **District Court:** no infringement because Limelight's customers performed one of the steps of the claimed method

Akamai Tech., Inc. v. Limelight Networks, Inc.

- The original Federal Circuit panel found no infringement:
  - "[J]oint liability may be found when one party 'control[s] or direct[s]' the activities of another party." 629 F.3d 1311, 1317 (Fed. Cir. 2010)
  - "[W]hat is essential is not merely the exercise of control or the providing of instructions, but whether the relationship between the parties is such that acts of one may be attributed to the other." *Id*. at 1319
  - "[A]s a matter of Federal Circuit law that there can only be joint infringement when there is an agency relationship between the parties who perform the method steps or when one party is contractually obligated to the other to perform the steps." *Id*. at 1320.
  - No substantial evidence supported a finding that Limelight's customers perform any of the steps of the claimed method as agents for Limelight; the contract does not obligate the customers to perform any of the method steps; instead, it "merely explains that the customer will have to perform the steps if it decides to take advantage of Limelight's service." *Id.* at 1321

McKesson Tech., Inc. v. Epic Systems Corp.

- **Patent:** electronic communication between patients and healthcare providers, whereby portions of defendant's software permitted patients to access their healthcare records directly from physicians

- **Defendant:** software did not perform *any* of the steps of the method; rather, performance of the steps of the patented method was divided between the patients and healthcare providers

- **District Court:** no infringement because patients (not Epic's customers) performed one of the steps of the claimed method

McKesson Tech., Inc. v. Epic Systems Corp.

- The original Federal Circuit panel found no infringement because (1) no party could be considered a direct infringer of the patent and (2) liability for inducing infringement is not actionable because there is no underlying direct infringement

Akamai Tech., Inc. v. Limelight Networks, Inc. *McKesson Tech., Inc. v. Epic Systems Corp.*

- *Akamai* rehearing question:
  - If separate entities each perform separate steps of a method claim, under what circumstances would that claim be directly infringed and to what extent would each of the parties be liable?
- *McKesson* rehearing questions:
  - If separate entities each perform separate steps of a method claim, under what circumstances, if any, would either entity or any third party be liable for inducing infringement or for contributory infringement?
  - Does the nature of the relationship between the relevant actors—e.g., service provider/user; doctor/patient—affect the question of direct or indirect infringement liability?

Akamai Tech., Inc. v. Limelight Networks, Inc. *McKesson Tech., Inc. v. Epic Systems Corp.*

- The Court held that a party may be liable for induced patent infringement (under 35 U.S.C. §271(b)), where the act of infringement is accomplished by a single actor, or through multiple actors having no agency or other relationship to the inducing party that would render the inducing party "vicariously" liable for direct patent infringement
- The Court remanded both the *Akamai* and *McKesson* cases for determinations of whether there was induced infringement
- The Court explicitly avoided any determination as to whether the separate actors might somehow be liable collectively for direct patent infringement (under 35 U.S.C. §271(a))

Ass'n for Molecular Pathology v. Myriad Genetics

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Ass'n for Molecular Pathology v. Myriad Genetics

Myriad Patent:

- Product claims directed to isolated DNA, cDNA, and fragments for BRCA1 and BRCA2 (mutations in the BRCA genes correlate with increased risk of breast / ovarian cancer):
    - An isolated DNA coding for a BRCA1
    - polypeptide, said polypeptide having an
    - amino acid sequence set forth in
    - SEQ ID NO: 2

Ass'n for Molecular Pathology v. Myriad Genetics

Myriad's Patent:

- Method claims directed to "analyzing" and "comparing" the isolated genes with those of a patient:
  - For example, Claim 1 of U.S. Patent No. 5,709,999 claims:

> A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises *analyzing* a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or *analyzing* a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1

Ass'n for Molecular Pathology v. Myriad Genetics S.D.N.Y (March 2010)

- Product Claims not patent eligible (§ 101)
  - isolated DNA falls under "product of nature" exception
  - isolated BRCA DNA not "markedly different" from naturally existing BRCA1/2

- Method Claims not patent eligible (§ 101)
  - claims directed to "analyzing" and "comparing" invalid under "machine-or-transformation" test (*Bilski*) – mental processes independent of physical transformations
  - claim directed to "comparing" cell growth rates "arguably recites certain transformative steps" but transformative steps are "nothing more than preparatory, data gathering steps to obtain growth rate information"

Ass'n for Molecular Pathology v. Myriad Genetics Federal Circuit

- Product Claims: Reversed; found claims patent eligible "Because isolated DNAs … have a markedly different chemical structure compared to native DNAs"

- Method Claims: Affirmed that claims directed to methods of "comparing" or "analyzing" gene sequences were not patent eligible because they claimed only abstract mental processes

Ass'n for Molecular Pathology v. Myriad Genetics

- On December 6, 2011, the ACLU petitioned the Supreme Court for cert asking the Court to consider (among other things) the issue of whether human genes are patentable
- The Supreme Court vacated and remanded for reconsideration in light of the *Mayo* decision
- The Federal Circuit reached the same conclusion (by a 2-1 majority) regarding patent eligibility for the method and DNA claims
- On November 30, 2012, Supreme Court granted cert limited to patent eligibility of human genes
- Oral argument set for April 15, 2013

Ass'n for Molecular Pathology v. Myriad Genetics

- The Federal Circuit posed the issue as addressing the patent eligibility of three categories of isolated DNA molecules:

  (i) containing the entire BRCA1 and BRCA2 genes,

  (ii) shorter molecules with as few as fifteen nucleotides corresponding to DNA sequence that occurs in the BRCA genes, and

  (iii) cDNA molecules corresponding to BRCA1 and BRCA2

Ass'n for Molecular Pathology v. Myriad Genetics

- Both J. Moore (concurring) and J. Bryson (dissenting) seemed to raise questions regarding the patent eligibility of claims to the entire BRCA1 and BRCA2 genes.
  - J. Moore considered these to be a "more difficult issue," but patent eligible because they had "truncations (with different ends) [than] naturally occurring DNA found as part of the chromosome in nature, are not naturally produced without the intervention of man."
  - J. Bryson did not find these patent eligible. In his opinion, the question was "whether an individual can obtain patent rights to a human gene." The process of extracting these genes, though it may be difficult, did not impart patent eligibility.

Ass'n for Molecular Pathology v. Myriad Genetics

Implications:

- Method claims: include "transformative" step
- Product clams: claim "isolated" not "purified" products; include claims to cDNA if possible
- Revisit pending/new applications and existing patents

Mayo Clinic v. Prometheus Laboratories

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Mayo Clinic v. Prometheus Laboratories

- The Federal Circuit found a claim related to optimizing dosage based on metabolite levels in a patient's blood, to be patent eligible – using machine or transformation test.
- Supreme Court granted cert, vacated and remanded in consideration of *Bilski* (machine or transformation not an exclusive test)
- Federal Circuit again found claims patent eligible
- Issue before the Supreme Court:
  - Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, when well-known methods used to administer prescription drugs and test blood may involve transformations of body chemistry

Mayo Clinic v. Prometheus Laboratories

- The patent claims methods for:
  - "administering" a drug that provides 6-TG to a subject;
  - "determining" the levels of the drug's metabolites, 6-TG and/or 6-MMP, in the subject; and
  - the measured metabolite levels are then compared to predetermined metabolite levels, "wherein" the measured metabolite levels "indicate a need" to increase or decrease the level of drug to be administered so as to minimize toxicity and maximize efficacy of treatment

Mayo Clinic v. Prometheus Laboratories

- The Federal Circuit had found that this claimed method met the "transformation" prong of *Bilski*
  - "When administering a drug such as AZA or 6-MP, the human body necessarily undergoes a transformation. The drugs do not pass through the body untouched without affecting it." 581 F.3d at 1346
  - The determining step is also transformative and central to the claimed methods because "[d]etermining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation, for those levels cannot be determined by mere inspection." *Id*.

Mayo Clinic v. Prometheus Laboratories

- A unanimous Supreme Court disagreed in a March 20, 2012 decision - found all claims patent ineligible
  - "The patent claims at issue here set forth processes embodying researchers' findings that identified [] correlations [between metabolite levels and drug dosage] with some precision."
  - "[T]he steps in the claimed processes (apart from the natural laws themselves [the correlations]) involve well-understood, routine, conventional activity previously engaged in by researchers in the field."
  - To transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature and add the words "apply it"

Mayo Clinic v. Prometheus Laboratories

- The Supreme Court's analysis of the claims
  - **"administering"** - simply refers to the relevant audience … doctors who treat patients with thiopurine drugs
  - **"determining" -** tells the doctor to determine the level of the relevant metabolites in the blood, by any process
  - **"wherein clause"** - simply tell a doctor about the relevant natural laws…
  - Combining these steps does not add anything to the "laws of nature" that each embody

Mayo Clinic v. Prometheus Laboratories

- Implications
  - Biological transformations don't count under the machine or transformation test
  - Claim relying on law of nature must do more than simply say "apply it" (adding well-known element insufficient, need an "inventive step") – transform process into inventive application of a formula
  - Discovery is not invention – can't preempt use of natural laws or inhibit their use

Mayo Clinic v. Prometheus Laboratories

- PTO Interim Guidelines – July 2012 (also adopted at MPEP 2106.01, Rev. 9, Aug. 2012)

- Is claim directed to process? If yes -
- Does claim focus on law of nature, or naturally occurring relation or correlation? If yes -
- Does claim include additional element/steps that integrate natural principle into the claimed invention such that it is practically applied and amounts to "significantly more" than the principle itself? If yes -
- Claim is patent eligible

Top 10 Biotech/Pharma Cases In 2012

1. Mayo (patentable subject matter)
2. Myriad (patentable subject matter)
3. Akamai / McKesson (divided infringement)
4. In re Antor Media (enabling prior art)
5. FTC v. Watson / In re K Dur Litigation (pay for delay)
6. Caraco v. Novo Nordisk (use codes)
7. Monsanto v. Bowman (exhaustion)
8. Momenta (271(e)(1) safe harbor for post approval activity)
9. Novartis / Exelixis (patent term adjustment)
10. Gore (willful infringement)

FISH & RICHARDSON

Thank You!

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