Spring 2013

Biotech Patent Law – Attack Outline

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1. SUBJECT MATTER ELIGIBILITY
   1. **Basic premise** – Anything that is new and useful can be patented
      1. § 101 – “Any new or useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof…”
      2. *Chakrabarty* – “Anything under the sun that is made by man”
   2. **Judicial exceptions** – Natural phenomena, Laws of nature, Abstract ideas
   3. **Cases**
      1. **Business Methods and Algorithms**
         1. *CLS Bank* (*En banc* Fed. Cir.) – Certifying question about whether or not algorithms are patentable
         2. *State Street* (Fed. Cir.) – Holding that there is no business method exception
         3. *In re Allapat* – Software is patentable so long as it is tied to a machine
         4. *In re Bilski* (2010) – Machine or Transformation Test is only a useful clue – Invalidated patent on hedging in the commodities industry
      2. **Historical**
         1. *O’Riley v. Morse* (1854) – Invalidated claims reading onto any use of electromagnetism to print characters at a distance
         2. *Funk Brothers* (1948) – Invalidated patent on mutually non-inhibiting nitrogen fixing bacteria as exploiting a natural phenomenon of the bacteria
         3. *Chakrabarty* (1980) – GM microorganism for cleaning up oil spills
            1. Distinct “name, character, and use”
            2. Created bacterium is markedly different than what is found in nature
            3. Dissent: Argument that Congress already considered biological materials in the Plant Patents
         4. *Benson* (1972) – Invalid computer algorithm for converting binary coded decimals with a computer – “Mental Steps”
         5. *Flook* (1978) – Invalid computer algorithm for adjusting alarm limits with a computer in the petroleum industry – Can’t make unpatentable subject matter patentable based on the draftsman’s art
            1. Concerns about insignificant post-solution activity
         6. *Diehr* – Patentable use of a computer algorithm as part of a system to create superior rubber products
      3. **Diagnostic**
         1. *Labcorp v. Metabolite* (2006) – Patent on measuring folate to determine B-12 deficiency by assaying blood for homocysteine metabolite (correlated with deficiency)
            1. Dismissed as improvidently granted – Breyer dissent foreshadows *Mayo*
         2. *Classen v. Biogen* (Fed. Cir. 2011) – Method of screening patients to determine optimal immunization schedules
            1. FC Held that anything that uses the blood of a human being and transforms it satisfies MOT test for § 101
            2. GVR in light of *Bilski*
         3. *Mayo v. Prometheus* (2012) – Invalidated patent on diagnostic method correlating metabolites of thiopurine drugs (6-thioguanine) with treatment outcomes
            1. Concerns about meaningless pre and post-solution activity – well-understood, routine, conventional activity
            2. When those steps as a whole add nothing significant beyond the sum of their parts taken separately – it does not transform unpatentable natural correlations into patentable applications of those correlations
            3. Identifies a patient population and tells doctors to “apply it”
            4. Criticism that the court is importing concepts from §§ 102, and 103 into § 101
      4. ***Myriad***
         1. Lourie Majority – Isolated DNA is patentable subject matter because it necessarily (not) requires breaking covalent bonds – different in name, character and use – composition of matter is distinct from a law of nature
         2. Moore Concurring – cDNA/primers are patentable subject matter; while isolated DNA should not be, in light of reliance on PTO practice, it should
         3. Bryson Dissenting – Isolated DNA is not patentable because they are not materially different from native genes – The patents read on millions of possible combinations, many of which are unknown
         4. Dreyfus argues that the level of incentive needed to spur diagnostics is much lower than the level necessary to spur therapeutics
         5. Consider DC opinion (Judge Sweet) arguing from perspective that DNA is information, not a chemical compound
   4. **Policy**
      1. § 101 as a cost filter?
         1. Concern that natural laws are the building blocks of science – necessary to help further innovation
      2. Co-equal to §§ 102, 103?
      3. *Prometheus* creates concerns about personalized medicine
         1. Old drugs that were thought to be ineffective are found to work fine on particular patients within a specific treatment window – can’t get a new patent on the use
2. UTILITY
   1. **Generally**
      1. § 101 – Invention must be “new and useful” to be patentable
      2. “Patent is not a hunting license” (*Brenner*)
   2. **Cases**
      1. *In re Fisher* (Fed. Cir. 2005) – Invalidated patent on ESTs when patentee had no idea what genes they identified. Patent claimed several generic uses for ESTs.
         1. Rejects microscope analogy – Microscope has a specific utility
         2. **Specific Utility** – Utility that is specific to the subject matter claimed
         3. **Substantial Utility** – Utility that defined a *presently available* “real world” use
         4. Commercial success can be a factor
         5. Rader dissenting: like not allowing patent on a microscope or other research tool
      2. *Brenner v. Manson* (1966)
         1. No patents on compounds that have no known utility
         2. Patent cited only general uses for steroids, but steroids are unpredictable
         3. Failed argument based on structural similarity to other steroids
      3. *In re Brana* – Demonstration of utility in a mouse model is sufficient for demonstrating utility in humans (but see written description and enablement)
3. **ANTICIPATION**
   1. Question of fact
   2. **Rule** – Anticipation requires a single prior art reference to disclose either expressly or inherently each element of a claimed invention 🡪 mapped on element-by-element
      1. “That which infringes if later anticipates if earlier”
   3. **Product by Process Claims** – Allows inventor to claim novel products that resist definition by anything other than the process by which they are made
      1. **Relevance** – Consider product by process claims for proteins that require unknown post-translational modifications in order to be functional
      2. *Abbott v. Sandoz* (Fed. Cir. *en banc* 2008) – Overrules *Scripps*, adopts *Atlantic Thermoplastic*
         1. Abbott was licensee of patent to a crystalline form of Omnicef produced by acidifying a solution maintained at room temp
         2. Generic manufacturer used a different process
         3. Holding: Product by process claim **is not infringed** by a product made by a different process
         4. *Scripps* (overruled by *Abbott v. Sandoz*) – Product is not limited to the specific product as produced by that process
         5. *Atlantic Thermoplastic* (Fed. Cir. 1992) – Holding that process terms serve as limitations in determining infringement
      3. *Amgen v. Hoffman La Roche* (Fed. Cir. 2009)
         1. Patent on recombinant EPO (product by process
         2. Prior art claimed purified EPO
         3. Holding
            1. For **infringement**, in product by process claims, the focus is on the **process of manufacture** as much as the product itself (must prove it is made by the same process)
            2. For **anticipation**, for product by process claims, the focus is on the **product itself** THEREFORE things that come earlier can anticipate, but don’t necessarily infringe if later
   4. **Inherency**
      1. Some molecules have properties that necessarily exist, but that are otherwise unknown at the time the original molecule is discovered – Not patentable later
         1. Property must be present 100% of the time
      2. *In re Cruciferous Sprout* (Fed. Cir. 2002) – Invalidated patent on picking specific sprouts at specific times to maximize their anti-cancer properties as inherently anticipated by farming practice
      3. *Smithkline v. Apotex* (Fed. Cir. 2005)
         1. Patent on Paxil® (SSRI) claiming the hydrate – generic generated the anhydrous
         2. Two issues
            1. FC held that anytime you generate the anhydrous, you inherently produce *some* hydrate
            2. Once a product is fully described in the art, future claims are precluded even if made by a new process
         3. Fed. Cir. *en banc* invalidates hydrate patent as inherently anticipated
      4. *Eli Lilly v. Barr* (Fed. Cir. 2001)
         1. Patent #1: Prozac compound
         2. Patent #2: Method of treating anxiety with Prozac
         3. Patent #3: Method of preventing serotonin reuptake with Prozac – Holding anticipated by patent on method for treating anxiety
      5. *Schering v. Geneva* (Fed. Cir. 2003) – Invalidated later patent on Claratin® metabolite as anticipated by original Claratin® patent
      6. *Elan v. Mayo* (Fed. Cir. 2002)
         1. Prior art discloses mutation in APP which can be used to produce animals with amyloidosis, but did not disclose animals
         2. Issue: Whether this prior art was sufficiently enabling or inherently anticipates
      7. *In re Seaborg* (1964) – Holding that claim on 95Am is not anticipated by Fermi reactor even though it necessarily produces trace amounts since that production was accidental, not discovered, and not useful as the Americium could not be purified
4. OBVIOUSNESS
   1. ***Graham v. John Deere***
      1. *Graham* Factors
      2. Secondary Considerations
   2. **Obvious to Try**
      1. *In re Deuel* (Fed. Cir. 1995)
         1. Isolated and purified Heparin Binding Growth Factor (HBGF)
         2. Purified and isolated DNA, created cDNA
         3. Prior art disclosed partial sequences of this protein, and standard techniques for producing the rest
         4. Holding: Reaffirms the principle that existence of a general method for isolating and producing cDNA is irrelevant in obviousness about whether prior art enabling a person to get the rest renders the subsequent claim on the sequence obvious
            1. Some argument that the prior art actually taught away (that the protein would only be present in the brain)
         5. Criticized in *KSR* (2007)
      2. *In re Kubin* (Fed. Cir. 2009)
         1. Prior art patent on NAIL protein teaches that the DNA and protein sequence can be obtained with conventional methods, lays out the protocol
         2. **Rule** – Obvious to try requires a reasonable expectation of success
            1. Huge concerns about hindsight bias
            2. When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, PHOSITA has good reason to pursue known options within his or her technical grasp.
            3. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense
      3. *Otsuka Pharmaceuticals v. Sandoz* (2012) – Denied Cert. – Question of hindsight bias when an antipsychotic drug is discovered from a family of drugs, none of which were known to have antipsychotic effects 🡪 Non obvious
         1. No motivation to combine/reasonable expectation of success
         2. **“Lead compound analysis”**
5. ENABLEMENT
   1. *In re Wands* (Fed. Cir. 1988) – Enablement Factors
      1. Breadth of the claims
      2. Nature of the invention
      3. State of the prior art
      4. Level of one of ordinary skill
      5. Level of predictability in the art
      6. Amount of direction provided by the inventor
      7. Existence of working examples
      8. Quality of experimentation needed to make or use the invention based on the content of the disclosure
   2. *Novo Nordisc v. Genetech* (Fed. Cir. 1997)
      1. Standing for the proposition that the patent can’t simply identify a problem then state that PHOSITA would know how to solve it
   3. *Amgen v. Chugai* (Fed. Cir. 1991)
      1. EPO patent, claim had some variables in the DNA sequence
         1. Patent claimed recombinant proteins with “EPO-like effects”
      2. Holding: Insufficient enablement – Making a handful of analogs whose activity is not ascertained does not enable all proteins with “EPO-like effects”
         1. Scope of the claim and scope of the disclosure must coincide – **Commensurate**
         2. Stems from problem that biological arts tend to be unpredictable
            1. Observation that a change in a single amino acid may have a profound effect on the end result
   4. Concern – Fighting for broad claim construction can result in invalidating you patent at a later stage of trial
      1. *Monsanto v. Syngenta* (Fed. Cir. 2007)
         1. “Plant cells” – Chimeric plant gene with promoter encoding sequence that confers glyphosphate resistance
         2. Patent covered all plant cells, but those cells could be divided into monocots and dicots, and only dicots were enabled
         3. They pursued a claim construction that encompassed both and lost the patent for lack of enablement
6. BEST MODE
   1. *Amgen v. Chugai* – Adequate written description and availability of starting materials is sufficient for best-mode requirement, deposit also would satisfy
   2. AIA – Best mode is no longer a basis for finding of invalidity
7. WRITTEN DESCRIPTION
   1. **Generally**
      1. § 112 – “The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any PHOSITA to make and use the same, and shall set forth the best mode contemplated by the inventor… of carrying out the invention”
   2. **Genus/Species**
      1. *In re Ruschig* (CCPA 1967)
         1. Application disclosing a chemical genus
         2. Court declines to limit the claim to the specific species disclosed
         3. Note: This is a penumbra situation – you can look at specific disclosed species and recombine preferred constitutents
      2. *Carnegie Mellon v. Hoffman La Roche* (Fed. Cir. 2008) – Description of a single species is insufficient to claim the genus in unpredictable arts
      3. **Policy**
         1. How many species must be disclosed in order to claim the genus?
         2. If a genus is disclosed, what is necessary to also claim the species?
         3. FOCUS on the properties of the genus and the specific species
   3. **DNA**
      1. *Fiers v. Revelle* (Fed. Cir. 1993) – Lourie, J.
         1. 3 groups in competition to find a specific DNA sequence
         2. Issue: At what point have you **conceived** a particular DNA sequence?
         3. Holding: Must actually describe the sequence, not just a method of isolation
      2. *Regents of the University of California v. Eli Lilly* (Fed. Cir. 1997)
         1. Transformed microorganism, claims include cDNA encoding for human insulin or vertebrate insulin generically, but only disclosure is for rat insulin
         2. Holding: Having one species is insufficient for a generic genus or other species claim
      3. *Enzo v. Genprobe* (Fed. Cir. 2002)
         1. Anomalous case holding that limited functional descriptions of a DNA sequence are allowable, but must be some kind of correlation between structure and function
         2. Holding: Written description and best mode can be satisfied by deposit
         3. **Deposit requirement** – Satisfies the enablement gap when claiming bacteria that is difficult to produce
            1. *See In re Argodoulas* (1970) – Approved use of biological deposits to satisfy enablement (But ask what you have actually enabled, i.e. DOE)
            2. Consider: Deposit of a naturally occurring, but purified bacteria for producing an antibiotic (then patent method of purification)
         4. Rader Dissenting – There is no written description requirement except for priority under § 120 (divisional/continuation)
   4. **Pathways**
      1. *Rochester v. Searle* (Fed. Cir. 2004)
         1. Inventors discovered COX-2 pathway and got coverage – superior to general COX inhibition because of GI problems stemming from chronic COX-1 inhibition
         2. Patent on “Inhibiting COX-2 enzyme with a COX-2 inhibitor” – i.e. not in possession of a specific COX-2 inhibitor despite recognition of the superiority of the pathway
         3. When patent issued, patentee did not have a selective COX-2 inhibitor
         4. Holding: Invalid for lack of written description
         5. *See also Ariad* (NF-κB claiming 3 generic pathways for drug approaches invalid for lack of written description – note that some claims would be infringed by sunlight striking the skin)
   5. **Antibodies**
      1. *Noelle v. Lederman* (Fed. Cir. 2004) – Written description for antibody is satisfied by description of the antigen
      2. *Centocor v. Abbott*
         1. “Gotcha” case – continuation in part claiming TNF-α antagonists
         2. Abbott has fully humanized monoclonal that inactivates TNF-α
         3. Centocor (J&J) sued for infringement of their similar antibody
         4. Issue: Does the patent enable making human antibodies if it describes a method for producing a chimera?
         5. Holding: Description of the chimera was insufficient to claim the humanized
            1. Note: Humanized antibody technology did not exist until after Centocor’s earliest priority they were trying to claim
      3. *Centicorp* (636 F.3d 1341)
   6. **Policy**
      1. Reissue/divisionals – ensure that earlier application has sufficient WD to encompass the later application
8. HATCH-WAXMAN ACT AND SAFE-HARBOR
   1. **Generally**
      1. Pre-Hatch Waxman ~11% generic prescriptions, not 70%+ due to mandatory substitution
      2. **ANDA** – Abbreviated New Drug Application – Generic manufacturer can show “bioequivalence” (equivalent metabolism usually)
         1. Cost of NDA is ~$800mil-1.5bil and 10-15y
         2. Cost of ANDA is ~$3-5mil and 2y
      3. **Orange book** – Listing of new drugs and their corresponding patents
      4. **Statutory exclusivity**
         1. 5y for new chemical entity
         2. 3y for new formulation
         3. Pediatric (6mo)
         4. Orphan Drug
         5. NOTE: ANDA can be filed at 4y but no approval til 5y
      5. **Litigation**
         1. Patents listed in orange book
         2. Generic must certify (¶1-4) against them
         3. Patentee can sue
         4. During that time, FDA can’t approve the generic (30mo stay)
   2. **Statute**
      1. § 271(e)(1) – Safe harbor period for experimentation for submission to government agency
         1. It shall not be an act of infringement to make, use, offer to sell, or sell within the US or import into the US a patented invention (other than a new animal drug or veterinary biological product which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other process involving site specific genetic manipulation techniques) **solely for uses** **reasonably related to the development and submission** of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products
   3. **Cases**
      1. *Roche v. Bolar*
         1. Overruled by § 271(e)(1) holding that generic use of patented drug to get FDA approval for launch on patent expiration is not “experimental use”
      2. *Eli Lilly v. Medtronic* (SC-USA, Scalia, J.)
         1. Patent on implantable defibrillators
         2. Holding: Safe harbor of Hatch Waxman applies to medical devices and drugs
         3. Reasoning
            1. Textual – Language focuses on submission of info to the FDA for approval
            2. “Dual Distortions” – If you can get term extension for FDA approval of devices, then safe harbor applies to the development of generics by competitors
      3. *Merck v. Integra* (SC-USA)
         1. Pre-clinical use of patented invention in rodents – peptides for use as potential angiogenesis inhibitors
         2. Issue: Does pre-clinical use that does not get included in FDA submission fall under safe harbor?
         3. Holding: Safe harbor includes pre-clinical studies that are appropriate for FDA submission – not just limited to drug safety data in humans
            1. Research must be **appropriate** not **necessary** for submission
            2. Pharmacological, toxicological, pharmacokinetic, and biological data
         4. Statutory language “reasonably related” to developments and submissions of **any** information – Does Δ have a reasonable basis for believing that the drug could be submitted to the FDA?
      4. *Classen v. Biogen* (Fed. Cir.)
         1. CDC requisitioned a study (subject to 5th Am. takings clause reasonable compensation) (Note: participation was not *required*, distinguished in *Momenta*)
         2. Holding: Safe-harbor does not apply to participation in CDC study to examine the claims in Classen’s patent (wack job)
         3. Safe harbor doesn’t apply to information that may be routinely reported to the FDA long after marketing approval has been obtained – reasoning that safe harbor is all about approval and this study was about debunking douche face’s patent
         4. Arguably this opinion is in sharp contrast to *Integra*
      5. *Momenta Pharms. v. Amphastar Pharms.* (Fed. Cir.)
         1. Δ used Π’s patented method of QC batch testing during and after FDA approval
         2. Holding: There is no limitation of the safe harbor to the drug-approval process thus Δ is under the safe harbor when the FDA requires continuing QC submissions after approval (FDA required the submission)
         3. Rader Dissenting – Safe Harbor should not include any post approval activity
9. BIOLOGICS AND BIOSIMILARS
   1. **Biologics Price Competition Innovation Act (BPCIA) (2010) (41 U.S.C. § 262)**
      1. Requires “biosimilarity” and “interchangeability”
      2. (a) – Biologics license – “NDA” – license to allow someone to make a new biologic
         1. (C) – Biologic has to be safe, pure, and potent, and the place where they manufacture it has to be such that it will continue to be safe, pure, and potent
      3. (i) – Definitions
         1. (1) Biological product means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative or arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure
         2. (2) Biosimilars – highly similar to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency
         3. (3) Interchangeability – biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product
      4. (k) – “Biosimilar” – licensing biological products as biosimilar or interchangeable
         1. (2)(A)(i) – need to demonstrate that the biological product is biosimilar to a reference product (analytic studies, animal, and clinical studies)
         2. (B) – Interchangeable – prove it is biosimilar and going to produce the same clinical result as the reference product in any given patient
   2. **Statutory Exclusivity**
      1. 12y for new biologics ((k)(7))
   3. **FDA Guidance**
      1. Concerns about natural complexity of protein structures
      2. Consider complexity in characterizing, mechanism of action, methods of manufacture
      3. Analysis
         1. Structural/functional characterization
         2. Animal experiments
         3. Clinical studies
   4. **Subsection (k) Application Information**
      1. Obligations to patentee of the reference product
         1. Within 20d, §(k) applicant must provide notice
         2. Within 60d, reference product holder must response with list of patents
         3. Within 60d, §(k) applicant must respond WRT the patents
         4. Within 60d, reference product holder must respond WRT infringement
         5. Negotiate, then litigate
      2. NOTE: No stay on approval as with Hatch-Waxman
10. INVENTORSHIP
    1. First to file went into effect March 16, 2013
    2. **Generally**
       1. Date of invention = Conception + Reduction to Practice
          1. On sale bar – No experimental use once reduced to practice
       2. *Nunc pro Tunc* Conception: Reduction to practice occurring prior to conception, or that they occur simultaneously
          1. Spot the issue: When subsequent events undermine the idea that conception occurred
       3. § 116 – Joint inventorship – Inventors *shall* apply for a patent jointly
          1. Note: § 116 allows PTO corrections, § 256 allows DC to correct
    3. **AIA**
       1. § 102(a)
          1. (1) – The claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention
             1. Otherwise available – NOT Patented, printed, in public use, or on sale

But no guidance about interpretation

* + - 1. (2) – The claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.
    1. § 102(b) – Grace Period
       1. (1) – Disclosures made 1 year or less before the effective filing date of the claimed invention.--A dis-closure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if-
          1. (A) – the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
          2. (B) – the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor
          3. NOTE: Grace period does not count for disclosures in other countries
       2. (2) – Disclosures appearing in applications and patents.--A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if-
          1. (A) – the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor
          2. (B) – the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor;
          3. (C) – the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person
    2. § 102(c)
    3. § 102(d)
  1. **Interferences**
     1. Two pending applications with overlapping claims
     2. 20-25 interferences/y result in later filed applicant winning based on earlier invention
     3. **Conception** – Formulation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is hereinafter to be applied in practice – Must be a solution, not just ID a problem, must have evidence of contemporaneous disclosure (C&C evidence)
        1. Uncorroborated testimony of the inventor is not enough
     4. **Cases**
        1. *Goeddel v. Sugano* (Fed. Cir.)
           1. Race for gene encoding β-interferon (proinflammatory cytokines)
           2. DNA encoding a mature fibroblast interferon and unaccompanied by a human fibroblast interferon pre-sequence
           3. Holding: Same principles that apply to written description apply to disclosure/possession for purposes of interference

Can rely on foreign filing for constructive reduction to practice so long as § 112 requirements are met

NOTE: Here, foreign filing didn’t enable

* + - * 1. Sugano had a sequence for whole β-interferon and prior art indicating where to cut the pre-sequence (post-translational modification) – not sufficient
  1. **Joint Inventorship**
     1. Can’t just be two groups working in parallel that come up with the same or related solution to a problem (*See Kimberly Clark v. Procter-Gamble*; *Eli Lilly v. Aradigm*)
     2. *Vanderbuilt Univ. v. ICOS Corp.*
        1. Holding: Allegedly omitted inventors failed to show by C&C that they were joint inventors – no communications between them and named inventor, no showing that their work which had been given to named inventor’s employer was actually used by named inventor in IDing the lead compound
        2. Note: co-inventor can contribute to only producing a starting material that produced the end compound, but contribution must be significant
  2. **Cases**
     1. *Yeda Research and Dev. Co. v. Imclone Sys. Inc.*
        1. Issue: Change in inventorship
        2. Application in 1988, dispute about inventorship in 2003
        3. During litigation 3 of 7 named inventors were stipulated to have not invented
           1. During litigation, other 4 are replaced by Yeda inventors
           2. Imclone filed declaratory judgment of invalidity
        4. Latches does not attach when delays in filing litigation were due to Δ’s unclean hands in not informing Π that they were filing a patent – clock normally starts on issuance
     2. *Ethicon v. US Surgical*
        1. Co-inventors have undivided co-ownership of the whole patent
        2. Safety trocar case – booted co-inventor grants license to infringing party
        3. Standing issue: All co-inventors must be joined in the suit
     3. *Israel Bioengineering v. Amgen*
     4. *University of Pittsburgh of Commonwealth System of Higher Educ. v. Hedrick*
        1. Action to remove some co-inventors under § 256 for claims to “adipose derived” stem cells
        2. **Test for Conception**
           1. Whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention; must be proven by corroborating evidence, preferably by showing contemporaneous disclosure
        3. Two issues
           1. Evidence may show that a claimed attribute is merely an obvious property of a greater discovery (that stem cells can divide at least 15 times, had particular cell surface antigens, and secreted hormones)
           2. Greater discovery is that stem cells can be derived from adipose tissue
     5. *Invitrogen Corp. v. Clontech Labs* (*See Burroughs Welcome*)
        1. Claims to mutant RT gene with DNA polymerase activity but no RNase activity
        2. Anticipated by prior invention under § 102(g) – Created 100 mutant genes, but didn’t figure out that they had the claimed IP til 3y later
        3. Holding: Conception didn’t occur til after testing, so no anticipation
     6. *Teva v. Astrazeneca* (Fed. Cir.)
        1. Don’t have to appreciate the *mechanism of action*
        2. Rejected patentee’s argument that Δ’s product couldn’t anticipate because Δ allegedly didn’t fully appreciate one of the claim limitations regarding stability being achieved by certain chemical components of the formulation
        3. Holding: Inventor appreciated that the product was stable, not defeated because they didn’t know precisely why
  3. **Policy – First to File**
     1. Clarity, Simplicity, Bright line, Easy to identify prior art

1. TRANSACTIONS
   1. In-Licensing – Acquiring patent rights
   2. Out-Licensing – Selling patent rights
   3. Material Transactions must be filed with the SEC
   4. **Structure of an Agreement**
      1. Heading: WHEREAS recitals identify parties and reasons for entering agreement
      2. Art. I – Definitions
         1. 1.3 “Affiliate” – Any person, any other person directly or indirectly controlling, controlled by or under common control with such other person. The term “control” (and the derivative terms “controlling” and “controlled”) as used herein means the possession
            1. Subsidiary – Part of a corporate family lower on the totem pole
            2. Affiliate – Any member of a corporate family
         2. 1.4-6 – Sections dealing with the rights having to do with products developed during the course of the relationship
         3. 1.7 “C225” – Chimerized monoclonal antibody to EGFr
            1. Schedule A – IgG1 antibody that inhibits EGF/TGFα (Transforming Growth Factor) induced activation of this TK-receptor
         4. 1.8 “Chemotherapy Patent” – The patents and patent applications specified in Schedule B as “Applications of Schlessinger *et al*. assigned to Rhone Poulec Rorer”
         5. 1.10 – “Net Sales”
         6. 1.20 – “Licensed Product Patent”
         7. Also include definitions WRT milestones, uses of the product, territory, etc.
      3. Art. II – Grant of Rights
         1. 2.1 – ImClone hereby grants to Merck **an exclusive license** with the **right to sublicense** as limited by Section 2.6, to **make, use and sell** Licensed Products and Alternative Products within the Territory and a non-exclusive license to use Licensed Product Technology and Alternative Product Technology for the manufacture of the Compound
            1. Sublicensing grant allows parent to move license to affiliates
         2. 2.2 – ImClone hereby grants to Merck an exclusive license, without the right to sublicense other than to Merck’s Affiliates or to sublicensees with ImClone’s prior written consent, which consent shall not be unreasonably withheld, the Radiotherapy Patent and the Chemotherapy Patent, respectively, to make, use and sell Merck Products within the Territory for a term beginning on the date of this Agreement and continuing throughout the life of the (patents)…
         3. 2.3 – Indicates Merck must use “best reasonable efforts”
            1. Indication that “best efforts” is a very high standard of effort – breach is easy
         4. 2.4 – Right of first refusal to Merck
         5. 2.5 – Term of agreement
      4. Art. III – Research and Development
         1. 3.7 – What happens to ongoing research at termination of the deal
      5. Art. IV – Payments
         1. 3 types
            1. ImClone issues shares that Merck buys at a particular price (aligns interests)
            2. Royalties – Graduated scale, “graduated down” 🡪 lower royalty if selling more, includes reporting obligation
      6. Art. V – Books and records
      7. Art. VI – Confidentiality – Includes some exceptions
      8. Art. VII – Patent filing, maintenance and expenses
      9. Art. VIII – Infringement – divides roles and costs in handling infringement actions, here ImClone has the first right to bring the lawsuit
      10. Art. IX – Representations and warranties
          1. 9.1(f) ImClone owns the Licensed Product Patents and such rights are not subject to any lien, encumbrance or claim of ownership of any kind by any third party
          2. *See also* (g), (h) (correct inventors), (i) (due diligence) – but all require bad faith
          3. 9.4 – No shop provision
      11. Art. X – Indemnification
      12. Art. XI – Duration and Termination
          1. 11.3 – Merck has unconditional right at their sole discretion to terminate
          2. 11.4 – If Merck determines product is unmarketable then they can terminate and ImClone has to pay back 50% of cash
          3. 11.6 – Bankruptcy – Usually ineffective
      13. Art. XII – Successors and Assigns – Non-transferrable without consent
      14. Art. XIII – Arbitration – “All disputes arising out of this agreement”
          1. Specifies arbitration company, language of proceedings, etc.
      15. Art. XIV – Notices
      16. Art. XV – Entire Agreement – Integration clause, no parole evidence
      17. Art. XVI – Misc. – Choice of law, etc.
          1. 16.8 – Contracting parties are not fiduciaries of each other
   5. 35 U.S.C. §§ 200-212 – Bayh-Dole Act (1981)
      1. NIH – ~$25bil in grants for research, $2bil for NIH campus
      2. Pre-Bayh-Dole – Cumbersome process for technology transfer, required petitioning the government – push was publication not patenting
      3. Post-Bayh-Dole – Title presumptively vests in the government contractor and can be out-licensed unless government exercises right of refusal
         1. March-in can occur on failure to commercialize, but never been used
   6. Material transfer agreement
      1. Typically includes ownership provision, specifications about uses, non-profit limitations, inventions derived from the material, acknowledgement of the source of the material, transfer does not result in license
   7. **Cases**
      1. *Medimmune* (SC-USA) – Holding that licensee may sue for declaratory judgment of invalidity without first breaching the license agreement
      2. *Stanford v. Roche*
         1. Stanford researcher collaborates at company, has standing duty to assign “will assign” with Stanford; at the door of company, signs “I hereby assign” agreement
         2. Researcher invents PCR techniques for detecting HIV in blood, Roche bought the collaborator and claimed to be a co-owner of the rights
            1. They couldn’t get royalties from Stanford (latches), but they couldn’t be sued to enjoin them from practicing
         3. Breyer Dissenting – Cites to *Film Tech.* drawing a distinction between an assignment of rights and a promise to assign patent rights in the future, argues that this leaves too much to the draftsman’s art
            1. “I hereby assign to you” 🡪 immediate assignment”
            2. “I hereby agree that I will assign to you” 🡪 Enforceable promise to assign in the future
      3. *Brulotte v. Thys Company*
         1. Patent holder engaged in aggressive licensing scheme – manufacturer sold machine and made purchasers pay a royalty for using it
         2. Royalties paid past the expiration of the term
         3. Holding: Post-expiration royalties are *per se* wrong, and may be an act of patent misuse voiding the patent
         4. NOTE: Simply have license fee step down after patent term to avoid this result
      4. *Scheiber v. Dolby Laboratories*
         1. Π sues Dolby for infringement – Dolby offers to pay lower royalties and have it continue post-expiration
         2. After expiration, Dolby stops paying
         3. Holding: Licensing agreement extending beyond the patent term is unenforceable
2. PTO ISSUES
   1. **Generally**
      1. Consider: Who is going to be the infringer? 🡪 If you have a method patent, and end user completes infringement, you’ll have to sue the manufacturing company
         1. Secondary liability – Contributory/induced infringement
            1. § 271(b): Induced – Knew or should have known Δ would induce actual infringement – must be affirmative action (*See Aro and Akami*)
            2. § 271(c): Contributory – Produce part of a product with no substantial noninfringing use knowing of the opposing patent rights (*See Aro/Sandisk*)
         2. Consider issues of proof
      2. Consider: Where will infringement occur? 🡪 Outside the US?
   2. **Claims**
      1. Dependent Claims – § 112(4) (now § 112(d)) – Has to be something in the independent claim that is further limited in the dependent claim
         1. *Pfiser v. Randbaxy* (Fed. Cir.) – Lipitor patent on hemi-calcium salt, claim limited to the acid form and since hemi-calcium salt wasn’t within that category, claim was invalidated
   3. **Specification**
      1. Why invention is significant
      2. Point out drawbacks in the prior art
      3. Why the invention has advanced the prior art in a meaningful way
         1. Work specifically under preferred embodiments
         2. Avoid limiting terminology – “critical” – i.e. “this is critical to the invention”
         3. Define words of degree 🡪 “about, approximately, etc.”
   4. Responses to the PTO are dangerous – Take care about limiting claims, or creating estoppel WRT scope
   5. OTDP can be solved with Terminal Disclaimer
   6. FDA Labeling requirements – Method of treatment claims need to correlate with approved label
   7. **Inequitable Conduct**
      1. Best way to invalidate a patent is to look for inconsistent statements made between jurisdictions, especially international prosecutions
      2. *Aventis v. Hospiria*
         1. Holdings
            1. Finding of non-infringement does not moot inequitable conduct claim
      3. **Elements (*Therasense*)**
         1. Materiality and intent
         2. C&C evidence standard
         3. Materiality – But-for the misrepresentation, the PTO wouldn’t have granted the claims, except in cases of affirmative, egregious conduct
         4. Intent – Accused infringer proves that patentee acted with deliberate intent to deceive the PTO, must be *the single most reasonable inference* based on circumstantial evidence
         5. Rule 9(b) heightened pleading
   8. **Extending Patent Term**
      1. § 154 – Patent term adjustments for delays due to the PTO
      2. § 156 – Term restoration for delays associated with FDA approval
         1. Counterpart to the safe-harbor – “Dual Distortions”
         2. Must apply within 60d of regulatory approval
         3. One extension per product – must be first commercial embodiment
         4. *Ortho-McNeil*
            1. Molecule with two enantiomers
            2. Issue: Does separating an enantiomer from a racemic mixture make a new product? 🡪 mixture already approved, isolated enantiomer = new?
            3. Isolated enantiomer had unique benefits and was itself patentable
            4. *See Pfizer v. Dr. Reddy’s* (2004)

Pfizer patent on salts of a particular active moiety

FDA approval on one salt + term restoration

Reddy’s NDA on another salt, argues they should launch at patent expiration not term extension

Holding: “Drug Product” means any salt or ester of the active drug 🡪 could not get term extension by replacing the salt

* + - 1. *PhotoCure*
         1. Later patent on pro-drug held to be a new product

1. LITIGATION
   1. AIA requires that individual infringement suits be brought against individual Δs, can’t automatically join all the Δs
   2. **Pleading**
      1. *In re Bill of Lading Transmission* (Fed. Cir. 2012) – Form 18 trumps modern pleading standards for direct, but not secondary liability (governed by *Twickbal*)
         1. So bare bones pleading for direct infringement (Subject to Rule 11)
   3. **Venue**
      1. Focus is in roughly 10 venues: DNJ, DDEL, EDTX, DMASS, SDCA, SDNY, EPENN
      2. Cost of venue fight can be $10-100k, over the perception that courts are more Π or Δ-favorable (e.g., TX is Π-friendly, CA is Δ-friendly)
      3. Old rules – Principal place of business, or state of incorporation, or regular place of business and has committed an act of infringement
      4. New rules – Can sue anywhere a corporation is doing business (*VE Holding Corp*, Fed. Cir. 1990), Anyone who injects a product into the stream of commerce is subject to jurisdiction anywhere the products reasonably end up (*Beverly Hills Fan Co.*, Fed. Cir. 1994);NOTE: PAE demand letters are insufficient contact to provide personal jurisdiction
      5. Forum shopping surrounds perceptions about MSJs
   4. **Jury**
      1. Guaranteed by 7th Am.
      2. But consider that patents originate in equity where jury was not guaranteed
      3. But since you get damages you get a jury – Infringement, validity, and damages
      4. Note: ANDA cases don’t have a right to jury trial
   5. **Declaratory Judgment**
      1. Often face motion to dismiss for subject matter jurisdiction (no case or controversy)
      2. Can be in response to a demand letter
         1. *See Medimmune* (SC-USA 2007) – Licensee paying royalties allowed to file declaratory judgment action without first breaking the license contract
   6. **DNJ Rules of Procedure**
      1. 3.1 – Disclosure of asserted claims and infringement contentions – has preclusive effect subject to 3.7 amendment requiring leave of the court
         1. (a) A claim construction by the Court different from that proposed by the party seeking amendment; (b) recent disco of material prior art despite earlier diligent research; (c) recent disco of nonpublic info about accused instrumentality which was not discovered despite diligent efforts before the case was served; (d) disclosure of an infringement contention by a Hatch-Waxman Act party asserting infringement under L. Pat. R. 3.6(g) that requires response by the adverse party because it wasn’t previously presented or reasonably anticipated, and (e) consent by the parties to the amendment and a showing it won’t lead to an enlargement of time or impact other scheduled deadlines
      2. 3.8 – Advice of counsel – pops up for willful infringement, or secondary liability where intent is an issue
      3. 4 – Claim construction – typically simultaneous opening and responding briefs
   7. **Cases**
      1. *Fiers v. Revelle* (1993)
         1. 3 groups of researchers chasing a target, case arises out of interference
         2. Cite this case for **conception**, **reduction to practice**, and **diligence** issues
         3. Party is second in time by ~2wks, both applications give full sequence, Fiers wins PTO interference by showing documented research plan that was enabling prior to Revelle 🡪 conception subject to later diligence and reduction to practice
         4. Holding
            1. For conception and adequate written description of DNA, must have sequence
            2. Conception doesn’t occur upon discovery of a method for obtaining the DNA without disclosure of the DNA’s nucleotide sequence
      2. *Amgen v. Hoffman La Roche* (2005)
         1. Amgen EPO patents
            1. Split under § 121 into 5 patents
            2. Typically invokes OTDP if terms are not coextensive
         2. Hoffman wanted to sell PEGylated EPO to design around Amgen’s patent
            1. PEG makes the compound last longer in circulation, and reduces immune response to the compound
            2. Note that this product is arguably superior
         3. Holding Anticipation: Claims were not indefinite or anticipated by natural EPO
            1. A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluents, adjuvant or carrier, wherein said erythropoietin is purified f/ mammalian cells grown in culture 🡪 Product by process claim interpreted by the court to contain a source limitation 🡪 “mammalian cells”
            2. New product may be patented by reciting source or process limitations so long as the end product is new and non-obvious

Distinguishing the previous patent on purified EPO from urine

First example of glycosylated protein produced recombinantly (contains post-translation modification 🡪 glycosylation)

Higher molecular weight, different charge, etc.

* + - 1. Holding Infringement: Infringing product need only be produced by the recombinant technique to show infringement (structural distinctions from anticipation arguments are not relevant)
         1. § 271(g) – Product made by patented process does not infringe so long as it is “materially changed by subsequent processes” prior to importation

Roche PEGylates the EPO after production 🡪 material change

Court doesn’t find PEGylation to be material, argument that the patent contemplated such modifications

* + 1. § 146 action – Applies when there is an interference proceeding – PTO determines then losing party can take the appeal to the Fed. Cir. (§ 141) or commence a new lawsuit in DC (§ 146) which can appeal later to Fed. Cir.
       1. § 146 is under *de novo* review and can introduce new evidence, vs. § 141 which is more APA-like

1. POLICY
   1. What role should patent policy/health policy have in resolving issues of patentability?
      1. Consider *Myriad* – If you deny protection to DNA sequences, what is the incentive to isolate them in the first place? 🡪 patent all the downstream inventions that come
      2. Concerns about public health 🡪 maximize access to diagnostics
      3. Lourie argues that these policy issues are for Congress, not to resolve § 101 issues
      4. Issues about how Bayh-Dole changed the incentives for Universities
      5. Incentive/policy issues seem to flow naturally from Art. I, § 8
      6. Consider Judge Sweet’s DC opinion in *Myriad* for concerns about behavior of litigants
   2. “Pay for Delay’
      1. During ¶4 litigation, parties settle such that branded pays the generic to delay launch
      2. Antitrust concerns – Patentee is agreeing with the one party that should be trying to invalidate the patent
      3. FTC position is this is *per se* unlawful – Industry argues rule of reason
      4. Circuit split 🡪 SC-USA has granted *cert.*
2. EXHAUSTION
   1. *Bowman v. Monsanto*
      1. Case regarding last sale doctrine and replanting of “Roundup ready seed”
      2. Fed. Cir. holding that patentee can contractually grant less than all the rights to practice the patented invention (person in privity with the patentee)
      3. Issue: Bowman got the seed from a grain elevator – not in privity
   2. **Policy**
      1. You can refill a pen that you buy, and we would balk at the idea of someone contractually obligating you to not do so
3. REMEDIES
   1. **Generally**
      1. Of the fortune 500 companies, 65% of their assets are “intangible” – R&D is a large cost, and IP makes up the lion’s share of the value in these companies
      2. Design patents: Π can seek profit disgorgement rather than lost profit/royalty
      3. 35 U.S.C. § 284 – “[A]dequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention”
   2. **Methods for Calculating Damages**
      1. **Lost Profits**
         1. “But-for” Test – The patent owner proves with a “reasonable probability that, but-for the infringement, the patent owner would have made the infringer’s sales” (*State Indus., Inc. v. Mor-Flo Indus., Inc.* (Fed. Cir. 1989)
         2. *Panduit* Factor Test
            1. Demand for the patented product or functionality
            2. No acceptable non-infringing alternatives
            3. Available capacity
            4. Quantifiable lost profits
            5. If all of the above 🡪 lost profits else reasonable royalty
         3. Two-Supplier Market Test
            1. Collapses the first two *Panduit* Factors – But-for causation may be inferred when the patent owner and the infringer are the only two suppliers
         4. Market Share (*Mor-Flo*) Approach
            1. Multiple suppliers
            2. Find a way to segment the market (e.g. price points) to reduce the # of competing products
         5. *Rite-Hite Corp. v. Kelley Co., Inc.* (E.D. Wis. 1991) – Lost profits allowed on unpatented products if they compete with the patented product, but functional relationship with the patented goods is required
      2. **Price Erosion** – Did patentee have to lower prices because of the infringer?
         1. Generics – Did infringer open up new market opportunities unavailable to the patentee?
            1. Is the market only the branded drug, or include broader swath of competing compounds?
      3. **Reasonable Royalty**
         1. Can be lump sum, running royalty or some combination
            1. E.g. Pre-launch R&D as amount of money infringer received from sponsors to fund the R&D
         2. Analytical Approach
            1. “Next best alternative” 🡪 No licensee would pay more than the increased cost of the next best alternative to the patented functionality (*TWM Manufacturing Co. v. Dura Corp.*, Fed. Cir. 1986)
         3. Hypothetical Approach
            1. *Georgia Pacific Factors* – See patent outline

Bucket into: Licensing History, Commercial Success, Benefits of Technology, Bargaining Position, Competition, Convoy Sales

* + - 1. *Uniloc v. Microsoft* – Eliminated the 25% rule – now smallest saleable unit
  1. *eBay* – Injunctions
  2. **Policy**
     1. Should lost profits extend to situations where a patentee sells a competing product which is not itself patented and doesn’t embody the patented invention?
     2. Should lost profits be reserved for those who commercialize the patented invention?
     3. Can patent owner receive lost profits where it can’t prove that it would have made all the sales the infringer made

1. EXTRATERRITORIALITY
   1. § 271(a) – Definition of infringement – Making, using, selling, offering to sell within the US, or importing to the US
   2. § 271(f) – Circumstances where an entity within the US is selling components with the intent of having those components leave the US and be assembled abroad into an infringing device
      1. “Whoever without authority supplies or causes to be supplied in or from the US all or a substantial amount of the components of a patented device in such a manner that they induce infringement outside the US, they will be liable as an infringer”
      2. *Microsoft v. AT&T* (2007) – “Golden CD” case
         1. Analogy – Ship a bacterium with patented plasmid abroad and produce the protein based on that inoculum
         2. Policy concern is that broad construction of § 271(f) would allow US patent law to reach conduct occurring outside the US
         3. § 271(f) was written to stop cases like the *Deep South Case* (1972) – patented shrimp de-veining machine where someone sent the parts of the machine out of the country to be assembled
         4. Consider § 271(f)(1) and § 271(f)(2) – (f)(1) requires intent because the parts have a substantial non-infringing use, (f)(2) doesn’t have the same requirement because the parts are specially adapted so there is no non-infringing use
      3. *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.* (FC 2009) – Cardiac sued St. Jude over method patent for stimulating hear using implantable heart stimulator
         1. Holding: § 271(f) does not apply to method/process patents
   3. § 271(g) – Process patents – This section covers patented processes that occur outside the US and send the final product in the US
      1. “Whoever imports into the US a product made by a patented process infringes the process patent even though the practice of the process occurred outside the US”
      2. A product made by a patented process isn’t infringing if it is materially changed by subsequent processes, or is only a trivial part of a much larger product
         1. *But see Amgen v. Hoffman La Roche* (2005) – PEGylated EPO
      3. *Housey* – Holding that the product must be tangible
         1. Patented experiments conducted abroad then the data is brought to the US
         2. Patented directed towards a method of determining whether a substance was an inhibitor or activator of a protein by inducing phenotypic response in cells – patentee then sues the entire pharmacology industry
   4. International Patent Exhaustion
      1. *See Bowman v. Monsanto*
         1. Issue: if you sell something abroad, do you exhaust your patent rights?
         2. FC has held that a patent owner that places its patented product for sale outside the US doesn’t exhaust patent rights (*Jazz Photo*)
      2. *Nine Star Case* – ITC Exclusion order to prevent importation of products covered by a patent – infringing company went ahead and imported anyways and got sanctioned
         1. Δ argued that they had purchased the products abroad and rights were exhausted – FC disagreed. – Holding First Sale Doctrine only attaches to sales made within the US (*Citing Jazz Photo*) – NOTE: SC-USA denied *cert*.
2. BIOETHICS
   1. “Knowledge yearning to be free” – If something can be put to bad uses, do you still publish it? 🡪 Consider genome of H1N1
   2. Use of biological techniques to enhance human performance – Doping, selecting for traits
   3. Consider ethics when technology is only available to wealthy people
   4. **Patenting life forms**
      1. Level of sophistication? 🡪 Bacteria vs. Chimpanzees
         1. What about Neanderthal?
      2. Onco-mouse – Consider the fact that these mice are “incapable” of living an otherwise normal existence
      3. Human beings (or parts thereof)
   5. What spurred biotechnology in the US over other countries?
      1. Question of acceptance by the general populace
      2. Question of patentable subject matter (*see Chakrabarty*)
   6. Access to healthcare/inventions
      1. Argument that more fundamental advances bring greater public condemnation if you assert the patent right
      2. Balance between IP limiting short/medium term access while spurring long term development
         1. Consider European NICE panel that considers based on cost-benefit, which drugs get reimbursement by national healthcare
   7. Vaccines
      1. Free-rider/herd problems
      2. Vaccines themselves are not risk free (*see* public fund for adverse vaccination events)
   8. Comparisons in spending: US spends ~18%, others spend 7-10% on healthcare, but have longer life expectancy
   9. SAC-GS – Government panel that Dreyfuss participates in
      1. Scenarios
         1. Aggressive IP assertion – Myriad/BRCA1/2 – 1 provider
         2. Non-exclusive licensing (cystic fibrosis, gene, and relevant mutations) – 20-30 providers
         3. No IP rights
      2. Findings
         1. Cost for tests was roughly equivalent
         2. Value gained by being able to compare results across providers
         3. Possible value of non-exclusive licensing is that it weeds out some fly-by-night operations that do shoddy work
   10. Traditional Knowledge
       1. Indigenous people eat the bark of a tree that has a medicinal property
          1. When you patent and commercialize that product, do you owe anything to those people? – *see* Convention on Biological Diversity – living organisms within territorial borders belong to the state
       2. Example: Merck had a statin patent and found a company was advertising Chinese red yeast dietary supplement with the statin
          1. Merck sues and discovers that even though the Chinese were using red yeast for a long time, it didn’t contain the statin – the company was producing it and spiking the supplement
   11. Can you legislate price controls on drugs?
       1. Possibly void for vagueness, possible federal preemption issues