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SELECTED TOPICS IN U.S. BIOTECH PATENT LAW

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SUBSTANTIVE REQUIREMENTS FOR PATENTABILITY

PATENTABLE SUBJECT MATTER

- §101 – “*process, machine, manufacture, or composition of matter*”
- Products of nature, without some manipulation, are not patentable.
- Patentability must involve the “hand of man.”
- Example 1 – Human anti-gp120 antibody is patentable subject matter if isolated, but *humanized* anti-gp120 antibody is patentable regardless of whether it is isolated.
- Example 2 – Vitamin B₁₂ is not patentable subject matter, unless isolated (*Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 160 (4th Cir. 1958)).
- Example 3 – Genetically modified bacterium is patentable subject matter (*Diamond v. Chakrabarty*, 447 U.S. 303 (1980)).

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- Example 4 – An anti-sense molecule targeting a cancer-causing gene is patentable subject matter.
- Example 5 – A method of treating Alzheimer's disease is patentable subject matter, as are therapeutic and diagnostic methods generally.

UTILITY

- This issue is addressed almost entirely during prosecution rather than during litigation.
- §101 – a patentable invention must be useful.
- Use must be *substantial, specific and in currently available form*.
- Example 6 – a method of making a new steroid compound having no disclosed use is not a useful method (*Brenner v. Manson*, 383 U.S. 519 (1966)).
- “[A] patent is not a hunting license.” *Id.*
- 2001 Utility Guidelines (64 Fed. Reg. 71,441) – a patentable invention must have a well-established utility. That is, (i) a person of ordinary skill would appreciate the invention's usefulness, and (ii) the utility is specific, substantial and credible.
- Example 7 – a genetically modified mouse useful only as snake food has no well-established utility, but one useful as a model for human cancer has well-established utility.
- Example 8 – a DNA probe that hybridizes to a non-specified gene does not have specific utility, but a DNA probe that hybridizes to a human p53 gene does.
- Example 9 – a DNA probe (e.g., EST) for conducting research to find target genes for treating disease does not have substantial utility, but a DNA probe that hybridizes to a human p53 gene does. Note: some EST's can be patented if their uses constitute well-established utilities.
- Example 10 – a method for “curing” AIDS would not have credible utility absent persuasive evidence to the contrary (i.e., successful human clinical trials), but a method for reducing the growth rate of a specified tumor would have credible utility assuming appropriate animal data are available.
- A patentable invention need only have *some* use.
- Utility is determined as of the filing date, but submitting *in vitro* and *in vivo* data during prosecution is a common means of overcoming utility rejections.

- Claiming a specific utility for a compound as a human therapeutic typically does not require actually demonstrating efficacy in humans.
- Example 11 – A compound that is shown to affect blood pressure and relax smooth muscle cells in animals has utility, even though human therapeutic use was not demonstrated, since a correlation was established between test results and therapeutic activity. (*Nelson v. Bowler*, 626 F.2d 853 (C.C.P.A. 1980)).

NOVELTY

- §102 – an invention lacks novelty if
 - the invention was known or used by others in the U.S., or patented or described in a printed publication anywhere, before the invention by applicant (§102(a)); or
 - the invention was patented or described in a printed publication anywhere, or in public use or on sale in the U.S., more than one year prior to the application filing date [even if the disclosure is the inventor's own] (§102(b)); or ...
 - the invention was described in a U.S. patent or published in a U.S. patent application filed before the invention by applicant (§102(e)); or ...
 - the invention was first invented by another, in a NAFTA or WTO country, and not abandoned, suppressed or concealed (§102(g)).
- A prior art reference must teach all elements of a claim to anticipate it.
- Example 12 – Claim provides an isolated human monoclonal antibody that binds to gp120. Prior art reference teaches a human antibody preparation containing a mix of antibodies, one of which is a monoclonal antibody that binds to gp120. No anticipation.
- A prior art reference must be enabling to anticipate. (*Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003)).
- Example 13 – Claim provides an isolated human monoclonal antibody that binds to gp120. Prior art reference teaches an isolated human monoclonal antibody that binds to gp120, but in a prophetic manner such that before the filing date, one skilled in the art could not have actually isolated the antibody. No anticipation.
- A prior art reference can anticipate by inherency.
- Example 14 – Claim provides the anti-histamine compound descarboethoxyloratadine (DCL). Prior art reference teaches loratadine. Loratadine is metabolized by the body

to form DCL and thus, administration of loratadine to a subject (per its intended use) necessarily results in DCL. The claim is therefore anticipated. (*Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003)).

- A disclosed species anticipates a genus claim, but a disclosed genus *generally* does not anticipate a species claim.
- Example 15 – Claim provides a specific oligonucleotide having a 5'-biotin label (i.e., the species). If the prior art reference teaches that same oligonucleotide, which can simply be "labeled" (i.e., the genus), there is no anticipation. If, however, the prior art reference teaches that the oligonucleotide can be 5'-labeled using any of 10 recited agents, one of which is identified as biotin, there is anticipation.
- Note: Claim sets should include narrow claims for important embodiments to ensure that at least some meaningful coverage remains if broad claims are invalid due to anticipation [or obviousness, etc. as discussed below].
- Example 16 – claim 1 provides CCGTAACCGTA having a label, and claim 2 provides CCGTAACCGTA having a 5'-biotin label. If the prior art reference teaches "labeled CCGTAACCGTA", claim 1 is anticipated but claim 2 is not.

NONOBVIOUSNESS

- §103 – an invention is not patentable if the differences between it and the prior art are such that the invention as a whole would have been obvious at the time of invention to a person of ordinary skill.
- Factors to consider include (i) scope and content of prior art, (ii) differences between the prior art and the invention, (iii) the level of skill in the art, and (iv) objective indicia of obviousness (i.e., secondary considerations such as unexpected results). (*Graham v. John Deere*, 383 U.S. 1 (1966)).
- To be nonobvious, an invention must constitute an improvement over the art which is "more than the predictable use of prior art elements according to established functions." (*KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007)).
- A finding of "unexpected results" is "tantamount to a finding of nonobviousness." (*Hoganas AB v. Dresser Indus.*, 9 F.3d 948, 954 n.28 (Fed. Cir. 1993)).
- Example 17 – A method of making a predetermined protein using a heterologous DNA in a bacteria was held obvious in view of prior art teaching (i) use of rRNA gene as the heterologous gene and (ii) likely success of substituting the rRNA gene with a protein-encoding nucleic acid to make the protein. (*In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)).

- Example 18 – A hybridoma producing anti-human fibroblast interferon MoAbs was held obvious over prior art teaching successful methods of generating MoAbs to various other antigens. (*Ex parte Erlich*, 22 U.S.P.Q.2d 1463 (BNA) (B.P.A.I. 1992)).
- Example 19 – Method of treating physical and emotional symptoms of PMS using fluoxetine was held non-obvious, since the prior art taught widespread failure of others to safely and effectively treat PMS. (*Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc.*, 2004 US Dist. LEXIS 14724 (S.D. Ind. July 29, 2004) *aff'd*, 2005 U.S. App. LEXIS 14583 (Fed. Cir. July 13, 2005)).
- Example 20 – A claim to a *particular* nucleic acid molecule (e.g., isolated human DNA) encoding a particular protein (e.g., human IGF) is not obvious over the amino acid sequence for that protein and known methods for isolating nucleic acids based on their encoded proteins. (*In re Bell*, 991 F.2d 781, 785 (Fed. Cir. 1993) [holding was based on the degeneracy of the genetic code]).
- Example 21 – But, a claim to “a” DNA sequence encoding a particular protein would be obvious over the amino acid sequence for that protein.
- Drafting tip – European problem / solution approach can be helpful in identifying and articulating unexpected features of the invention.
- Drafting tip – unexpected features should be clearly identified as such in the patent application, and contrary teachings (i.e., teachings “away” from) stressed in the background section. That is, make your non-obviousness argument in the application.

ENABLEMENT, WRITTEN DESCRIPTION AND BEST MODE

- §112, First Paragraph – the specification must “contain a written description of the invention” and must “enable any person skilled in the art ... to make and use same, and shall set forth the best mode contemplated by the inventor of carrying out [the] invention.”
- These requirements must be satisfied as of the filing date.
- This paragraph applies to priority determination.
- To satisfy the written description requirement, applicant must show “possession” of invention – i.e., allow one to visualize or recognize the identity of the subject matter purportedly described.
- Description of every species is not necessarily required, nor is *ipsis verbis* recitation in the application.

- Factors considered include
 - existing knowledge in the field,
 - extent and content of the prior art,
 - maturity of the technology, and
 - predictability of the aspect at issue.

- Example 22 – If a claim provides a recombinant microorganism containing human insulin-encoding human cDNA, yet the description discloses only the human insulin amino acid sequence and a method for obtaining the human cDNA, the written description requirement is not satisfied. (*Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997)).

- Example 23 – if a claim provides a method for selectively inhibiting COX-2 enzyme by administering a “non-steroidal compound that selectively inhibits activity of the COX-2 enzyme”, and the description discloses no such compounds, the written description requirement is not satisfied. (*Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed. Cir. 2004)).

- Example 24 – Disclosing rat insulin-encoding DNA in the specification does not support a claim to all cDNA encoding vertebrate insulin. (*Univ. of Cal. v. Lilly*).

- Example 25 – disclosure of a fully characterized antigen supports claiming an antibody specific to that antigen. (*Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004)).

- Red Flag Terms – Care should be taken when using certain claim terms absent sufficient description – e.g., “homologous”, “functional analog”, “sufficient activity” and “structural variant.” This caveat also applies to the §112, second paragraph clarity requirement.

- To satisfy the enablement requirement, applicant must show how to make and use the invention.

- It is not necessary to disclose what is well known in the art. However, novel aspects must be disclosed.

- The specification must disclose more than a starting point for further research that might lead to the invention.

- No undue experimentation can be required in order to practice the invention. But, routine experimentation is permitted. Courts may consider a number of factors to determine whether undue experimentation is required. (*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)).

- *Wands* factors include
 - Quantity of required experimentation
 - Amount of guidance provided by the specification
 - Presence of working examples in the specification
 - Nature of the invention
 - State of the prior art
 - Relative skill of a person of “ordinary” skill in the art
 - Predictability or unpredictability of the art
 - Breadth of the claim

- Biological deposits can be used to satisfy the enablement requirement.

- The §101 utility and §112 enablement requirements are related, since one cannot teach how to use an invention if it has no use. Thus, utility and enablement rejections are typically issued jointly.

- To satisfy the best mode requirement, applicant must disclose in the application the best mode contemplated by the inventor of carrying out the invention as of the filing date.

- Post-filing changes in the best mode do not negate initial compliance.

- Failure to satisfy the best mode requirement is seldom the basis of an invalidity holding.

ETHICAL OBLIGATIONS

- The duty of candor is key in U.S. practice.

- Patent applicants, as well as all associated individuals (attorney and others substantively involved with the application’s prosecution), are obligated to disclose information material to patentability. Rule 1.56.

- Information Disclosure Statements are the means for satisfying this obligation, which continues so long as the application is pending.

- Failure to disclose material information, or the submission of materially false information, can constitute inequitable conduct if coupled with intent to deceive the Patent Office.

- A finding of inequitable conduct by a court renders a patent unenforceable.

- Examples of inequitable conduct can include the following acts if combined with an intent to deceive –

- Submitting fabricated data,
- Using the past tense to describe prophetic experiments,
- Improperly including or excluding someone as an inventor,
- Failing to disclose a material reference cited abroad during prosecution,
- Failing to disclose adverse data, and
- Improperly claiming small entity status (in pending and new applications) after a change to large entity status.

INVENTORSHIP

- Inventorship requires conception and reduction to practice (actual or constructive).
- Conception can be sole or joint. §116.
- “Conception is the touchstone of inventorship, the completion of the mental part of the invention.” (*Burroughs Welcome Co. v. Barr Labs.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994)).
- Conception requires a definite and permanent idea of the complete and operative invention.
- Example 26 – An inventor need not know that an invention will work for conception to be complete. In *Burroughs*, the claimed invention was a method of treating AIDS in humans using AZT, based on animal but not human data. NIH scientists who subsequently tested AZT in humans and demonstrated efficacy were not co-inventors.
- Example 27 – Providing a goal to be achieved without direction is not conception. A laboratory head instructing a post-doc to “find a way to increase CD4+ cell levels in HIV-infected subjects”, without providing guidance, has not conceived of a later-claimed method of increasing CD4+ cell levels in HIV-infected subjects by administering compound X.

- Example 28 – Carrying out confirming experiments does not constitute conception. For example, a laboratory assistant who tested prostaglandins on an animal model for glaucoma was not a co-inventor of a method for treating glaucoma in humans using prostaglandins, since (i) the animal model experiments were already determined by the named inventor to be desirable, (ii) the assistant's efforts constituted routine work, and (iii) the assistant did not understand the effect of prostaglandins on glaucoma. (*Stern v. Trs. of Columbia Univ.*, 434 F.3d 1375 (Fed. Cir. 2006)).
- Incorrect naming of inventorship renders a patent invalid.
- Errors in naming inventorship can be corrected in a patent if made without deceptive intent. If deceptive intent is found, inventorship cannot be corrected and/or the patent can be held unenforceable.

CLAIM CONSTRUCTION AND PATENT INFRINGEMENT

CLAIM CONSTRUCTION

- Claim construction is a matter of law. (*Markman v. Westview Instr., Inc.*, 517 U.S. 370 (1996)). "*Markman* hearings" are now common for construing claims.
- Claim construction is also a predicate for invalidity and infringement determination.
- Procedure for construing claims is flexible and differs from court to court as to timing and approach.
- Generally, "intrinsic" evidence (i.e., patent claims, in light of the specification and file history) is given primary consideration, followed if necessary by "extrinsic" evidence (e.g., dictionaries and expert testimony). (*Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005)).
- A claim's preamble may limit the claim, depending on the facts.
- Transition phrases have special meaning –
 - "consisting" – having what is recited and no more.
 - "consisting essentially of" – having what is recited and nothing more which materially affects the novel properties of the invention.
 - "comprising" – having what is recited and optionally more.

- Drafting Tip – Claims should include language accounting for all relevant forms of a therapeutic or routes of administration, etc. For example, a compound claim should include the molecule per se, its salts, and its pharmaceutical compositions. Treatment claims should include all appropriate routes of administration (systemic, iv, oral, topical, etc.), as well as biological effects (e.g., method of increasing CD4+ cells in a subject by administering agent X).

TYPES OF PATENT INFRINGEMENT

- Direct infringement – making, using, offering for sale or selling a patented invention in the U.S., or importing a patented invention into the U.S. (§271(a)).
- Example 29 – A patent claims antibody X, and a third-party company sells antibody X in the U.S.
- Inducing infringement – inducing another to make, use, offer for sale or sell a patented invention in the U.S., or import a patented invention into the U.S. (§271(b)).
- Example 30 – a patent claims a method of treating a subject for cancer using antibody X, and a third-party company sells antibody X in the U.S. with a label for treating cancer.
- Contributory infringement – importing, offering to sell, or selling in the U.S. (i) a component of a patented article or composition, or (ii) a material or apparatus for practicing a patented process, constituting a material part of the invention, knowing same to be made or adapted for infringing such patent, and not suitable for any non-infringing use. (§271(c)).
- Infringement by supplying, or causing to be supplied, in or from the U.S. (a) all or a substantial portion of components of a patented invention so as to induce assembly abroad (§271(f)(1)), or (b) any component of a patented invention with the intention that the component will be combined abroad in a manner which would constitute contributory infringement if in the U.S. (§271(f)(2)).
- Infringement of a process patent by importing into the U.S., or offering to sell, selling or using a product made by the process. (§271(g)).
- Infringement can be literal or under the doctrine of equivalents. The doctrine of equivalents is tempered by a patent's prosecution history.

- Example 31 –
 - Claim provides a peptide comprising the sequence Ala-Gly-Ser-Ser-Phe-Tyr, having apoptosis-inducing activity, and having a size of 1.5kD.
 - Accused product is a peptide comprising the sequence Ala-Gly-Ser-Ser-Phe-Tyr, having apoptosis-inducing activity, and having a size of 1.48kD.
 - Absent prosecution history to the contrary, the peptide likely infringes under the doctrine of equivalents even though it does not literally infringe.

- Example 32 –
 - Claim provides a peptide comprising the sequence Ala-Gly-Ser-Ser-Phe-Tyr, having apoptosis-inducing activity, and having a size of 1.5kD.
 - Accused product is a peptide comprising the sequence Ala-Gly-Ser-Ser-Phe-Tyr, having apoptosis-inducing activity, and having a size of 1.48kD.
 - But, in the prosecution history, the originally filed claim was narrowed from “about 1.5kD” to “1.5kD” to overcome art teaching a 1.48kD peptide.
 - The peptide would not infringe literally or under the doctrine of equivalents.

- Example 33 –
 - Claim provides a DNA molecule having the sequence GTAAGTGGCTAAGCTTAGC.
 - Accused product is a DNA molecule having the sequence GTAAGTGGCTAAGCTTAGC (i.e., at least 90% homologous).
 - But, in the prosecution history, the originally filed claim was narrowed from “a DNA molecule having the sequence GTAAGTGGCTAAGCTTAGC, or a DNA molecule having at least 90% homology thereto” to the present claim of “a DNA molecule having the sequence GTAAGTGGCTAAGCTTAGC.”
 - The accused DNA would not infringe literally or under the doctrine of equivalents.

DEFENSES

- Most common defenses to an infringement charge include noninfringement, invalidity and unenforceability.

PROCEDURAL AND TACTICAL ISSUES

PATENT TERM

- For a U.S. patent issuing from an application filed on or after June 8, 1995, the term of the patent begins on the date of issuance and expires 20 years from the earliest claimed priority date, subject to any terminal disclaimers.

- For a U.S. patent issuing from an application filed before June 8, 1995, the term of the patent begins on the date of issuance and expires on the later of 17 years thereafter or 20 years from the earliest claimed priority date, subject to any terminal disclaimers.
- The term of a patent can be extended by up to five years due to delay caused by regulatory approval by the FDA (§156).
- The term of a patent can also be extended (“adjusted”) due to specified types of delay by the Patent Office in processing and examining the patent application. (Rule 1.701, et seq.).
- For biopharmaceutical patents, the final portion of patent term is often the most valuable, making patent term extension an important consideration.

CONTINUING APPLICATION PRACTICE

- U.S. practice permits the filing of one or more continuing applications that claim priority to a pending application.
- A continuing application must be filed while its parent application is pending, and must have at least one inventor in common with its parent application.
- There are three types of continuing applications: divisionals, continuations and continuations-in-part (CIP’s).
- A divisional application is filed to pursue claims that were not elected in response to a restriction requirement. That is, a divisional application claims an invention that the Patent Office has deemed independent and distinct from the invention elected for prosecution in the parent application. It shares the same specification and priority date with its parent application.
- A continuation application is filed to pursue subject matter disclosed in the parent application, but not yet claimed. It shares the same specification and priority date with its parent application.
- A CIP is filed to pursue claims to subject matter that may or may not have been disclosed in the parent application. Its specification contains new matter (e.g., experimental data and definitions) with respect to its parent application. A CIP has a “split” priority date – i.e., a priority date that is the same as that of its parent application regarding common subject matter, and a priority date as of the CIP filing date regarding the added subject matter.
- Biotech patent practice frequently employs filing continuing applications due to the multiple aspects of a given invention, thus giving rise to large patent families.

- Example 34 –
 - A parent application as filed claims (i) an antibody useful as a diagnostic tool for cancer, (ii) a kit, (iii) a method of diagnosing cancer using the kit, and (iv) a method of making the antibody.
 - Following a restriction requirement, invention (i) (the antibody) is elected, and the remaining claims are withdrawn.
 - Before issuance of the antibody patent, three divisionals are filed claiming the kit, the diagnostic method and the method of antibody production.
 - Before the diagnostic method patent issues, a continuation is filed to claim a method of diagnosing pancreatic cancer, which was disclosed but never claimed in the grandparent application.
 - At the end of prosecution, five patents have issued, all having the same specification and priority date.

- Caveat – Care should be taken when deciding to file a CIP to claim new subject matter, rather than filing a new application that is not a continuation. Filing a CIP in a situation where a new application could have been filed instead will result in needless loss of patent term.

PROVISIONAL APPLICATION PRACTICE

- U.S. practice permits the filing of a “provisional” patent application (§111(b)).

- A provisional application
 - need not contain any claims,
 - is not examined,
 - cannot claim priority of another application, although it can serve as a priority application for later filed regular applications,
 - becomes abandoned after 12 months from filing, and
 - is not counted when calculating patent term.

- Typically, a provisional application filing is followed after 12 months by a U.S. non-provisional or a PCT International Application designating the U.S.

- Since provisional applications effectively extend U.S. patent term by one year, these applications are almost always filed for inventions such as biopharmaceuticals where the expected product life exceeds 20 years, and the value of the patent at the end of its term is high.

- Caveat – Whenever possible, provisional applications should be filed as complete applications including claims, definitions and full discussion of the invention, rather than “skeletal” outlines. This helps ensure that the provisional application can serve as a priority document with regard to all aspects of the invention that might later be claimed.

UPCOMING CHANGES

PATENT LEGISLATION

- House Bill H.R. 1908 (approved) and pending companion Senate Bill S. 1145 stand to fundamentally change the patent law in many ways – some good and others not.
- Some key provisions are
 - First to file replacing first to invent (harmonizes U.S. with other countries),
 - Creation of “cancellation” proceedings (analogous to Europe’s opposition proceedings), with certain mutually exclusive effects on invalidity assertions later at trial,
 - Creation of a new, proportionate damages calculation system (favoring accused infringers),
 - More stringent standards for proving inequitable conduct (favoring patentees), and
 - Granting the Patent Office additional rule-making authority concerning continuing applications (potentially harmful to biotech industry).

PATENT RULES

- Recently introduced Patent Office rules package on claim and continuation practice (the “Final Rule”) was temporarily enjoined from its November 1, 2007 implementation, and then recently held void by a U.S. District Court.
- This package was widely criticized, especially by the biotech industry (e.g., for improperly limiting number of permitted claims and continuations), and would have severely harmed the biotech industry internationally.
- It remains unclear whether the Patent Office will again attempt to pursue some or all of these rule changes.
- In the meantime, the Patent Office has proposed rule changes for IDS submissions that would create severe substantive and economic hurdles if implemented. It is unclear whether the Patent Office will pursue these changes in view of the recent court decision voiding its other proposed changes.

BIOSIMILARS LEGISLATION

- Competing bills are pending in the House and Senate which would create a “generic” biopharmaceuticals industry much the way the Hatch-Waxman Act created the generic pharmaceutical industry for small molecule drugs.
- It is unclear when, and in what form, a U.S. biosimilars system will come into being.

TABLE OF SELECTED AUTHORITIES

STATUTES

- 35 U.S.C. §101
- 35 U.S.C. §102(a), (b), (e), (f) and (g)
- 35 U.S.C. §103
- 35 U.S.C. §112, first paragraph
- 35 U.S.C. §156

BILLS

- H.R. 1908 (approved)
- S. 1145 (pending)

RULES

- 37 C.F.R. 1.56
- 37 C.F.R. 1.701, *et seq.*

GUIDELINES

- 2001 Utility Guidelines (64 Fed. Reg. 71,441)

CASES

- *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed. Cir. 2003).
- *Brenner v. Manson*, 383 U.S. 519 (1966).
- *Burroughs Welcome Co. v. Barr Labs.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994).
- *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
- *Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc.*, 2004 US Dist. LEXIS 14724 (S.D. Ind. July 29, 2004) *aff'd*, 2005 U.S. App. LEXIS 14583 (Fed. Cir. July 13, 2005).
- *Ex parte Erlich*, 22 U.S.P.Q.2d 1463 (BNA) (B.P.A.I. 1992).
- *Graham v. John Deere*, 383 U.S. 1 (1966).
- *Hoganas AB v. Dresser Indus.*, 9 F.3d 948, 954 n.28 (Fed. Cir. 1993).
- *In re Bell*, 991 F.2d 781, 785 (Fed. Cir. 1993) .
- *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).
- *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).
- *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007).
- *Markman v. Westview Instr., Inc.*, 517 U.S. 370 (1996).
- *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 160 (4th Cir. 1958).
- *Nelson v. Bowler*, 626 F.2d 853 (C.C.P.A. 1980).
- *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004).

- *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005).
- *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).
- *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373 (Fed. Cir. 2003).
- *Stern v. Trs. of Columbia Univ.*, 434 F.3d 1375 (Fed. Cir. 2006).
- *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed. Cir. 2004).