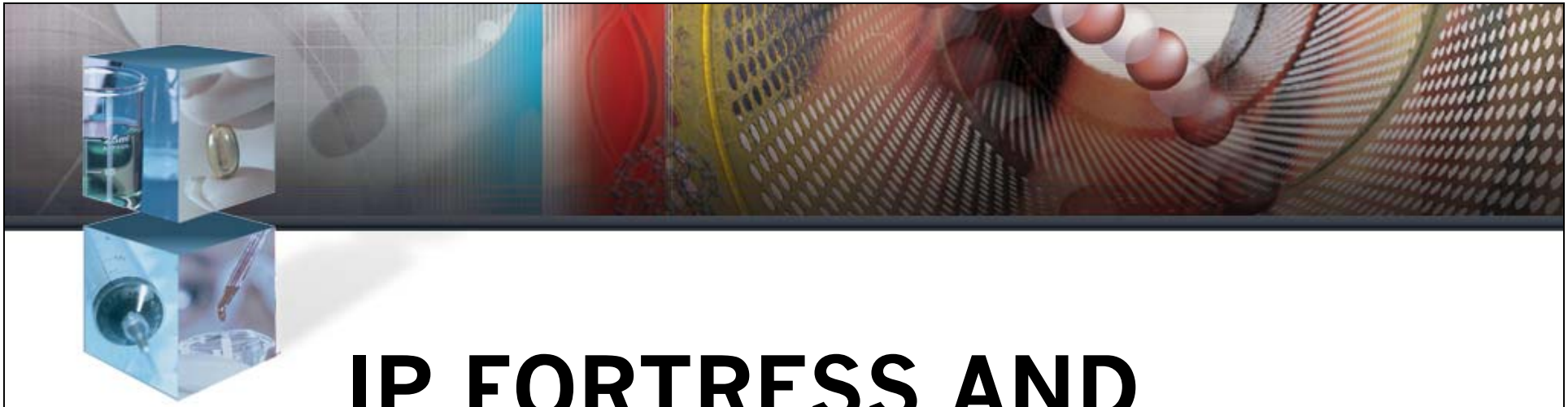

IP FORTRESS AND IP FREEDOM

Richard J. Warburg
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June 2007

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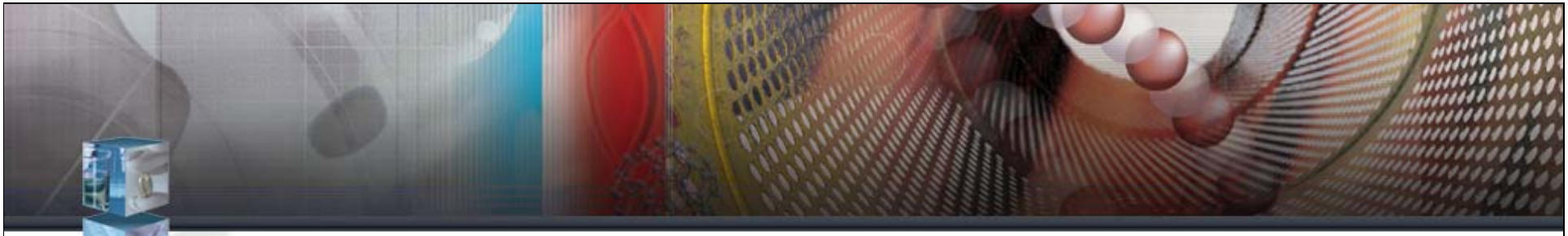
Outline

- General Patent Rights
- Requirements for Patentability in Drug Delivery
  - Utility
  - Written Description
  - Non-obviousness
- Patent strategies and business plans
- Recent Developments in Patent Law



"Congress intended statutory subject matter to include anything under the sun that is made by man"

U.S. Supreme Court in Diamond v. Chakrabarty, 447 U.S. 303 (1980)

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Patents

- Inventions
- Monopoly
- Right to exclude others from
  - Making
  - Using
  - Offering for sale
  - Selling

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Standard Patent Term

- Utility patent - for applications filed on or after June 8, 1995, 20 years from earliest effective U.S. filing date
- For applications filed prior to June 8, 1995 or for patents in force on June 8, 1995, the longer of 17 years from issue or 20 years from earliest effective filing date

Patentability Considerations

- **New** – It has not already been discovered by someone else
- **Useful** – It has a useful purpose
- Application must provide a **written description** of the invention and **enable** one of skill in the art to make and use the invention
- **Non-obvious** – It is not already taught or suggested by a pool of existing knowledge, i.e., a genuine discovery!

Patentability: Utility

- 35 U.S.C § 101
- Whoever invents or discovers any new and **useful** process, machine, manufacture, or composition of matter, or any new and **useful** improvement thereof, may obtain a patent therefor . . .

Utility: In Re Fisher (421 F.3d 1365; Fed. Cir. 2005)

- Patent claimed the sequences of five expressed sequence tags (ESTs)
- An EST is a short nucleotide sequence representing a portion of an expressed gene
- The structure and function of the genes or the proteins represented by the claimed ESTs were not known at the time of filing

Utility: In Re Fisher cont. . .

- The functions of the genes represented by the ESTs were not known. Thus, each of the claimed ESTs act as no more than research intermediates that may help isolate and study the genes.
- Accordingly the ESTs are "mere 'objects of use-testing,' to wit, objects upon which scientific research could be performed with no assurance that anything useful will be discovered in the end"

Utility: In Re Fisher cont. . .

"we conclude that the claimed ESTs, which do not correlate to an underlying gene of known function, fail to meet the standard for utility intended by Congress"

Patentability: Written Description

- The specification must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in **possession** *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*."

- Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-4 (Fed. Cir. 1991)

Written Description: Lilly (1997)

- Regents of Univ. of CA v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997)
- Patent claims are directed to claims directed to a human insulin cDNA
- The specification disclosed the nucleotide sequence of rat insulin cDNA and the amino acid sequence of human insulin chains but no human insulin cDNA sequence.
- HOLDING: Claims invalid for lack of written description

Written Description: Rochester (2004)

- ***Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004)**
  - Patent claimed a method of selectively inhibiting COX-2 activity by administering a non-steroidal compound
  - The patent described the COX-2 enzyme and assays for identifying COX-2 inhibitors
  - BUT there was no disclosure of any compounds that can be used in the claimed methods
  - HOLDING: "Without such disclosure, the claimed methods cannot be said to have been described."

Written Description: Capon (2005)

- Capon v. Eshhar, **418 F.3d 1349, 76 USPQ2d 1078 (Fed. Cir. 2005).**
  - Claims directed to chimeric DNA in which an antibody gene fragment is linked to a signalling protein gene fragment
  - HOLDING: there is no *per se* requirement that the sequence of claimed DNA be recited in the specification if the sequence is known in the art.
  - DICTA: The predictability or unpredictability of the science is relevant to deciding how much experimental support is required to adequately describe the scope of an invention.

Patentability: Non-Obvious

- **35 U.S.C. § 103(a):**
- "A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

Obviousness cont. . .

- Graham et al. v. John Deere Co. of Kansas City et al., 383 U.S. 1 (1966)
- Obviousness should be determined by looking at:
  1. the scope and content of the prior art;
  2. the level of ordinary skill in the prior art;
  3. the differences between the claimed invention and the prior art; and
  4. objective evidence of nonobviousness

Obviousness cont. . .

- Federal Circuit Test:
- "TSM" (Teaching, Suggestion, Motivation):
  1. The prior art must disclose each and every limitation of the claim;
  2. There must be a reasonable expectation of success; and
  3. There must be some motivation (either in the prior art references or in the knowledge of the person of ordinary skill in the art) to modify or combine the reference teachings to arrive at the claimed invention

Obviousness cont. . .

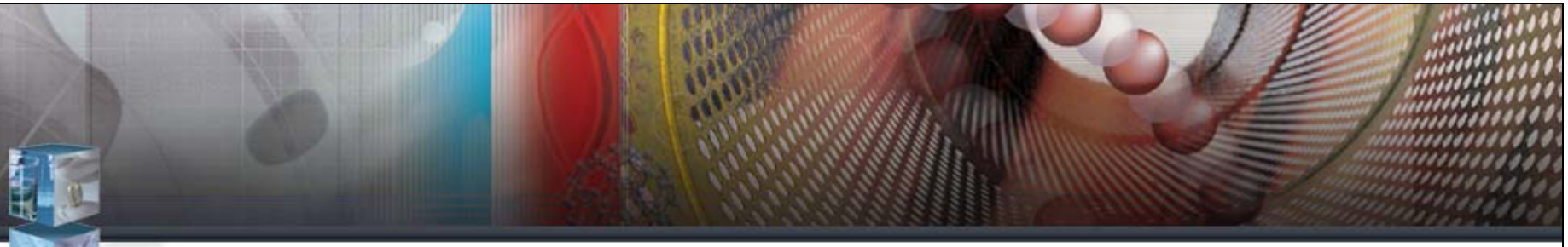
- *KSR International Co. v. Teleflex Inc.*, US Supreme Court, April 2007.
  - Patent at issue was to sensors for automobile gas pedals.
  - District Court found patent invalid as obvious over prior art
  - Federal Circuit overturned on grounds that the District Court did not apply the TSM test strictly enough.
  - Supreme Court reversed the Federal Circuit, holding the claims invalid as obvious

Obviousness cont. . .

- *KSR International (*US 2007) cont...
- In its holding the court:
  1. Reaffirmed the obviousness standard set forth in Graham
  2. Did not reject the TSM test, but held that Federal Circuit applied the test to narrowly and rigidly.

Obviousness cont. . .

- *KSR International (*US 2007) cont...
  - The obviousness inquiry "must ask whether the improvement is more than the predictable use of prior art elements according to their established functions"
  - "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed."
  - "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton"



Patent Strategies and Business Plans

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Claim Broadly and Deeply

- Consider **all patentable aspects** of the invention; e.g.,
  - Composition
  - Methods to make composition
  - Methods to use composition
  - Three deuces can beat an ace (or at least keep you in the game)
  - Blocking or trading chips

Claiming in a Multi-Dimensional Space

- Why keep filing?
- Portfolio development vs. one application
- Keep updating strategy and value

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Is It Always Worthwhile Patenting?

- Even if you DO know infringement is occurring, can you enforce the patent?
- Can you afford to incur large legal costs and perhaps lose anyway?
- Will the patent be broad enough to provide valuable protection?

What Are the Other Options for Protection?

- Trade secret protection
  - Can you really keep it a secret?
  - Will someone else discover it soon and patent it for themselves?
- File patent application in the U.S. and don't publish
  - Safety strategy

Thank You!

- For more information, please contact:

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The Game

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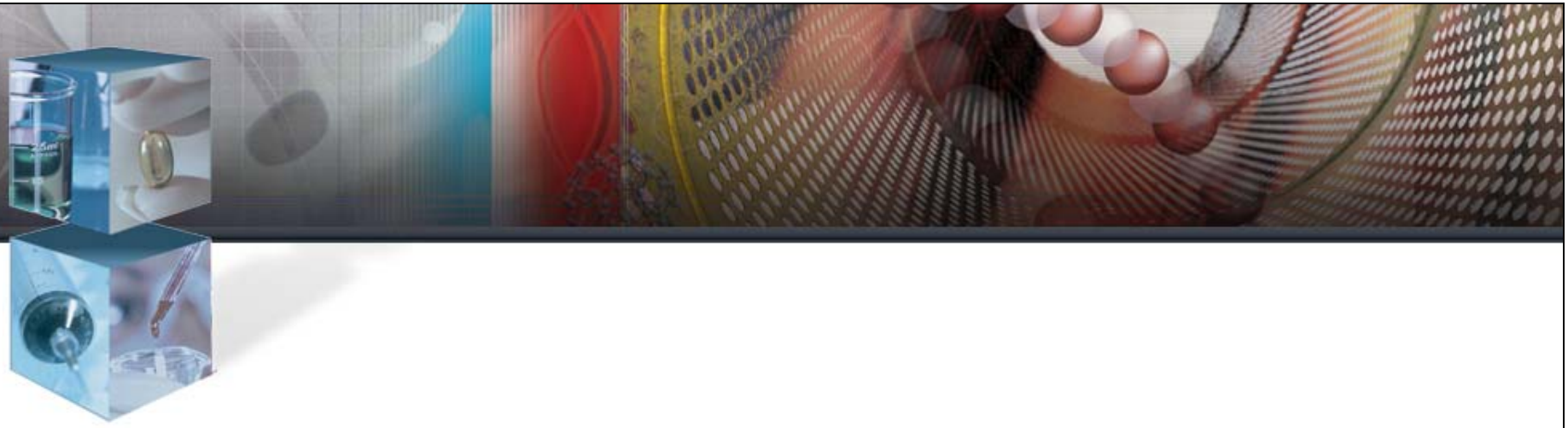

EXTRA SLIDES

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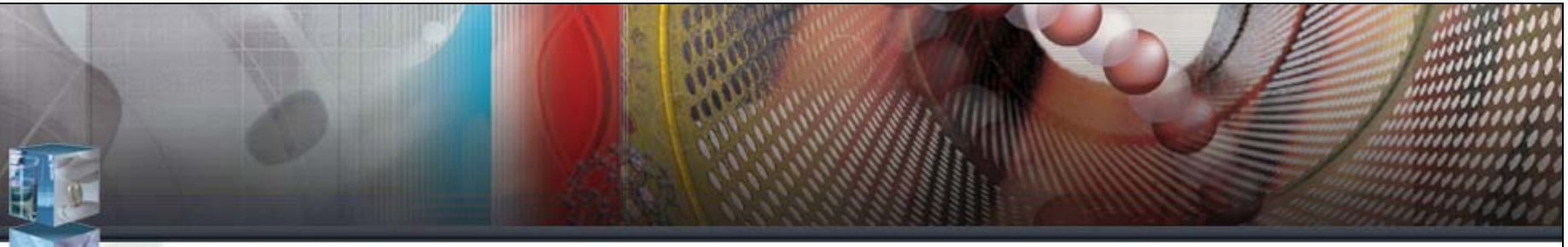

- Written Description / Claim Construction

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Claim Construction

- The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art."

  Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005)

Claim Construction: Honeywell

- The meaning of two terms in the claims of a patent were disputed:
- 1) The court interpreted the claim term "**fuel injection system component**" as limited only to a "fuel filter"
- 2) And held that term "**electrically conductive fibers**" excludes "carbon fibers"

Claim Construction: Honeywell cont. . .

- The plain meaning of the terms indicate broader scope than the Court's interpretation
- The patent provided no specific definition of the terms explicitly indicating the narrower interpretations adopted by the court

Claim Construction: Honeywell cont. . .

- **Factors considered:**
- 1. Narrowing Language:
- "This invention relates to. . ."
- "According to the present invention. . ."
- "This and other advantages of the present invention. . .,"

Claim Construction: Honeywell cont. . .

- **Factors considered:**
- 2. Preferred embodiment:
- The written description did not indicate that a fuel filter is merely a preferred embodiment of "fuel injection system component," nor did the specification disclose or suggest any other fuel injection system

Claim Construction: Honeywell cont. . .

- **Factors considered:**
- 3. Disavowal:
- The court found that the specification specifically described particular disadvantages of carbon fibers as electrically conductive fibers, and concluded that the derogatory statements are the equivalent to disavowal from the scope of that patent's claims.

- **Slides regarding 271(e)(1) and Merck v. Integra**

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The Problem of Regulatory Delays

- Regulatory delays are common
- May take many years to herd a product through the FDA or another regulatory agency
- Uses up years of valuable patent term while product cannot be sold since it has not cleared regulatory hurdles

The Stakes of Patent Term Extension

- By one estimate, at least 40 drugs will come off patent by the end of 2002
- $16 billion in U.S. market value and a daily revenue stream, per drug, averaging in excess of $1 million

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Solution

- The Drug, Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act, 35 U.S.C. 156)
  - Extends patent term to make up for regulatory approval phase
  - Allows generic companies to obtain regulatory review without infringing prior to patent expiration
- Serious debate now in Congress about new amendments (strong pressure to bring down prescription costs)

Patent Term Extensions for Regulatory Delays

- Hatch-Waxman Act (1984)
- Allowed for extension of patent terms due to regulatory delay
- Limited in various ways

Basic Requirements

- (a) product has been subject to a regulatory review period
- (b) first commercial sale or use of the product
- (c) application for extension must be filed within 60 days of marketing approval
- (d) must file before patent expiration ("interim" extension may be obtained after NDA is filed if patent is about to expire)
- (e) patent has never before been extended under § 156
- (f) patent "claims" the approved product

Basic Requirements

- Courts have summarized the requirements as “one patent extension per patent, one patent extension per product, and one product per patent extension”

Scope of Rights During Extension

- Entire scope of the patent is NOT extended – only that portion of each claim which applies to the approved product and its approved indication is extended
- Statute appears to permit scope of rights to expand if a subsequent indication for the same product is approved during the extended term
- But scope of rights CANNOT expand beyond original claim scope of patent

Scope of Rights During Extension

- Product claims – limited to uses of the product approved **before or after** the applicable regulatory review period
- Method claims - limited to uses **claimed in the patent** and approved **before or after** the applicable regulatory review period
- Important consequence: scope of rights may expand for product or method of use patent, but this has not been confirmed by any litigated case (FDA has stated at a conference that the rights should expand to include subsequent indications)

Strategic Considerations

When multiple patents are eligible:

- Which patent has the latest expiration date?
- If subsequent indications may follow, which patent has the broadest original claims that could potentially be expanded during the extended term to cover subsequently approved indications for the same product?
- Which patent has the strongest prospects for being upheld as valid?
- Which patent offers easiest proof of infringement (beware of off-label use problem with method claims)?
- Consider filing multiple patent term extension applications (esp. where claim coverage may be questionable) and then pick one

The Case of Bolar Pharmaceuticals

- Bolar Pharmaceuticals wanted to market a generic version of plaintiff's drug on expiration of the patent. Because FDA approval took up to 2 years, Bolar obtained the drug from a foreign source and began testing before expiration of the patent to obtain the necessary data.
- Plaintiff Roche Products sued for infringement of the patent.

The Case of Bolar Pharmaceuticals

- The Federal Circuit held Bolar liable for infringement because it performed regulatory testing of a patented drug during the term of the underlying patent, stating the use was solely for business reasons.
  - Roche Products, Inc. v. Bolar Pharmaceuticals (Fed. Cir. 1984)

The Bolar Amendment to Hatch-Waxman

- Congress responded with Bolar Amendment
- Sanctions use of a patent drug by a generic manufacturer during patent term, so long as use is reasonably related to meeting FDA requirements for market approval
- Provides for a “head start”
- FDA may not approve a generic drug during the term of a relevant patent

35 U.S.C. § 271(a) Patent Infringement

- Except as otherwise provided in this title, whoever, without authority makes, uses, offer to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

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Exceptions of Patent Infringement

- Experimental Use Exception - de minimus activity
- 271(e)(1)

Experimental Use

- Not an act of infringement if the use is for purposes of research or experimentation and not for profit
  - does not apply if the experimental use is coupled with a commercial use
    - Roche Products, Inc. v Bolar Pharmaceuticals Co., Inc., 733 F.2d 858 (Fed. Cir. 1984)

Pure research exemption

- Judge made
- Mere philosophical curiosity
- Duke v. Maddey
  - Cannot assume University does pure research
- Infigen v. Advanced Cell Technology
  - Wishful thinking
- Integra (district court)
  - Pre-Merck funding only

35 U.S.C. § 271(e)(1)

- It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States, a patented invention...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.

Not limited to generic drugs

- Eli Lilly v. Medtronic (Supreme Court, 1990) (class III devices - defibrillator)
  - "Under a Federal Law" refers to entire statutory scheme of regulation rather than a single section of the Federal Food, Drug, and Cosmetic Act
    - Not just relate to patents on drugs vs. devices
      - Language could have been made clear to be limited to drugs
      - Patent term extension applies generally not just to drugs (the product was subject to review)

Abtox v. Exitron (Fed. Cir. 1997)

- Plasma sterilizer – collected data necessary for filing with FDA for approval of Class II device.
  - Purpose for approval or to promote device to customers? Court not look to purpose but to use. Here is reasonably related to approval process.
- Eligible for term extension?
  - Class I – minimal regulation
  - Class II – potentially more harmful, not need advanced approval (no patent term extension)
  - Class III – supporting human life or prevent impairment to health – vigorous review (get patent term extension)

Which acts exempt?

- Intermedics v. Ventritex (N.D.Cal 1991)
  - Only acts which would constitute infringement
  - Test
    - Would it have been reasonable, objectively, for a party in defendant's situation to believe that there was a decent prospect that the "use" in question would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant in the processes by which the FDA would decide whether to approve the product?
  - Fed. Cir. approved this test in Telectronics v. Ventritex in 1992.

Protected activity

- Amgen v. Hoechst
  - Shipping to Japan to evaluate alternate manufacture procedures
  - Purity testing
  - Consistency batches
  - Viral clearance tests – needed for EP approval
- Telectronics
  - Presentation of data to investors, journalists and analysts
  - Cannot revoke application of 271(e)(1) once it applies.

Not protected activity

- Stock piling of drug in anticipation of approval (Biogen v. Schering D. Mass. 1996) – unknown if exempt

- Shipping for foreign testing
  - NeoRx v. Immunomedics (D.N.J. 1994) AND Biogen supra.
  - Could be exempt if later used information for FDA approval process.

Amgen v. Hoechst (D. Mass. 1998)

- In order to come within the protection of section 271(e)(1), the Defendants thus must make, use, or sell the patented invention in ways that objectively bear reasonable prospects of yielding information that might be relevant in the FDA process. If the Defendants have confined themselves to such uses, then their subsequent use of the information gathered, their ulterior motives for engaging in the research, and the existence of other more promising or less extensive uses that also might have lead to FDA acceptance are all statutorily irrelevant factors.

One Court Disagrees With This Broad Reading of the Exemption

- *Infigen v. Advanced Cell Technology, Inc.* 65 F.Supp.2d 967 (W.D. Wisc. 1999)

- Cloning-related patents at issue
  - Activation of oocytes
  - Media for growing embryo

One Court Disagrees With This Broad Reading of the Exemption (Infigen cont. . .)

- ACT raised 35 U.S.C. §271(e)(1) as a defense
  - The court stated §271(e)(1) must be read in conjunction with 35 U.S.C. §156; when so interpreted, §271(e)(1) applies only to patents covering certain products identified in §156(f) that were subject to a regulatory review; defense was rejected

Integra v. Merck

- Supreme Court case
- RGD peptides used in University setting
- No exception except for generic drugs
- Issue regarding damages
- Supreme Court granted Cert. on 271(e)(i) issues

Integra Statements

- Court cannot "quibble" with the exemption "does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process"

Not Research Tool?

- Basic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not “reasonably related to the development and submission of information” to the FDA

Issue Raised

(1) experimentation on drugs that are not ultimately the subject of an FDA submission or

(2) use of patented compounds in experiments that are not ultimately submitted to the FDA

Research Tools Not Addressed

- We therefore need not – and do not – express a view about whether, or to what extent, §271(e)(1) exempts from infringement the use of "research tools" in the development of information for the regulatory process

Holding

- We thus agree with the Government
  - The use of patented compounds in preclinical studies is protected under §271(e)(1) as long as there is **a reasonable basis** for believing that the experiments will produce "the types of information that are relevant to an IND or NDA"

Similar to Jury Instruction

- The relevant jury instruction provided only that there must be a "decent prospect that the accused activities **would contribute, relatively directly**, to the generation of the kinds of information that are likely to be relevant in the processes by which the FDA would decide whether to approve the product in question"

Summary

- Generic Drugs
  - Not affected
- Research tools
  - Not affected
- New drugs (proprietary)
  - Freedom
- Biologics
  - Freedom?
- Stem Cells
  - Freedom?

Exclusivity and Patent Term Extension

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Five Types of Exclusivity

- New Chemical Entity
- New Clinical Study Exclusivity
- 180 Day Generic Drug Exclusivity
- Orphan Drug Exclusivity
- Pediatric Market Exclusivity

New Chemical Entity

- Available for formulations that contain an active moiety not previously approved by the FDA
- 5 year ban from date of New Drug Application for FDA to receive an application from competitors based on published data or an Abbreviated New Drug Application for a drug that contains the same moiety

New Clinical Study Exclusivity

- 3 year exclusivity for a New Drug Application for a new indication

180 Day Generic Drug Exclusivity

- 180 day exclusivity for a first generic manufacturer's Abbreviated New Drug Application - 180 days from the earlier of 1) the date when the first ANDA commences marketing; or 2) the date of a decision holding the relevant patent invalid
- FDA will not approve a second ANDA for the 180 day period

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Other Exclusivities

- These Exclusivities are Independent of Hatch-Waxman
  - Orphan Drug Exclusivity
  - Pediatric Market Exclusivity

Orphan Drug Exclusivity

- Orphan Drug Act
- Exclusivity relating to drugs that are indicated for a disease affecting 200,000 or fewer individuals
- For 7 years from date of product approval, FDA will not approve the same drug for the same indication

Pediatric Market Exclusivity

- FDA Modernization Act of 1997
- Marketing exclusivity in relation to any active moiety for which the sponsor submitted pediatric use data
- effectively adds 6 months to the regular term of a patent or to an applicable NCE or new study exclusivity

Strategic Considerations

- Consider interplay of other forms of exclusivity with extended patents:
  - Orphan drug exclusivity (7 years)
  - New chemical entity (data exclusivity), usually 5 years (only 3 years for isomer where racemate was previously approved)
  - Others – pediatric exclusivity

Conclusions

- When multiple patents are eligible and multiple indications are a possibility, it may be useful to model the potential extensions
- Consider extent to which clinical trials for different indications can be coordinated with patent life cycle strategy
- Consider the interplay of other forms of exclusivity (orphan, NCE, pediatric)
- Use checklist of questions to assess pros and cons of each eligible patent

What Is the Length of the Patent Term

- Can the patent term be lengthened?
  - Regulatory delay
  - Administrative delay in the PTO
  - Exclusivities available [non-patent]
    - Pediatric - 6 months
    - Orphan Drug - 7 years
    - Generic - 9 months

International Importation

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35 U.S.C. 271(g)

- It is an act of infringement to import the product of a patented method of manufacture
- Federal circuit cases:
  - Lilly re importation of protein made from DNA using patented method is infringement
  - BTG re drug made from intermediate by claimed method not infringement
  - Bayer imported into the U.S. products made abroad using a screening method, which Housey argued infringed their patent. Court held no infringement as not method of manufacture
  - Blackberry case