



American Chemical Society

Western Regional Meeting

October 27-30, 2004

Protecting the Product Life Cycle – Patent Law for Chemists

Moderated by: Jeffry S. Mann, Ph.D., J.D.

October 28, 2004
Sacramento, California

Morgan, Lewis & Bockius LLP
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Morgan Lewis
COUNSELORS AT LAW

The 101, 102, 103, and 112 of Chemical Patent Law

Presented by: Richard G. A. Bone, Ph.D., J.D.*

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* Limited Recognition to Practice before the U.S. PTO under 37 C.F.R. § 10.9(b).

What you need to know

- Publish *AND* Perish
- Tell *ALL*

Benefit of the Bargain

Right to exclude others from

Making

Using the invention

Selling

Offering to sell

In return for an *enabling* disclosure

Patenting Timeline

- Inventive Activity
- Prepare Patent Application
- File Patent Application
- Patent Prosecution
 - Foreign filing – 1 year
 - Application publishes – 18 months
- Patent Issues
 - Duration: 20 year term from filing date

4 Statutory Requirements

- **Useful** – 35 U.S.C. § **101**
- **New** – 35 U.S.C. § **102**
- **Non-obvious** – 35 U.S.C. § **103**
- **Fully disclosed** – 35 U.S.C. § **112**

Usefulness – 101

Untested PTO guidelines:

Invention must have “Well-established utility”:

- Immediately apparent to one of ordinary skill
- Utility is:
 - Specific
 - Substantial (no further research into utility)
 - Credible

Novelty – 102 . . .

Any pre-filing activity or events

- Public disclosure
 - Published papers (online or hard copy)
 - Conference presentations
 - Theses
 - Patents / patent publications
- Commercial activity

. . . Novelty – 102 . . .

- Work of Others
- Art Search?
 - No obligation
- Secret Prior Art
 - Inventive activity
 - Unpublished patent applications

. . . Novelty – 102 . . .

Critical Dates

- U.S.
 - 1 year grace period
- RotW
 - *No grace period*

. . . Novelty – 102 . . .

Publish AND Perish

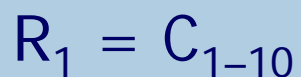
Publish your *own* Work:

- > Loss of foreign filing rights (worldwide)
- > Loss of U.S. filing rights – after 1 year

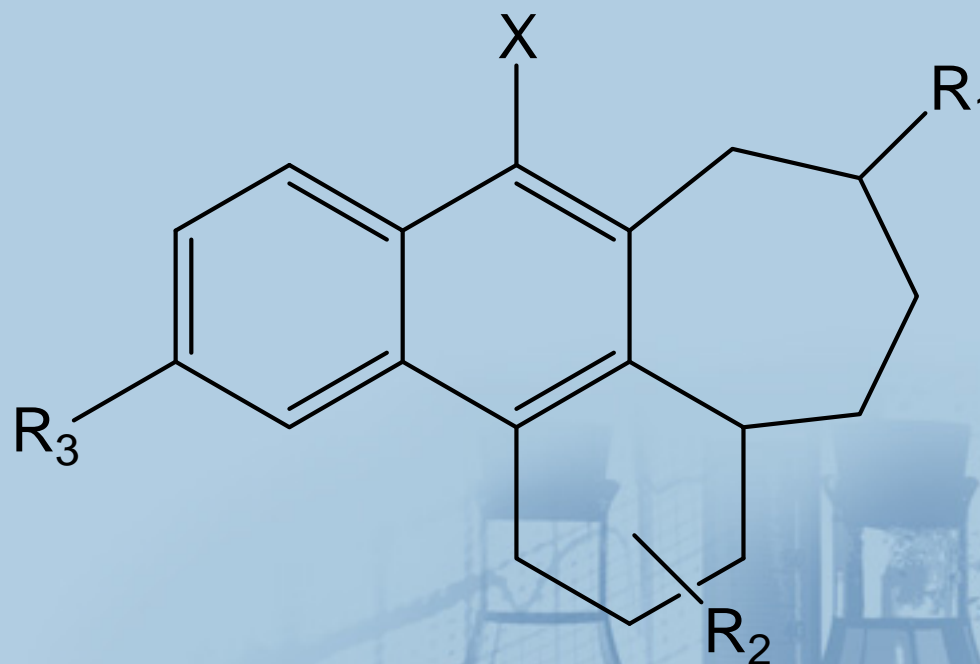
. . . Novelty – 102 . . .

Compositions of Matter

Genus



Species



. . . Novelty – 102 . . .

Claim

- Genus
- Species

Defeated by prior art ...

- Species
- Subgenus
- Overlapping genus
- Species
(Explicit or “at once envisaged”)

Coupled with method of synthesis

. . . Novelty – 102

New use of old compound?

- Only where use is not based on an *inherent* property and is nonobvious

Nonobviousness – 103 . . .

- Combination of prior art teachings renders invention trivial
 - Your own work
 - Work of Others
- Can be overcome by various showings

. . . Nonobviousness – 103 . . .

- Legal standard
 - Determine scope + content of prior art
 - Ascertain differences between invention and prior art
 - Resolve level of ordinary skill in the art
- Fact based analysis

. . . Nonobviousness – 103 . . .

Claim

Can be defeated by prior art ...

■ Genus

- Closely similar Species
- Subgenus
- Overlapping genus

■ Species

- Closely similar Species
- Genus with “markers”

Coupled with method of synthesis

. . . Nonobviousness – 103

“Close similarity”:

- Homologs
- Analogs
- Isomers
- Purity
- *Reasonable expectation of similar properties*

Disclosure – 112

- No “hiding the ball”
- Enablement: how to *make and use* the invention
 - Compositions: method(s) of synthesis
 - A useful application
- Best mode
- Don't be vague
 - Chemical names

Recapitulation

- Publish *AND* Perish
 - Don't do it ... (*yet*)
- Tell *ALL*
 - Just do it ... *now*

“Inventing” a Broad Class of Compounds: To Claim or Not to Claim

Presented by:

Elizabeth C. Weimar, J.D.

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October 28, 2004

Sacramento, California

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Claiming Chemical Compounds

Species -- a single compound

Subgenus -- some substituent variants allowed

GENUS -- core structure

Conception: The Beginning

Write down your starting point and identify

- your specific goal
- problem you are solving
- experimental design
- structure/activity theories

Conception: The Beginning

Structure/activity theories

- 1) - minimal structural characteristics
 - specific charge features
 - binding/catalytic site 3D structure
 - specific reactive moiety

Conception: The Beginning

Structure/activity theories

- 2) Structure unknown - natural source is known and theory of compound type exists
- 3) Structure known - modification desired to accomplish specific goal
- 4) Chemical library approach

Claiming Chemical Compounds

Complete your experiment

Input from others - advantages of genus, heteroatoms, keto reduction, substituent substitutions

Critical point for inventor involvement

Claiming Chemical Compounds

17 vs. 20 year term

Examination - Restriction

The Offer

Filing Divisional Applications

Summary

Articulate starting point

Constantly note structure/activity theories

Participate in application and claim development

IP Protection for Chemical Products Obtained from Life Forms

Presented by:

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Overview

- 1. Patentable subject matter**
- 2. Patent examples**
- 3. Some non-patent considerations**
- 4. The whole picture**

Patentable Subject Matter

- ◆ **“...any new and useful process, machine, manufacture, or composition of matter...”**

35 U.S.C. § 101

- ◆ **“anything under the sun that is made by man”**

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

Unpatentable Subject Matter

- ◆ Subject matter that is not a practical application or use of an idea, a law of nature or a natural phenomenon
- ◆ Humans

Unpatentable Subject Matter

- ◆ Subject matter that is not a practical application or use of an idea, a law of nature or a natural phenomenon

$$E=mc^2$$

Magnetism, electricity, law of gravity

New mineral discovered in the earth

New plant found in the wild

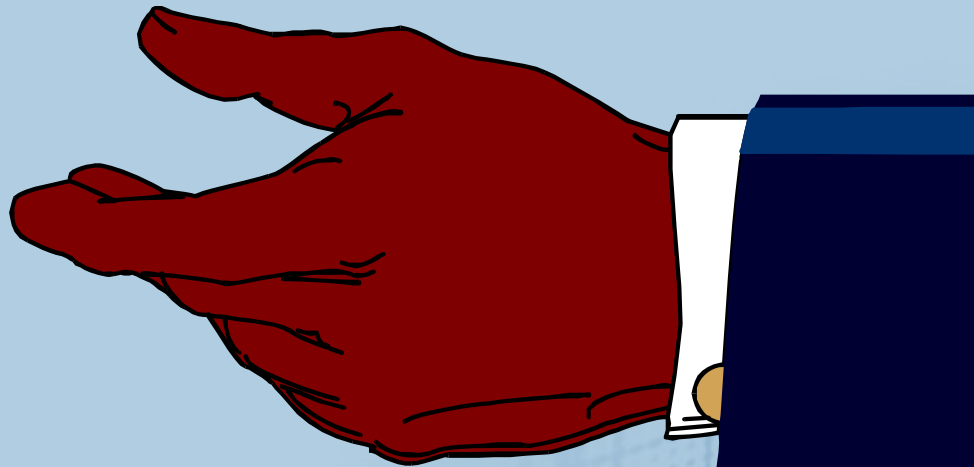
U.S. Pat. No. 5,861,302

A microorganism which produces taxol or taxane and is isolated from a tree of the genus Taxus.

U.S. Pat. No. 5,861,302

A microorganism which produces taxol or taxane and is isolated from a tree of the genus Taxus.

“made by the hand of man”



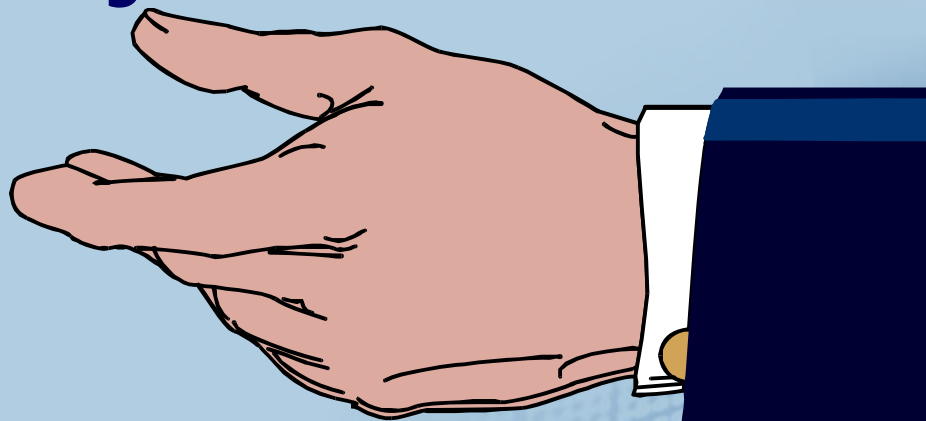
U.S. Pat. No. 5,667,783

A composition for treating an HIV positive subject . . . comprising a mixture of an aqueous extract of an *Asphodelus tenuifolius* herb, cortisone and a pharmaceutically acceptable carrier.

U.S. Pat. No. 5,667,783

A composition for treating an HIV positive subject, . . . comprising a mixture of an aqueous extract of an *Asphodelus tenuifolius* herb, cortisone and a pharmaceutically acceptable carrier.

“made by the hand of man”



U.S. Pat. No. 5,420,318

A process for preparing an extract containing over 15% azadirachtin, an insecticidally active neem seed component, which comprises:

- a) stirring ground neem seeds . . .
- b) separating the liquid phase . . .
- c) contacting . . . and
- d) desorbing the extract . . .

U.S. Pat. No. 6,555,109

An isolated and purified fraction of the venom of *Vipera xanthina* wherein the fraction is substantially non-toxic and wherein the fraction has a UV absorbency at a wavelength of 280 nm.

Types and Uses of Such Chemicals is Boundless

- ★ Food supplements/nutriceuticals
- ★ Medicines
- ★ Pesticides
- ★ Specialty oils

Some Non-Patent Considerations

❖ Access to the organism

Is permission to “harvest” necessary?

If so, who grants the permission?

Are there import and/or export restrictions?

❖ Ownership of the organism

Private or public ownership?

Some Non-Patent Considerations

❖ Availability of the organism

Geographical distribution?

Plentiful or rare?

Renewable?

❖ Benefit sharing

Indigenous rights?

Money or “in kind” restitution?

The Legal Framework

- 👉 **International laws**

 - Convention on Biological Diversity**

 - Convention on International Trade in Endangered Species and Flora and Fauna (CITES)**

- 👉 **National laws/regulations**

- 👉 **Regional laws/regulations**

- 👉 **Community traditions**

Avoid Negative Headlines

Neem tree

Turmeric

Basmati rice

Hoodia

???

The Whole Picture

Many valuable chemicals obtained from organisms.

Intellectual property protection may be available for such chemicals.

Practical considerations often very important.

Laws, regulations, rules and traditions may influence access, ownership, and use of such chemicals.

Technology Transfer – Academic/Industry Cooperation

Presented by:

Erich E. Veitenheimer, III, Ph.D., J.D.

&

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Outline

Goals of University and Industry

Drug Discovery in Industry

Typical University Practices

Finding Common Ground

Constraints on the University Scientist

Conflicting Goals?

University

Basic research

Publication

Not profit oriented

Expectations

Industry

Product development

Confidentiality

Profit oriented

Expectations

Drug Discovery in Industry

Current Model

- **Identify Molecular Drug Discovery Target**
Protein A → Receptor B → Disease C
- **Screen for Compounds That Bind**
Screening → Lead Compounds
- **Optimize Leads**
Optimization → Development Compounds
- **Refine Drug Candidates**
Preclinical Development → Clinical Development → Drug Product

Drug Discovery in Industry

New technologies have been applied to this model but model has not changed

Genomics, Proteinomics, Bioinformatics →
Drug Discovery Targets

- Combinatorial Chemistry, Molecular Modeling, Cheminformatics, HTS → Leads and Development Compounds

Typical University Practice

**File Provisional Patent Application
on Basic Finding
(and keep it inexpensive!)**

**Inventor Publishes, Accumulates New
Data, Publishes Again, etc.**

**File Non-provisional And/or International
Application**

University Decisions

Market to Industry Partner at What Stage?

Sponsored Research Agreement?

Standard License?

or

Initiate Start-up Company

Finding Common Ground

There needs to be trust between the parties.

Finalize agreements early in the process

Must be crystal clear regarding assignment and license rights

Don't go forward unless you have inventor's full buy-in to the process

Finding Common Ground

Triage early and often

**Determine commercial potential early,
preserving resources**

**File a broad, complete provisional patent
application, thereby preserving foreign
rights**

**Carefully strategize in selecting countries
where patent protection makes sense**

Constraints on the University Scientist

Collaboration with others?

Publication?

Sending out invention-related materials to others?

Technology transfer practices of the university?

A Recipe For Successful Technology Transfer

A commercially viable invention +
Common (and mutually evolving) goals and expectations +
Frequent communication between parties +
Clear legal responsibilities =
Trust and A Better Chance for Success

FDA Regulatory Issues Related to the Approval and Manufacture of Pharmaceuticals and Pharmaceutical Ingredients

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Overview

- Sources of Law
- What is a “Drug”?
- Drug Development Overview/Phases
- New Drug Application and Review
- Post-Approval Regulatory Issues

Sources of Law

- The Federal Food Drug & Cosmetic Act (FFDCA) (21 U.S.C. §§ 301 et seq.)
- Significant Amending Legislation
 - Drug Amendments of 1962 (effectiveness requirement)
 - Orphan Drug Act (drugs for rare diseases)
 - The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) (process to approve generic drugs)
 - Food and Drug Administration Modernization Act of 1997 (FDAMA) (drug approval processes, off-label promotion)
 - Prescription Drug User Fee Act (PDUFA) I, II, & III

Sources of Law

Regulatory Sources

- Title 21, Code of Federal Regulations
- Regulation Preambles (from Federal Register)
- FDA Guidance Documents
- FDA Regulatory Procedures Manual
- US Pharmacopoeia (USP)
- International Conference on Harmonization (ICH) Documents

What is a “Drug”?

FFDCA § 201(g)(1)

- Articles recognized in US Pharmacopoeia, National Formulary or Homeopathic Pharmacopoeia
- Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals
- Articles (other than food) intended to affect the structure or any function of the body of man or animals
- Articles intended for use as a component in any of the above

What is a “Drug”?

Intended use can be shown by:

- Labeling
- Advertising
- Statements of manufacturer/representatives
- Knowledge of actual use by doctors/consumers

“New Drug”

What is a “New Drug” - FDCA § 201(p)

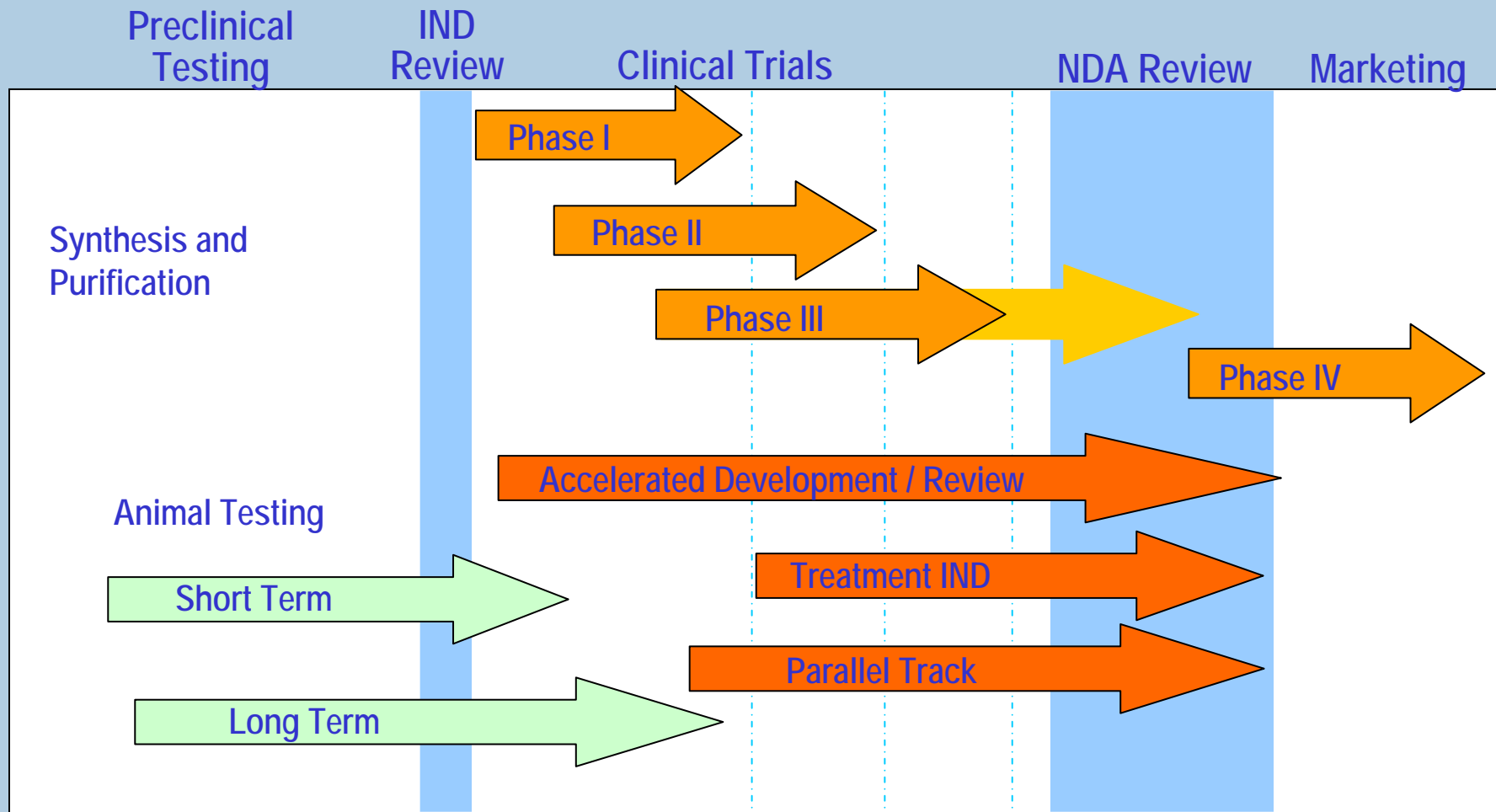
- Any drug not generally recognized as safe and effective (GRAS/E) by qualified experts under conditions prescribed, recommended or suggested in the labeling; and/or
- Any drug which has not been used for a material extent and a material time under such conditions

If a drug is a “new drug,” FDA approval through an NDA is required prior to marketing

Drug Development Overview

- Drug Discovery
- Pre-Clinical Testing
- Clinical Trials
- New Drug Application (NDA)
- NDA Review by FDA
- Marketing

Drug Development Phases



New Drug Application

NDA Content:

- Description of drug product (API) and drug substance (final product, including excipients)
- Clinical and pre-clinical data
- Chemistry, Manufacturing, Controls (CMC)
- Proposed labeling
- Patent information (Paragraph IV certification)
- Debarment certification
- Clinical investigator financial disclosure
- PDUFA fees

New Drug Application

Approval Standard

- Substantial evidence that drug is safe and effective
- Adequate manufacturing and controls
- Adequate and well controlled studies (2 studies)
- Appropriate labeling

New Drug Application

Safety standard

- Risk/benefit in context of indication or intended use
 - Do the benefits of the drug outweigh the known and potential risks of the drug?
 - Consider the severity of the disease and the absence of satisfactory alternative therapy
- Based on laboratory and animal studies, as well as human adverse event profile
- Risks may be managed through labeling e.g., black box warning, or risk management plan for distribution of drug

New Drug Application

Effectiveness standard

- Drug has the effect it purports, or is represented to have, under the conditions of use prescribed, recommended or suggested in the labeling
- Effectiveness is relative to what other therapies exist for the particular disease or condition

NDA Review/Process

NDA Process

- Filing (60 days); can receive Refusal to File (RTF)
- Review by CDER team
- Advisory Committee review and recommendation
- Labeling review / negotiation
- Pre-approval site inspection (PAI)
- Approvable / not approvable (may soon be replaced by "Complete Response" letters)
- Approval Letter

Review Period

- Standard review time = 10 months
- Priority review time = 6 months

Post Approval Regulatory Issues

- Periodic Reports
- Notification of Changes
- Adverse Event Reporting
- GMPs

Product Clearance: Steering a Safe Course to Market

Presented by: Jeffrey S. Mann, Ph.D., J.D.

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Freedom to Operate

What is Freedom to Operate?

- The freedom to make, use and sell a product reasonably believing that you will not infringe the valid, enforceable patent of another
- Permission to infringe the patent of another - license

Infringement - 35 U.S.C. §271

- “Except as otherwise provided in this title, whoever without authority makes, uses, offers 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.”
- Infringing compound must have each claimed feature of patented compound

Freedom to Operate

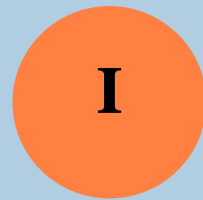
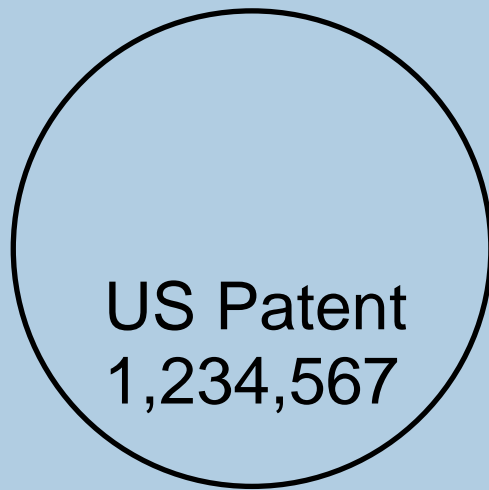
The Search

- A Freedom to Operate analysis generally begins with a structured search for enforceable patents that include claims that might encompass the product (“Dominating Patent”)
- Electronic databases (e.g., CAS, STN, USPTO, EPO, etc.)
- USPTO search using the USPTO classification system

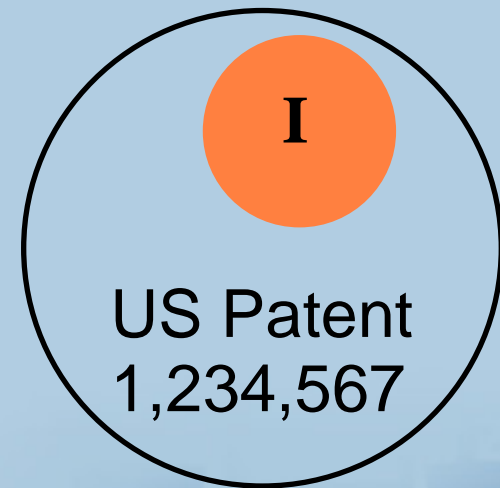
Freedom to Operate

- No dominating enforceable patent exists
 - OR
- Non-infringement of apparently dominating patent by making, using and/or selling product
- Invalidity of dominating patent
- Licensing of dominating patent

Dominating Patent



or

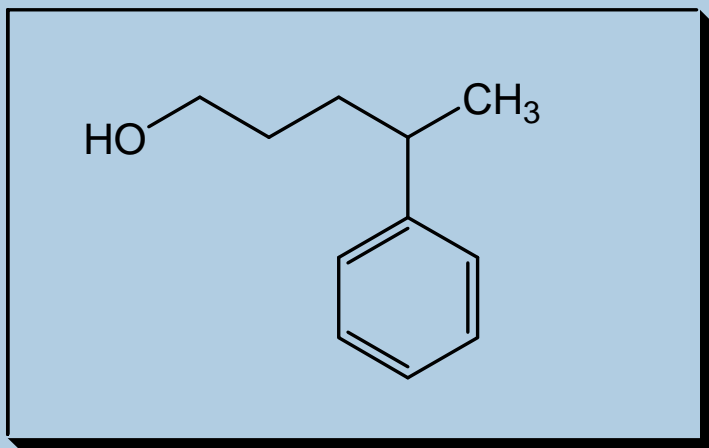


'567 patent does
not dominate

'567 patent dominates

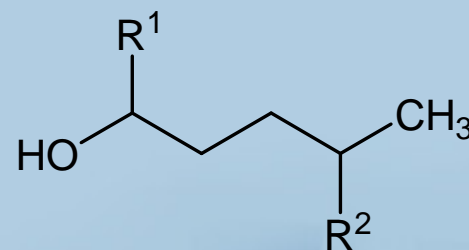
Dominating Patent

Product



US Patent No. 1,234,567

1. A compound having the formula:



wherein

R¹ is H, CH₃ or phenyl ; and
R² is substituted or unsubstituted aryl

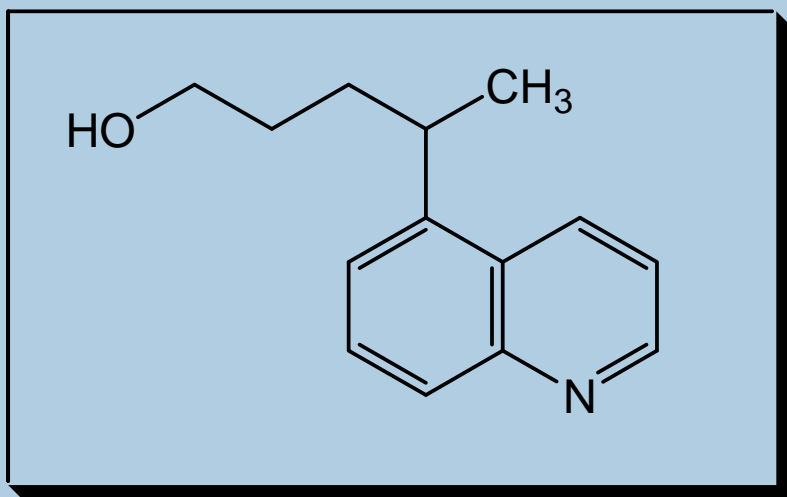
Freedom to Operate

Why seek a Freedom to Operate Opinion from Counsel?

- Informed, detailed legal and technical analysis of the product and its place in the patent landscape
- Increased protection from finding of willful infringement and treble damages if infringement is found

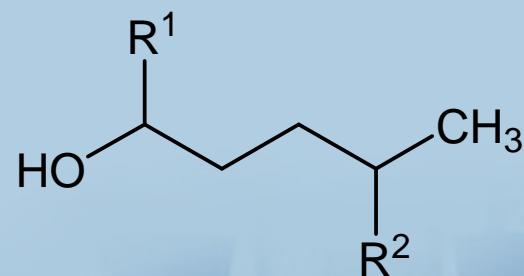
Non-Infringement

Product



US Patent No. 1,234,567

1. A compound having the formula:

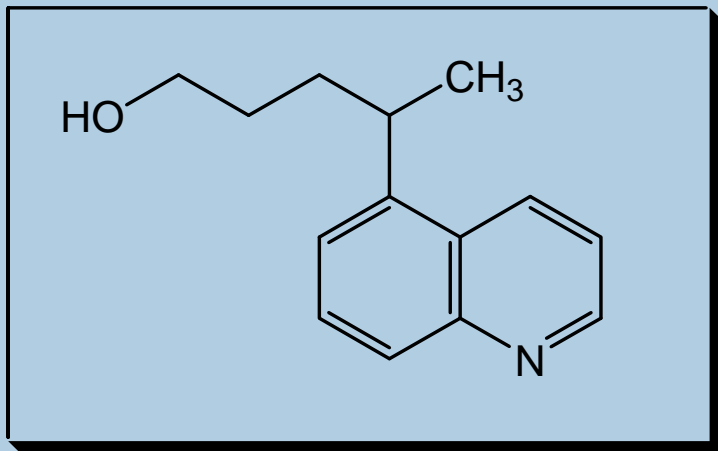


wherein

R¹ is H, CH₃ or phenyl ; and
R² is hydrocarbyl

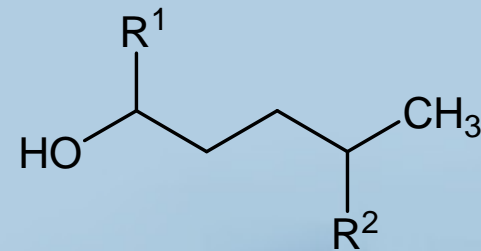
Non-Infringement ?

Product



US Patent No. 1,234,567

1. A compound having the formula:



wherein

R¹ is H, CH₃ or phenyl ; and
R² is substituted or unsubstituted aryl

Non-Infringement ?

- Does the term “aryl” encompass the fused heteroaryl moiety at R² ?
- Applicability of the term “aryl” to the heteroaryl moiety R² is uncertain
- Review the specification for a definition of the term “aryl”

Non-Infringement

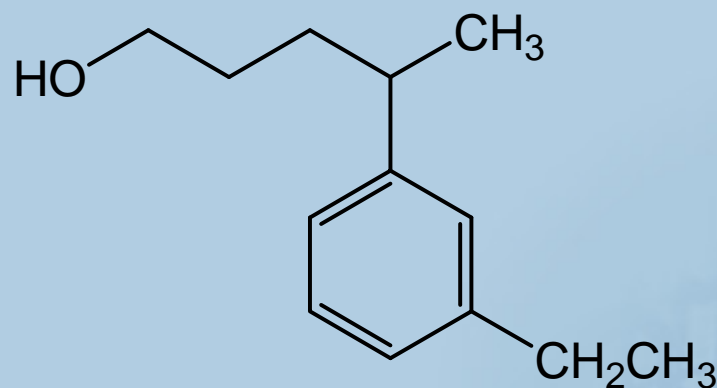
- “As used herein, the term “aryl” refers to aromatic hydrocarbyl moieties, e.g., substituted or unsubstituted phenyl, substituted or unsubstituted naphthyl, substituted or unsubstituted pyrenyl, and the like.”
- Manufacture, use and sale of the product does not infringe U.S. Patent No. 1,234,567

Invalidity

- An invalidity analysis generally begins with a structured search for one or more reference that was publicly available prior to the priority date of the patent
- Electronic databases (CAS, USPTO, EPO, etc.)
- Hand search (USPTO)

Invalidity - Anticipation

- A paper authored by Early, appeared in the Golden State Journal of Chemistry on January 1, 1988
- Early discloses the compound:

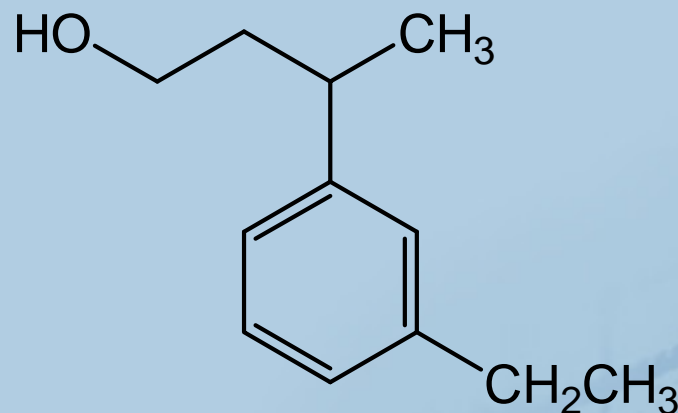


Invalidity - Anticipation

- The priority date for the application that matured into U.S. Patent No. 1,234,567 is March 15, 1988
- Early et al. disclose a compound that is within the scope of the claims of the '567 patent
- The '567 patent is invalid as anticipated by the disclosure of Early et al.

Invalidity - Obviousness

Early also discloses a compound that is a homologue of the claimed compound, differing by a single carbon:



Invalidity - Obviousness

- Under the “Hass-Henze Doctrine” a homologue of a known compound, differing only by a single carbon atom (“adjacent homologue”) is obvious over the known compound
- *Exception* - The patentee successfully argued that the homologue has properties unexpected in view of those of the known compound

Conclusion

- Potentially dominating patents must be identified and their strength ascertained prior to introducing a new product to market
- An apparently dominating patent can be removed as a substantial concern by a well-reasoned opinion of counsel that the patent is not infringed and/or invalid

Litigation of a Chemical/Biotech Patent Action

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Overview of Patent Litigation

- Patent basics -- rights, claims, and interpretation.
- Pre-filing investigation, analysis.
- Filing of Complaint/Answer (affirmative defenses).
- Discovery -- facts and experts.
- Resolution -- motions, summary judgment?, trial, post-trial.
- Damages -- lost profits, reasonable royalty, willfulness (enhanced damages and attorneys fees).
- Appeal, remand?

What is a patent?

- A patent confers a right to exclude others from making, using, selling, offering for sale, or importing the claimed product or process.
 - – Patent does not confer a right “to do” anything.
 - – Patents may overlap. May need multiple licenses.
 - – A license is only a promise not to sue. It does not guarantee the licensee can “do” anything.
 - – Patent can be enforced only by owner, assignee, or exclusive licensee (owner joined voluntarily or not)

Elements of a patent

- Claims: Define scope of invention
 - – Limitations serve as “checklist” to determine claim scope for infringement or invalidity analysis.
 - – A limitation not included in claim is not relevant to scope.
- Specification: Written description of invention, embodiments, examples (real or prophetic), prior art.
- Prosecution (or file) history: History of proceedings before U.S. PTO, *e.g.*, application, office actions, amendments, reasons for allowance, etc.

Claim construction (interpretation)

- “The claim is the name of the game” (Fed. Cir.)
 - – Claim construction is often dispositive of case.
 - – Construction is “question of law,” decided by judge. Cases are often decided on summary judgment, if there are no questions of fact.
- Main tools for construing claim terms:
 - – Ordinary meaning of term to persons skilled in the art. Dictionaries, treatises commonly used.
 - – Did inventor define term differently? Consider usage in specification and prosecution history. Prior art?
 - – Extrinsic evidence (*e.g.*, inventor or expert testimony). Heavily disfavored, unless term is too ambiguous.

Pre-filing investigations: What to do before dropping the hammer

- Patentee:
 - – Obtain as much information as possible about competitor's product or process to evaluate case for infringement.
 - – Who to sue? For what? Theories of infringement:
 - Direct infringement. Claim covers product or process, either literally or by equivalents. May sue maker, user, seller, importer of product.
 - Indirect infringement -- two types:
 - Contributory infringement. Accused infringer (e.g., supplier) sells non-staple item used by another to infringe.

Pre-filing investigations: What to do before dropping the hammer (cont'd)

- Induced infringement. Accused infringer aids another to perform acts that constitute infringement, *e.g.*, training, education.
- Indirect infringement requires showing of direct infringement, although direct infringer need not be named as a party.

Pre-filing investigation: Patentee (cont'd)

- Patentee should also consider:
 - – Validity of claims, *e.g.*: Prior art? Indefinite? Enabled?
 - – Likelihood of damages? Preliminary injunction?
 - – Notify competitor of alleged infringement? Offer license? Avoid strong language to avoid declaratory judgment action.
 - – Where to sue? Want forum to be convenient for patentee, inconvenient for infringer. But court must have personal jurisdiction over defendant, *e.g.*, sales of infringing products in that district, other affirmative acts in that district.

Pre-filing investigations (cont'd)

- Competitor/accused infringer:
 - – If patentee sends warning letter, consider getting opinion of counsel re: non-infringement and/or invalidity.
 - Well reasoned opinion is a defense to willfulness (enhanced damages).
 - Opinion is privileged unless used in defense. Scope of waiver.
 - Address only “good news.” “Bad news” should be oral, not written.
 - Absence of opinion is no longer basis for adverse inference. Patent search and clearance opinion often make sense, even w/o letter.

Pre-filing investigations (cont'd)

- – Weigh litigation vs. damages, injunction. Take a license? Settle? Modify product or process? Abandon it altogether?
- – If threatened by suit, consider declaratory judgment action. Take the initiative; choose forum. But weigh carefully.

Complaint and Answer

- Complaint: Notice pleading, not fact pleading.
 - – Does not require lengthy statement of facts, or even identification of accused products. (Or, may be more factual to educate judge or signal the defendant).
 - – How many patents to assert? How many defendants?
 - – Must have good-faith belief in allegations (Rule 11).
- Answer:
 - – Affirm or deny allegations in complaint.
 - – Or, move to dismiss, *e.g.*, lack of personal jurisdiction?
 - – Seek to transfer to another forum?
 - – Counterclaims?

Answer (cont'd)

- Answer will also assert affirmative defenses, e.g.:
 - – Invalidity over prior art:
 - **Anticipation (lack of novelty), e.g.:**
 - Single reference published more than one year before priority date of patent discloses all claim elements, expressly or inherently. The “gold standard” for invalidity.
 - In public use or on sale more than year before priority date.
 - Known or used by others in U.S. before invention date.

Answer (cont'd)

- **Obviousness.**
 - Combination of references discloses all claim elements.
 - Requires motivation to combine. Not hindsight reconstruction.
 - But must also consider “objective indicia of non-obviousness,” e.g., commercial success of invention, failure of others, long-felt but unmet need, copying, licensing, praise of invention.

Answer: Affirmative defenses (cont'd)

- – Invalidity due to patent's internal deficiencies, *e.g.*:
 - Written description does not enable a person skilled in the art to practice the invention (lack of enablement).
 - Failure to set forth inventor's "best mode" to carry it out.
 - Claims are indefinite, "insoluble ambiguity."
 - Written description inadequate to show inventor(s) were "in possession" of invention at the time application was filed.
 - Improper inventorship. May be fixable in PTO if no deceptive intent.

Answer: Affirmative defenses (cont'd)

- – Inequitable conduct (“fraud on the Patent Office”).
 - *E.g.*, patentee did not inform PTO of known, material, non-redundant prior art. Or, covered up errors in examples, tests.
 - Requires showing of intent to deceive. So generally not pled in original Answer but added later if evidence comes to light.

Fact discovery

- Fact discovery. Timing is set by judge. Tools include:
 - Interrogatories (questions), e.g., identify factual info relating to infringement, defenses, products, persons, insurance, etc.
 - – Document requests, e.g., “all documents relating to” accused product/process, patent-in-suit, sales, the parties, opinions, etc.
 - Confidentiality of documents typically ensured by protective order.
 - – Depositions. Examination of witness under oath.
 - Fact witnesses, e.g., inventors, persons identified above.
 - Rule 30(b)(6) -- witness(es) designated by company to testify on specific topics outlined by the other, deposing party.

Fact discovery cont'd

- – Requests for admission. Handle with care -- binding on party!
- – Subpoenas. Obtain documents, testimony from third parties.

Expert discovery

- Experts help develop theories of claim construction, infringement, invalidity, and/or damages.
 - Typically have access to all confidential info.
- Party identifies its expert(s), subject to objections.
 - Some parties retain experts just to deny them to other side.
- Experts prepare detailed reports on their opinions.
- Then prepare rebuttals of other side's expert reports.
 - Privileged waived re: notes, attorney communications, etc.
- Experts will be deposed on their opinions.
- Will testify again at trial, if any.

Resolution of the litigation

- Settlement. Most patent cases settle, e.g., a non-exclusive license, a halt to infringing activity, etc.
- Motion for summary judgment. If there are no facts at issue, case can be resolved as a matter of law.
 - – E.g., Typically no factual dispute over product, so case turns on claim construction. Judge can decide infringement.
 - – Processes may be more obscure, more difficult to decide.
 - – SJ may be granted on invalidity too, if prior art is clear.
 - – SJ may be granted for indefiniteness, enablement, etc. Even if seemingly fact issues arise, indefiniteness, etc. are defined as “questions of law,” which judge can decide without jury.

Resolution of litigation (cont'd)

- When all else fails, go to trial.
 - – Can be costly, lengthy process, depending on the issues.
 - – Courts experimenting with new technologies to make it easier for judge, jurors to understand complex issues.
- Post-trial motions: If at first you don't succeed ...
 - – Motion for reconsideration. Ask judge to reconsider decision. Opinion may be corrected, but rarely reversed.
 - – Judgment as a matter of law (JMOL). Overturn verdict if not supported by substantial evidence. Verdict not just a "little bit" wrong, but very wrong. Rarely granted.

Resolution of litigation (cont'd)

- Appeal.
 - – Federal Circuit is only court to hear patent appeals.
 - – Fed. Cir. reviews “questions of law” *de novo* (lower threshold for reversal). Reviews “questions of fact” for clear error (higher threshold).
 - – Fed. Cir. frequently reverses claim construction (*de novo*), so many decisions are reversed and remanded.
 - – Many other issues are questions of law (*e.g.*, SJ motions, indefiniteness, enablement, inventorship, etc.) or question of law based on underlying facts (*e.g.*, obviousness), so reversal rate tends to be relatively high.

Damages

- Damages are set by statute, and can include:
 - – Permanent injunction to stop infringing activity. Typically included in final judgment.
 - – Preliminary injunction.
 - Consider near the beginning of litigation. Involves shortened, more focused discovery schedule. If granted, typically ends the case.
 - But high hurdles -- patentee must show it is likely to succeed on the merits of the case and facing irreparable injury. Not often granted.

Damages cont'd

- – Lost profits.
 - Patentee must be selling the product and show it would have made the infringer's sales but for the infringement. Two-supplier market easy; multi-supplier market gets difficult.
 - Price erosion is also considered.
 - Convoys sales? May extend to related products or services.
- – Reasonable royalty.
 - Patentee is entitled to at least a reasonable royalty. Royalty may be in addition to or instead of lost profits.
 - Does not require that patentee make or sell the good.

Damages (cont'd)

- Assumes hypothetical negotiation between willing parties before infringement. A “legal fiction,” or “judicially-sanctioned speculation,” yet requires sound economic basis.
- Many factors considered, *e.g.*, established royalty rates; patentee’s licensing practices; infringer’s need for the patented technology and other licenses; infringer’s profits (as evidence as to what it might have expected its profits to be); degree of competition between patentee and infringer; “entire market rule,” consider product as a whole and not just infringing element; etc.

Damages (cont'd)

- Willful infringement (willfulness).
 - – May increase damages up to 3x (treble damages).
- Prejudgment interest.
- Attorneys' fees? Rarely granted, in absence of discovery abuses or other offensive conduct.

Toxic Substance Control Act Requirements For Chemical Manufacturers, Importers and Processors

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Purpose

- I. Regulate chemical substances and mixtures which present an unreasonable risk to human health or environment

Primary Elements

- II. A. List of All Existing Chemical Substances
 - B. Pre-manufacture Notice for New Chemical Substances or Significant New Uses
 - C. Request for Data for Existing or New Chemical Substances
 - D. Recordkeeping and Reporting for Adverse Health Effects or Environmental Impacts

What Chemicals Are Regulated

A. Chemical substances

1. any organic or inorganic substance of a particular molecular identity
 - a. Includes – any combination of substances occurring in whole or in part as a result of chemical reactions or occurring in nature
2. Does not include mixtures of chemical substances
 - a. Mixture – any combination of chemical substances if not occur in nature or as a result of a chemical reaction

What Chemicals Are Regulated

- B. Exemptions

1. Pesticides

- a. chemical substances manufactured, processed, or distributed for pesticide purposes
- b. chemical substances used as intermediates to produce pesticide are subject to TSCA

2. Food, food additive, drug, cosmetic or device

What Chemicals Are Regulated

3. Tobacco or tobacco products
4. Any source material, special nuclear material or byproduct material as defined in Atomic Energy Act
5. Chemicals intended for export

Who is covered by TSCA?

1. Manufacturers
 - a. "Manufacture" means to manufacture, import or produce
2. Importers
3. Processors
 - a. Process means preparation of chemical substance or mixture, after its manufacture, for distribution in commerce
 - (i) in same or different form as received
 - (ii) as part of an article containing chemical substance or mixture

Inventory of Existing Chemicals

- 1. Initial inventory published in 1985-58,000 chemical substances
- 2. Updated inventory published in 1990-63,000 chemical substances
- 3. Public Inventory
 - a. U.S. Government Depository Libraries
 - b. Chemical Abstract (CA) Index Name and Chemical Abstracts Service (CAS) Registry Number

Inventory of Existing Chemicals

- 4. Confidential Inventory
 - a. Includes chemical substances covered by confidentiality claims
 - b. TSCA Accession Number and generic chemical name

Pre-manufacture Notice for New Chemical Substances

1. Basic Requirement – Notice to EPA 90 days prior to manufacture or import of new chemical substance
2. Exemptions
 - a. Small quantities solely for research and development – No PMN notice required
 - b. Test Marketing
 - (i) Manufacturer may apply to EPA for exemption if demonstrate no unreasonable risk of injury to health or environment
 - (ii) PMN Notice – 45 days prior

Pre-manufacture Notice for New Chemical Substances

2. Exemptions (cont'd)

c. Low Volume Exemption

- (i) Manufacture or Import less than 10,000 kg/yr.
- (ii) 30 day advance notice to EPA

d. Low Release and Low Exposure (LOREX)

- (i) 30 day advance notice to EPA

e. Polymers – No PMN Notice required for certain polymers

Pre-manufacture Notice for New Chemical Substances

3. What Information Must Be Included In Pre-manufacture Notice
 - a. EPA Form 7710-25
 - b. Chemical Identity
 - (i) Class I Substances – clearly identifiable chemical structure (e.g., sodium chloride, 1,3-butadiene, benzene)
 - (a) Chemical Abstract (CA) name
 - (b) Chemical Abstract Service (CAS) name

Pre-manufacture Notice for New Chemical Substances

b. Chemical Identity (cont'd)

- (ii) Class II Substances – Not clear chemical structure
 - (a) CA Index Name or CA Preferred Name
 - (b) Identity of chemical precursors by CA name and Chemical Abstract Service Registry Number (CASRN)
 - (c) No trade names or generic names (e.g. "reaction product of X, Y, Z")

Pre-manufacture Notice for New Chemical Substances

- b. Chemical Identity (cont'd)
 - (iii) Molecular formula
 - (iv) Structural diagram
- c. Impurities
- d. Chemical Byproducts

Production, Import and Use Information

- (i) Estimated annual production or import volume for initial 3 years
- (ii) Low Volume and LOREX
 - (a) EPA evaluation based on 10,000 kg/yr. unless specify lower production volume

Production, Import and Use Information

e. Production, Import and Use Information (cont'd)

(iii) Use Information

(a) Function – e.g. degreaser, catalyst, plasticizer

(b) Application – e.g. degreaser for cleaning circuit boards

(c) Production volume for each use category

Production, Import and Use Information

- (d) Distribution in commerce
 - (1) Industrial
 - (2) Commercial
 - (3) Consumer
 - (4) Limited to on-site use

Human Exposure and Environmental Release Information

- (1) No requirement to perform toxicity or health effect studies for PMN
- (2) Should submit any toxicity or health effect studies or data
- (3) Submit information on potential to release new chemical substances to environment
 - a) e.g. air emissions, wastewater, method of disposal

EPA Review of PMN

1. EPA review potential for risk to human health or environment
 - a. Review toxicity and exposure information
 - b. Review potential toxicity based on chemical structure analysis
2. Completeness Determination
 - a. 90 day PMN review period not commence until EPA determine that PMN notice is complete

EPA Review of PMN

3. Unfavorable EPA Decisions

a. Potential EPA actions:

- (i) Issue regulation prohibiting manufacture or import of new chemical
- (ii) Issue regulation limiting use and distribution of new chemical while toxicity or environmental studies are performed
- (iii) Enter into Consent Order sec. 5(e) – Specify testing requirements and limit to production or import

EPA Review of PMN

4. Manufacturer may begin manufacture or import of new chemical unless receive notice from EPA during 90 day review period
 - a. Notice of commencement of manufacture—must submit notice to EPA within 30 days after actually begin manufacture or import
 - (i) New chemical added to inventory of existing chemicals

Test Requirements for Existing Chemicals

1. EPA may issue regulation requiring manufacturers and processors of existing chemicals to perform testing
 - a. Criteria—EPA must determine that chemical may present an unreasonable risk
 - (i) considering both toxicity and exposure

Test Requirements for Existing Chemicals

2. Negotiated Testing Agreements

- a. Federal Register notice notifying manufacturers of EPA intent to require testing
- b. Submission of testing proposed by group of manufacturers and processors
 - (i) Cost sharing agreements and obligations
- c. Exemptions for small quantity manufacturers