Introduction To Intellectual Property
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Robert Silverman, PhD, Esq; General Counsel
Concert Pharmaceuticals
Course Outline

• What is Intellectual Property?

• All about patents
  – Technical parts
  – Prosecution
  – Foreign patents
  – Costs

• IP Considerations for License Agreement
Course Outline Continued

• Patent Versus Regulatory Exclusivity
• Strength of Patent and Scope of Claims
• How to Work with an IP Attorney
  – Freedom to operate issues
  – Opinion of counsel
  – Due diligence
  – Valuation of IP
• In the News – current topics
Intellectual Property

- Intellectual property is a bundle of exclusive rights over creations of the mind, both artistic and commercial.

- Two-thirds of the value of large businesses in the U.S. can be traced to intangible assets.

- Likewise, industries whose reliance on IP protections are estimated to produce 72 percent more value per added employee than non-IP industries.
PRIMARY TYPES OF INTELLECTUAL PROPERTY

• **Copyright**
  – Property right in an original work of authorship that is fixed in a tangible form.

• **Trademark**
  – Distinctive sign that is used by a company to identify its products or services as its own.

• **Trade Secret**
  – Formula, practice, process, design instrument or information not generally known to the public that affords a commercial advantage over your competitors

• **Patent**
Patents

• A **patent** is a set of exclusive rights granted by a government to an inventor or assignee for a fixed period of time in exchange for disclosure of its secrecy

• A Constitutional Right
  – The Congress shall have power to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

• Historically, patents date back to 1623 English Statute of Monopolies granted for **new** inventions.

• Jefferson was the father of our patent system and Congress enacted the first patent law in 1790.
United States Patent [19]
Weber et al.

[54] METHOD FOR THE TREATMENT OF PARKINSON'S DISEASE

[75] Inventors: Richard J. Weber, Silver Spring; Robert J. Plunkett, Gaithersburg, both of Md.; Scott E. Ewing, Chicago, Ill.

[73] Assignee: The United States of America as represented by the Department of Health and Human Services, Washington, D.C.

[21] Appl. No.: 892,485

[22] Filed: Jun. 3, 1992

Related U.S. Application Data

[51] Int. Cl. ........................................... A61K 35/14
[52] U.S. Cl. ............................................ 424/93 V
[58] Field of Search .................. 424/93 V; 435/2, 240.2

US005284654A


[56] References Cited
U.S. PATENT DOCUMENTS
4,902,288 2/1990 Ingram .......................... 424/534

OTHER PUBLICATIONS

Primary Examiner—Jacqueline Stone
Attorney, Agent, or Firm—Office of Technology Transfer, National Institutes of Health

[57] ABSTRACT
The present invention is directed to a method for the treatment of Parkinson's disease which affect the dopaminergic system by implanting into the brain of a host in need thereof an anti-neurodegenerative effective amount of activated leukocytes.

3 Claims, 1 Drawing Sheet
METHOD FOR THE TREATMENT OF PARKINSON’S DISEASE

This application is a continuation of application Ser. No. 07/401,141 filed on Aug. 31, 1989, now abandoned, the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Parkinson’s disease is a dopaminergic neurodegenerative disorder which affects an estimated 1% of the population over the age of fifty. The disease is primarily characterized by tremor, rigidity, impaired postural reflexes, and paucity of movement resulting from the loss of dopaminergic neurons in the substantia nigra which normally project to the corpus striatum. Because parkinsonian patients have a low concentration of dopamine in this region of the basal ganglia, current therapies have been directed at restoring normal levels of dopamine using the dopamine precursor L-dopa, with a peripheral decarboxylase inhibitor such as carbidopa. However, L-dopa’s effectiveness diminishes with continued use and troublesome side effects often occur. Thus, alternative therapies are being sought. Strategies to promote functional recovery by implantation of fetal dopaminergic cells in specific dopamine-depleted areas of the brain are currently being evaluated in Parkinsonian animal models as well as in certain patients with Parkinson’s disease. No doubt this investigational treatment will be confronted with some opposition on moral grounds.

The present invention has been accomplished with the above disadvantages in mind.

SUMMARY OF THE INVENTION

The present invention is directed to a method of treating neurodegenerative disorders which affect the dopaminergic system by implanting into the brain of a host in need thereof an anti-neurodegenerative effective amount of activated leukocytes.

BRIEF DESCRIPTION OF THE DRAWINGS

1. 5,284,654

2. (PHA), Sigma Chemicals Company, St. Louis, Mo.; lipopoly-saccharide (LPS), Difco Laboratories, Detroit, Mich.; and pokeweed mitogen (PWM). Examples of the lymphokines useful in activating the leukocytes

to be utilized in the present invention are interleukin-2 (IL-2), Cetus Corporation, Calif.; and interleukin-3 (IL-3), Genzyme Corp., Boston, Mass. Examples of cytokines useful in activating the leukocytes utilized in the present invention are interleukin-1 (IL-1) and tumor necrosis factor (TNF), etc., both obtained from Collaborative Research, Lexington, Mass.

The activated leukocytes can be administered to the locus of the lesion by surgical implantation in a one time or a number of surgical implantations sufficient to elicit the desired response. The dosage amount to be implanted can be from about $1\times10^9$ to $1\times10^{10}$ cells. The cells can be administered in any known pharmaceutically conventional carrier such as normal saline. The dose, of course, will vary from patient to patient, depending on the severity of the lesion and/or the disease state and can readily be ascertainable by one skilled in the art.

The leukocytes can be activated either in vivo or in vitro. When activated in vitro, the thus produced activated leukocytes are surgically implanted to the lesioned area of the brain. When treating humans the leukocytes could be activated in vitro. In case of Parkinson’s Disease the locus of the lesion is known to be in the striatum.

The present invention overcomes a number of disadvantages associated with the prior art therapies. For example, with respect to L-Dopa therapy, the present invention can reduce or totally eliminate L-Dopa therapy, thus decreasing or eliminating the untoward side effects associated therewith. The present therapy would also be an alternative to fetal implantation therapy, thus eliminating any moral issues raised by such a therapy.

Since in most instances it would be the patients’ own autologous leukocytes which are activated, the cells to be utilized in the surgical procedure would be readily available and the chances of host rejection would be slim to none.
ydopamine (6-OHDA), a catecholaminergic neurotoxin, was stereotaxically injected into the pars compacta of the right substantia nigra following anesthesia with 350 mg/kg of chloral hydrate administered intraperitoneally. Ten days after lesioning, rats were tested for rotational behavior induced by D-amphetamine, a dopamine releasing agent. Rats in which the dopaminergic nigrostriatal pathway has been unilaterally destroyed rotate toward the side of the lesion when given amphetamine. The number of full body clockwise and counterclockwise turns of each rat was recorded in a rotameter as described by Ungerstedt, Brain Res. 24 (1970). Rats turning consistently at least 5 clockwise turns/min over a 90 minute period for 4 trials, which reflects 98% or greater destruction of the striatum on the lesioned side were divided into two groups: unimplanted (n = 10), sham-implanted (n = 7), and implanted (n = 3).

**EXPERIMENT 2**

Rats in the sham-implanted and implanted groups received 5 microinjections of medium or a total of 5 ml of 107 activated leukocytes, respectively, aimed at the following coordinates: A 0.20 mm, V 5.4 mm, L 2.2 mm (bevel rostral); A 0.20 mm, V 6.4 mm, L 2.2 mm (bevel rostral); A 1.60 mm, V 5.2 mm, L 2.0 mm (bevel rostral); A 1.60 mm, V 5.2 mm, L 2.0 mm (bevel rostral); A 1.60 mm, V 5.2 mm, L 2.0 mm (bevel caudal), using the technique described in Plunkett et al., J. Neurosurg. 69, 228 (1988). The needle was left in place for 2 min before being withdrawn at 1 mm/min. R. J. Plunkett, R. J. Weber, E. H. Oldfield, J. Neurosurg. 69, 228 (1988). The leukocytes were stained with 0.32% sucrose from the periventricular cavity of normal Sprague-Dawley rats that had been injected intraperitoneally 48 hours earlier with 1 mg phytohemagglutinin (PHA). Analysis of the activated leukocytes by flow cytometry were described in Weber et al., Cell Immunol. 104, 400 (1987) revealed predominantly macrophages and T-lymphocytes. Monoclonal mouse IgG1 antibody to Thy 1.1, clone OX-7, culture supernatant 40 and monoclonal mouse IgG2a antibody to rat macrophage antigen ON 41 ascitic fluid were purchased from Cappel Laboratories, Inc. (Gartensburg, Md.). Trypan blue exclusion immediately after harvesting and during the period of implantation confirmed cell viability (>95%).

**FIG. 1** shows the results of the three groups which were tested weekly for amphetamine-induced rotation during the 13 weeks following implantation. Turning decreased on average of 47% at 8 weeks in the rats implanted with leukocytes (p = 0.006; Wilcoxon signed rank). As can be seen by **FIG. 1** neither the rats in the sham-implanted group nor those in the control group showed a significant decline in turning. Improvement was rapid in the implanted rats, with an average decrease in amphetamine-induced rotation of 22% one week after implantation. In the two rats showing complete improvement, recovery was noted by the fourth and fifth week. Only two of the rats receiving leukocytes failed to show an increase in dopamine content or TH reactivity.

**Punch biopsies** were taken from the rostral striatum in 8 rats that failed to improve behaviorally (2 sham, 4 controls, and 2 unimplanted implanted rats). Identical biopsies were taken from 7 of the leukocyte-implanted rats that improved. Dopamine content of the lesioned right striatum was determined by high performance liquid chromatography to be 0.1% of the intact left striatum in unimplanted implanted rats. The results are reported in **Table 1**.

<p>| TABLE 1 |
|-----------------|-----------------|------------------|
| <strong>DOPAMINE LEVELS</strong> (ng/mg protein) | (mean ± S.D.) |</p>
<table>
<thead>
<tr>
<th>Right Caudal</th>
<th>Left Caudal</th>
<th>R/L</th>
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<tbody>
<tr>
<td>I. Control</td>
<td>100.3 ± 30.4</td>
<td>1.9</td>
</tr>
<tr>
<td>II. Sham</td>
<td>94.1 ± 33.8</td>
<td>1.6</td>
</tr>
<tr>
<td>III. Implant</td>
<td>65.4 ± 33.1</td>
<td>6.7</td>
</tr>
<tr>
<td>IV. Implant</td>
<td>131.4 ± 44.2</td>
<td>0.1</td>
</tr>
</tbody>
</table>

The dopamine content in the right striatum of rats implanted with leukocytes was restored to 6.7% of the left striatum.

Previous studies have shown that dopamine-rich grafts can provide complete compensation of amphetamine-induced turning in 6-OHDA lesioned rats and restore dopamine levels to 10-15% of normal. The results reported herein show that stereotaxically implanted leukocytes alone may be sufficient to bring about behavioral recovery.

All reference articles discussed, supra, are incorporated herein by reference.

While the invention has been described with regard to certain preferred embodiments, it is understood that various changes and modifications may be made without departing from the scope of the invention which is defined in the Claims.

**We claim:**

1. A method for treating the dopaminergic neurodegenerative disorder Parkinson's Disease by administering to a locus of a lesion of a patient suffering from said disorder an anti-neurodegenerative effective amount of in vitro activated leukocytes.

2. The method according to claim 1, wherein said anti-neurodegenerative effective amount is from about 1 x 10⁷ to 1 x 10⁹ cells.

3. The method according to claim 1, wherein said leukocytes are derived from said patient suffering from said dopaminergic neurodegenerative disorder.

* * *
We claim:

1. A method for treating the dopaminergic neurodegenerative disorder Parkinson’s Disease by administering to a locus of a lesion of a patient suffering from said disorder an anti-neurodegenerative effective amount of in vitro activated leukocytes.

2. The method according to claim 1, wherein said anti-neurodegenerative effective amount is from about $1 \times 10^5$ to $1 \times 10^7$ cells.

3. The method according to claim 1, wherein said leukocytes are derived from said patient suffering from said dopaminergic neurodegenerative disorder.

* * * * *
DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

By dopaminergic neurodegenerative disorders is meant those disorders which affect the dopaminergic system, e.g., Parkinson’s Disease and other such diseases which result in a loss of CNS regulated function.

By host is meant any patient afflicted with such conditions, including humans, and is in need of said therapy. The leukocytes to be utilized from the present invention should be histo-compatible. Preferred leukocytes are autologous tissue.

The leukocytes of the present invention are activated by conventional means known in the art where the known activators are brought into contact with the cells. Examples of known activators are plant mitogens, lymphokines and cytokines as are described in William E. Paul, Fundamental Immunology, Raven Press, New York, 1984, page 271–274 and page 299. Examples of
BACKGROUND OF THE INVENTION

Parkinson’s disease is a dopaminergic neurodegenerative disorder which afflicts an estimated 1% of the population over the age of fifty. The disease is primarily characterized by tremor, rigidity, impaired postural reflexes, and paucity of movement resulting from the loss of dopaminergic neurons in the substantia nigra which normally project to the corpus striatum. Because parkinsonian patients have a low concentration of dopamine in this region of the basal ganglia, current therapeutics...

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[73] Assignee: The United States of America as represented by the Department of Health and Human Services, Washington, D.C.

[21] Appl. No.: 892,485
[22] Filed: Jun. 3, 1992

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Primary Examiner—Jacqueline Stone
Attorney, Agent, or Firm—Office of Technology
Transfer, National Institutes of Health

[57] ABSTRACT
The present invention is directed to a method for the treatment of Parkinson's disease which affect the dopaminergic system by implanting into the brain of a host in need thereof an anti-neurodegenerative effective amount of activated leukocytes.

3 Claims, 1 Drawing Sheet
How to Obtain a Patent

Invention Disclosure Form

1. TITLE OF INVENTION
   The title should describe what the invention does, but not how it is made or how it works.

2. SEARCH TERMS (up to 10)
   The OTM uses the Internet as a research tool when searching databases and markets. To make our searches efficient, please provide a short list of words, common industry phrases and/or categories.

3. BRIEF OVERVIEW OF THE INVENTION (1-4 paragraphs)
   a) Provide a short, general description of how the invention works.
   b) What is the purpose of the invention? For example, “What problem does it solve?”
   c) Is it a new product, process, or composition of matter? Or is it a new use for or improvement to an existing product, process or composition of matter?
   d) What are the features and benefits of the invention?

4. TECHNICAL DESCRIPTION, DETAILS AND SUPPORTING DATA
   Provide results, data or other evidence demonstrating how the invention works. Any papers or visual material that you may already have, published or unpublished, can be attached as answers to this question.

5. PRIOR ART: METHODS, APPARATUS, DEVELOPMENTS AND PUBLICATIONS
   a) Provide a complete description of the closest known methods or apparatus in existence and the disadvantages or problems of each that are solved by the present invention.
   b) Cite any of your own publications and patents, and those of anyone else believed by you to disclose ideas most closely related to the invention.
   Please attach all relevant publications, patents, advertisements, etc., if available.

6. STAGE OF DEVELOPMENT (2-3 paragraphs)
   Describe the development status (concept only, laboratory tested, prototype, etc.) and briefly indicate what further development may be necessary to commercialize it.

7. POTENTIAL LICENSEES
   Identify companies that you think could benefit from the use of this technology.
Process steps for a patent

- Patent Assessment
- Provisional Application
- International Application - 12 Months
- National Stage – 30 Months
Patent Assessment

- The process of determining if the preparation of a patent application is warranted
- Asking:
  - Is the invention novel?
  - Is the invention inventive?
  - Is the invention commercially important?
Provisional Applications

• Typically the first application filed
• They should be fully enabled
• Should not be a *cheap* application without claims
• Are never examined
• Die a natural death after 12 months
PCT Applications

• International application
• Filed by 12 month anniversary of provisional
• Begins 20 year period of patent life
• No substantive examination
• Circles globe for 18 months then lands
PCT APPLICATIONS CIRCLE THE GLOBE
National Stage

• Begins at **30 months**

• This is where you **LAND** the PCT Plane

• $$$ Pick your countries wisely $$$
### Business Development Fundamentals

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#### International Publication Details

- **International Publication Number**: WO 01/42446 A2
- **Priority Date**: 16 October 1999
- **Publication Date**: 14 June 2001

#### Application Information

- **Inventors**: Damson, Dean; Szwed, John; Weber, Kenneth; Bouzaglou, Tatiana; and Currif, Cindy
- **Applicant**: Amgen, Inc.
- **Agent**: Kilpatrick Townsend & Stockton LLP

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#### The Invention

**Title**: A Functional Gene Array in Yeast

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**Diagram**

![Diagram of gene arrays](attachment:gene_array_diagram.png)
Jargon

• Patent Estate = Patent Portfolio
  – This is everything the company owns

• Patent Families
  – Each invention is a patent family comprising
  – U.S. and international applications and issued patents

• Members = Individual Patents or Applications
This tells us where the patent application was filed.

When was it published?

Australia
Canada
Japan
United States
Prosecution

• This is the process by which the applicant and the government determine if the invention merits a patent

• The patent office will search the invention for novelty and inventiveness

• The applicants will respond by argument or amending the claims

• From application to enforceable patent can take up to 5 years of your 20 year patent life
Estimated Costs in 2015
For Each Family in an Estate

- Patent assessments - $4500
- Provisional applications - $15000
- PCT applications - $8000
- National stage - $30k- $60k
- Total for 1st 7 years - $120k
- Lifetime of 20 years - $220k
Common types of patent claims

- Composition of matter
- Method of treating or using
- Method of making or producing
- Method of diagnosing
- Method of reducing side affects
IP CONSIDERATIONS FOR LICENSE AGREEMENTS
Foremost Considerations for IP License Deal

• Freedom-to-operate

• Licensed patents
  – When do they expire?
  – What is the scope of the patent claims?
  – How strong are the patent claims?

• Regulatory exclusivity (FDA exclusivity)

• IP needs differ depending on the type of deal
  – Late stage product is not the same as research deal
Patent versus Regulatory Exclusivity
Types of Exclusivity Periods in the US

• **Patent** Exclusivity (USPTO)
  – Natural patent term = 20 years from filing
  – Patent term adjustment (PTA) = added to natural term for delays by USPTO
  – Patent term extension (PTE) = added to natural term for delays in regulatory approval

• **Regulatory** Exclusivity (FDA)
  – 3 to 7 years depending on the type of regulatory exclusivity
  – Mostly runs in parallel to patent term
Hatch Waxman Act (1984)

• The Hatch-Waxman Act to promote generic competition
  – Heavily negotiated
  – Careful balance between competing interests of brand vs generic pharma

• In 1984, generics accounted for about 17% of all prescriptions

• In 2013, generics accounted for about 86% of all prescriptions
  (IMS Health, April 2014, Medicine Use and Shifting Cost of Healthcare)
Hatch Waxman Act Balances Interests

• Benefits to Generics – the ANDA Process
  – Clinical studies before patent expires do not infringe patent
  – Can reference NDA data as part of the ANDA application
  – Can challenge the patent before coming to market with a Paragraph IV certification
  – Para IV certification keeps other generics out for 6 mos.

• Benefits to Pharma
  – Regulatory exclusivity (delays ANDA approval)
  – Patent term extension (PTE) for delays in regulatory approval (up to 5 years) based on a formula
  – After a Para IV certification pharma can bring a patent suit that triggers an automatic 30 month stay of FDA approval of the ANDA application
Regulatory Exclusivity Periods

• Regulatory submissions are important intellectual property

• FDA provides data exclusivity after FDA approval
  – ANDA (Abbreviated New Drug Application) for a generic drug cannot get approved during FDA exclusivity period
  – 5 years for NCE (new chemical entity)
  – 7 years for Orphan Drug (disorder affects < 200,000 people in US)
  – 6 months more for pediatric exclusivity
  – 3 years for new use of an approved drug

• European Union provides 10 years of data exclusivity for NCE after market authorization (8+2+1 rule)

• In U.S., follow-on biologics (biosimilars) have 12 years of data exclusivity under the Biologics Price Competition and Innovation Act (March, 2010)
Regulatory versus Patent Exclusivity

- FDA exclusivity prohibits others from referencing clinical data for a period of time (e.g., 5 years for NCE)
- Patent prohibits others from making, using, selling or offering to sell the claimed invention
- FDA exclusivity may be as effective as patent exclusivity
  - Generic companies reference data, do not conduct full development
Exclusivity Periods in a Competitive Landscape

*Hypothetical*

Newco wants to license its new JAK kinase inhibitor for myelofibrosis. Competitive JAK kinase inhibitors include ruxolitinib (approved drug) and momelotinib (Phase 3). Newco drug has much greater value if it can get to market before the competitive drugs become generic.

• What are the patent terms for ruxolitinib and momelotinib?

• Ruxolitinib is approved \(\rightarrow\) go to the Orange Book

• Momelotinib still in development \(\rightarrow\)
  – Search patents and
  – Estimate patent term exclusivity
### Searching Orange Book for Drug Exclusivity of NCEs

#### Google Orange Book

- **Search by Active Ingredient**
- **Search by Applicant Holder**
- **Search by Proprietary Name**
- **Search by Application Number**
- **Search by Patent**

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Active Ingredient: RUXOLITINIB PHOSPHATE

Dosage Form;Route: TABLET;ORAL

Proprietary Name: JAKAFI

Applicant: INCYTE CORP

Application Number: N202192

Approval Date: Nov 16, 2011

RX/OTC/DISCN: RX

Patent and Exclusivity Info for this product: View

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Estimating Patent Term for Unapproved Drug

- Database Search to Identify Patents
  - Thomson Reuters Integrity℠ (formerly Prous) or SciFinder are popular databases
- Google.com/patents is quick and free
- Find priority data – patent term is 20 years from non-provisional filing
- Estimate patent term extension for U.S. (PTE is additional patent term for regulatory delay)

IND Filing → NDA Filing → Approval

- PTE limited to: no more than 5 years and PTE cannot extend patent term to more than 14 years after date of approval
- PTE can only be applied to one patent per drug product
- Integrity℠ and other sources often have regulatory information useful for estimating PTE
- SEC filings can be a useful source of patent information
STRENGTH OF PATENT

AND

SCOPE OF CLAIMS
### Which Patents Matter the Most?

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Google FDA Orange Book.
Generally, Composition of Matter Claims are Most Ideal

- COM claims are directed to the drug or product itself
  - “A compound of formula A ...”
  - “A compound selected from the following ...”
  - “A pharmaceutical composition comprising [compound] and a pharmaceutical excipient.”
  - “A humanized antibody which binds the HER2 receptor ... [further description of Avastin]” Genentech US Patent 6,054,297
  - “An isolated DNA comprising an altered BRCA1 DNA having at least one of the alterations set forth in...” Myriad US Patent 5,693,473

- COM claims exclude *any* use of the composition of matter
Do Other Types of Claims in Later Patents Extend Exclusivity

- Claims to new salts or formulations of a compound
  - May be vulnerable to easy design-around by generic
  - These claims are more susceptible to patent challenge after the Supreme Court decision in *KSR v Teleflex*

- Claims to polymorphs and other solid forms
  - Polymorph is a particular crystalline form of a compound
  - Polymorphs can have different properties, e.g., solubility
  - Key question: can generic competitor access a different, but suitable polymorph?
  - No injunction if only a small amount of claimed polymorph is generic product (based on Supreme Ct. decision in *eBay v MercExchange*)

- Bottom line: Scrutinize these types of claims carefully
Strength of Licensed Patent and Risk Sharing

Hypothetical
You are considering a license for patent applications still in prosecution. Your patent counsel is not sure if the USPTO will allow the claims and grant a patent. Furthermore, even if a patent is granted, its validity may be challenged under the America Invents Act.

Problem - Licensee does not want to pay royalties without patent protection. Licensor wants royalties at least while a patent application is pending.

Common Risk Sharing Approach

• First, define “Royalty Term” to include pending applications

“Big Pharma shall pay to Newco royalties on Net Sales of each Licensed Product ... until the later of:

(i) the last to expire Valid Claim covering the manufacture, use, sale ... of Licensed Product in the country or

(ii) 10 years after Launch of the Licensed Product in the country (“Royalty Term”).”

• Then, provide royalty reduction when there are no patents covering the Licensed Product

“... the royalty rates shall be reduced to 50% of the otherwise applicable rates ... during any period within the Royalty Term when no Valid Claim covers the manufacture, use, offer for sale, sale or importation of the Licensed Product ...”
Licensing the Full Scope of the Invention – The Medivation, Aragon and UCLA Story

- In 2005, Medivation licensed Xtandi from UCLA for a type of prostrate cancer
- In 2009, UCLA licensed ARN-509 to Aragon Pharmaceuticals

- Challenge is to find the proper scope
  - Licensee needs full scope of the invention including improvements to protect the value of the license
  - But Licensor wants freedom to pursue “unrelated” inventions
Working with Patent Counsel

- Due diligence
- Freedom to operate analysis
- Opinion of counsel
“I don't want a lawyer to tell me what I cannot do. I hire him to tell how to do what I want to do.”

J.P. Morgan

A good lawyer should tell you what you cannot do, but also suggest ways to move forward. That requires that your lawyer know the deal background and your business goals.

“A good lawyer knows the law. A great lawyer knows the judge.”

- anonymous

Good lawyers know the law. The best ones understand risk; they describe and weigh risk when advising a client in a negotiation.
The Due Diligence Checklist Covers Many Areas

- List of materials / information to obtain from target
- Ownership – requires a high degree of certainty
- Review of license agreements relating to target IP
- Patent validity
- Claim scope
- Patent terms and regulatory exclusivity
- Ex-U.S. filings
- Freedom-to-operate – sometimes most difficult
- Enforcement Issues
Freedom to Operate

• Patentability versus FTO
• Dealing with an FTO Issue
• How an attorney carries out an FTO analysis
• Example
• Typical costs
Patentability ≠ Freedom to Operate

• A patent is the right to exclude others

• A patent does not grant the right to practice an invention

• Example:
  
  – Tom has a patent that claims the combination of A and B
  
  – Amy has a patent to “A”
  
  – Tom can exclude others from making, using, selling A + B

  – But Amy’s patent presents an FTO concern for Tom
General Steps For FTO Analysis

• Identify features of the product that might be subject to 3rd party patents
• Search features
• Create binders for each feature
• No validity issues addressed
# PCR Diagnostic Kit

## Helicobacter pylori PCR detection Kit

<table>
<thead>
<tr>
<th>Product</th>
<th>Helicobacter pylori PCR detection Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>A qualitative diagnostic kit for detection of <em>H. pylori</em> DNA in clinical samples like biopsy. Kit contains reagents for Polymerase Chain Reaction technique. Ready to use PCR mix, positive control and other qualified reagents along with an easy to follow protocol are included. Specific primers amplify conserved region in <em>H. pylori</em> genome. Using this kit, as low as 10 copies/ml of bacterial genome can be detected.</td>
</tr>
<tr>
<td><strong>Storage</strong></td>
<td>-20°C</td>
</tr>
</tbody>
</table>

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WHERE DO YOU BEGIN?

- The PCR primers
- The bacteria
- The disease
- The polymerase
- The amplified target
- The label
- Special additives
- Hot start technology
- The box
- The caps on the tubes
- The blue plastic holder
Searching For Third Party Patents

• Each feature requires a search costing $5-7K.
• Decide carefully how many features you will search
• Provide a binder for each feature searched
• There is no analysis beyond plain meaning of the claims.
• What do you do about air claims in applications?
Dealing with an FTO Issue

Tom wants to market A + B and Amy has a patent to “A”

• Initial question – does Amy’s claim really cover A?
  – An infringement analysis determines whether A is within the scope of Amy’s claim

• Second question – is Amy’s claim valid?

• These may be difficult questions with no clear answer
  ----> it often involves an assessment of risk

• Tom has choices:
  – Assume the risk / negotiate a license from Amy / challenge Amy’s patent (new opportunities to challenge with America Invents Act)
License Agreement Terms Regarding FTO

Tom licenses \( A + B \) patent to Harry

- License agreement will have various terms regarding 3\(^{rd}\) party patents that might interfere with commercialization of \( A + B \)

- Harry will want a representation of non-infringement:
  - “To the best of Tom’s knowledge, the commercialization of Licensed Product, as formulated and manufactured as of the Effective Date, does not and will not infringe the patent rights of any other Person”

- If a 3\(^{rd}\) party license is needed, Tom wants to pay a lower royalty:
  - “Harry may deduct from the royalties otherwise due to Tom royalties payable for a Third Party License, provided that the deduction may not reduce Tom’s royalties by more than 50%.”
FTO Opinions and Analysis Performed by Other Side

• Should you get a legal opinion in **writing**?
  – Yes, for FTO issues that present a particularly important risk
  – Most other legal opinions should be communicated verbally

• Probe attorney for licensor regarding any FTO analysis they may have performed; ask if they have written opinions

• Ask to see the written opinion
  – Many attorneys will refuse request, but ...
  – Ask what triggered the opinion
  – Ask what references formed the basis of the opinion

• Few patent issues will be “black and white”
  – Attorneys tend to hedge when providing an opinion, but strive for an opinion that enables you to make a decision
IP Due Diligence: When and How Much?

• Initial interest under CDA
  – Get copies of relevant patents / patent applications; summary of status
  – Determine exclusivity periods
  – Preliminary assessment of freedom-to-operate and patentability

• Greater diligence with Term Sheet goal
  – Conduct full freedom-to-operate analysis
  – Conduct full patentability analysis
  – Comprehensive interview of licensor attorney; ask for all useful information

• Especially for large deal, strive to complete diligence prior to execution of non-binding Term Sheet

• IP issues uncovered after finalized Term Sheet can be messy; may require additional reps and warranties in the agreement
The Due Diligence Checklist Covers Many Areas

- List of materials / information to obtain from target
- Ownership – requires a high degree of certainty
- Review of license agreements relating to target IP
- Patent validity
- Claim scope
- Patent terms and regulatory exclusivity
- Ex-U.S. filings
- Freedom-to-operate – sometimes most difficult
- Enforcement Issues
Recent IP Developments

IN THE NEWS

• SUPREME COURT DECISION

• CONGRESS
  – Protecting American Talent and Entrepreneurship Act of 2015
SUPREME COURT OF THE UNITED STATES

Syllabus

TEVA PHARMACEUTICALS USA, INC., ET AL. v. SANDOZ, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT


Held: When reviewing a district court’s resolution of subsidiary factual matters made in the course of its construction of a patent claim, the Federal Circuit must apply a “clear error,” not a de novo, standard of review.
Glatiramer acetate is a random polymer (average molecular mass 6.4 kD) composed of four amino acids that are found in myelin basic protein.
TEVA SUED SANDOZ AND A LITIGATION

BATTLE OVER: WHAT IS THE MOLECULAR WEIGHT of Copaxone

CLAIM SAID: a molecular weight of 5 to 9 kilodaltons

Trial Court said okay; Fed Cir said Not okay and SCOTUS said defer to Trial Court

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Protecting American Talent and Entrepreneurship Act of 2015

PROTECTION AGAINST TROLLS

Bipartisan support

– Trolls pay fees and costs if claims not objectively reasonable
– Stay of discovery
– Customer stay of litigation- as manufactures fight
– Violation of § 5 of FTC act – deceptive practices
Questions?

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