Establishing and Protecting Your Intellectual Property

Diane Grob Schmidt
2015 ACS President

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Establishing and Protecting Your Intellectual Property

Intellectual Property Overview

ACS Program-in-a-Box Webinar Presentation
Robert Koch
November 10, 2015
Topics

1) What constitutes IP?
2) Types of “protection”
3) Evaluation of IP
4) IP as incentive
5) Costs of obtaining IP
6) Costs of enforcing IP
7) Examples of success stories and missed opportunity

Catch-all term for many creations of the intellect

- Property means more than just physical things
- But ideas are not included

Focus for Chemical Business Groups

- Patents
- Copyrights
- Trademarks
Types of Patents: **Utility**

U.S. Utility Patents number **over 9 million.**

Although the first U.S. utility patents were issued in **1790**

An additional **9,500** patents issued between **1790** and **1836**

The current numbering system did not begin until **1836**

About **1/3** of all issued utility patents are currently in-force.
Types of Patents: Design

U.S. Design Patents number about **800,000** since **1843**.

**(Prior to that they were included with utility patents)**

Types of Patents: Plant

U.S. Plant Patents number over **25,000** since the first issued in **1931**.
Cover Page of Utility Patent

Design Patent First Page
Plant Patent Cover Page

Other Types of IP

- Industrial Designs
- Trade Dress
- Trade Secrets
- Plant Varieties
- Know How
- Domain Names

www.yourdomainname.com
Other Types of Protection Regulatory Protection

Hatch-Waxman Genetically Modified Organisms Toxicity

Evaluation of Intellectual Property

What is it worth?

- Appraisals
- Transactions
- Pricing
- Licensing
- Securitization
- Collateralization
- Tax Planning
- Compliance
IP as an Incentive

US Constitution - Article 1, Section 8, Clause 8

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.

Incentives (cont)

- The right to exclude others in return for full disclosure of the new useful and non-obvious invention.
- Such disclosure enables further developments and improvements
- Means for measurement of R&D output
- Compensation and reward systems
- Favored assets for venture capitalists
- Kind of trading currency
Costs of Obtaining and Enforcing Patent Rights

Prosecuting a patent application before the U.S. Patent and Trademark Office

- Basic filing fee
- Patent search fee and opinion
- Attorney fees

Litigating a patent infringement case in federal court

- Attorney fees
- Expert witness fees
- Costs and disbursements
Success Stories: Otsuka v. Sandoz (Fed. Cir. 2012)

Patent claims covering aripiprazole, the active ingredient in Abilify® for treatment of schizophrenia

7-{4-[4-{2,3-dichlorophenyl}-1-piperazinyl-butoxy]-3,4-dihydrocarbostyril

“2,3-dichloro propoxy”  “OPC-4392” (2,3-dimethyl propoxy carbostyril compound)
Success Stories: Otsuka v. Sandoz (Fed. Cir. 2012)

“Unsubstituted butoxy” disclosed in Otsuka’s earlier ’416 patent
- One example within broad genus of 9 trillion compounds

More potent compounds had different structures
- Ethoxy substituent on phenyl ring
- Compounds with propoxy linkers

General disclosure of antihistaminic and central nervous controlling action

Success Stories: Otsuka v. Sandoz (Fed. Cir. 2012)

Obviousness requires a showing that a person of ordinary skill in the art would have been motivated to choose a lead compound and modify it with a reasonable expectation of successfully arriving at the claimed compound.
**Success Stories: Otsuka v. Sandoz (Fed. Cir. 2012)**

No motivation to choose any of defendants’ lead compounds

- Earlier antipsychotics such as clozapine or risperidone would have been more promising lead compounds

![Chemical structures](image)

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**Success Stories: Otsuka v. Sandoz (Fed. Cir. 2012)**

Defendants’ proposed modifications were pure hindsight

- Defendants’ case represented a “poster child for impermissible hindsight reasoning”

- Antipsychotic drug discovery is highly unpredictable
Missed Opportunity: Pfizer v. Ranbaxy (Fed. Cir. 2006)

Patent claims covering atorvastatin calcium, the active ingredient in Lipitor® cholesterol medication

Claim 1 was a broad genus claim covering atorvastatin acid or atorvastatin lactone, or pharmaceutically acceptable salts of these compounds.

Claim 2 depended from claim 1 and specified only atorvastatin acid.

Claim 6 further depended from claim 2 and specified only the hemicalcium salt of the compound of claim 2.

Claim 6 invalid under 35 U.S.C. 112 ¶ 4, which requires that "[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers".

Claim 6 does not narrow the scope of claim 2, as required; rather, claim 6 and claim 2 deal with non-overlapping subject matter.

In theory, a claimed acid could be construed liberally to include corresponding salts, but claim 2 does not specify "pharmaceutically acceptable salts thereof".
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Questions & Answers
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