Maschoff Brennan
Intellectual Property and Complex Litigation

IP Strategy for Small Startup Biotech Companies

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What Every Startup Should Do?

- **Consider Freedom-To-Operate**
- **Get Patents**
  - Fast
  - Protect Against Post Grant Challenges
- **Protect Against Trade Secret Litigation**

Why Freedom-To-Operate ?

- A 3rd party patent covering your intended commercial product can stop you from selling the product
- No product, no revenue

Get Patents

- **Pharma**: Stop Generics
- **Biotech**: Stop Biosimilars
- **Med Device**: Stop Copiers
- Impress Investors & help funding
- Stop Potential Competitors

Protect Against Post Grant Challenges

- Before the ***America Invents Act***, your patent could only be challenged by someone who is potentially infringing

- ***Today***: Your patent can be challenged even if nobody is infringing
  - Inter Partes Review
  - Post Grant Review

Protect Against Trade Secret Litigation

Why should you care? Do you have action in place?

- Dr. Lee works at Company A
- *Dr. Lee leaves Company A and comes to work for Company B*
- Dr. Lee takes a file from his computer at Company A
- *Dr. Lee saves the file onto his computer in his office at Company B*
- Company A sues Company B for trade secret misappropriation, alleging that the file Dr. Lee took from his computer at Company A contained trade secrets

IP Strategy for Small Startup Biotech Companies

1. High Value Patent Prosecution
2. High Value Freedom-To-Operate
3. Protecting Against Post Grant Challenges
4. Protecting Against Trade Secret Challenges

High Value Patent Prosecution

1. High Value Patent Drafting
   - Avoid Unnecessary Expenses
   - Flexible Drafting

2. Continuation Practice

Unnecessary Expenses In Patent Applications

1. Excessively long invention disclosures
   - except for experimental portion, disclosure should be about 2 pages or less
2. Long Background Sections

   ~~It has been shown that X inhibitors may be effective in treating diseases related to Y (Chang, J. Med. Chem., Vol. 38, p. 29-35).~~

   Instead, put information in the detailed description without references

   e.g. In some embodiments, X inhibitors may be effective in treating diseases related to Y.
3. Poor formatting: tables, chemical structures, use of symbol font
4. Poorly written experimentals
5. Too many claims – *should target ~ 20 claims in US*
6. Excessive back and forth between client and lawyers

Maximizing Value-Avoid Excess Verbiage

- Many attorneys do not remove extra disclosure, such as boilerplate, under the theory that "it cannot hurt."

- Is this familiar to you: you give very little information to an attorney, and the patent attorney come backs with a very long patent application?

- However, ***extra disclosure can hurt*** in at least the following ways:
    1. Extra cost
    2. Prior art against later applications
    3. Undesired claim construction
    4. Complications in prosecution

Maximizing Value-Avoid Excess Verbiage

Extra Cost:

- Increased translation time - $$$
- Potential increased attorney time - $$$
- Increased cost to client - YOU

Translation Fee:

Pages in Application: 250

Translation into Chinese: approximately $20,000

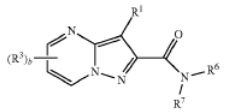
High Value Patent Drafting

1. Simple claiming
   - Simple claims are less expensive, and less likely to contain mistakes

2. Rich descriptions
   - It is much less expensive to put very extensive descriptions into the specification, and build flexibility into the application

Simple Claiming

2. A compound having the Formula 1A[1]:



1A[1]

or a pharmaceutically acceptable salt thereof, wherein:

R^1 is selected from the group consisting of (C_3-C_8)cycloalkyl, (4- to 10-membered)-heterocycloalkyl, (C_6-C_{10})aryl and (5- to 14-membered)heteroaryl, and, where chemically permissible, the (C_3-C_8)cycloalkyl, (4-to 10-membered)heterocycloalkyl, (C_6-C_{10})aryl and (5- to 14-membered)heteroaryl moieties are optionally substituted with one to three R^2;

when present, each R^2 is independently selected from the group consisting of halogen, oxo, cyano, hydroxy, —SF_5, nitro, optionally substituted (C_1-C_6)alkyl, optionally substituted (C_2-C_6)alkenyl, optionally substituted (C_2-C_6)alkynyl, optionally substituted (C_1-C_6)alkylthio, optionally substituted (C_1-C_6)alkoxy, —$N(R^4)(R^5)$, —$N(R^4)(C(=O)R^5)$, —$C(=O)_N(R^4)(R^5)$, —C(=O)—O—$N(R^4)(R^5)$, —C(=O)—R^4, —C(=O)—OR^4, and optionally substituted (C_3-C_8) cycloalkyl;

when present, each R^3 is independently selected from the group consisting of halogen, cyano, hydroxy, —SF_5, nitro, optionally substituted (C_1-C_6)alkyl, optionally substituted (C_2-C_6)alkenyl, optionally substituted (C_2-C_6)alkynyl, optionally substituted (C_1-C_6)alkylthio, optionally substituted (C_1-C_6)alkoxy, —$N(R^4)(R^5)$, —$N(R^4)(C(=O)R^5)$, —$C(=O)_N(R^4)(R^5)$, —C(=O)—O—$N(R^4)(R^5)$, —C(=O)—R^4, and —C(=O)—OR^4;

R^4 and R^5 are each independently selected from the group consisting of hydrogen, and optionally substituted (C_1-C_6)alkyl;

R^6 and R^7 are each independently selected from the group consisting of hydrogen, optionally substituted (C_1-C_6) alkyl, (C_3-C_8)cycloalkyl, (4- to 10-membered)heterocycloalkyl, (C_6-C_{10})aryl, and (5- to 10-membered)heteroaryl, and where chemically permissible, the (C_3-C_8) cycloalkyl, -(4- to 10-membered)heterocycloalkyl, (C_6-C_{10})aryl, and (5- to 10-membered)heteroaryl are optionally substituted with one to three R^8; or

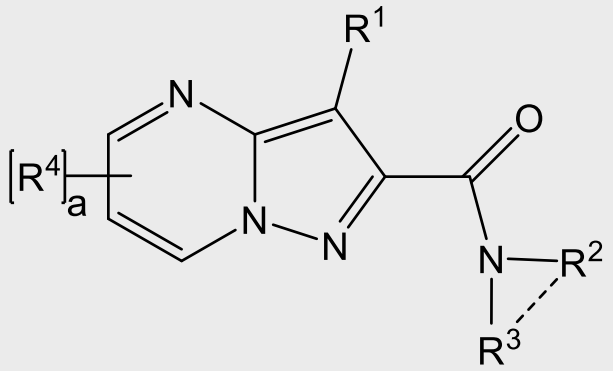
R^6 and R^7 taken together with the nitrogen to which they are attached form a (4- to 10-membered)heterocycloalkyl, and where chemically permissible, the (4- to 10-membered)-heterocycloalkyl is optionally substituted with one to three R^9;

when present each R^8 is independently selected from the group consisting of halogen, oxo, cyano, hydroxy, —SF_5, nitro, optionally substituted (C_1-C_6)alkyl, optionally substituted (C_2-C_6)alkenyl, optionally substituted (C_2-C_6)alkynyl, optionally substituted (C_1-C_6) alkylthio, optionally substituted (C_1-C_6)alkoxy, —$N(R^4)(R^5)$, —$N(R^4)(C(=O)R^5)$, —$C(=O)_N(R^4)(R^5)$, —C(=O)—O—$N(R^4)(R^5)$, —C(=O)—R^4, and —C(=O)—OR^4;

when present each R^9 is independently selected from the group consisting of halogen, oxo, cyano, hydroxy, —SF_5, nitro, optionally substituted (C_1-C_6)alkyl, optionally substituted (C_2-C_6)alkenyl, optionally substituted (C_2-C_6)alkynyl, optionally substituted (C_1-C_6) alkylthio, optionally substituted (C_1-C_6)alkoxy, —$N(R^4)(R^5)$, —$N(R^4)(C(=O)R^5)$, —$C(=O)_N(R^4)(R^5)$, —C(=O)—O—$N(R^4)(R^5)$, —C(=O)—R^4, and —C(=O)—OR^4; and

b is represented by an integer selected from 0 or 1.

A compound represented by a formula:



or a pharmaceutically acceptable salt thereof;

wherein a dashed line represents the presence or absence of a bond;

R^1 is an optionally substituted C_{3-10} carbocyclic group or an optionally substituted C_{4-14} hetercyclyl group;

R^2 and R^3 are independently R^a, an optionally substituted C_{3-10} carbocyclic group, or an optionally substituted C_{4-14} hetercyclyl group;

R^4 is F, Cl, Br, I, CN, OH, $-SF_5$, NO_2, C_{1-6} hydrocarbyl, $-OR^a$, $-SR^a$, $-NR^aR^b$, $-NR^aCOR^b$, $-CONR^aR^b$, $-COONR^aR^b$, $-COR^a$, $-CO_2R^a$;

each R^a and R^b is independently H or optionally substituted C_{1-6} alkyl;

and a is 0 or 1.

We would draft this way.

Flexible Description

- Focus description, with both breadth and detail, on what you have done or are likely to do in the next 18 months
- Devote little or no description to technology that you are unlikely to work on in the next 18 months

Avoid Excess Verbiage

Prior art against later applications

Early disclosure can be used as prior art against a later application:

Example-Formulations:

e.g. drug delivery system

- Compound A is invented in 2010. Although the inventors were not using compound A in drug delivery system X, Application disclosed drug delivery system X for use with compound in Application 1 filed in 2010.
- In 2017, it was discovered that drug delivery system X is really useful with Compound A.
- Now Application 1 is prior art against any new application filed in 2017.

Preparing A Flexible Specification

Common Practice:

In a further aspect, the present invention relates to a formulation comprising from **about 0.05 mg to about 15 mg** trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3- ,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, wherein the single dose administration of formulation provides an in vivo plasma profile comprising (i) a mean **C_{max}** of less than about 26.3 ng/mL, (ii) a mean **$AUC_{0\text{-}infin}$** of more than about 2 ng.hr/mL and (iii) a mean **T_{max}** of about 3 or more hours. For example, the formulation provides an in vivo plasma profile comprising (i) a mean C_{max} of less than about 22.5 ng/mL, (ii) a mean $AUC_{0\text{-}infin}$ of more than about 3 nghr/mL and (iii) a mean T_{max} of about 3 or more hours.

In one embodiment, the formulation comprises **about 0.1 mg** trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]cyclohexyl}-3,- 3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, wherein the single dose administration of formulation provides an in vivo plasma profile comprising (i) a mean **C_{max}** of less than about 0.2 ng/mL, (ii) a mean **$AUC_{0\text{-}infin}$** of more than about 2 ng.hr/mL and (iii) a mean **T_{max}** of about 3 or more hours. For example, the formulation provides an in vivo plasma profile comprising (i) a mean C_{max} of less than about 0.2 ng/mL, (ii) a mean $AUC_{0\text{-}infin}$ of more than about 3 ng.hr/mL and (iii) a mean T_{max} of about 3 or more hours.

In one embodiment, the formulation comprises **about 0.25 mg** trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3- ,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof, wherein the single dose administration of formulation provides an in vivo plasma profile comprising (i) a mean **C_{max}** of less than about 0.5 ng/mL, (ii) a mean **$AUC_{0\text{-}infin}$** of more than about 5 ng.hr/mL and (iii) a mean **T_{max}** of about 3 or more hours. For example, the formulation provides an in vivo plasma profile comprising (i) a mean C_{max} of less than about 0.4 ng/mL, (ii) a mean $AUC_{0\text{-}infin}$ of more than about 7 nghr/mL and (iii) a mean T_{max} of about 3 or more hours.

Preparing A Flexible Specification

Better Practice:

In some embodiments, a formulation comprises trans-1{4-[2-[4-(2,3-dichlorophenyl)-piperazin-1-yl]-ethyl]-cyclohexyl}-3- ,3-dimethyl-urea, or a pharmaceutically acceptable salt thereof (referred to herein as a "subject compound" for convenience). Any therapeutically ***effective amount*** of a subject compound may be used, such as about 0.05-15 mg, about 0.1 mg, or about 0.25 mg. (More ranges are desirable)

With respect to formulations comprising a subject compound (referred to herein as a "subject formulation" for convenience), in some embodiments the formulation provides a mean C_{max} of less than about 26 ng/mL, less than about 23 ng/mL, less than about 0.5 ng/mL, less than about 0.4 ng/mL or less than 0.2 ng/mL. (More ranges are desirable)

Some subject formulations provide a mean T_{max} of at least about 3 hours. (More ranges are desirable)

Some subject formulations provide a mean $AUC_{0\text{-}infin}$ of at least about 3 ng•hr/mL, at least about 5 ng•hr/mL, or at least about 7 ng•hr/mL. (More ranges are desirable)

Continuation Practice

- First Patent: $10-20K or more
- Continuation Patent: likely to be $1-5K
- Very useful to strengthen against challenge
- If you want 40 claims, two patents with 20 claims each are likely to be cheaper than one patent with 40 claims

High Value Freedom-To-Operate

- Timing and investment considerations
- Doing your own searches
- What not to write

High Value Freedom-To-Operate

A. Timing and investment considerations
   - Written FTO can be $20-30K or more
   - Written documents are risky for law firms = much more expensive
   - Could do a limited search with an oral report for far less ($3-6K depending upon extent of search)

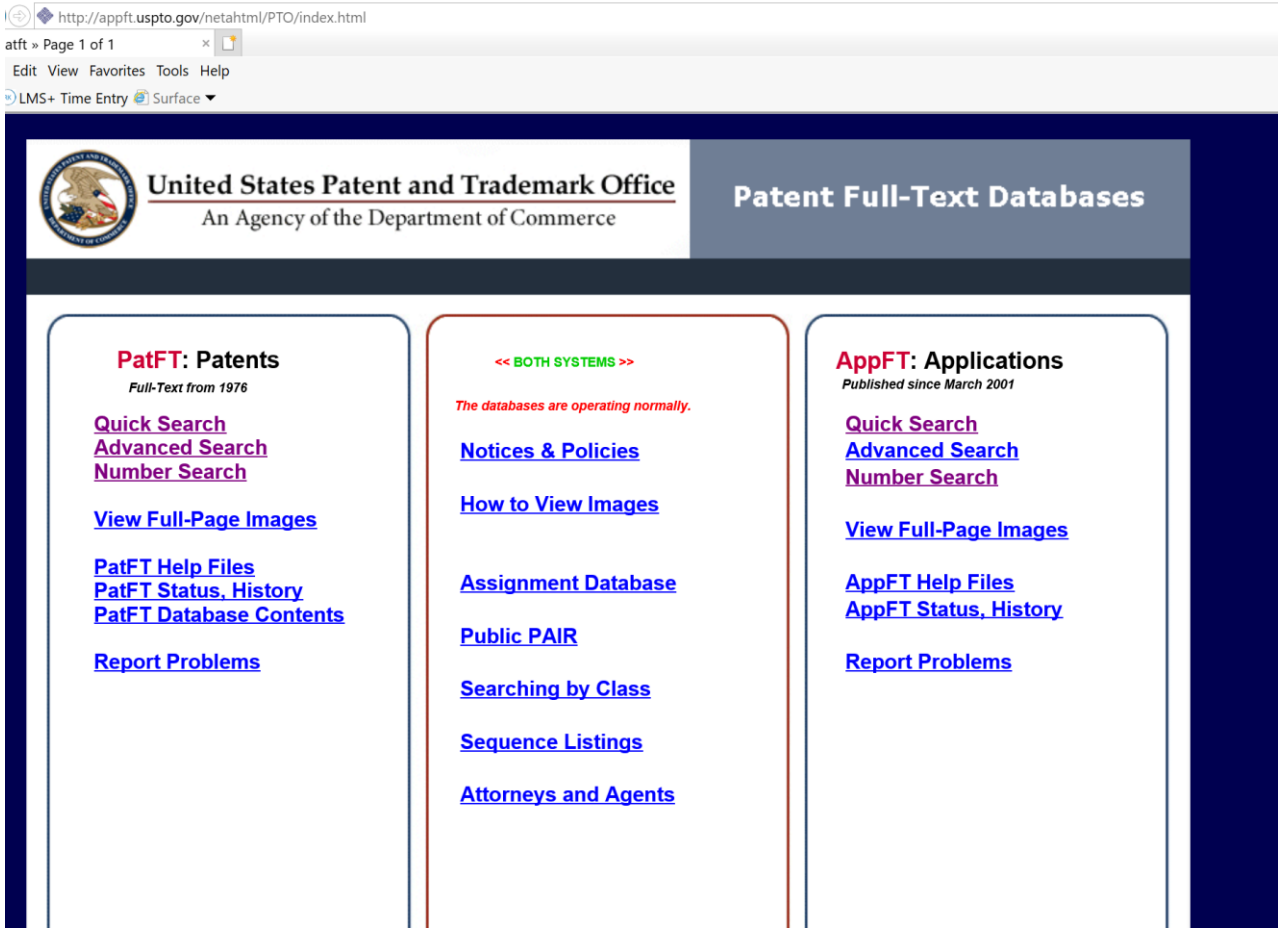
B. Doing your own search
   - Understand the difference between a patent and a patent publication
   - Managing your lawyer's time
   - What not to say

Doing your own searches

1. Use PTO and WIPO database
2. For structure searching, may need to use SciFinder
3. There are commercial searching firms that will do a search as well
4. Determine whether you think any patents may be a problem
5. Bring your search results to your patent attorney

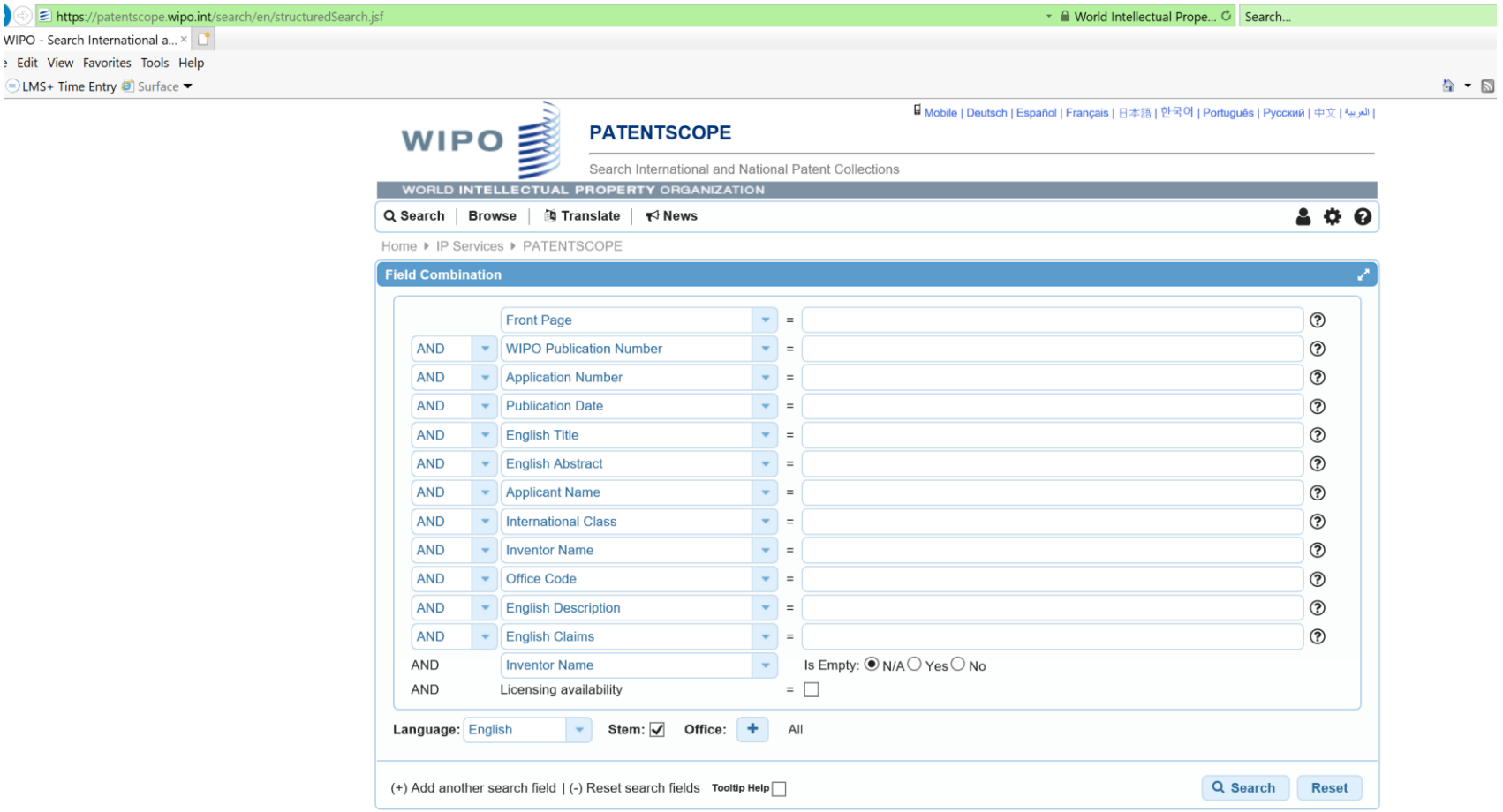
USPTO Database

http://appft.uspto.gov/netahtml/PTO/index.html



WIPO Database

https://patentscope.wipo.int/search/en/structuredSearch.jsf



Patent Versus Patent Publication

US

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(19) **United States**

(12) **Patent Application Publication**
DELAVENNE et al.

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(43) **Pub. Date: Apr. 4, 2019**

(54) **ANTIBACTERIAL USE OF HALOGENATED SALICYLANILIDES**

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H01L 23/485 (2006.01)

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(12) **United States Patent**
Marron

(10) **Patent No.: US 10,000,000 B2**
(45) **Date of Patent: Jun. 19, 2018**

(54) **COHERENT LADAR USING INTRA-PIXEL QUADRATURE DETECTION**

(71) Applicant: **Raytheon Company**, Waltham, MA (US)

(72) Inventor: **Joseph Marron**, Manhattan Beach, CA (US)

(73) Assignee: **Raytheon Company**, Waltham, MA (US)

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2003/0076485	A1	4/2003	Ruff et al.	
2006/0227317	A1 *	10/2006	Henderson	G01B 11/026 356/28

FOREIGN PATENT DOCUMENTS

WO	WO 2005/080928	A1	9/2005

OTHER PUBLICATIONS

Is a Patent - You Could Infringe

Not a Patent, You Cannot Infringe - But Might Need to Monitor

Managing your lawyer's time

If you think a patent might be a problem, ask a very narrow question for your patent attorney to answer:

e.g. "If we make compound X, is it likely that we literally infringe Patent 9,999,999?"

Open ended questions increase costs.

- Make it clear that you are not interested in attorney doing any additional FTO at this time.

- Tell your lawyer you understand that there may be other patents out there, but that you are only concerned about this one at this time.

What Not To Say

AS A GENERAL RULE, NEVER WRITE DOWN BAD NEWS

- Best to have any discussion of FTO orally without any written record
- If you must have a written record, say something like:
  - *"Patent 9,999,999 should be examined more closely to determine its scope"*
- What not to say:

- Any admission that you infringe any patent, e.g. Doing X would infringe patent 9,999,999.

- Any admission that anything is not patentable, e.g. We cannot patent compound X because Jones makes it obvious.

Protecting against Post Grant Challenges

Scope

- **Before** *Inter Partes* and *Post Grant Review*, the Patent Owner chose whether to bring a lawsuit and risk a challenge to a patent
- Broad claims were safe unless Patent Owner decided to risk the claims
- **Now**, any party can challenge any patent that it wants

Advantages of Narrow Scope

The Actual Patent Claim subject to Post Grant Review:

- A method of treating disease X, comprising orally administering Compound A to a human being in need thereof, wherein the human being receives about **80 mg to about 500 mg** of Compound A within a period of six months.

There were three players in this space, our claim covered all three:

- Company M: For disease X, would have used 100 mg within a period of six months
- Our client: Targeting about 300 mg within a period of six months
- Company T: Targeting about 480 mg within a period of six months
- Company T challenged the patent

Advantages of Narrow Scope

Instead to have 3 separate patents

1. A method of treating disease X, comprising orally administering Compound A to a human being in need thereof, wherein the human being receives about 80 mg to about 250 mg of Compound A within a period of six months.

- Covers Company M's Product

2. A method of treating disease X, comprising orally administering Compound A to a human being in need thereof, wherein the human being receives about 250 mg to about 350 mg of Compound A within a period of six months.

- Covers Client's Product

3. A method of treating disease X, comprising orally administering Compound A to a human being in need thereof, wherein the human being receives about 350 mg to about 500 mg of Compound A within a period of six months.

- **Covers Company T's Product**

- Taken together, the coverage is the same as the single patent, but challenging one patent does not risk the entire scope
- PGR against Patent covering Company T's Product, but Client's other Patents not at risk.

Protecting Against Post Grant Challenges

A. Quantity

- *Each patent has to be challenged individually*
- *More patents mean more opportunities to maintain a valid patent*

B. Continuation

- *When patents are challenged, can get new patents that address weaknesses in the patent.*

Protecting Against Trade Secret Litigation

(do you have right policy in place?)

- Need Stringent Controls
- Don’t allow new employees to download files onto company computers
- Before starting employment, tell new employees not to remove any files from the computers at work without permission from their current employer
- Interview new employees to insure compliance

Save Money
(Dos & Don’ts)

Dos

- Draft short patent application
- Do your own prior art search
- Consult patent attorney for overall IP portfolio strategy
- Aim for multiple patents
- Protect against PGR & Trade Secret Litigation

Don’ts

- Draft long patent application
- Not consult patent attorney for overall IP portfolio strategy
- Have lawyer do extensive search and/or FTO for you
- Aim for single patent

To focus on high value IP

Don’t focus on saving money only