

Patent Reform

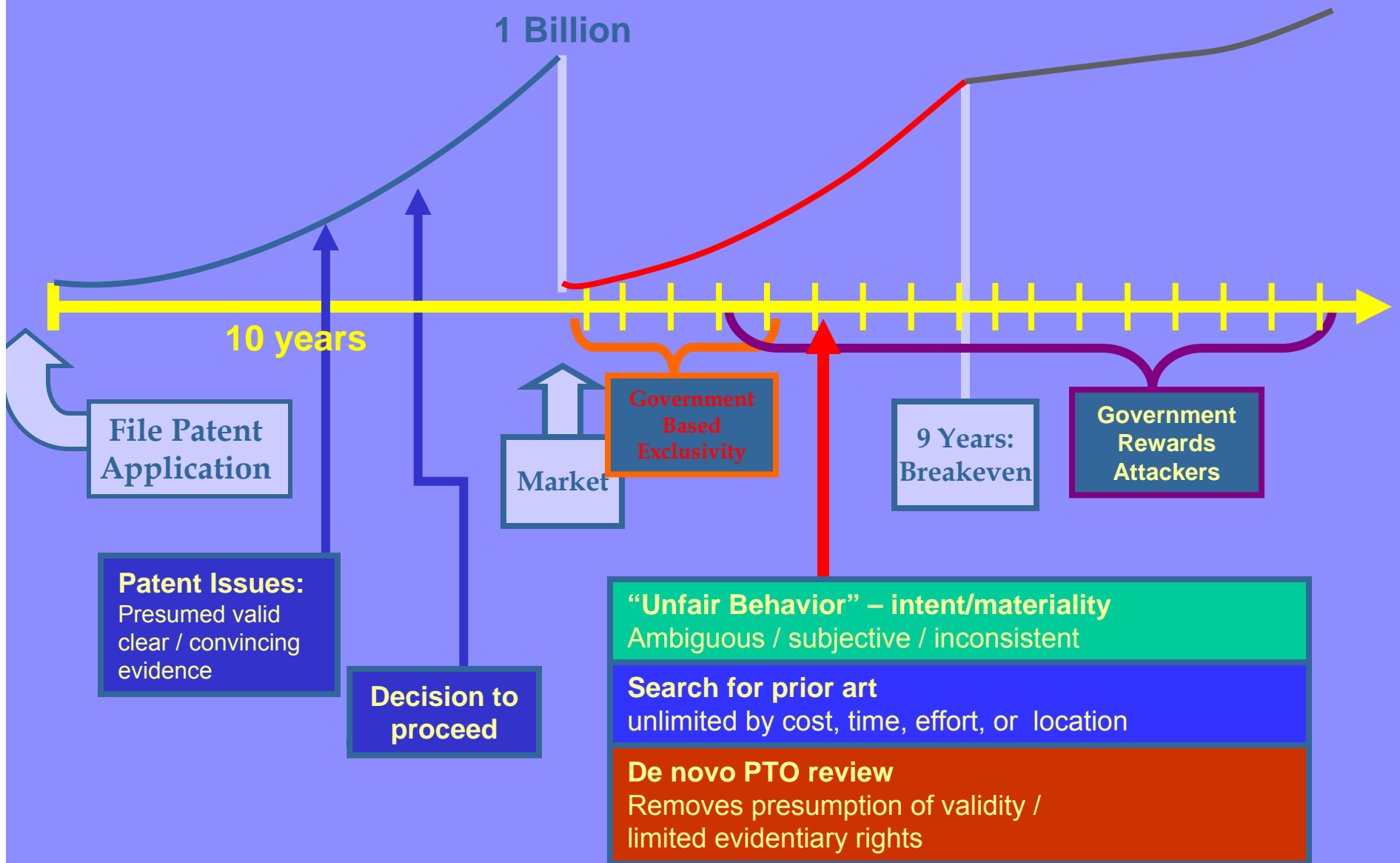
What should it look like?



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Would you start this business?



USPTO Position (AQS)

1. PTO in dire situation

- ↑cases ↑backlog ↑average pendency time
- Allowance rate dropping, yet Allowance error decreasing
- Many cases submitted with no references or too many reference
- Easy to search online

Proposal: Transfer examination obligation to the applicant (AQS)

- Applicant does search (online?)
- Applicant create its own first office action (analysis)



Applicant Quality Submission Draft Language (S. 1145)

The Director shall, by regulation,
require

(1)a **search report and analysis**
relevant to patentability; and

(2) **any other information** relevant to
patentability that the **Director in his
discretion, determines necessary**

(b) FAILURE TO COMPLY.--application
shall be regarded as abandoned.

S. 1145



PTO Final Rule 1.265 Examination Search Document

If submit > 5 independent/25 total claims

Certify pre-examination search of

- **US Patents, patent application publications, foreign patent documents and non-patent literature**
 - Search directed to each limitation of each claim
 - Identify each limitation of claims in each reference
 - Detailed explanation how ind. Claims patentable over each reference



GSK Letter to Hon. Leahy and Specter on AQS (Jan 2008)

A statute must provide intelligible principles to guide and limit the scope of the delegated authority to an agency. Proposed Section 123(a) fails to do that.

- Authorizes PTO to direct applicant to search all patent and literature of entire world without regard to bounds, cost, time, effort, or location
- Gives the PTO free license to define “any other information relevant to patentability” in any way the agency sees fit to do.

May be fixed with a limited scope regulation
but see Proposed PTO Final Rule 265
(*Tafas/GSK vs. Dudas*,)



Applicant Quality Submission

- **Courts may be forced to hold statute**
 - an improper, unbounded grant of authority or
 - impose a narrowing construction.
- **Could transfer the role of Congress to the courts and further dilute Congress' control over national patent policy.** *See, e.g., Industrial Union Dep't, AFL-CIO v. American Petroleum Inst., 448 U.S. 607 (1980).*



GSK Recommendations

Prior Art Searches and Analyses

- **Delink the search function from applicant**
- **PTO should select, train and certify a number of private search companies**
- **Applicant can select whether to**
 - Do search itself
 - Pay to have an approved vendor do search
- **Vendor indicates why it considered each cited prior art reference relevant**
 - Statements would not be attributable to applicants
- **Does not excuse applicant from 1.56 duty**



GSK Recommendations to PTO Change the Fee Structure

US Extra Claims fee \$50 >20
EPO 200€>15

Graduated fee as increase
number of claims

US Con/Div app. \$1000
EPO app. €3000

Graduated fee scale for each
successive con/div

US Prior Art Submission:
FREE regardless
of number of
references!!!!!!

First 15 references free then pay
by the page for consideration of
additional references





GSK Recommendation Delayed PTO Examination

- Applicant can delay examination up to 3-4 years on payment of yearly fee
- Balance PTO workload versus public desire for certainty in freedom to operate
- Works well in Japan/Canada
- A number of the current backlogged apps may already be stale



Inequitable Conduct

PTO: Will IC Reform improve information to the PTO?

- **Depends what the reform looks like**
- **Only one of many reasons to fix IC**



Inequitable Conduct

Social Cost of a Broken System

Loss of jobs

- *Purdue Pharma vs. Endo* (56% workers fired before reversed)

Destruction of businesses

- Purdue Pharma (destroys oxycontin market before reversal)

Damage to reputation of respected workers

- *Amphastar vs. Aventis* (350 articles/Galien Award)

Loss of stockholder value

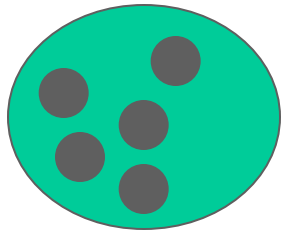
Most important cost is invisible to the public

Fewer new drugs that may save lives

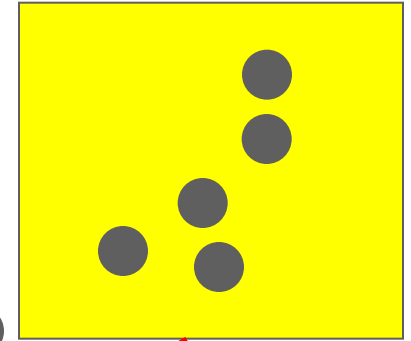


Tangential

But For



UNPREDICTABLE



Mistake

(Cases listed in Chisum §19.03 + CAFC Cases 2004-to Present)

Fraud

Inequitable conduct

**CAFC reverses over 50% of
District Court determinations on IC**

Source: CAFC Opinions 2006-2008 12/22 Opinions

**Reversal rate of
Markman claim constructions
Up to 40%**



GSK Position Inequitable Conduct

Claim by Claim analysis
Only asserted claims

High standard of materiality (But for)
Intent conscious and deliberate (c/c evidence)

Must separately prove intent and materiality

Can't apply where all claims valid

Can't find until one claim held invalid

Each patent stands on own (no infectious IC)

Comprehensive Cure mechanism





CAFC Discord over IC standard

Compare: en banc *Kingsdown v. Hollister*

Amphastar vs. Aventis (Moore, Proust, Rader)

D. Ct. never considered validity or infringement

PTO reissued patent during litigation and agreed to remove dose information from specification

Rader dissent: IC should be limited to extreme cases of fraud and deception

Nilssen v. Osram (misclaiming small entity status held inequitable conduct)

General Electric vs. Samick (Petition to Expedite with only “informal search” held IC)

Compare: ***Star Scientific vs. Reynolds Tobacco*** (Linn, Michel, Lourie)

Time right for another en banc CAFC Decision



Claim by Claim analysis

Can CAFC change law to remove
unenforceability in valid patent context?

Whenever *without deceptive intention*, a claim of a patent is **invalid**, an action may be maintained for the infringement of a claim of the patent which may be valid.

35 USC 288

When a court has finally determined that IC occurred in relation to one or more claims during prosecution of the patent application, the entire patent is rendered unenforceable.

en banc, Kingsdown v. Hollister (CAFC 1988)



Should IC be taken out of court?

- Remanded to PTO for reissue process
- Consideration of fair sanctions/fines/penalties
- Removes litigation gamesmanship
- Let PTO decide if information is material



GSK Against PTO Suggested Civil Penalties for Misconduct

Already have sufficient penalties

- **Criminal penalties**
 - Lying to the government punishable by fines and up to five years of imprisonment.
- **Antitrust laws**
- **Sanctions for misconduct by attorneys appearing before the PTO.**

Result of Civil Penalties:

Reduce number of attorneys joining Patent Bar

