

Patent Protected?

The Myths, Metrics, and Methods for Maximizing Value

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M•CAM[®]



Seminar Objective

- **WHAT IS A PATENT?**
- **HOW MUCH DILIGENCE IS DUE?**
- **HOW DO I INVEST OR BUILD A BUSINESS AROUND PATENTS?**

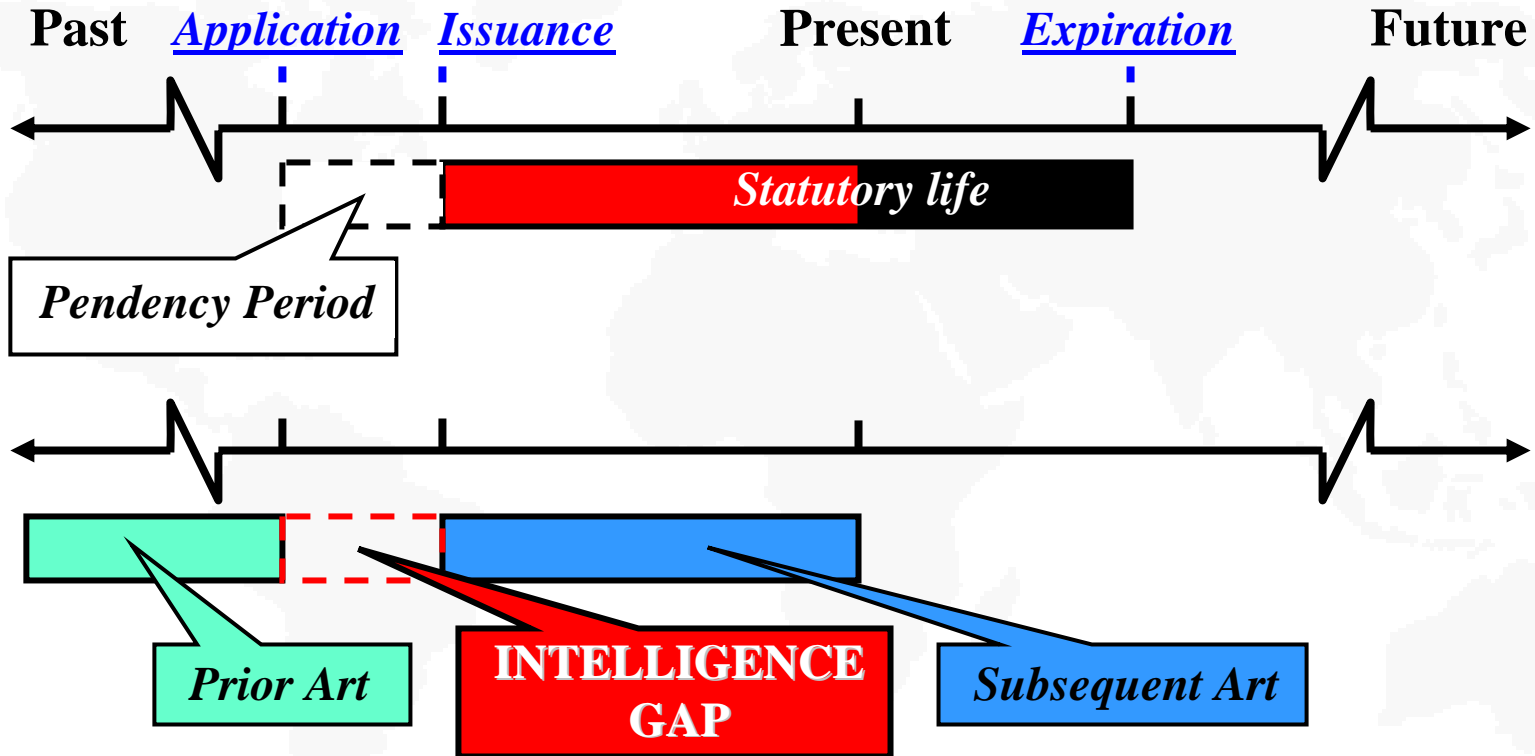


What must a patent contain?

Novelty 35 U.S.C. § 102	Not know or used by others prior to the date of application; not published by any party more than 1 year from application; and not offered for use or sale more than one year prior to application
Non-obviousness 35 U.S.C. § 103	A person of ordinary skill “in the art” should not be able to obviously practice the invention
Reduction to Practice & Useful 35 U.S.C. § 101	The patent must disclose the precise methodology whereby a person skilled in the art can “practice the invention” and should have some utility or meet some need



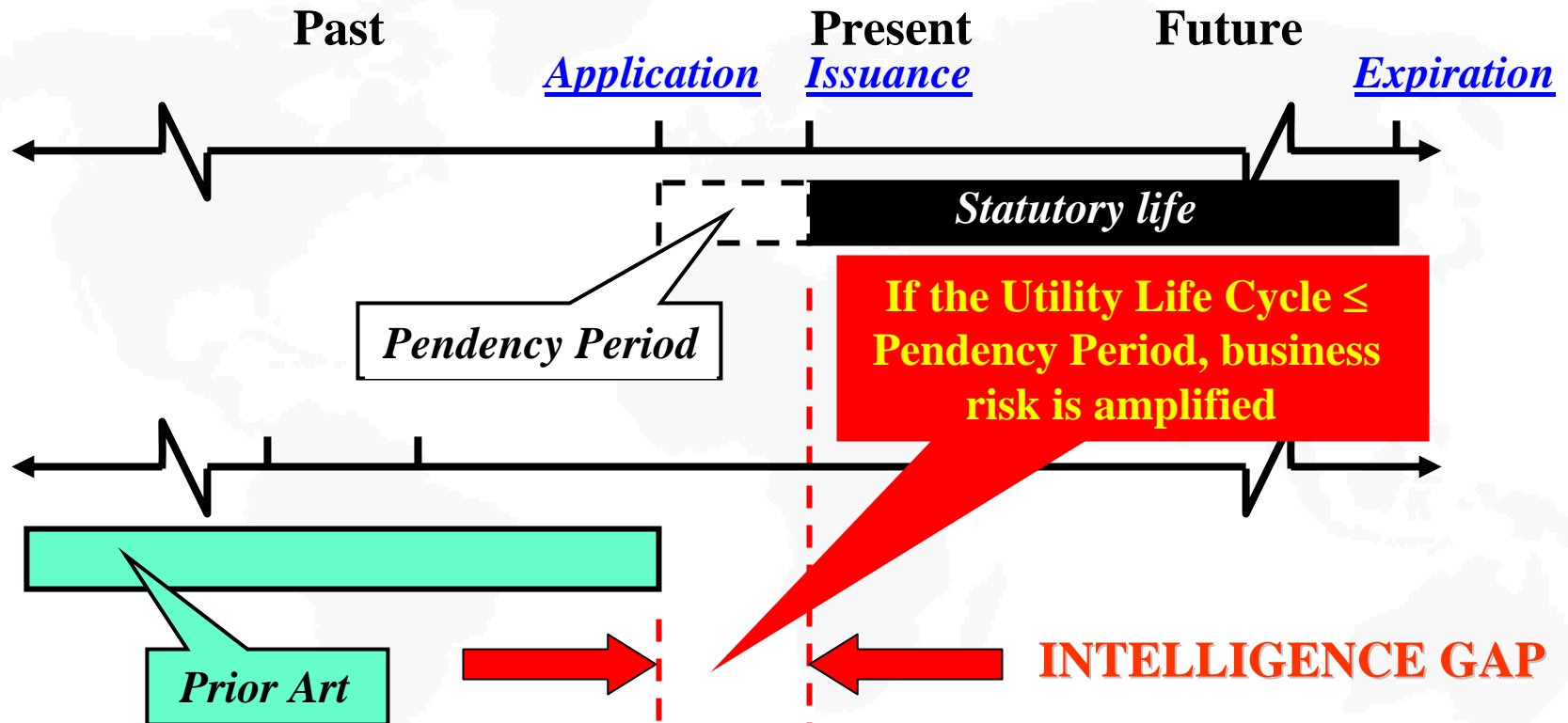
IP Chronology: Conventional



The conventional perspective is “discontinuous”.



IP Chronology: Conventional

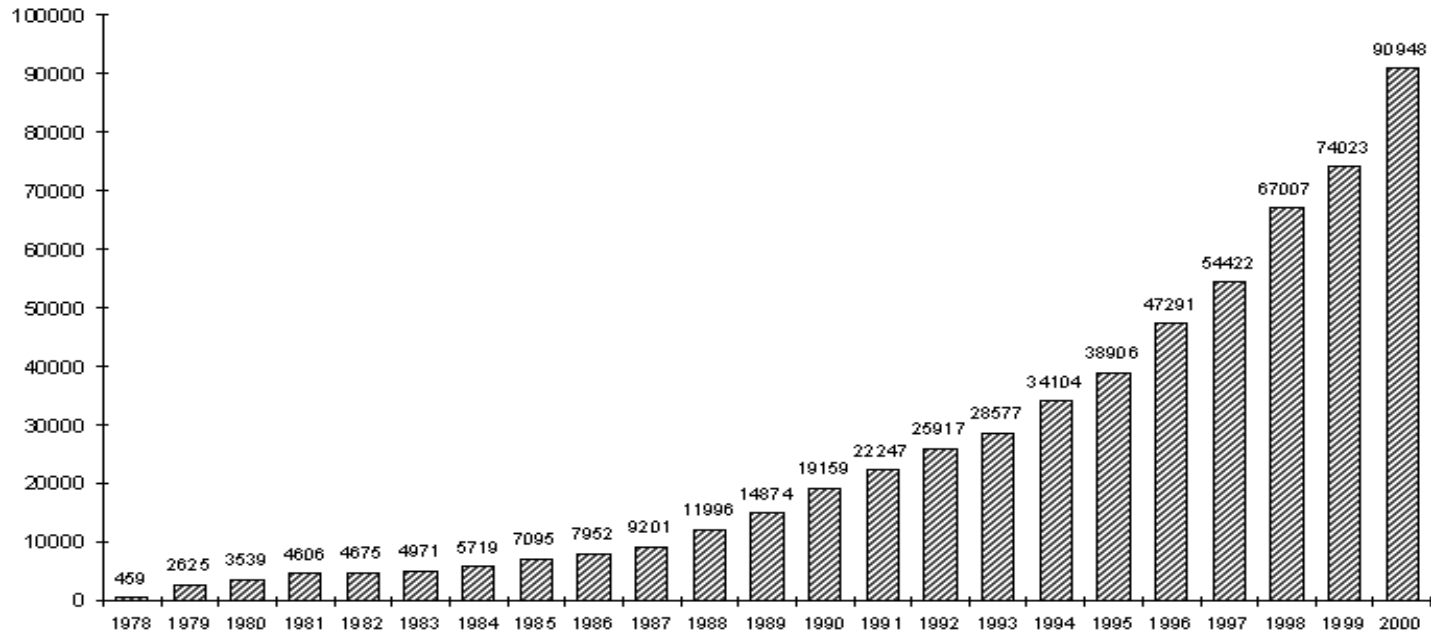


The "Intelligence Gap" widens along with pendency period.



Background: Global

International Patent Filings (“PCT’s”)* CY 1978 through CY 2000



We're evolving into a global, knowledge-driven economy.

* Source: WIPO; *The Patent Cooperation Treaty (PCT) in 2000*; Geneva, February 13, 2001



Background: Net Result

- More data - *information overload*
- Higher probability of overlapping initiatives - *inefficient resource management*
- Increasing globalization of IP - *higher stakes on R&D investments*
- Longer time intervals between patent filing and issuance (pendency period) - *increasing vulnerability to infringement*

Increasing need for reliable, auditable, relevant information.



Terminology

Statutory Validity

Level 1:

The process by which the legal aspects of the patenting process, the assignment of the patent and its current status as related to international filings and maintenance fees are all verified.

Commercial Validity

Level 2:

The process by which the uniqueness of the property is evaluated, thereby establishing whether the patent is a genuine asset or a liability. Since a patent is a *limited monopoly to exclude others*, failure to meet the standard may reduce or eliminate any independent commercial value the patent may have had.

Risk Mitigation

Level 3:

The process by which the patent is evaluated for potential liabilities, the degree of risk associated with such liabilities and the possible strategies by which such liabilities may be reduced or completely eliminated.



Statutory Validity

- Identify relevant jurisdiction and patent standard
 - What country laws apply? Are markets protected?
- Review first “enabling disclosure” and time to patent application
 - Did someone publish the “crown jewels” before securing IP?
- Evaluate claims vs. intended use(s)
 - Patents are exclusionary rights, not affirmative. Therefore, establishing dependency limits down-stream infringement risk





How much diligence is due?



Due Diligence Objectives

- Statutory Validity
 - Breadth of coverage + International scope
- Commercial Validity
 - True Innovation or the “Thesaurus Patent”
 - Delimitations and Limitations
- Risk mitigation
 - Likely challengers and probability of success



Classic IP due diligence steps

- Collect and review patent documents, publications, and other corporate materials to evaluate procedural compliance
- Conduct keyword searches for obvious overlapping patents
 - USPTO, JPO, EPO, WIPO, Derwent, others...
- Consult with an attorney for a positive opinion letter as to affirmative statements vis-à-vis granted rights



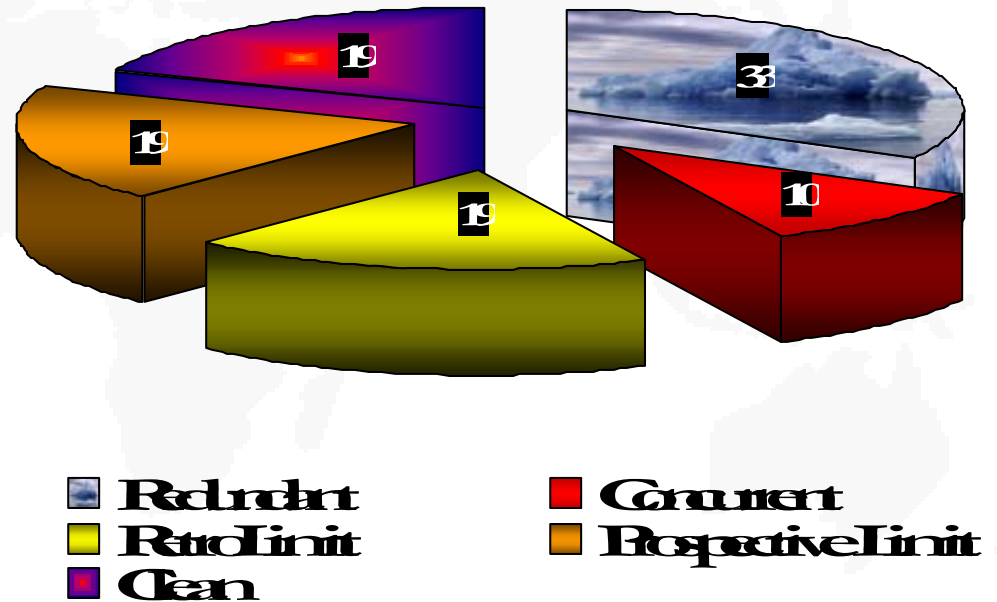
Keyword Search Example

- **Amino Acid Sequence**
 - U.S. > 10,300 patents
 - WIPO <50 patents
 - JPO >1,400 patents
- **Target Kinase**
 - U.S. > 50 patents
 - WIPO <10 patents
 - JPO <10 patents
- **Drug Discovery**
 - U.S. 1 patent
 - WIPO <20 patents
 - JPO <20 patents



Commercial Validity

- Is the patent **UNIQUE?**
- Is the patent **DEPENDENT?**
 - If so, on whom?
 - If not, are there public domain reasons why?



Patent Concept-driven Uniqueness Testing

- Children's Hospital of Boston patent licensed by KERYX Biopharmaceuticals for identifying drug candidates for "kinase functional genomics"
 - 43 patents that predate platform with considerable redundancy in key elements

M-CAM DOORS™ SEQUENCING THE INNOVATION GENOME

Jump to...

search terms	found	unique	action	total number with frequency of 2: 43	total number with frequency of 1: 2561
a.LSF: target kinase	1910	1868	hide		
b.LSF: drug discovery	57	55	hide		
c. keyhole: 6174993	73	73	hide		
d.LSF: serine/threonine kinase	607	565	hide		
totals:	2647	2561			

2 change cut o

Descriptor:

Run number:

(un)highlight self

The Patents

f	patent no.	title assignee	filed issued	6174993
<input type="checkbox"/>	2 US6337188	De novo or "universal" sequencing array Orchid BioSciences, Inc.	25-AUG-00 08-JAN-02	
<input type="checkbox"/>	2 US3995018	Method of binding immunoglobulin employing a polypeptide from Pharmacia Aktiebolag	25-OCT-73 30-NOV-76	
<input type="checkbox"/>	2 US6291183	Very large scale immobilized polymer synthesis Affymetrix, Inc.	17-NOV-99 18-SEP-01	
<input type="checkbox"/>	Use of oxidase enzyme systems in chemiluminescent assays	11-JUN-90	



Who thinks they own it too?

Polaris™
Polaris results for:
DiabetesVaccine Morph Sets

Statistics
total number with frequency of 3: 19
total number with frequency of 2: 210
total number with frequency of 1: 6842

Modify/Update this set
3 change cut off point
Descriptor:
Run number: add set

search terms

search terms	found	unique	action
a. keyhole: 6316609	23	23	hide
b. LSF: recombinant protein	1096	1003	hide
c. LSF: dna vaccine	754	705	hide
d. LSF: transferase	2559	2416	hide
e. LSF: gene sequence	1643	1495	hide
f. LSF: diabetes	1244	1200	hide
totals:	7319	6842	

The Patents

f	patent no.	title assignee	filed issued	6316609	where from						
					a	b	c	d	e	f	
<input type="checkbox"/>	3 US5258498	Polypeptide linkers for production of biosynthetic proteins Creative BioMolecules, Inc.	01-OCT-92 02-NOV-93								
<input type="checkbox"/>	3 US5866785	Recombinant plant viral nucleic acids Biosource Technologies, Inc.	07-JUN-95 02-FEB-99								
<input type="checkbox"/>	3 US5879933	Mammalian Retrotransposons Nature Technology Corporation	30-JUN-94 09-MAR-99								
<input type="checkbox"/>	3 US6284492	Recombinant animal viral nucleic acids Large Scale Biology Corporation	07-JUN-95 04-SEP-01								
<input type="checkbox"/>	3 US6027722	Vectors for gene transfer Nature Technology Corporation	14-MAR-94 22-FEB-00								
<input type="checkbox"/>	3 US6027725	Multivalent antigen-binding proteins Enzon, Inc.	05-OCT-98 22-FEB-00								

- Identification of parties already holding patents claiming or describing overlapping compounds or use



Risk Mitigation

<p>Cited Prior Art assignee classification</p>	<p>Patent US5091513 Creative BioMolecules, Inc. top bibliographic claims description bottom</p>	<p>Citing Subsequent Art assignee classification</p>
<p>Patents by Assignee</p> <ul style="list-style-type: none"> US4355023 The Massachusetts General Hospital US4474893 The University of Texas System Cancer Center US4642334 DNAX Research Institute of Molecular and Cellular Biology, Inc. US4666837 SmithKline-RIT US4704692 Ladner; Robert C. US4816397 Celltech, Limited US4816567 Genentech, Inc. 	<p>United States Patent 5,091,513 Huston, et al. February 25, 1992</p> <p>Biosynthetic antibody binding sites</p> <p style="text-align: center;">Abstract</p> <p>Disclosed are a family of synthetic proteins having affinity for a preselected antigen. The proteins are characterized by one or more sequences of amino acids constituting a region which behaves as a...</p>	<p>Patents by Assignee</p> <ul style="list-style-type: none"> US5359046 Cell Genesys, Inc. US5434075 Board of Trustees of the University of Illinois US5455030 Enzon Labs, Inc. US5482858 Creative BioMolecules, Inc. US5534254 Chiron Corporation US5631158 Creative BioMolecules, Inc. US5652118 Creative BioMolecules, Inc. US5658763 Creative BioMolecules, Inc. US5674844 Creative BioMolecules, Inc.

Network Diagram Data:



















Entity	Count
of Texas System Cancer Center	138
CELLTECH LIMITED	115
Celltech, Limited	109
Ladner; Robert C.	74
ular and Cellular Biology, Inc.	63
IONAL GENETIC ENGINEERING, INC.	1
GENEX CORPORATION	1
Massachusetts General Hospital	1
SmithKline-RIT	1
Genentech, Inc.	1
Creative BioMolecules, Inc.	107
Enzon Labs, Inc.	1
Medical Research Council	1
Creative BioMolecules, Inc.	1
The General Hospital Corporation	1
Creative BioMolecules, Inc.	1
Creative Bio Molecules, Inc.	1
Chiron Corporation	1
The General Hospital Corporation	1
Medical Research Council	1
The General Hospital Corporation	1
Creative BioMolecules, Inc.	1
The Massachusetts General Hosp	1
Matritech, Inc.	1
The General Hospital Corporation	1
Creative BioMolecules, Inc.	1
Creative BioMolecules, Inc.	1
Matritech, Inc.	1
Novartis Corp.	1
Chiron Corporation	1
Whitehead Institute for Biomedic	1
Rosetta Inpharmatics, Inc.	1
Rosetta Inpharmatics, Inc.	1
Rosetta Inpharmatics, Inc.	1

Patent No. US5091513
filed: 02-JAN-91
issued: 25-FEB-92

- Inconsistency between “search” logic and real life
 - Patents written to confuse – keyword “due diligence” *isn’t*
- Thesaurus Patents aren’t assets, they’re liabilities
- Know who else is playing (noticed or unnoticed) to gauge risk acceptability



But I thought that the Patent Office reviewed all that!

	US4303644	Norden Laboratories, Inc. Lincoln NE USA	Feline infectious peritonitis virus vaccines 424/ 89 Drug, bio-affecting and body treating compositions	4/754 6/827	16-OCT-79 01-DEC-81	
	US4581231	The United States of America as represented by the Secretary of Health USA	Inactivation of viruses containing essential lipids 424/101 Drug, bio-affecting and body treating compositions	1/754 3/827	31-AUG-83 08-APR-86	
	US5328688	Arch Development Corporation Chicago IL USA	Recombinant herpes simplex viruses vaccines and methods 424/2051 Drug, bio-affecting and body treating compositions	11/754 18/827	10-SEP-90 12-JUL-94	
	US5187087	AKZO N.V. Arnhem NLX	Recombinant herpesvirus of turkeys and live vector vaccines derived 435/1721 Chemistry: molecular biology and microbiology	1/754 3/827	30-NOV-90 16-FEB-93	
	US5965138	Syntro Corporation Lenexa KS USA	Recombinant chimeric virus and uses thereof 424/1991 Drug, bio-affecting and body treating compositions	15/754 21/827	22-DEC-94 12-OCT-99	
	US5763217	University of British Columbia Vancouver CAX	Method of using, process of preparing and composition comprising 435/ 691 Chemistry: molecular biology and microbiology	1/754 3/827	11-OCT-95 09-JUN-98	
	US5641651	Arch Development Corporation Chicago IL USA	Synthetic herpes simplex virus promoters 435/ 691 Chemistry: molecular biology and microbiology	11/754 18/827	31-OCT-94 24-JUN-97	
	US5714153	Arch Development Corporation Chicago IL USA	Method of inducing antibody production against an infectious agent in a 424/2311 Drug, bio-affecting and body treating compositions	11/754 18/827	29-JUL-96 03-FEB-98	
	US6120773	Arch Development Corporation Chicago IL USA	Recombinant herpes simplex viruses vaccines and methods 424/2051 Drug, bio-affecting and body treating compositions	11/754 18/827	08-JUL-94 19-SEP-00	

Delimiting Innovation

Limiting Innovation

Concurrent patents

How unique - how thorough the review?

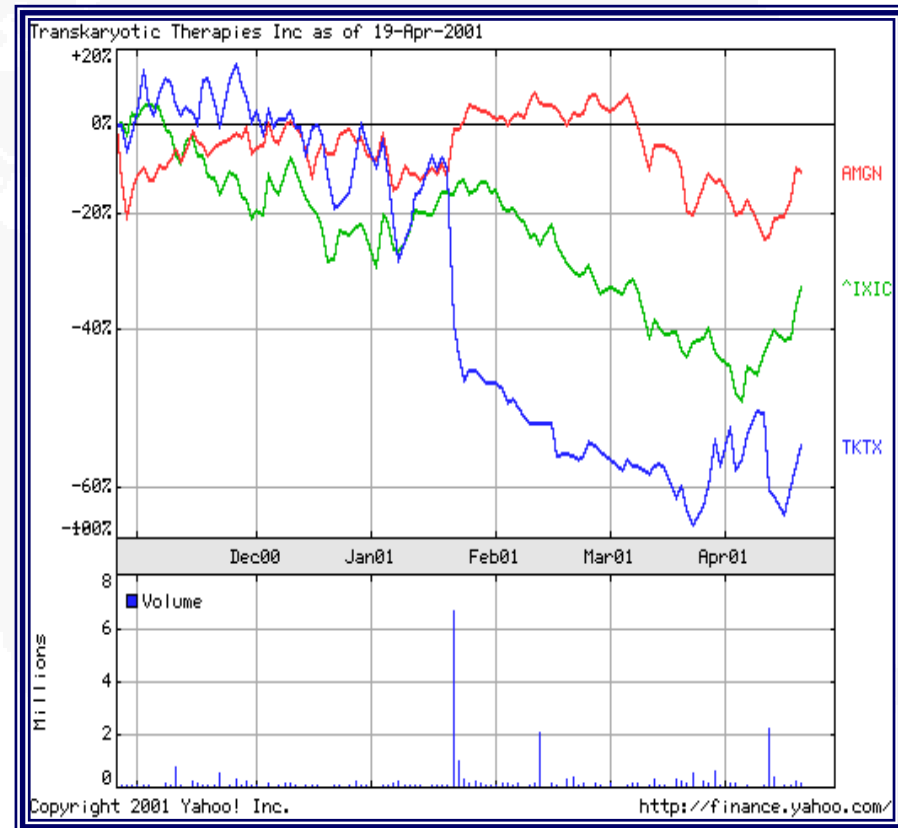


Market Impact

2.5 month lead time on predicting a one day loss of >53% market cap (TKTX) with an associated 10% up tick for Amgen.

Patents all “valid” per patent offices and opinion letters but non-novel upon more careful analysis

Short positions netted one large investment bank >\$100mm



Assets vs. Liabilities

- Patents are *not necessarily* assets
 - Redundant, Plagiarized, Dependent on other protected properties, Re-patented
 - You get to sue to establish title
 - You get to pay the success tariffs (read “infringement damages”)
- Mitigate liability by identify threats prior to commercial success



License (the right patents)

Early & Often

- Objective assessment of uniqueness can right size licensing costs
- Licensing during R&D provides more leverage than when product dependencies have been established
- Identify patents upon which competitors rely but about which competitors are unaware



Objective Standards

- Lessen reliance on the “lobbying” of interested parties – both patent holders and investors
- Provides adequate risk rating for investor’s capital allocations
- Reduces risk of “post success” litigation
- Focuses management on IP quality and protection – after all, the IP IS your exit

