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# A BIOINFORMATICS BUSINESS MODEL AND THE BOLD PATENT STRATEGY BEHIND IT: THE CASE OF INCYTE GENOMICS

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John Storella

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Once upon a time there was a  
company that decided to patent the  
human genome ...

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# The Biotech Boom of the late 1990's and early 2000's

- Genomics as a business model:
    - Incyte Genomics, Celera, Millennium, Human Genome Sciences
  - Incyte Genomics: A bioinformatics “Pure Play”
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# The Incyte Business Model

- Sequence the human genome
  - Collate sequence and expression data into annotated databases
  - Sell subscriptions to the databases to pharma
  - Collect reach-through royalties on pharmaceutical drugs developed using the database
  - Most pharma companies signed up
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# The Business Plan Required An Ambitious Patent Strategy

- Business Goals:
    - Assure subscribers of freedom-to-operate if they found something valuable using the database
    - Use patent licenses as basis of reach-through royalties
  - Patent strategy: Patent the human genome
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# Incyte's Patent Program

- Filed over 2000 patent applications
  - Covered about 11,000 full-length gene sequences
  - Large internal patent group
  - Cost estimated at \$5M to \$10M per year
  - But in the PTO ...
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# The Utility Requirement

- 35 U.S.C. § 101 Inventions Patentable
  - Whoever invents or discovers any new and useful [invention] may obtain a patent therefor ....



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# Purpose Of The Utility Requirement

- *Brenner v. Manson*, 383 U.S. 519, 534-535 (1964)
    - The *quid pro quo* for granting patent monopoly is a benefit to the public
    - The utility requirement prevents overreach into undeveloped technical areas, thereby tying them up against development by others
    - Specific benefit must exist in currently available form
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# The USPTO Guidelines for Utility

- Three-part test for utility:
    - Credible Utility
      - Not wholly inoperative
    - Specific Utility
      - In contrast with “general” utility
    - Substantial Utility
      - “Real world” utility that does not need further research to confirm
      - Not a “self-referential” utility
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# Patent Examination: Irresistible Force Meets Immovable Object

- “Polynucleotides coexpressed with matrix-remodeling genes”
    - U.S. Pub. 2002/0019000
    - Representative claim:
      - 2. An isolated polynucleotide comprising a nucleic acid sequence of SEQ ID NO:6, or the complement thereof.
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## Immovable Object: Patent Office Rejection For Lack Of Utility

- Co-expression of claimed gene with known matrix remodeling genes does not show biological function for protein encoded by the gene
  - Diagnosis, prognosis and therapy of disease were “general” utilities and not “specific” utilities
  - The asserted utilities also were not “substantial” because further research would be needed to identify a real world utility.
  - The examiner did not address the issue of credible utility.
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## Irresistible Force: Incyte Responds

- No biological activity necessary:
    - The claimed gene had utility as a “surrogate marker” for the known matrix-remodeling genes.
  - The claimed gene was useful as a probe for gene expression monitoring in the context of drug development and toxicology testing
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## Immovable Object: Final Rejection

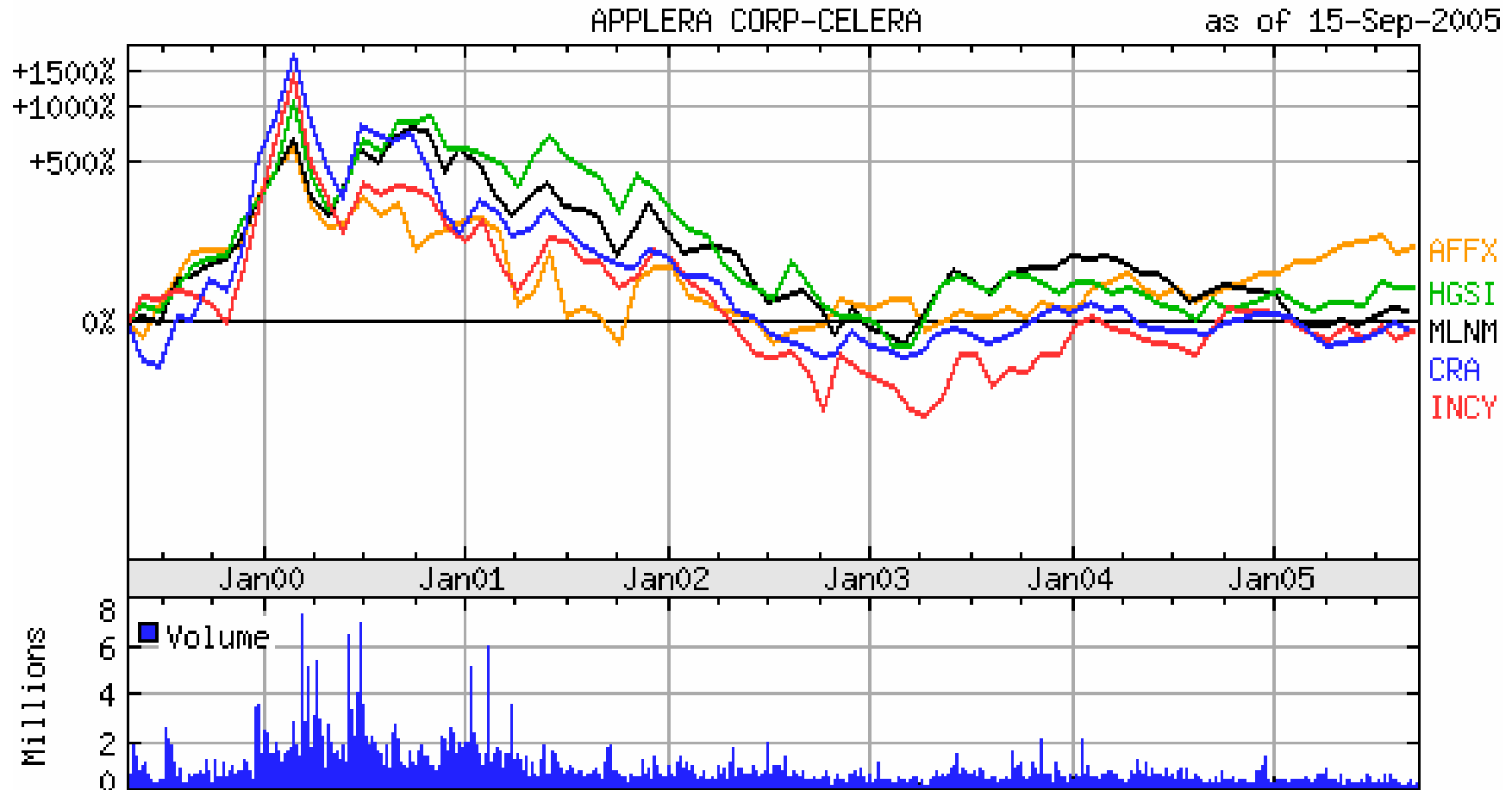
- The specification did not “establish any toxin which would induce the expression of SEQ ID NO: 6 or NO: 22 ... so that SEQ ID NO: 6 and NO: 22 can be part of a pattern of expression in response to the toxin.”
  - (Incyte abandoned the application in October 2004)
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# Incyte Changes Its Business Plan And Abandons Its Patent Strategy

- November 2001:
    - Incyte replaces senior management with team specializing in drug development
  - December 2002:
    - Incyte Genomics changes its name to Incyte Corporation
  - February 2004:
    - Incyte shuts down Palo Alto facility, lays off 257 employees, including patent staff
    - Incyte terminates development of LifeSeq™
  - September 2005:
    - Incyte and the other genomics companies fall out of favor
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# Stock Prices Of Incyte, Millennium, Celera and Human Genome Sciences ... and Affymetrix



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# Did The Patent Strategy Make Business Sense?

- Incyte's strategy of patenting 11,000 human genes depended on generating royalty stream that was greater than the cost to generate it
  - Factors in modeling the net present value of the patent portfolio depend on:
    - Cost to establish and maintain the portfolio
    - Expected royalties on drugs under patent
    - Discount rate
  - Optimistic and pessimistic assumptions place the net present value between \$600M and negative value.
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# Whither The Utility Requirement: *In re Fisher*

- *In re Fisher* – CAFC decision September 7, 2005
  - Appeal from BPAI decision
  - Issue: Whether EST's from unidentified maize genes have patentable utility
  - Asserted utilities:
    - To identify presence or absence of a polymorphism
    - To isolate promoters
    - To use as a marker on a genetic map
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# Whither The Utility Requirement: *In re Fisher*

- Held: ESTs lack patentable utility
    - Utilities are not “substantial” because there was no showing that the ESTs had been used for the asserted purposes
      - ESTs are “research intermediates” or “objects of research”
    - Utilities are not “specific” because any maize EST has the potential to be used for these purposes
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# Whither The Utility Requirement: *In re Fisher*

- Dissent (Judge Rader)
    - ESTs have utility as research tools
    - Decision is a distortion of the utility rule
    - Proper tool for assessing patentability is “non-obviousness” requirement
      - Do ESTs really involve an “inventive step”?
    - Federal Circuit has deprived PTO of this tool through the *Deuel* line of cases
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# Conclusion: How To Demonstrate Utility

- Credible utility:
    - Narrow utilities are more credible than broad ones
  - Substantial utility:
    - Include in the patent application as much information about the biological activity of the molecule as possible
  - Specific utility:
    - Assert utilities that are not widely shared among other molecules in the same class
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John Storella  
Special Counsel  
Wilson Sonsini Goodrich & Rosati  
650-849-3245  
[jstorella@wsgr.com](mailto:jstorella@wsgr.com)

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