



# Litigating DNA Trade Secrecy

Jacob S. Sherkow

Professor of Law and Medicine

University of Illinois Urbana-Champaign

Sept. 19, 2024

# Are DNA Sequences Trade Secret Subject Matter?



30+ years of scholarship has assumed so, but

- *Very few* litigated cases directly on point;
- Almost no statutory authority—and where it exists, it's non-specific
- \*\*\*Reading of the statute (DTSA/UTSA) in light of advances in genomic technology suggest the answer is...

NO

# Are DNA Sequences Trade Secret Subject Matter?



30+ years of scholarship has assumed so, but

- *Very few* litigated cases directly on point;
- Almost no statutory authority—and where it exists, it's non-specific
- \*\*\*Reading of the statute (DTSA/UTSA) in light of advances in genomic technology suggest the answer is...

*REALLY?*

# The Rise of Next-Generation DNA Sequencing



## Before 2001

- Sanger sequencing
- Costly, uncertain, difficult

## 2001

- Draft sequence of the Human Genome Project
- Reference sequencing

## 2005

- Next Generation Sequencing (NGS) Technology
- Illumina (fka Solexa)

# The Rise of Next-Generation DNA Sequencing



## Whole Genome Sequencing Options



### Basic

Whole Genome Sequencing

**\$99** ~~\$299~~

Good choice if you want to start exploring your family history and learn about predisposition to common traits and conditions.

Add to cart

Decodes the most important parts of your DNA



Best value

### Deep

Whole Genome Sequencing

**\$299** ~~\$999~~

The best choice for most users. It gives deep insight into ancestry and allows you to learn about common as well as rare traits and conditions.

Add to cart

Decodes 100% of your DNA



Ultra high accuracy

### Ultra Deep

Whole Genome Sequencing

**\$999** ~~\$2999~~

The most advanced DNA test on the market that decodes your entire genome with ultra-high accuracy enabling most comprehensive and accurate reports.

Add to cart

Decodes 100% of your DNA with ultra high accuracy

# The Rise of Next-Generation DNA Sequencing



CORRESPONDENCE

## Ultrarapid Nanopore Genome Sequencing in a Critical Care Setting

1 Citing Article

TO THE EDITOR:

Rapid genetic diagnosis can guide clinical management, improve prognosis, and reduce costs in critically ill patients.<sup>1,2</sup> Although most critical care decisions must be made in hours, traditional testing requires weeks and rapid testing requires days. We have found that nanopore genome sequencing can accurately and rapidly provide genetic diagnoses. Our workflow combines streamlined preparation of commercial nanopore sequencing, distributed Cloud-based bioinformatics, and a custom variant-prioritization approach (Figure 1).<sup>3</sup>

Between December 2020 and May 2021, at two hospitals in Stanford, California, we enrolled 12 patients who were generally representative of persons living in the United States with respect to race, ethnic group, and sex (Tables S1 and S2 in the [Supplementary Appendix](#), available with the full text of this letter at NEJM.org). We obtained an initial genetic diagnosis in 5 of the patients (Table S3). The shortest time from arrival of the blood sample in the laboratory to the initial diagnosis was 7 hours 18 minutes.

February 17, 2022  
N Engl J Med 2022; 386:700-702  
DOI: 10.1056/NEJMc2112090  
Metrics  
Chinese Translation 中文翻译

**Figure 1.**

Workflow and Performance of Ultrarapid Nanopore Genome Sequencing.

ADVERTISEMENT

HARVARD MEDICAL SCHOOL Postgraduate Medical Education

Effective Writing for Health Care

June 2022

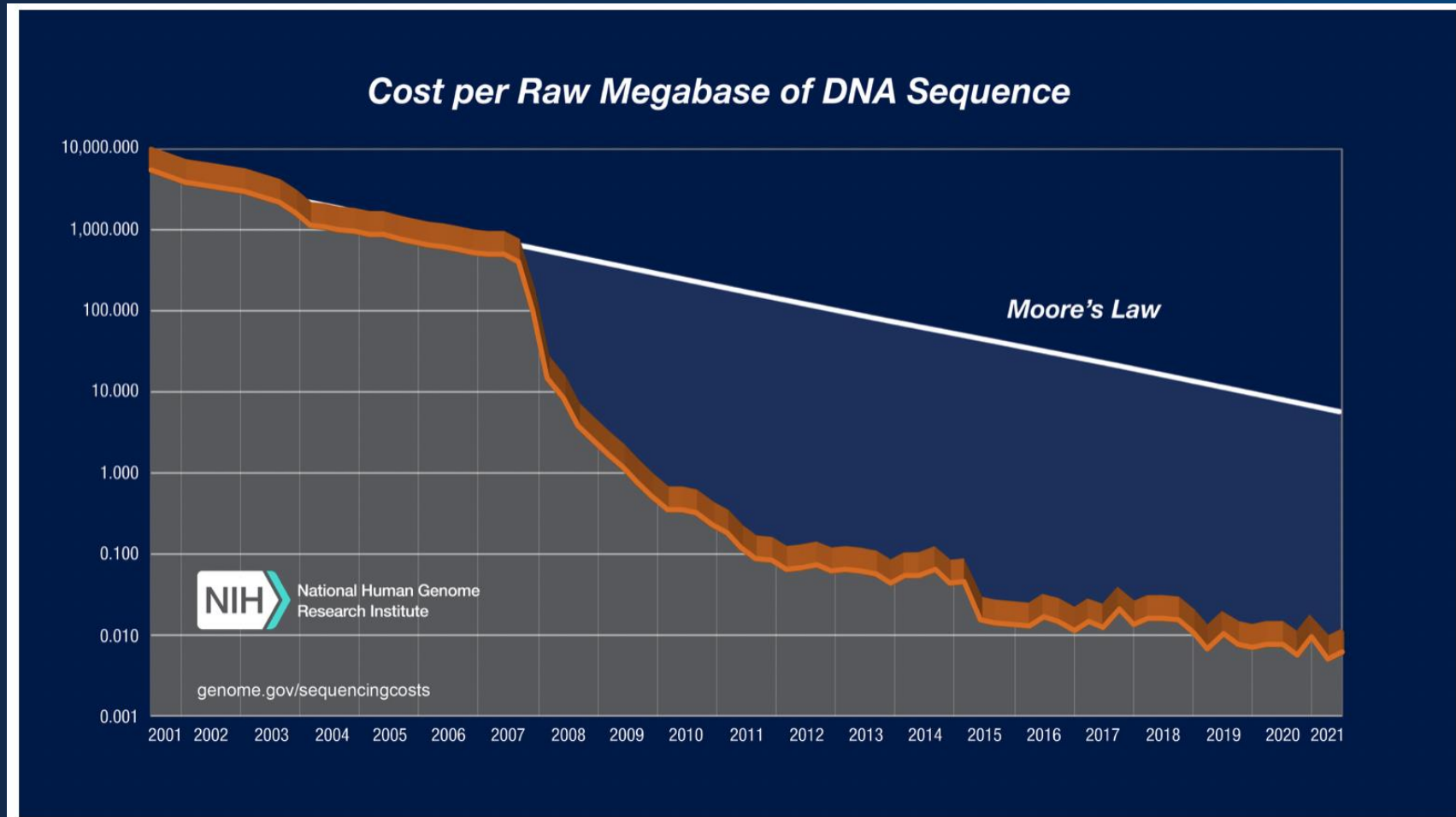
LEARN MORE

NEJM CareerCenter

PHYSICIAN JOBS MARCH 2, 2022

Neurology Staff Neurologist Cambridge, Massachusetts

# The Rise of Next-Generation DNA Sequencing



# The Rise of Next-Generation DNA Sequencing



BUSINESS

## Fruity with a hint of double helix: A startup claims to tailor wine to your DNA



By [Rebecca Robbins](#) Oct. 27, 2016

[Reprints](#)





# Can Commoditized Information Be a Trade Secret?



## Scholarship

- Almost exclusively uses Myriad Genetics as a case study
  - Sequencing dynamic has changed since 1994!
  - Paired with other *functional* information, e.g., clinical outcomes
- Little engagement with trade secret elements
- Little engagement with rise of NGS
- Some excellent counter-examples: Burk, Joly, Knoppers, Glitter

# Can Commoditized Information Be a Trade Secret?



## Cases

- Very few: 30 unique lawsuits, total
- Some explicitly *reject* DNA sequences as trade secret subject matter
  - SinoMab Bioscience Ltd. v. Immunomedics, Inc. (2009)
  - Brigham Young University v. Pfizer, Inc. (2012)
- None address the ease of sequencing issue
- Some are idiosyncratic to agriculture/animal breeding industry

# Can Commoditized Information Be a Trade Secret?



Cases that *reject* DNA sequences as trade secret subject matter

- Brigham Young University v. Pfizer, Inc. (2012), No. 2:06-CV-890, 2012 WL 1029289 (D. Utah Mar. 26, 2012)
  - Summary Judgment: whether sequence of mouse COX genes were “readily ascertainable”
  - *Yes*; *known* sequences that are “functionally identical” to disclosed sequence renders them “readily ascertainable” and therefore not protectable

# Can Commoditized Information Be a Trade Secret?



## Cases that *reject* DNA sequences as trade secret subject matter

- SinoMab Bioscience Ltd. v. Immunomedics, Inc., No. 2471-VCS, 2009 WL 1707891 (Del. Ch. June 16, 2009)
  - JMOL: whether certain antibody sequences disclosed to former employee were trade secrets
  - “With respect to the DNA sequence that Immunomedics claims that Leung took, I find that this sequence is not the type of protectable information that New Jersey protects as a trade secret. It was a slight variation on publicly known information which Leung created in a few hours using publicly known methods. And, there is no record evidence that this sequence was particularly valuable to either Leung or Immunomedics or that the Sequence gave Leung some unfair advantage vis-a-vis his former employer.”

# Can Commoditized Information Be a Trade Secret?



Cases that *uphold* DNA sequences as trade secret subject matter *but* are idiosyncratic to animal breeding

- North American Deer Registry, Inc. v. DNA Solutions, Inc., No. 4:17-CV-00062, 2017 WL 2402579 (E.D. Tex. June 2, 2017)
  - Motion for preliminary injunction on genetic “map” of breeding deer lineages
  - *Granted*—but (1) only entirety of database was trade secret, not just genomic sequences of deer; (2) “economic value of the Registry flows from the deer lineages”—not from genomic information

# Can Commoditized Information Be a Trade Secret?



Cases that *uphold* DNA sequences as trade secret subject matter *but* are idiosyncratic to animal breeding

- TB Food USA, LLC v. Am. Mariculture, Inc., No. 2:17-cv-9-FtM-29NPM, 2022 WL 3028061 (M.D. Fla. Aug. 1, 2022).
  - Acknowledgment that “no court in the United States has ever found that the genetics of bred animals constitute a trade secret under the DTSA or the FUTSA”
  - Upholding jury determination that shrimp DNA database was trade secret (“sufficient evidence” standard)
  - *Reversed* by 11th Circuit on other grounds

# Can Commoditized Information Be a Trade Secret?



## Statute (DTSA/UTSA)

- Subject to reasonable efforts to maintain secrecy;
- Not readily ascertainable
  - Cost, technical ease, financial “efficiency”
- Derives “independent economic value” from being secret
  - Must be more than a trivial amount
  - Is it worth *more* as a secret than not?

# Can Commoditized Information Be a Trade Secret?



## Next-Generation Sequencing

- Subject to reasonable efforts to maintain secrecy?
  - Likely; specific to plaintiff, not technology or information
- Not readily ascertainable
  - Sometimes not! Cost, technical ease, financial “efficiency” of sequencing from *known* genomic sources *low*
- Derives “independent economic value” from being secret
  - Doubtful; only valuable as secret when combined with *other* information, see, e.g., *N. Am. Deer Registry, Inc. v. DNA Solutions, Inc.*



## *Hang on a second*



- This cuts against *decades* of scholarship and common understanding!
- Cheap and easy doesn't necessarily mean "readily ascertainable"
- Isn't it protectable when it's combined with other data?
- Other areas of trade secrecy law have a paucity of cases

# Hang on a second



This cuts against *decades* of scholarship and common understanding!

- Guilty. But no one's done the analysis, no one's really grappled with where genomics are now situated

Cheap and easy doesn't necessarily mean "readily ascertainable"

- Perhaps not—but the standard says otherwise: not "difficult, costly, or time-consuming"

Isn't it protectable when it's combined with other data?

- Yes! But that's the point! It's not protectable alone; really only good as an identifier

Other areas of trade secrecy law have a paucity of cases

- Maybe they're wrong too!
- Other areas *do* have robust cases, e.g., economic models, customer lists, real technological innovations

# Practical Implications



## No misappropriation claims!

- Likely shift from federal to state causes of action (e.g., breach of contract)
- State level variability on non-TS confidentiality enforcement
  - E.g., California vs. New York
- Relative decrease in damages
- Restrictions on injunctions

# Theoretical Implications



## New basis for trade secret termination

- Termination due to changed technological conditions

## Technological blurring of trade secret defenses

- Line drawing among ready accessibility, reverse engineering, independent derivation

## Evidence for a comedy of the commons

- Very, very few holdouts
- Production is high—hard to imagine it being *higher*

# Litigating DNA Trade Secrecy Cases



As Defendant (accused misappropriator):

- Raise lack of subject matter! E.g., *TB Food USA, LLC v. Am. Mariculture, Inc.*
- Show sequence information was “readily accessible”
  - Underlying genomic source known e.g., large patient population, biobank, and could be accessed or collected with minimal effort
  - Conduct sequencing (~\$ thousands) or obtain quote from DNA services laboratory
- Demonstrate sequence had no “independent economic value”
  - Show absence of licensing or absence of licensing for related fields
  - Show value from sharing (as opposed to secrecy) by showing derivative uses from information
  - Show disconnect between value of product and value of non-secret product

# Litigating DNA Trade Secrecy Cases



As Plaintiff (trade secret holder):

- Must show “subject to reasonable efforts to maintain its secrecy”
- Show sequence information was *not* “readily accessible”
  - Underlying genomic source was not available or could only be constructed with some effort, e.g., choices about which samples to use not apparent
  - *Type* of sequencing was costly, e.g., single-cell RNA sequencing on certain tissue type vs. genomic DNA
- Prove “independent economic value”
  - Licensing! (if you’ve got it)
  - Market demand for test or product beyond services lab
  - Absence of substitutes in related area

# A Word of Caution...



- Still, decades later, a “novel” area, precedent runs in multiple different directions
- “Devil’s in the details” on lack of subject matter claims
  - Fact intensive
  - Science intensive
  - Possibly costly to litigate (e.g., need for experts, SJ briefing)
    - Perhaps only makes sense where liability is high and facts are “bad”



?

**I** ILLINOIS