



Keeping Secrets While Promoting Innovation: Litigating Trade Secrets Disputes in the Life Sciences Industry

Association of Corporate Counsel
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Introduction



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Agenda



Trade Secret Basics



Case study: *Genentech v. JHL*



Case study: *Medidata v. Veeva*



Questions?

What is a Trade Secret?



Statutorily Defined

Each statute is a little different, but generally, a trade secret is information that:

- (1) Derives *independent economic value* from not being generally known,
- (2) [cannot be *readily ascertained* by proper means], and
- (3) is the subject of *reasonable efforts to maintain its secrecy*.

“Trade secrets are a peculiar kind of property. Their only value consists in their being kept private.”

-- *DVD Copy Control Ass'n v. Bunner*,
31 Cal. 4th 864, 880 (2003) (citations omitted).

What is a Trade Secret?

Very Broad Definition

A wide variety of information in the life sciences sphere has been found to be a trade secret, including:

- **Testing protocols, procedures, and test results**
- **Manufacturing methods and techniques**
- **Formulas and specifications**
- **Product road maps**
- **Pricing information and sales data**
- **Negative know-how**

What is a Trade Secret?

Negative Know-How in Practice: *Genentech v. JHL et al* (ND Cal) – February 2019 hearing

JHL attorney: [Plaintiffs] have the burden of putting in evidence that whatever they've identified as a specific trade secret qualifies as a trade secret, and that JHL is using it...

Judge Alsup: No, see, that's an incorrect test. "Is using it" is not the standard. It could be that it's like negative knowhow ... They could use negative knowhow in order to save time in order to come up with -- or they could look at what Genentech did, and said: Okay, they had a pretty good procedure, but we're going improve on it, we're going to start with what they did and we're going to improve on it. So at the end of the day they're not using it. They're using an improved version. But still, they used it to get there. Listen. People go to prison for that.

JHL attorney: And that may qualify as misappropriation. But that doesn't give them a basis for an injunction. To get an injunction –

Judge Alsup: Yes, it does. Where do you get that idea? ... Because you steal their stuff and then you get a head start, and now you're saying: Well, we're doing something even better, we don't need -- well, yeah, but you wouldn't even be there if you hadn't taken their stuff and gone to school on it.

What is a Trade Secret?

A Trade Secret May Be a Compilation of Otherwise Public Information

“[W]hile the SOPs may include some public information, there is no evidence that [they] are simply wholesale copies of public information. There is also evidence suggesting that AllCells invested at least some time and research in deriving specific steps, formulations, etc. in producing the SOPs. This is not to say that Defendants will not have meritorious arguments on some or all of the SOPs—if, e.g., they merely reflect information already known in the industry or were simply small ‘tweaks’ of publicly available SOPs and were thus effectively generally known. But at this juncture in the proceedings, AllCells has met at least the lesser standard of serious questions going to the merits.”

AllCells, LLC v. Zhai, No. 16-CV-07323-EMC, 2017 WL 1173940, at *3 (N.D. Cal. Mar. 29, 2017).

Elements of Trade Secret Misappropriation

Plaintiff must prove that:

- (1) the plaintiff owned a trade secret,
- (2) the defendant acquired, disclosed, or used the plaintiff's trade secret through improper means, and
- (3) the defendant's actions damaged the plaintiff.

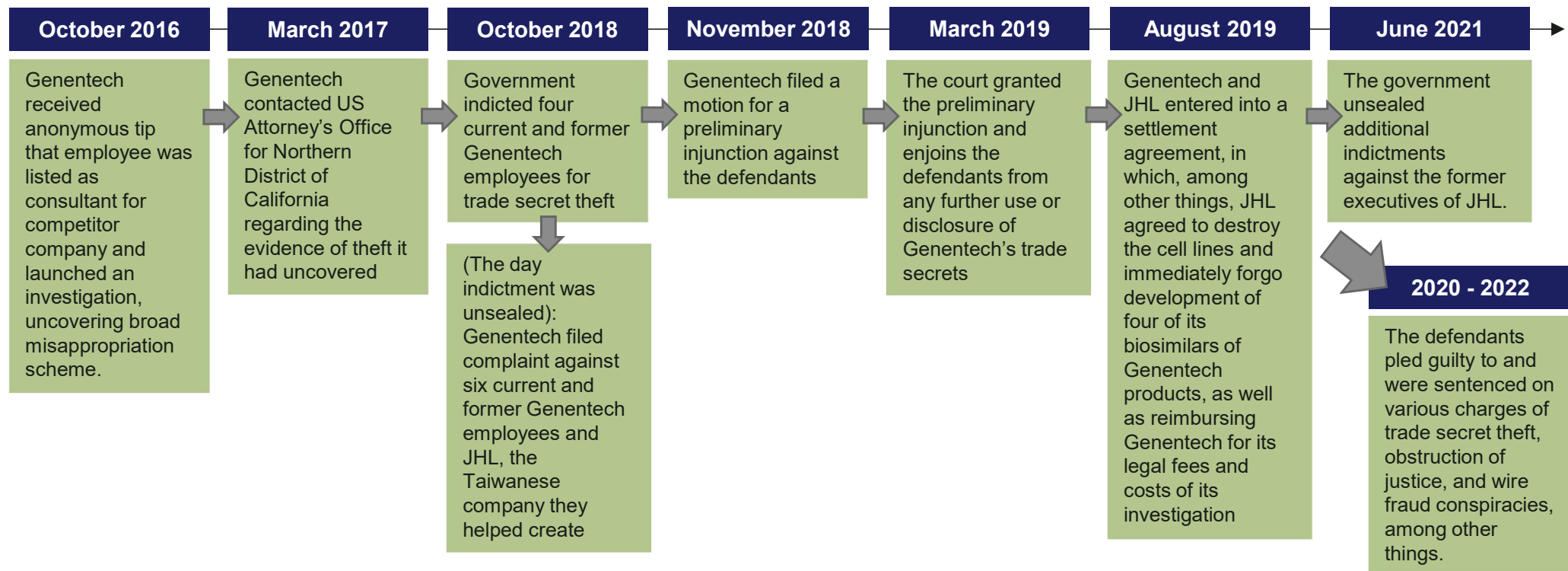
Sargent Fletcher, Inc. v. Able Corp., 110 Cal. App. 4th 1658, 1665 (2003).



Genentech v. JHL

Genentech v. JHL

Overview: Investigation & Litigation Timeline



Genentech v. JHL

The Trade Secrets At Issue

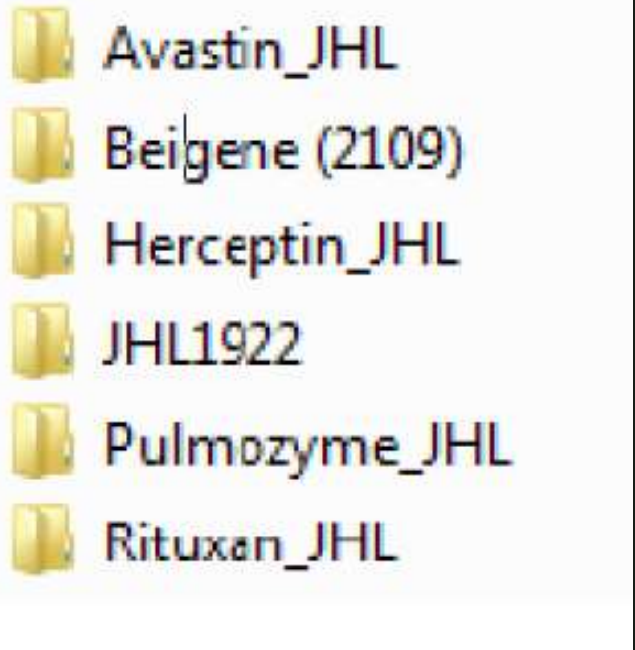
- Analytical methods to test and ensure the stability, potency, purity, and identity of four Genentech biologics (Rituxan, Avastin, Herceptin, and Pulmozyme)
- Manufacturing processes and analytical methods to test and ensure the quality of its biologics; and
- Information regarding development and selection of a formulation for the biologic



Genentech v. JHL

The Misappropriation Scheme

Employees downloaded massive troves of documents from Genentech's repository of technical documents.



- Avastin_JHL
- Beigene (2109)
- Herceptin_JHL
- JHL1922
- Pulmozyme_JHL
- Rituxan_JHL

Genentech v. JHL: The Misappropriation Scheme

From: <alam@jhlbiotech.com>

Date: 1/7/2014 3:55 PM

To: Racho Jordanov <rjordanov@jhlbiotech.com>

CC: Rose Lin <rlin@jhlbiotech.com>, Debbie Lou <dlou@jhlbiotech.com>, David Kapitula <dkapitula@jhlbiotech.com>, Wan-Ting Hsieh <wthsieh@jhlbiotech.com>, ML <mlsheung2@gmail.com>

Racho,

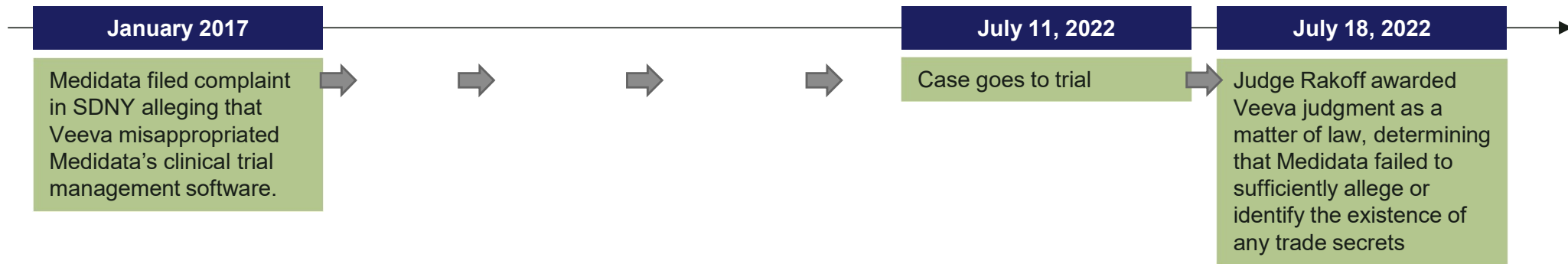
Attached is the methyl green activity assay used by the innovator. The assay is rather lengthy, but is doable. At least the assay is familiar to the FDA/EMEA, and acceptable to them.



*Medidata Solutions Inc v. Veeva
Systems Inc.*

Medidata v. Veeva

Overview: Litigation Timeline



Protecting Your Trade Secrets

Taking “reasonable efforts”

- Confidentiality Agreements
- Company Policies and Training
- IT/Digital Security
- Physical Barriers
- Labeling
- Exiting Departing Employees Properly



Taking “reasonable efforts”

Consider ramifications of disclosures to:

- Regulatory agencies (at home and abroad)
- Manufacturing partners
- Broader scientific community (patents, presentations, or publications)



Genentech v. JHL

“Reasonable efforts” in practice

Third party confidentiality agreements

3 Further, he who seeks equity must do equity. That is, Genentech must also account for
4 those sixty-six Genentech documents referenced in (and appended to) its Statement Regarding
5 Trade Secrets. Within **THIRTY-FIVE (35) CALENDAR DAYS** of the date of Genentech’s posting
6 of bond, Genentech must provide a log to JHL’s counsel (or the Court) explaining the extent to
7 which the aforementioned documents have been disclosed by Genentech — including (1) all
8 persons and/or entities (*e.g.*, vendors, regulatory agencies, hospitals) to whom Genentech has
9 disclosed any of the aforementioned documents and whether those persons and/or entities were
10 subject to a non-disclosure agreement, and (2) all articles, presentations, patents, emails, or any
11 other similar publication by Genentech that disclosed to a third party any of the aforementioned
12 documents or any significant portion contained therein.

Genentech v. JHL

“Reasonable efforts” in practice

Employee confidentiality agreements

1	A. Genentech’s Proprietary Agreement
2	29. When Ms. Lam was hired in 1986, Genentech required her to sign, as a condition
3	of employment, an “Employee’s Proprietary Information and Inventions Agreement”
4	(“Proprietary Agreement”). Ms. Lam signed that agreement on August 19, 1986. Attached
5	hereto as Exhibit 20 is a true and correct copy of the “Employee’s Proprietary Information and
6	Inventions Agreement,” signed by Ms. Lam. By signing the Proprietary Agreement, Ms. Lam
7	confirmed that, in consideration of her employment and the compensation received, she would
8	“keep in confidence and trust all Proprietary Information.”

Genentech v. JHL

“Reasonable efforts” in practice

Ongoing employee training and certification

11	41. Under both the GGOP and the Code of Conduct, every Genentech employee is
12	required to take training and certify compliance with the company’s policy including those
13	regarding protection of Genentech’s confidential information. Under the GGOP, managers were
14	directed to “make sure...employees fully understand and adhere to our GGOP.” And under the
15	Code of Conduct, managers are directed to ensure that “all employees reporting to them receive
16	the help and advice they need to comply with the Code of Conduct.”
17	42. Ms. Lam was trained on the GGOP in 2008 and certified compliance with the
18	GGOP in 2011. Ms. Lam took Genentech’s Code of Conduct training on April 8, 2011, and
19	certified compliance with the Code of Conduct on multiple occasions, including on July 5, 2017;
20	July 2, 2016; July 10, 2015; May 6, 2014; and May 13, 2013. ²
21	43. The annual training certification requires Genentech employees to certify that they
22	have not violated the Code of Conduct, and specifically asks whether employees are aware of
23	“any conduct either by yourself or others that has occurred that you believe may violate any
24	federal, state, or local law, regulation, rule, or other requirement, or any Company policy,
25	procedure, or directive.”

Trade Secret Defense

Onboarding Practices

- Agreements
- Onboarding interviews focusing on third-party information
- Enhanced practices for employees formerly at a competitor
- Identify areas of prior work
- USB drive/cloud access – forbid copying over systems
- Walling off?

Trade Secret Defense

Protecting Third Party Information

- Have clear, written policy on handling third party information
- Know who has access to third party proprietary information
- Limit access to those with true need to know
- Prevent spill-over into competitive areas
- Regular trainings and certifications
- Prevent/limit use of personal/cloud devices for third party information
- Documented “clean rooms” for developing new products

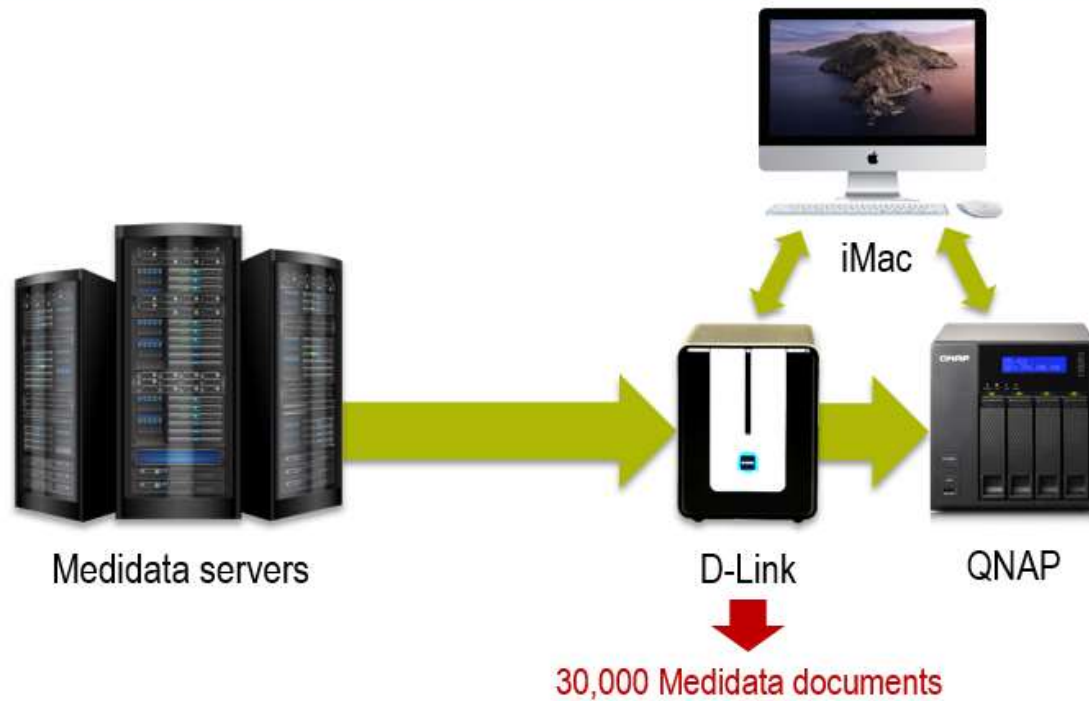
Trade Secret Defense

Whole Company Effort

- Business executives should attend and support proprietary info training sessions
- Encourage legal department involvement
- Make part of company culture
- Encourage employees to flag issues
- Anonymous reporting / tip line

Medidata v. Veeva

A cautionary tale



Protecting Your Trade Secrets

Confirming Suspicions: The Investigation

- Physical access
- Electronic access
- Flashdrive use
- Wiping software
- Preservation
- Interviews



Genentech v. JHL

Protecting Your Trade Secrets: The Investigation

Steps taken AFTER suspected misappropriation

4 18. HCO's investigation also revealed that, on three occasions in the summer of 2017,
5 Ms. Lam's log-in credentials were used to connect her Genentech-issued laptop to Genentech's
6 Virtual Private Network (VPN), which provides remote access to Genentech's secure network
7 and that hundreds of Genentech documents containing Genentech's confidential manufacturing
8 policies and protocols were accessed and downloaded during those three VPN sessions on July 9,
9 July 16, and July 26, 2017. Genentech was subsequently able to identify the documents that were
10 downloaded during those VPN sessions by reviewing the "Downloads" folder in a back-up of Ms.
11 Lam's laptop. HCO's review of the "Downloads" folder also uncovered additional downloads of
12 manufacturing policies and protocols on August 13, 2017. The list of documents that were
13 downloaded during the VPN sessions in July and those downloaded on August 13, 2017 are listed
14 in Appendix 5 attached to Genentech, Inc.'s Statement Regarding Trade Secrets, filed
15 concurrently with this declaration.

Genentech v. JHL

Protecting Your Trade Secrets: The Investigation

Reasonableness of steps taken depends on the circumstances!

2 JHL next contends that Genentech failed to take reasonable measures to protect the
3 information's secrecy. It does not dispute that Genentech's policy of limiting access to the
4 information, entering into confidentiality agreements with its employees, prohibiting
5 unauthorized disclosure or use of confidential information during employment, and storing
6 information in password-protected repositories constitutes sufficiently reasonable efforts to
7 maintain secrecy (*see* Kirshman Decl. ¶¶ 26–60). Rather, it argues Genentech lacked
8 reasonable efforts by allowing Xanthe to continue on as normal for eleven months after learning
9 of her consulting work for competitors. Genentech, for example, did not take any action to curb
10 her access to proprietary information, such as using commercially available monitoring
11 software that identify and block email with certain attachments or to certain addresses (Dkt. No.
12 77 at 16; Racich Decl. ¶¶ 11, 14). This order disagrees. Genentech immediately launched an
13 investigation into Xanthe's conduct but avoided taking any action that might have alerted
14 Xanthe to the FBI investigation because of the government's request. Once the FBI searched
15 her house, Genentech took immediate action and fired Xanthe soon after (Kirshman Decl. ¶¶ 4,
16 19). Under these circumstances, this order finds that Genentech's efforts were reasonable.

Identifying Your Trade Secrets

Trade Secret Identification

- CCP § 2019.210: pre-discovery identification of trade secrets with “reasonable particularity” – no discovery at all before this is done.
- A plaintiff must identify with particularity to get discovery or to obtain a preliminary injunction.
- A plaintiff need not identify trade secrets with particularity in its complaint, or to survive a demurrer.
- Non-California courts may apply § 2019.210-type disclosure as a case management tool. *Savor, Inc. v. FNR Corp.*, 2002 WL 393056 (Del Super. Ct. 2002).
- Frequent litigation around whether the identification is sufficient.

Medidata v. Veeva

July 15, 2022

Medidata lost at trial because it failed to sufficiently identify its trade secrets

10 Indeed, I think a more general problem with
11 plaintiffs' case is they seem to think that just about anything
12 in the world can be a trade secret. And that, of course, would
13 mean that you could never hire away an employee from another
14 company because anything they said, one word out of their
15 mouth, would indirectly reveal something they had learned at
16 their prior employment, couldn't really be helped; and so it
17 would be impossible for a company to hire away an employee
18 because it wanted to develop some new competitive aspect to its
19 business. And both the statutes here involved and also
20 legislative history make clear that that was not the intent of
21 the legislators and presumably would have been a gross
22 antitrust violation if it had been the intent of the
23 legislators.

Medidata v. Veeva

Examples of Medidata's descriptions of its trade secrets:

- Medidata's "confidential plans to improve and further develop its [electronic data capture] product in the future," which "were based on and reveal (1) Medidata's confidential and proprietary knowledge and analysis of the needs and desires of its large customer base, (2) its business strategies around prioritization of those needs and desires, and (3) its industry and technical know-how."
- "[H]ow Medidata implements its designs and integration concepts to deliver software to its customers," which includes "Medidata's confidential documentation regarding the process of writing software code, the proprietary software code and configurations themselves, and information gained through the trial-and-error process inherent in creating complex software products."

Medidata v. Veeva

Judge Rakoff determined that these descriptions were too vague:

“[W]hat I got was basically a rehash of the generalized terms and, similarly, nothing further in the way of specification was presented to the jury ... So as to the great bulk of the alleged trade secrets, they were never presented to the jury with anything like the specificity that would allow a jury to determine whether the specific trade secrets had been misappropriated or not. By the way, many of them ... may well not have been trade secrets at all, but I don't need to reach that because there was, in the Court's view, a clear lack of specificity.”

Taking Action

So, you've protected your trade secrets, you've investigated suspected misappropriation, and you've identified the specific trade secrets at issue.



Trade Secret Statutes

Several laws barring trade secret theft:

- (1) CUTSA (California Uniform Trade Secret Act)
- (2) UTSA (Uniform Trade Secret Act – may vary by state)
- (3) DTSA (Defend Trade Secrets Act – federal law)
- (4) 18 U.S.C. § 1832 (Economic Espionage Act - criminal theft of trade secrets)
- (5) 18 U.S.C § 1030 – CFAA (Computer Fraud and Abuse Act)
- (6) CDAFA (California Computer Data Access and Fraud Act)

Trade Secret Litigation

Referring matters to law enforcement

- Benefits
 - Powerful investigative tools
 - Important deterrent effect
- Disadvantages
 - Government timelines may be slower
 - Requires additional disclosure of trade secrets
 - Government investigation may require a lot of employee time

Genentech v. JHL

Referring matters to law enforcement – in practice

- Criminal case timeline
- Effects of criminal investigation on civil lawsuit
- Evidence uncovered by the FBI

Trade Secret Litigation

Civil Remedies

- Injunctive Relief
- Monetary Damages
 - Actual loss
 - Unjust enrichment
 - Reasonable royalty
 - Exemplary (2x damages)
- Key Question: How to value the misappropriated trade secret?
 - Lost profits?
 - Head-start?

Injunctive Relief: TROs and PIs

Injunctions are often litigated early

- Evidentiary Hearing (documents, declarations, testimony, experts)
- Likelihood of Success on the Merits
 - Are actual trade secrets at issue?
 - Was there misappropriation and damage?
- Irreparable Harm
 - Not speculative, but actual and imminent
 - Did plaintiff delay in seeking an injunction?
- Balance the equities

Genentech v. JHL

Importance of preliminary injunction

- Successfully enjoined JHL from further use or disclosure of Genentech trade secrets, and from selling, marketing, or commercializing any drugs that were developed, in whole or in part, with the benefit or use of Genentech's trade secrets.
- Ordered JHL to turn over ALL Genentech documents, whether or not qualifying as trade secret.
- Within five months of the preliminary injunction being issued, the parties entered into a settlement agreement.



Questions?

KEKER
VAN NEST
& PETERS

Thank you!
