Seyfarth

Protecting Trade Secrets in the Pharmaceutical Industry in the Age of COVID-19

Julie McCarthy, General Counsel and Vice-President of Legal Genomics Institute of the Novartis Research Foundation

Dean Fanelli, Partner, Seyfarth Shaw LLP

Dawn Mertineit, Partner, Seyfarth Shaw LLP

Katherine Perrelli, Partner, Seyfarth Shaw LLP

Seyfarth Shaw LLP

Seyfarth

Legal Disclaimer

This presentation has been prepared by Seyfarth Shaw LLP for informational purposes only. The material discussed during this webinar should not be construed as legal advice or a legal opinion on any specific facts or circumstances. The content is intended for general information purposes only, and you are urged to consult a lawyer concerning your own situation and any specific legal questions you may have.

Speakers

Julie McCarthy
General Counsel and Vice-President of Legal Genomics Institute of the Novartis Research Foundation

Dean Fanelli
Seyfarth Partner
Washington, DC

Dawn Mertineit
Seyfarth Partner
Boston, MA

Katherine Perrelli
Seyfarth Partner
Boston, MA

Agenda

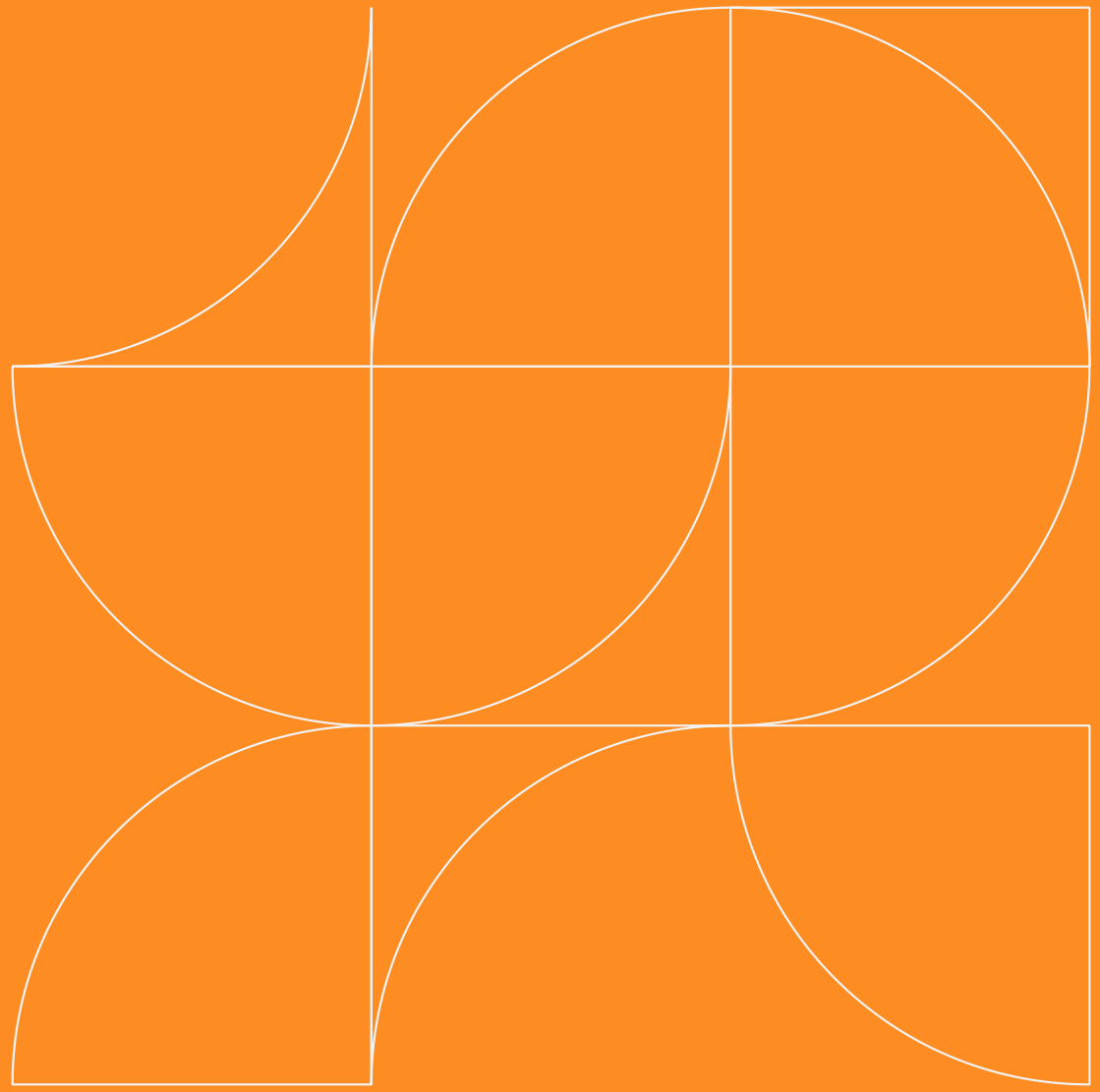
01 Why are We Here? COVID-19 and Pharma in the News

02 Overview of Trade Secrets in the Pharma Industry

03 Increased Risks Due to COVID-19 – and How to Handle

04 Trade Secret Protection Protocols

Why are We Here? COVID-19 and Pharma in the News



Pharma in the News

How big pharma firms are quietly collaborating on new coronavirus antivirals

Behind the scenes, companies including Novartis, Takeda, and Gilead are collaborating in a loose alliance. Their work might not be done in time to stop COVID-19, but they hope it can prevent the next pandemic

by ***Lisa M. Jarvis***

MAY 1, 2020 | APPEARED IN **VOLUME 98, ISSUE 18**

Pharma giants including Novartis collaborate on COVID-19 therapies

Richard Staines

March 26, 2020

A consortium of life sciences companies including pharma giants such as Novartis and Johnson & Johnson, are to collaborate to develop and manufacture vaccines, diagnostics and treatments for COVID-19 in a response to the coronavirus pandemic.

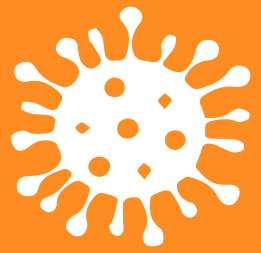
The Great Coronavirus Collaboration And The Future Of Drug Discovery

Standish Fleming Contributor ⓘ
Healthcare
I cover entrepreneurial finance and innovation in pharma.

The Great Covid R&D Collaboration - Cooperation accelerating drug development GETTY

Pharma battles coronavirus with a mega-collaboration; its own health requires competitive balance.

COVID-19 is Creating More Pronounced IP Risks



- Remote work environments
- Furloughs/Layoffs
- Increase in collaborative IP initiatives to further the COVID-19 relief effort
- Competitive threats
- Delay in enforcement

Trade Secret Issues Facing In-House Executives

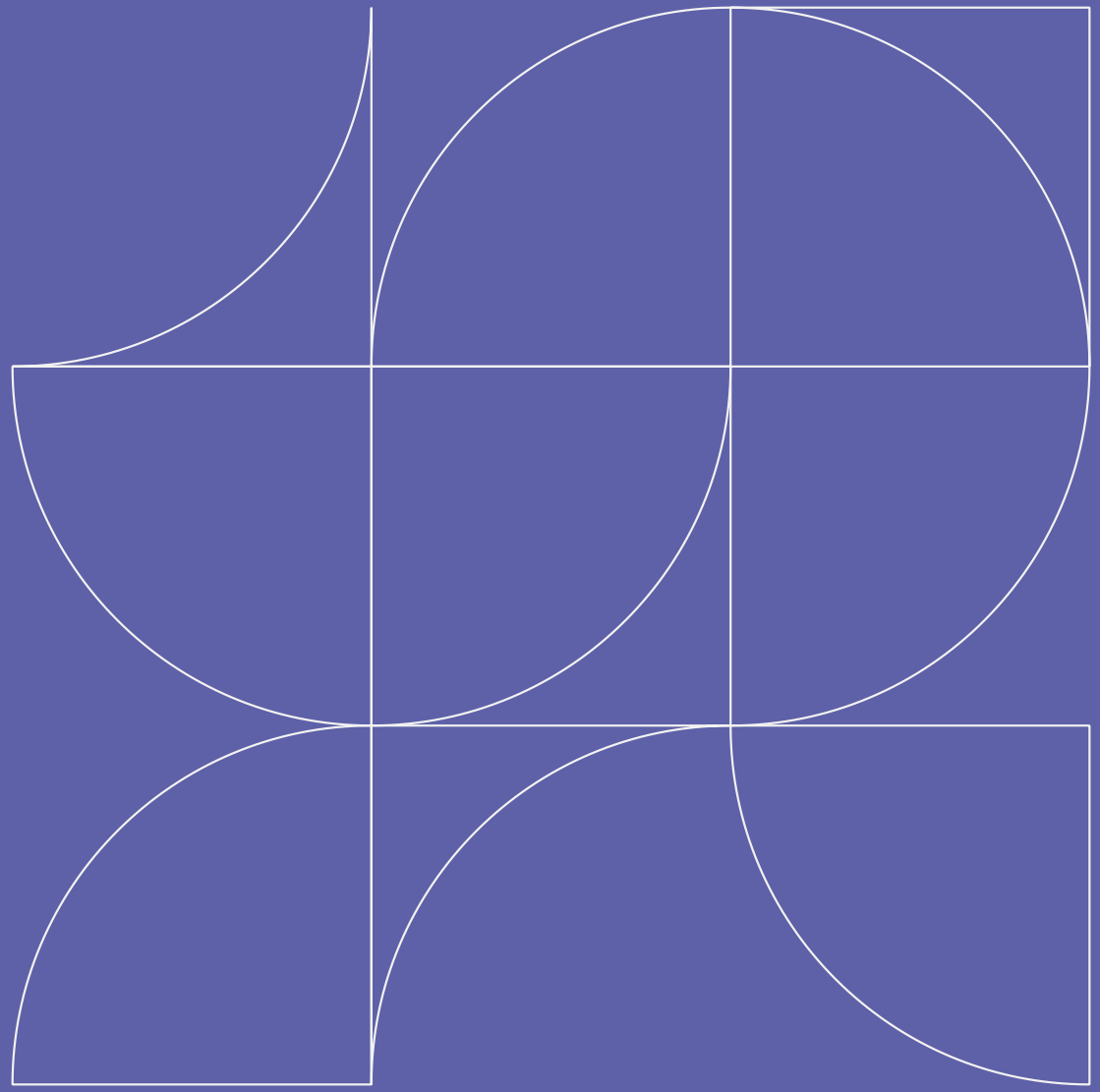
Even in a non-COVID-19 world, in-house executives face challenges with respect to trade secret protection and enforcement:

- Need to identify and catalogue trade secrets, much like other IP
- Insufficient security protocols and procedures
- Insufficient employee training
- Failure to limit trade secret access to “need to know” basis
- Failure to foresee and address new threats in a COVID-19 environment

In-House Perspective
– COVID-19 Impact on Protecting Trade Secrets

- More important than ever to rely on trade secret protections (in addition to patent protections)
- COVID-19 vaccine/treatment research and development has created an even faster paced environment – companies need to be able to invoke trade secret protections
- Increased need for documenting external collaborations
- Increased need for training

An Overview of Trade Secrets in the Pharma Industry



Overview: What is a trade secret?

- The Defend Trade Secrets Act of 2016 ("DTSA") defines trade secrets as:

  "all forms and types of financial, business, **scientific**, technical, economic, or engineering information, including patterns, plans, compilations, program devices, **formulas,** designs, prototypes, **methods, techniques, processes, procedures,** programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if—

  (A) the owner thereof has taken reasonable measures to keep such information secret; and

  (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information[.]"

- Most state trade secrets misappropriation statutes have a substantially identical definition.

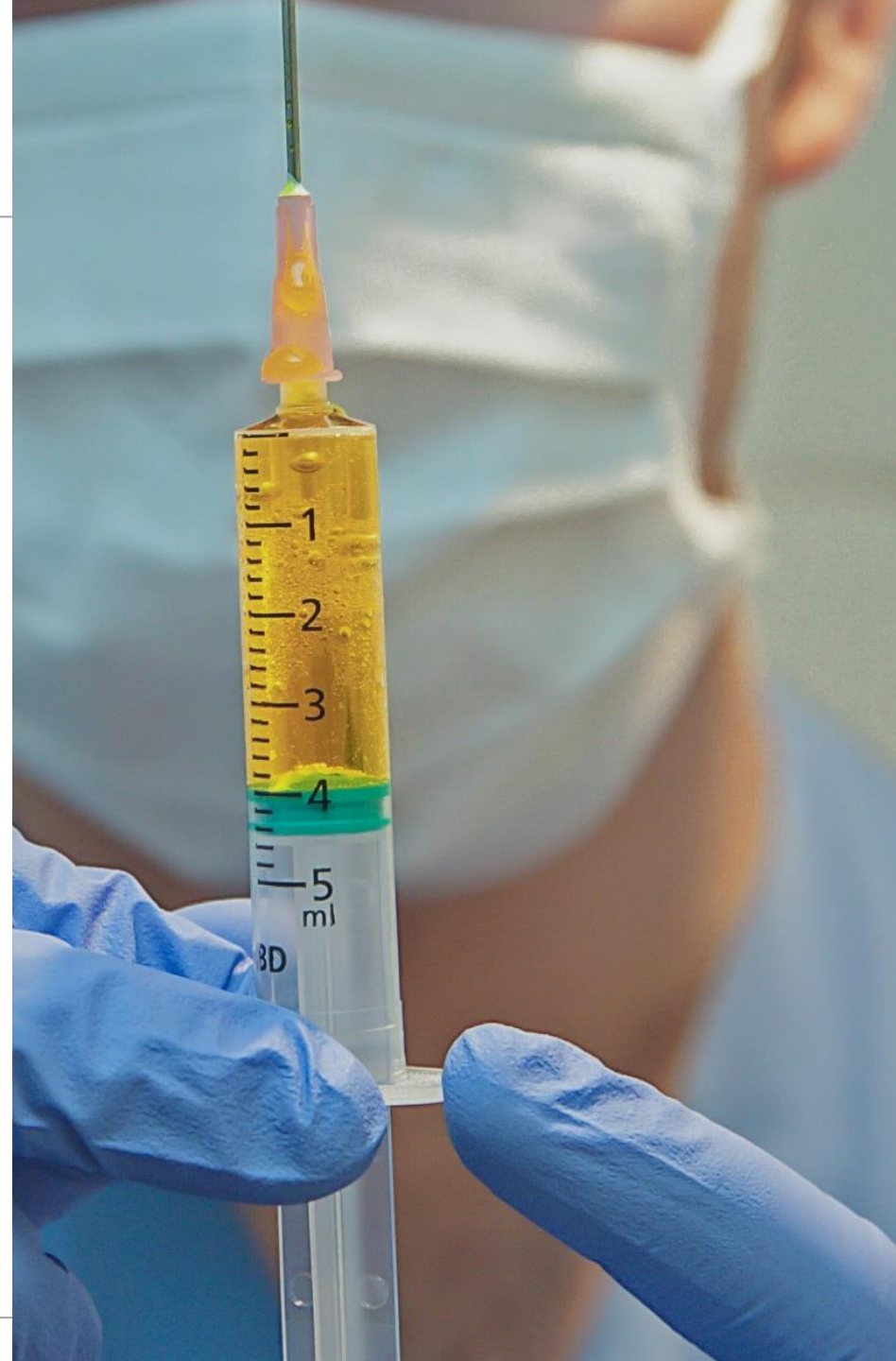
Examples of Information in the Pharmaceutical Industry That May be Trade Secrets

Research and Development

- Tangible products
- Processes
- Data on which candidates work/don't work, data that point in a certain direction
    - Theft could be:
        - to directly compete (race) to the drug
        - to indirectly compete via separate product
        - to apply for patent under "first to file" system

Strategic Business Plans

- Market analyses
- Identification of potential acquisitions
- Identification of new products and areas of future research
- Profitability information



©2017 Seyfarth Shaw LLP. All rights reserved. Private and Confidential

Examples of Information in the Pharmaceutical Industry That May Be Trade Secrets (cont'd)

Internal Opportunities and Trends

- Personnel information
- Identification of new opportunities
- Emerging markets

Post-Approval Commercial Information

- Sales data
- Customer lists;
- COGS

R&D Development Pathway

- "vision plan"
- screening
- lead candidate
- early mfg

- lead candidate
- optimization
- bench trial
- synthesis (organic or recombinant)
- formulation
- safety and efficacy (pharma/tox)
- clinical trials (sites, data)

- dossier
- FDA interactions
- REMS
- cGMP stds
- QA/QC controls
- ICH compliance

- sales data
- mktg plans
- customers
- feedback
- COGS
- supply chain
- forecasts

- new plans
- feedback
- ADE's
- new indications/combos
- Phase IV data

Trade Secrets in Biologics Development

Trade Secrets could be in:

- Protein sequence identity
- Cell lines used for production
- Media conditions for those cell lines
- Isolation protocols
- Storage and delivery conditions
- Type and location of post-translational protein modifications
- Structure-function studies
- Lot-to-lot variation studies

- All of the above represent critical information for companies eager to create biosimilar versions of existing biologics; troubleshooting without this info is an enormous barrier to market entry

- Trade Secrets (and 12-year market exclusivity) are thus particularly valuable as patent rights directed to the composition may have long since expired

Overview: What is misappropriation?

Under the DTSA, misappropriation is defined as:

(A) Acquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means; or

(B) Disclosure or use of a trade secret of another without express or implied consent by a person who—

(i) used improper means to acquire knowledge of the trade secret;

(ii) at the time of disclosure or use, knew or had reason to know that the knowledge of the trade secret was—

(I) derived from or through a person who had used improper means to acquire the trade secret;

(II) acquired under circumstances giving rise to a duty to maintain the secrecy of the trade secret or limit the use of the trade secret; or

(III) derived from or through a person who owed a duty to the person seeking relief to maintain the secrecy of the trade secret or limit the use of the trade secret; or

(iii) before a material change of the position of the person, knew or had reason to know that—

(I) the trade secret was a trade secret; and

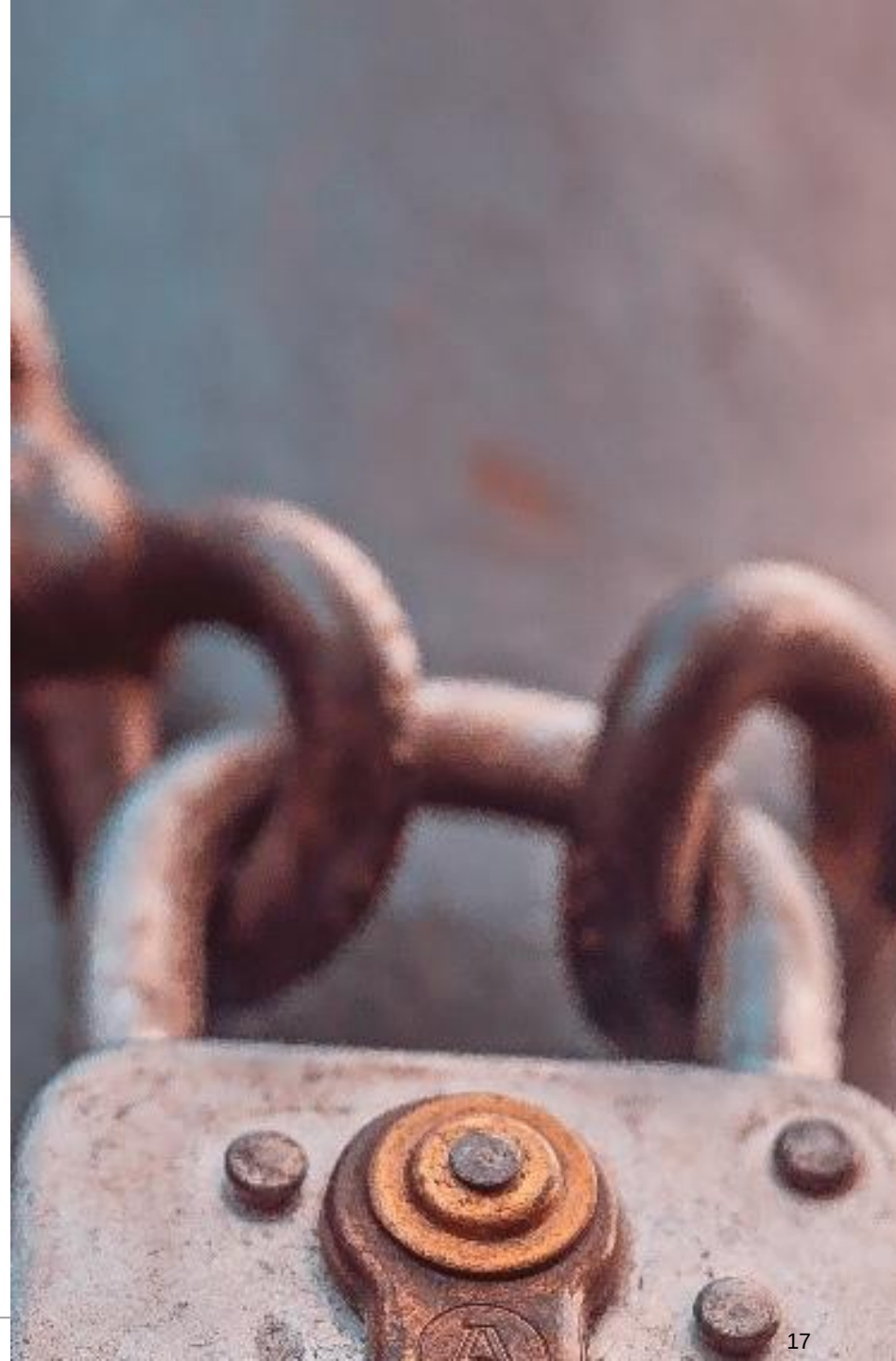
(II) knowledge of the trade secret had been acquired by accident or mistake[.]

Companies must make sure that they are keeping trade secrets a secret

Publicly available information is *not* a trade secret. *Ferring Pharm. Inc. v. Braintree Labs., Inc.*, 38 F. Supp.3d 169 (D. Mass. 2014).

Failure to take reasonable precautions to maintain secrecy defeats claim of trade secret misappropriation. *Hoffman-La Roche v. Yoder*, 950 F. Supp. 1348 (S.D. Oh. 1997).

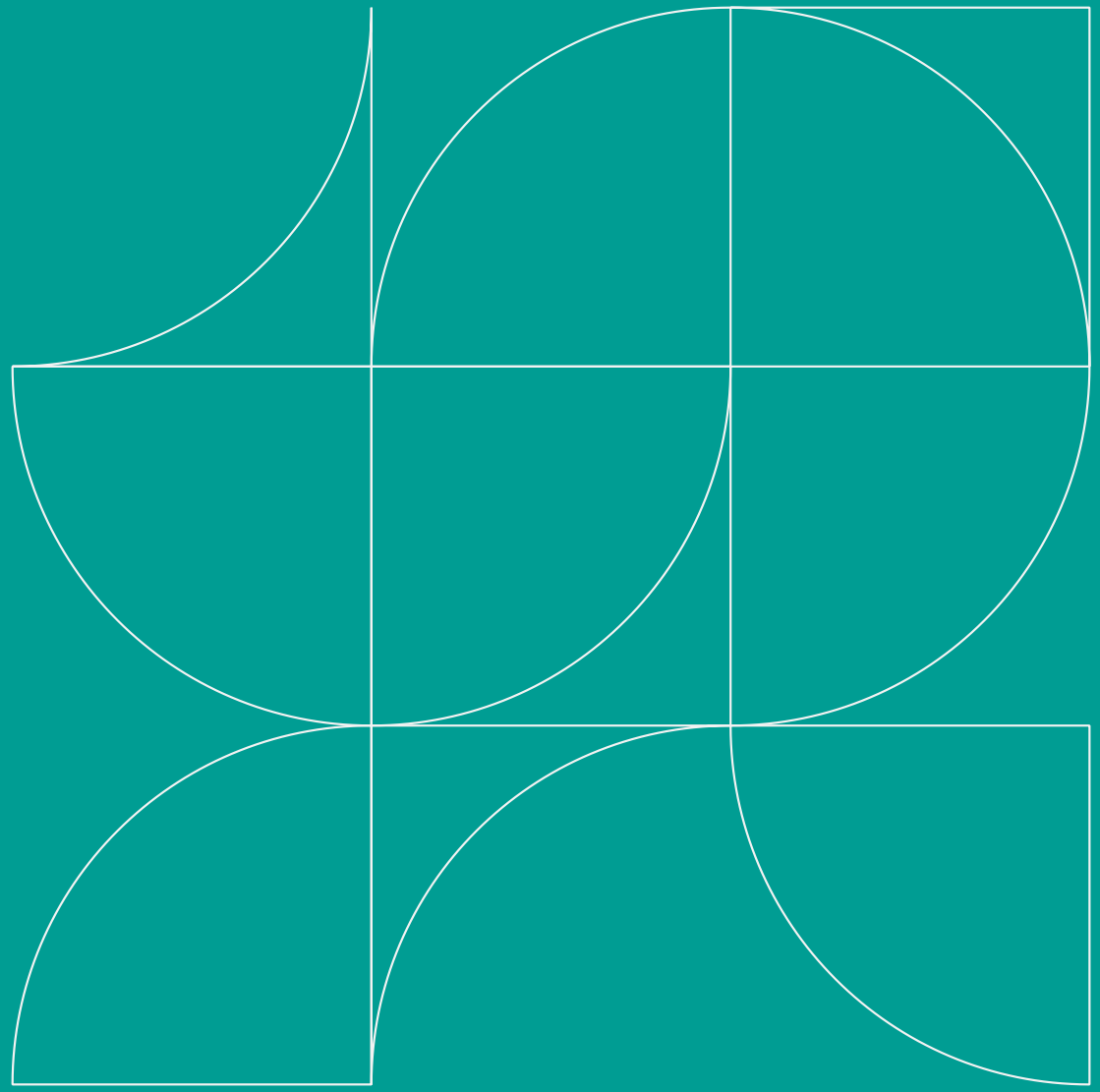
Even disclosure of trade secrets at trial, without appropriate limiting instructions, can defeat claim that information is a trade secret. *Glaxo Inc. v. Novopharm Ltd.*, 931 F. Supp. 1280 (E.D.N.C. 1996).



What level of security is required?

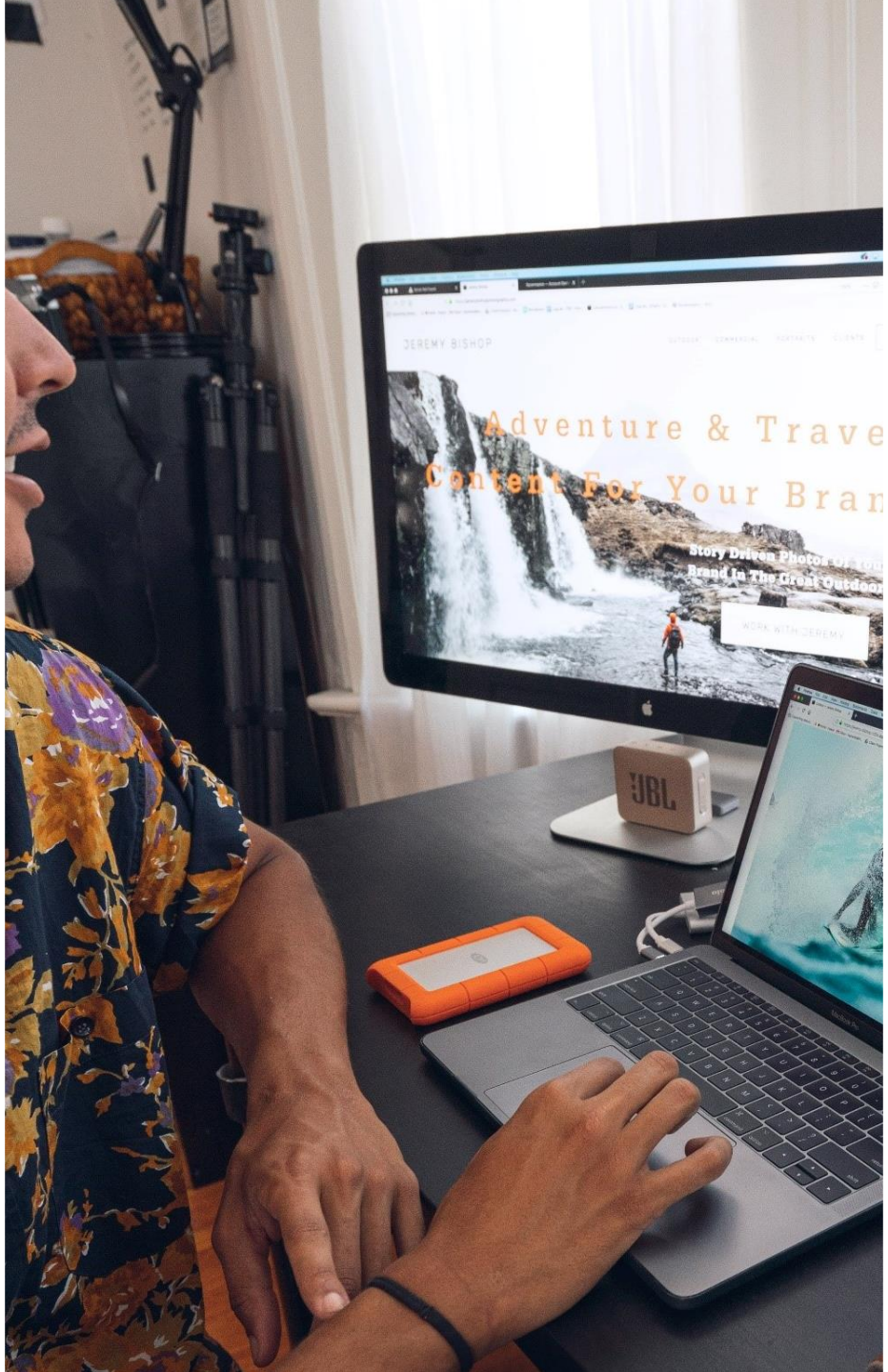
- Absolute secrecy and heroic measures are not required – only measures that are “reasonable under the circumstances”
- “Proportionality”
- However, if a trade secret is leaked and the company does not try to fix the leak and minimize damage, its value to the company may be severely compromised and lost forever.
- Courts will carefully scrutinize whether the company took appropriate steps to safeguard security

Increased Risks Due to COVID-19 – and How to Handle Them



Remote Work Environments: Challenges

- All but a handful of states have implemented stay-in-place orders, with a significant percentage of the work from home.
- Even with companies opening and employees returning to work, many companies are considering keeping and expanding their remote work force beyond the pandemic.
- Companies may be inclined to relax otherwise well thought out document management rules or allow for workarounds from the usual security measures in the interest of business continuity, and the extreme conditions of pandemic.
- Employees may make assumptions that they have wider latitude to email, copy, send, print, or download information.



Remote Work Environments: Challenges

- Compounding these insider risks are a series of unknowns, such as whether your employees' home networks have security anywhere near on par with in-office network security that could allow outsiders to intrude or access data.

- Various videoconferencing platforms being used to connect a remote workforce have security concerns:
  - "Zoombombing"
  - Inability to see who is present and/or listening in
  - Ability to surreptiously record

- In addition, personnel may use tablets and personal email accounts that may result in theft of data.

Remote Work Environment: Best Practices

For Ongoing Remote Work:

- Choose videoconference platforms wisely
- Remind employees of confidentiality obligations
- Ensure you have written policies for remote work protocols, including prohibition on sharing documents, and disseminate early and often
- Ask employees what devices they are using from home
- Only allow remote access through secure VPN with encryption
- Prohibit work from public places (coffee shops etc.) and on public Wi-Fi

Remote Work Environment: Best Practices

For Return to Work:

- Reminder to employees of their confidentiality obligations
- Require return of hard copy notes or other documents
- Instruct employees to identify and/or delete any copies of documents stored on personal devices
- Consider signed certifications regarding non-retention and non-dissemination of confidential information and trade secrets

Furloughs & Layoffs: Challenges

- Disgruntled employees may engage in nefarious conduct
- Even well-meaning individuals who are looking for new employment may think that sharing confidential information and trade secrets with a prospective employer will give them a leg up
- Non-competes against laid off employees may be unenforceable
- Potential delay in obtaining company-issued assets from departing employees, and delay in forensic analysis of such devices

Furloughs & Layoffs: Best Practices

- Remind employees of obligations, including signing a separation agreement reaffirming obligations
- Remind new employers of former employee's obligations
- Exit interviews (by videoconference, ideally)
- Collection of company devices and, where appropriate, forensic review

Increased and Rapid Fire Collaborative IP Initiatives

- Accelerating COVID-19 Therapeutic Interventions and Vaccine (ACTIV)
  - ACTIV brings NIH together with a variety of government agencies and representatives from academia, philanthropic organizations, and nearly 20 biopharmaceutical companies (including Novartis), for a coordinated research response to the COVID-19 pandemic.

- COVID-19 Technology Access Framework
  - University-initiated commitment to COVID-19 patenting and licensing strategies that are consistent with the goal of facilitating rapid global access.

- Open COVID Pledge
  - Pledge to make intellectual property available free of charge for use in ending the COVID-19 pandemic and minimizing the impact of the disease
  - Currently 25 organizations have taken the pledge, including Facebook, Amazon, Microsoft, and Sandia National Laboratories

Collaborative IP Initiatives: Challenges

- While pharma companies look to share their IP and collaborate on COVID-19 research, treatments, etc., they should be aware of the risk of disclosure of trade secrets

- In addition, risk of costly disputes if the parties' roles, responsibilities, and rights aren't well-defined in advance

- Consider chain of title issues that may arise with JDA's that create "Joint IP" and employment contracts that assign inventions.

Collaborative IP Initiatives: Best Practices

- Use of NDAs to prevent dissemination of confidential information and trade secrets beyond collaborators is critical

- Care must be taken to ensure that shared information is limited to *only* data that the company intends to disseminate (i.e. ensuring proper protocols to avoid sharing of non-COVID-19 research)

- Consider implications of Bayh-Dole Act with Public/Private Partnerships & 28 U.S.C. 1498

Competitive Threats: Challenges

- The Federal Bureau of Investigation (FBI) and the Cybersecurity and Infrastructure Security Agency (CISA) issued a Public Service Announcement warning organizations researching COVID-19 of likely targeting and network compromise by China
- CISA has announced that China's efforts to target these sectors pose a significant threat to the US's COVID-19 response
- Nefarious actors (whether garden-variety hackers or competitors) may likewise seek to gain access to trade secrets and confidential information

Competitive Threats: Best Practices

- Healthcare, pharmaceutical and research sectors working on COVID-19 response should all be aware they are the prime targets of this activity and take the necessary steps to protect their systems, including:
  - Assume press coverage may lead to increased threat by bad actors
  - Implement patches for internet vulnerabilities
  - Require multi-factor authentication
  - Scan web apps for unauthorized access and/or anomalous conduct
  - Work with your IT experts on additional measures

Delay in Enforcement: Challenges

- In-house counsel and other key stakeholders have less time due to:
  - Remote work concerns and return to work planning
  - Layoffs and furloughs
  - New laws/regs spurred by COVID-19
  - For many, childcare issues have made available working hours dwindle
- Difficulty getting into court due to closures
- Due to other pressing matters, some companies may be inclined to put trade secret protection on the backburner

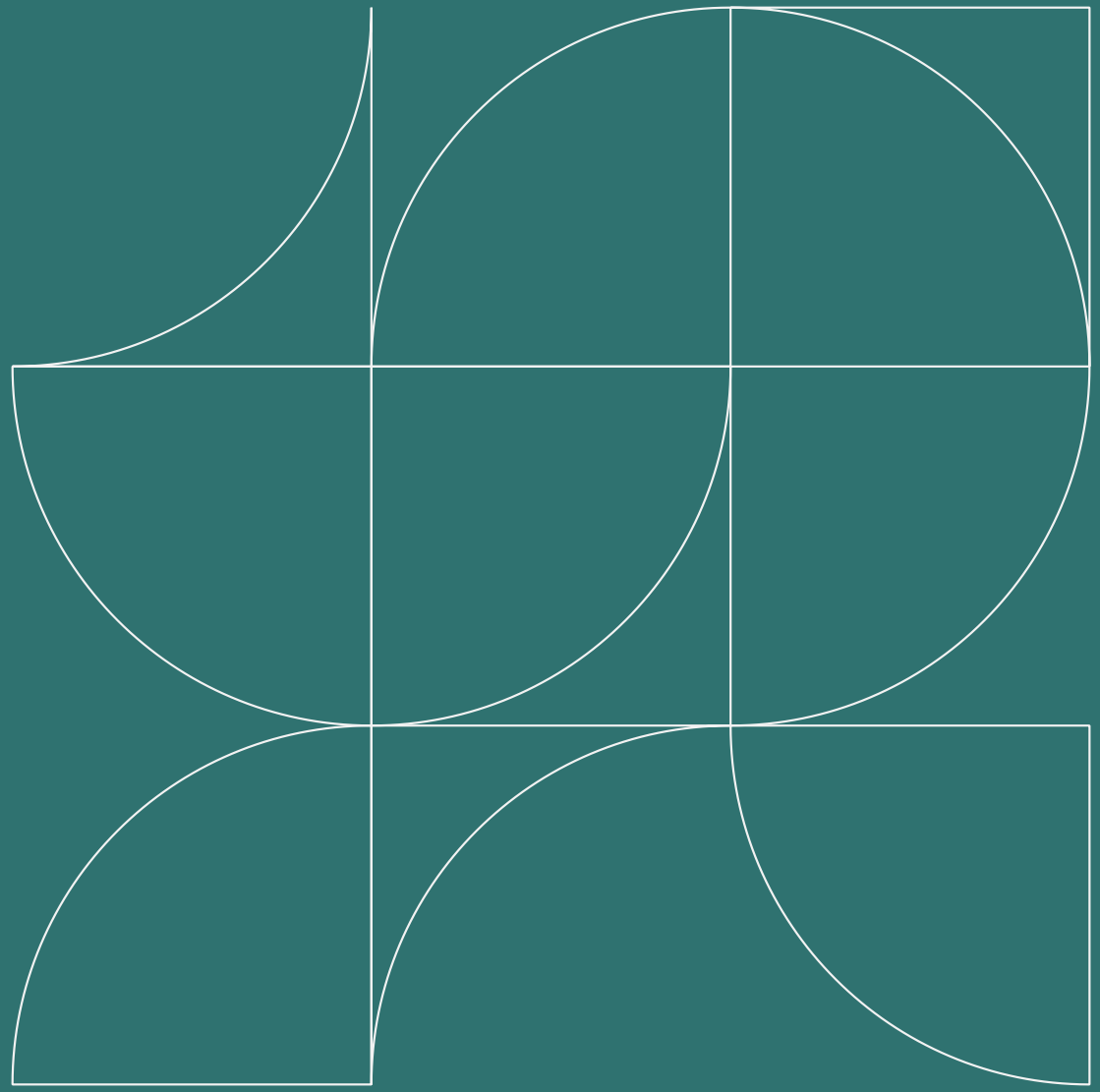
Delay in Enforcement: Best Practices

- In light of new concerns, all the more reason for companies to have their “trade secret” house in order

- Remember: while protective measures only need to be “reasonable” under the circumstances, companies must still vigorously enforce their rights to maintain trade secret protection

- Being proactive, rather than reactive, will best position a company to respond to threats even when in-house contacts have less time to deal with them

Trade Secret Protection Protocols



Trade Secret Protection Protocols

- Trade secret identification
  - More courts are mandating prompt disclosure/identification of trade secrets in litigation
  - Identifying in advance will not only help move swiftly in litigation, but may help the company identify misappropriation more promptly
  - Remember to regularly update with new developments/research!
- Robust agreements
  - Restrictive covenants agreements and other IP agreements with employees
  - Licensing agreements, NDAs, and others with partners/collaborators
- Onboarding instructions and training
- Automatic protocols for departing employees or other “red flags”

Create a Culture of Confidentiality

- Ensure employees understand what company considers confidential
- Provide training modules with examples of “dos” and “don’ts”
- **MARK THINGS CONFIDENTIAL!!!**
- Make security protocol familiar and uniform
- Even more important in COVID-19 remote work environment!
- Consistency is key

Trade Secret Audits

A trade secret audit, and the resulting protection plan, should have three primary goals:

(1) Ensure that a company's trade secrets are adequately protected from disclosure.

(2) Ensure that a company has taken adequate steps to protect itself in litigation if a trade secret is misappropriated.

(3) Limit the risk of exposure to other companies' claims of trade secret misappropriation.

Steps for an Audit

- **PLAN** the various steps of the audit
- **COMMUNICATE** with key stakeholders and custodians of key information
- **GATHER** relevant information
- **IDENTIFY** trade secrets
- **REVIEW** data, policies, and other information
- **DETECT** gaps in organization's trade secret protection
- **REMEDIATE** major issues

Protection against the rogue or sloppy employee

1. Limit access to trade secrets on a need-to-know basis.
2. Use robust restrictive covenants agreements.
3. Onboarding and training.
4. Limit access of employee use of non-approved cloud solutions.
5. Monitor access and downloading of files.
6. Conduct exit interviews.
7. Collect and secure materials of terminated employees; forensic analysis.
8. Send reminders/cease and desist letters when appropriate.

Enforce: What to do in case of theft, loss, or breach

1. Secure information and assess damage (forensic imaging and review). Reputable forensic experts can accomplish a lot even remotely.
2. Send cease and desist letters **promptly.**
3. Where necessary, pursue legal action to enforce NDAs/confidentiality agreements/other restrictive covenants.
4. Determine whether client or individual notice is required (state and federal breach notification laws).
5. Notify insurers.
6. Re-evaluate company procedures, agreements, policies, and training; obtain participation of leadership, IT, and operations.

thank you

For more information please contact us

Dean Fanelli: **dfanelli@seyfarth.com**
Dawn Mertineit: **dmertineit@seyfarth.com**
Katherine Perrelli: **kperrelli@seyfarth.com**