The LEXIS PRACTICE ADVISOR Journal™
SPRING 2019
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The LEXIS PRACTICE ADVISOR Journal™

Practical guidance backed by leading attorneys from Lexis Practice Advisor®

AI CAN CREATE ART, BUT CAN IT OWN COPYRIGHT IN IT, OR INFRINGE?

Biosimilars and the Biologics Price Competition and Innovation Act

Drafting the Misunderstood Merger Clause

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Spring 2019

Contents SPRING 2019

The
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Eric Bourget, Editor-in-Chief

ARTIFICIAL INTELLIGENCE (AI) CONTINUES to expand and impact many different areas that touch our business and personal lives. In this issue we examine copyright issues and rights related to AI-created art and other works—questions such as who is the actual author? Can such works be copyrighted? Is copyright infringement possible with AI-created art? We analyze a recent trend in caselaw on these AI-art issues that helps determine how to handle these legal issues.

Data analytics is another topic impacting business, industry, and our personal lives more and more each year. From suggested shopping references when browsing the internet to resource recommendations, data is constantly being collected, stored, and analyzed. In this edition, we offer guidance about managing, storing, and collecting data and the insurance implications related to data analytics management.

Another developing topic is the emergence of biosimilar drugs in the pharmaceutical industry and the abbreviated process companies can now use to bring biologic drugs to market when they are biosimilar to previously-approved drugs. This edition includes a look at the resolution process when patent disputes arise between the creators of the original drug and the manufacturer of a biosimilar one.

In recent editions of the Lexis Practice Advisor Journal we have included considerable coverage on new consumer-oriented data privacy and security laws, ranging from the European General Data Protection Regulation (GDPR) and the California Consumer Privacy Act (CCPA). A new law in Ohio takes a different approach to data protection by creating a safe harbor for companies that create and maintain cybersecurity programs that comply with the recently passed Ohio Data Protection Act. The law incentivizes adoption of strong cybersecurity protections and provides an affirmative defense for companies that conform to the law's requirements.

Our drafting advice relates to merger or integration clauses and why this standard, boilerplate language included in so many contracts is often misunderstood, which can expose your clients to unnecessary risk. This important guidance discusses what needs to be included along with the language that should be used in merger clauses to best protect your clients' interests.

Our market trends report examines recent trends in Employee Stock Option Plans (ESOPs) and provides guidance on structuring ESOPs. We evaluate the advantages of these plans for longer company lifecycles, employment length, and increased employee benefits.

The Lexis Practice Advisor Journal provides you with a broad sampling of practical guidance and insights that may be found in our online Practical Guidance tool, Lexis Practice Advisor, as well as relevant articles that will bring you up to speed on current issues and trends, which will undoubtedly serve as entry points into deeper analytical research.

Our mission

The Lexis Practice Advisor Journal™ is designed to help attorneys start on point. This supplement to our online practical guidance resource, Lexis Practice Advisor®, brings you a sophisticated collection of practice insights, trends, and forward-thinking articles. Grounded in the real-world experience of our 850+ seasoned attorney authors, the Lexis Practice Advisor Journal offers fresh, contemporary perspectives and compelling insights on matters impacting your practice.

STATE ATTORNEYS GENERAL FILE APPEAL FROM RULING INVALIDATING AFFORDABLE CARE ACT

ATTORNEYS GENERAL FROM 16 STATES AND THE DISTRICT of Columbia have filed a notice of appeal with the U.S. Court of Appeals for the Fifth Circuit following a ruling by a Texas federal judge striking down the Patient Protection and Affordable Care Act (ACA) (111 P.L. 148) in its entirety.

U.S. Judge Reed O'Connor of the Northern District of Texas ruled December 14 that as a result of a provision contained in the Tax Cuts and Jobs Act of 2017 (TCJA) (115 P.L. 97) effectively reducing to zero the ACA's individual mandate tax penalty as of January 1, the individual mandate is no longer a valid exercise of Congress' taxing power. Further, the judge said, the individual mandate is inseverable from the remainder of the ACA, rendering the entire statute invalid. Texas v. United States, 2018 U.S. Dist. LEXIS 211547 (Dec. 14, 2018).

"Congress was explicit: The Individual Mandate is *essential* to the ACA, and that essentiality requires the mandate to work *together* with the Act's other provisions," Judge O'Connor said. "If the 'other provisions' were severed and preserved, they would no longer be working *together* with the mandate and therefore no longer working as Congress intended. On that basis alone, the Court must find the Individual Mandate inseverable from the ACA. To find otherwise would be to introduce an entirely new regulatory scheme never intended by Congress or signed by the President."

Following passage of the TCJA in December 2017, a group of Republican state attorneys general led by Attorney General Ken Paxton of Texas filed suit in the Texas court challenging the constitutionality of the ACA. In addition to Texas, the plaintiff states were Alabama, Arizona, Arkansas, Florida, Georgia, Indiana, Kansas, Louisiana, Maine, Mississippi, Nebraska, North Dakota, South Carolina, South Dakota, Tennessee, Utah, West Virginia and Wisconsin. Democratic attorneys general from 16 states—namely, California, Connecticut, Delaware, Hawaii, Illinois, Kentucky, Massachusetts, Minnesota, New Jersey, New York, North Carolina Oregon, Rhode Island, Vermont, Virginia, Washington—and the District of Columbia intervened as defendants. The same 17 attorneys general are parties to the appeal filed with the Fifth Circuit.

Judge O'Connor issued a stay of his ruling on December 30, citing the uncertainty that enforcement would create during the appeal process.

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > Health Plans and Affordable Care Act > Articles*

CONTRACT PROVISION CONTROLS ON ARBITRABILITY QUESTION, U.S. SUPREME COURT RULES

A CONTRACT PROVISION DELEGATING TO AN ARBITRATOR the question of whether a claim is subject to arbitration is controlling despite a judicial finding that the arbitration request is without merit, the U.S. Supreme Court has ruled in Henry Schein Inc. v. Archer & White Sales Inc., 2019 U.S. LEXIS 566 (Jan. 8, 2019).

In a unanimous ruling, the justices found that the judicially created "wholly groundless" exception to arbitrability is inconsistent with the Federal Arbitration Act (9 U.S.C.S. § 1, et. seq.) and Supreme Court precedent.

The Court's ruling reverses a decision by the U.S. Court of Appeals for the Fifth Circuit in Archer & White Sales Inc. v. Henry Schein Inc., 878 F.3d 488 (5th Cir. 2017), which affirmed a lower court's ruling denying a motion to compel arbitration in a suit brought by Archer & White Sales Inc. against Henry Schein Inc.

Archer & White sought money damages and injunctive relief in a suit filed in the U.S. District Court for the Eastern District of Texas alleging violation of federal and state antitrust law by Schein. A clause in the parties' contract provided that, with the exception of intellectual property claims, disputes under the contract would be resolved by arbitration in accordance with American Arbitration Association rules. Schein moved to compel arbitration; a federal magistrate judge granted the motion, but a federal judge vacated the order, finding that the dispute was not arbitrable.

On appeal, the Fifth Circuit affirmed, finding Schein's claim that the dispute is arbitrable is "wholly groundless" within the meaning of its own holding in Douglas v. Regions Bank, 757 F.3d 460 (5th Cir. 2014).

In an opinion written by Associate Justice Brett Kavanaugh—his first since taking the bench—the Court said, "The exception is inconsistent with the statutory text and with our precedent. It confuses the question of who decides arbitrability with the separate question of who prevails on arbitrability. When the parties' contract delegates the arbitrability question to an arbitrator, the courts must respect the parties' decision as embodied in the contract."

The justices remanded the case to the Fifth Circuit for consideration of whether the contract in fact delegated the arbitrability question to an arbitrator. "The Court of Appeals did not decide that issue," the Court said. "Under our cases, courts 'should not assume that the parties agreed to arbitrate arbitrability unless there is clear and unmistakable evidence that they did so.'"

RESEARCH PATH: *Civil Litigation > Arbitration and Other ADR > Articles*

SUPREME COURT TO CONSIDER APPROPRIATE STANDARD FOR PRE-MERGER CONDUCT CLAIMS

THE QUESTION OF WHETHER SHAREHOLDERS MUST show intentional wrongdoing in order to pursue class action claims related to pre-merger activities under Section 14(e) of the Securities Exchange Act of 1934 (15 U.S.C.S. § 78n(e)) will come before the U.S. Supreme Court later this year. (Emulex Corp. v. Varjabedian, No. 18-459, U.S. Sup. Ct.)

The justices on January 4 granted a petition by Emulex Corp. for review of a ruling by the U.S. Court of Appeals for the Ninth Circuit, Varjabedian v. Emulex Corp., 888 F.3d 399 (9th Cir. 2018), reinstating a securities class action alleging that Emulex Corp. concealed from shareholders that an acquisition offer from Avago Technologies Ltd. was too low.

The Ninth Circuit's ruling came in a putative class action filed in the U.S. District Court for the Central District of California by Jerry Mutza on his own behalf and that of former Emulex shareholders contending that Emulex misled them by failing to share expert analysis showing that the premium offered to investors as part of a merger offer from Avago was below the industry average. The merger was completed, with Emulex shareholders receiving $8 per share, representing a premium of 26.4% on the Emulex stock price the day before the merger was announced.

U.S. Judge Cormac J. Carney dismissed the action in Varjabedian v. Emulex Corp., 152 F. Supp. 3d 1226 (C.D. Cal. 2016), finding that the shareholders failed to show intentional misconduct as required by Section 14(e). On appeal, the Ninth Circuit reversed and reinstated the suit, holding that Section 14(e) requires only a showing of negligence, not intent.

In so ruling, the Ninth Circuit parted company with five other federal appeals courts—the U.S. Courts of Appeals for the Second, Third, Fifth, Sixth, and Eleventh Circuits—but said that it is "persuaded that intervening guidance from the Supreme Court compels the conclusion that Section 14(e) of the Exchange Act imposes a negligence standard."

The case is expected to be heard in the spring, with a decision issued before the end of the Supreme Court's term in late June.

RESEARCH PATH: Corporate and M&A > Tender Offers > General Considerations in a Tender Offer > Articles

PATENT AND TRADEMARK OFFICE ISSUES GUIDANCE ON PATENT ELIGIBILITY

THE U.S. PATENT AND TRADEMARK OFFICE (USPTO) has issued new guidance for patent examiners to follow when considering applications that contain abstract ideas that could otherwise lead to a finding of ineligibility. 2019 Revised Patent Subject Matter Eligibility Guidance, Department of Commerce, U.S. Patent and Trademark Office, No. PTO-P-2018-0053, https://www.federalregister.gov/documents/2019/01/07/2018-28282/2019-revised-patent-subject-matter-eligibility-guidance.

The guidance, which is published in the Federal Register for public comment, governs all applications, and all patents resulting from applications, filed on or before January 7. Written comments on the guidance must be received by the USPTO by March 8.

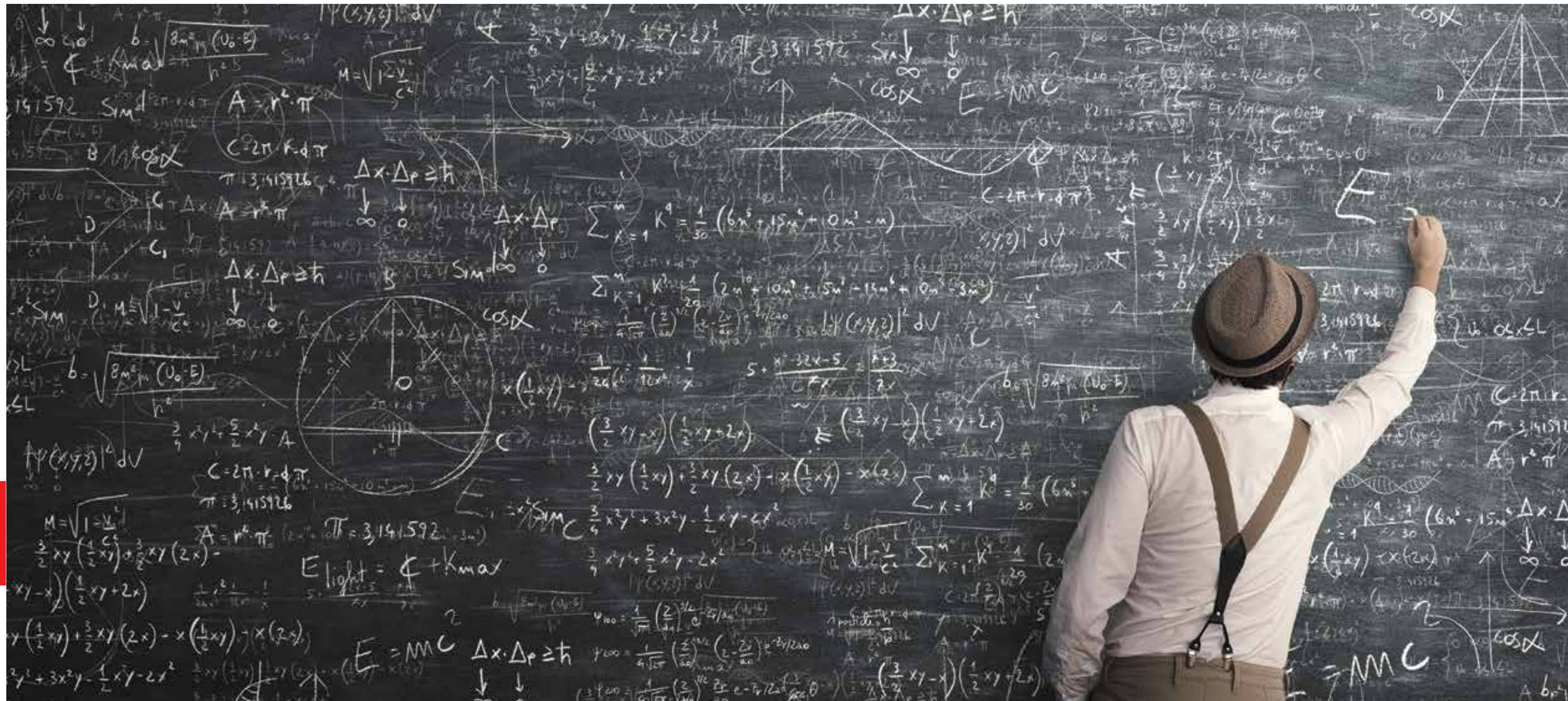
The USPTO issued the guidance in response to what it called "uncertainty" in the legal community about the application of the *Alice/Mayo* test for eligibility under Section 101 of the Patent Act (35 U.S.C.S. § 101), set forth by the U.S. Supreme Court in Alice Corp. v. CLS Bank, 573 U.S. 208 (2014). In *Alice*, the high court, citing its own decision in Mayo v. Prometheus, 566 U.S. 566 (2012), established a two-part test for determining patent eligibility: (1) whether the claims are directed to a patent-ineligible concept and (2) whether the elements of the claim, both individually and in combination, transform the nature of the claims into a patent-eligible application.

The new guidance lists three categories of inventions deemed to constitute abstract ideas or "judicial exceptions" that, standing alone, are patent-ineligible: mathematical concepts, such as mathematical relationships, formulas or equations, and calculations; certain methods of organizing human activity, including economic principles or practices, commercial or legal interactions, and managing personal behavior or relationships; and mental processes or concepts performed in the human mind. All other inventions, with limited exception, do not fall within the definition of abstract ideas, the guidance states.

If an invention falls within one of the three categories, the guidance says, the examiner should determine if the idea is "integrated into a practical application." If the idea is not integrated into a practical application, it is considered to be "directed to" the abstract idea under the guidance and is not patent eligible, according to the guidance.

In a statement, Andrei Iancu, director of the USPTO, said that the new guidance will "improve the clarity, consistency, and predictability of actions across the USPTO." The agency will provide training to examiners and administrative patent judges to ensure proper administration of the guidance.

RESEARCH PATH: Intellectual Property & Technology > Patents > Patent Litigation > Articles



Ohio Law Provides Legal Safe Harbor for Compliant Cybersecurity Programs

Chad Perlov LEXIS PRACTICE ADVISOR

THIS ARTICLE DISCUSSES THE OHIO DATA PROTECTION Act's (ODPA) new legal safe harbor against data breach claims and how to comply with the requirements set out in the statute. Effective November 2, 2018, businesses and nonprofit entities that create and maintain a cybersecurity program in accordance with the ODPA's requirements can assert their compliance as an affirmative defense to any tort action brought in Ohio alleging that the failure to implement reasonable information security controls caused a data breach.[1]

Ohio is the first state to incentivize entities to adopt strong cybersecurity practices, rather than punish them for failing to adhere to a specific regulatory framework.[2] Entities are eligible for the safe harbor if they create, maintain, and comply with a cybersecurity program that, among other things, reasonably conforms to one of the industry-recognized cybersecurity frameworks listed in the OPDA.

Entities Eligible for the Safe Harbor

The ODPA applies to any business that accesses, maintains, communicates, or processes personal information or restricted information in or through one or more systems, networks, or services located in or outside of Ohio (covered entity).[3]

The ODPA defines business as any for profit or nonprofit:

- Limited liability company
- Limited liability partnership
- Corporation
- Sole proprietorship
- Association or other group
- Financial institution organized, chartered, or holding a license authorizing operation under the laws of Ohio, any other state, the United States, or any other country
- Parent or subsidiary of any of the foregoing[4]

1. Ohio Rev. Code Ann. § 1354.02. 2. Press Release, Ohio Attorney General, Data Protection Act Will Incentivize Cybersecurity to Protect Customer Data (Nov. 3, 2017), available at https://www.ohioattorneygeneral.gov/Media/News-Releases/November-2017/Data-Protection-Act-Will-Incentivize-Cybersecurity. 3. Ohio Rev. Code Ann. § 1354.01(B). 4. Ohio Rev. Code Ann. § 1354.01(A).

Types of Data Breaches Subject to Liability

The ODPA defines data breach as:

- Any unauthorized access to and acquisition of computerized data
- That compromises the security or confidentiality of personal information or restricted information
- Owned by or licensed to a covered entity
- That causes, reasonably is believed to have caused, or reasonably is believed will cause a material risk of identity theft or other fraud to a person or property[5]

The ODPA does not consider either of the following situations to be a data breach:

- **Employment.** Good faith acquisition of personal information or restricted information by the covered entity's employee or agent for the purposes of the covered entity's, provided that the personal information or restricted information is not used for an unlawful purpose or subject to further unauthorized disclosure.[6]
- **Legal obligation.** Acquisition of personal information or restricted information pursuant to a search warrant, subpoena, or other court order, or pursuant to a subpoena, order, or duty of a regulatory state agency.[7]

For the purposes of this statute, the ODPA defines personal information as an individual's name, consisting of the individual's first name or first initial and last name, in combination with and linked to any one or more of the following unencrypted, unredacted, or unaltered data elements:

- Social Security number
- Driver's license number or state identification card number
- Account number or credit or debit card number, in combination with and linked to any required security code, access code, or password that would permit access to an individual's financial account[8]

Personal information does not include publicly available information that is lawfully made available to the general public from:

- Federal, state, or local government records
- Any of the following media that are widely distributed:
  - Any news, editorial, or advertising statement published in any bona fide newspaper, journal, or magazine, or broadcast over radio or television
  - Any gathering or furnishing of information or news by any bona fide reporter, correspondent, or news bureau to news media described above
  - Any publication designed for and distributed to members of any bona fide association or charitable or fraternal nonprofit corporation
  - Any type of media similar in nature to any item, entity, or activity identified in the foregoing[9]

Restricted information means any information about an individual, other than personal information, that, alone or in combination with other information, (including personal information):

- Can be used to distinguish or trace the individual's identity or that is linked or linkable to an individual
- Is not encrypted, redacted, or altered by any method or technology in such a manner that the information is unreadable
- The breach of which is likely to result in a material risk of identity theft or other fraud to person or property[10]

Establishing a Cybersecurity Program

Covered entities seeking the safe harbor under the ODPA must create, maintain, and comply with a written cybersecurity program that:

- Contains administrative, technical, and physical safeguards for the protection of personal information or restricted information (or both)
- Reasonably conforms to one of the industry-recognized cybersecurity frameworks described in the statute[11]

A covered entity must design its cybersecurity program to achieve the following objectives:

- Protect the security and confidentiality of the information
- Protect against any anticipated threats or hazards to the security or integrity of the information
- Protect against unauthorized access to and acquisition of the information that is likely to result in a material risk of identity theft or other fraud to the individual to whom the information relates[12]

In addition, the ODPA requires each covered entity to tailor its cybersecurity program to ensure that it appropriately considers:

- The size and complexity of the covered entity
- The nature and scope of the activities of the covered entity
- The sensitivity of the information to be protected
- The cost and availability of tools to improve information security and reduce vulnerabilities
- The resources available to the covered entity[13]

5. Ohio Rev. Code Ann. § 1354.01(C). 6. Ohio Rev. Code Ann. § 1354.01(C)(1). 7. Ohio Rev. Code Ann. § 1354.01(C)(2). 8. Ohio Rev. Code Ann. § 1349.19(A)(7)(a). 9. Ohio Rev. Code Ann. § 1349.19(A)(7)(b). 10. *See* Ohio Rev. Code Ann. § 1354.01(E). 11. Ohio Rev. Code Ann. § 1354.02(A)(1) and (2). 12. Ohio Rev. Code Ann. § 1354.02(B). 13. Ohio Rev. Code Ann. § 1354.02(C).

Complying with a Cybersecurity Framework

A covered entity's cybersecurity program is eligible for the safe harbor if it reasonably conforms to:

- An industry-recognized framework specified in the ODPA
  - Existing federal or state laws under which the covered entity is already regulated
  - A combination of industry-recognized frameworks specified in the ODPA[14]

Industry Frameworks

The ODPA lists the following industry-recognized frameworks to which a covered entity's cybersecurity program must reasonably conform:

- Framework for Improving Critical Infrastructure Cybersecurity, developed by the National Institute of Standards and Technology (NIST)
- NIST special publication 800-171
- NIST special publications 800-53 and 800-53a
- Federal Risk and Authorization Management Program (FedRAMP) Security Assessment Framework
- Center for Internet Security Critical Security Controls for Effective Cyber Defense
- The International Organization for Standardization/International Electrotechnical Commission 27000 Family - Information Security Management Systems[15]

PCI Data Security Standard (PCI DSS)

A covered entity may also seek a safe harbor if its cybersecurity program reasonably complies with both the current version of the PCI Data Security Standard (PCI DSS) and conforms to the current version of another applicable industry-recognized cybersecurity framework listed above.[16]

Existing Federal or State Law

A covered entity also may claim the safe harbor if it is regulated by Ohio or the federal government (or both), or is otherwise subject to the requirements of any of the laws or regulations listed below, and the cybersecurity program reasonably conforms to the entirety of the current version of the laws under which it is regulated:

- The security requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. No. 104-191, 110 Stat. 1936 (Aug. 21, 1996))
- Gramm-Leach-Bliley Act of 1999 (GLBA) (Pub. L. No. 106-102, 113 Stat. 1338 (Nov. 12, 1999))
- Federal Information Security Modernization Act of 2014 (FISMA) (Pub. L. No. 113-283, 128 Stat. 3073 (Dec. 18, 2014))
- Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) (42 U.S.C.S. § 201 et seq.)[17]

Required Cybersecurity Program Updates

Industry Frameworks

If a covered entity relies on an industry-recognized framework for compliance purposes under the ODPA, it must ensure that its cybersecurity program reasonably conforms to any revision of the framework no later than one year after the publication date stated in the revision.[18]

PCI DSS Standard

If a covered entity relies on the PCI DSS Standard for compliance purposes under the ODPA, it must ensure that its cybersecurity program reasonably conforms to any revision of that standard no later than one year after the publication date stated in the revision.[19]

Federal or State Law

A covered entity regulated by Ohio or the federal government (or both) must ensure that its cybersecurity program reasonably conforms to any revision of the applicable law or regulation no later than one year after the amendment's effective date.[20]

Combination of Frameworks

If a covered entity's cybersecurity program reasonably conforms to a combination of industry recognized cybersecurity frameworks, or complies with a standard (e.g., PCI DSS), and two or more of those frameworks are revised, the covered entity must ensure that its cybersecurity program reasonably conforms to all of the revised frameworks no later than one year after the latest publication date stated in the revisions.[21]

Asserting an Affirmative Defense in Ohio

Courts in Ohio consider an affirmative defense to be:

> A defense in the nature of confession and avoidance as it admits the plaintiff has a claim but asserts a legal reason that the plaintiff cannot recover on it. An affirmative defense attacks the legal right to bring a claim as opposed to attacking the truth of the claim. It is more than a mere denial or a contradiction of the evidence but is a substantive or independent matter which the defendant claims exempts him from liability even if the facts of the complaint are conceded.[22]

In Ohio, the defendant must prove an affirmative defense by a preponderance of the evidence.[23] As a result, a covered entity bears the burden of proving its cybersecurity program complies with the requirements of the ODPA.

A covered entity should consider taking the following steps to help ensure that its cybersecurity program both complies with the ODPA and supports an affirmative defense against future legal claims resulting from a data breach:

- **Maintain a written cybersecurity policy**. Implement and maintain a written policy or policies describing your cybersecurity program for protecting your information systems and nonpublic information stored on those information systems. The policy should address, at a minimum:
  - Information security
  - Data governance and classification
  - Asset inventory and device management
  - Access controls and identity management
  - Business continuity and disaster recovery planning and resources
  - Systems operations and availability concerns
  - Systems and network security
  - Systems and network monitoring
  - Systems and application development and quality assurance
  - Physical security and environmental controls
  - Customer data privacy
  - Vendor and third-party service provider management (as discussed below)
  - Risk assessment
  - Incident response
- **Perform risk assessments.** Conduct periodic risk assessments of your information systems sufficient to inform the design of your cybersecurity program. Update your risk assessment as reasonably necessary to address changes to your information systems, nonpublic information, or business operations.
- **Perform penetration testing and vulnerability assessments.** Conduct monitoring and testing as part of your cybersecurity program. Develop all testing and monitoring processes in accordance with your risk assessment and ensure that they assess the effectiveness of your cybersecurity program. Include periodic penetration testing and vulnerability assessments as part of your monitoring program.
- **Limit access.** As part of your cybersecurity program, you should limit user access privileges to information systems that provide access to nonpublic information and periodically review such access privileges.

14. Ohio Rev. Code Ann. § 1354.03. 15. Ohio Rev. Code Ann. § 1354.03(A)(1). 16. Ohio Rev. Code Ann. § 1354.03(C)(1). 17. Ohio Rev. Code Ann. § 1354.03(B)(1). 18. Ohio Rev. Code Ann. § 1354.03(A)(2). 19. Ohio Rev. Code Ann. § 1354.03(C)(2). 20. Ohio Rev. Code Ann. § 1354.03(B)(2). 21. Ohio Rev. Code Ann. § 1354.03(D). 22. R.C. Olmstead, Inc. v. GBS Corp., 2009 Ohio App. LEXIS 5700 (Dec. 18, 2009). 23. Home Sav. Bank v. Loeffler, 2018 Ohio App. LEXIS 4552 (Oct. 15, 2018).

Related Content

For a detailed discussion on preparing data breach avoidance and response plans, see

> **DATA BREACH PLANNING AND MANAGEMENT**

RESEARCH PATH: *Data Security & Privacy > Data Breaches > Planning > Practice Notes*

For guidance on preparing plans for avoidance of a data breach and how to respond in the event of a breach, see

> **DATA BREACH AVOIDANCE AND RESPONSE PLAN CHECKLIST**

RESEARCH PATH: *Data Security & Privacy > Data Breaches > Planning > Checklists*

For assistance in creating a cybersecurity resilience implementation plan, see

> **CYBERSECURITY RESILIENCE IMPLEMENTATION PLAN**

RESEARCH PATH: *Data Security & Privacy > Cybersecurity Risk Management > Forms*

For an example of an internal information security plan, see

> **WRITTEN INFORMATION SECURITY PLAN**

RESEARCH PATH: *Data Security & Privacy > Cybersecurity Risk Management > Forms*

- **Develop application security protocols.** Ensure that your cybersecurity program uses secure development practices for in-house developed applications that your company uses, and procedures for evaluating, assessing, or testing the security of any externally developed applications that your company uses.
- **Use qualified cybersecurity personnel.** Use only qualified cybersecurity personnel employed by your company, an affiliate, or a third-party service provider sufficient to manage your cybersecurity risks and to perform or oversee the performance of the core functions of your cybersecurity program. Provide cybersecurity personnel with cybersecurity updates and training sufficient to address relevant cybersecurity risks. Verify that key cybersecurity personnel take steps to maintain current knowledge of changing cybersecurity threats and countermeasures.
- **Use multifactor authentication.** Use effective controls to protect against unauthorized access to nonpublic information or information systems. Multifactor authentication typically means authentication through verification of at least two of the following types of authentication factors:
  - Knowledge factors (e.g., password)
  - Possession factors (e.g., token or text message)
  - Inherence factors (e.g., biometric characteristic)
- **Develop a third-party service provider security policy.** Implement written policies and procedures designed to ensure the security of information systems and nonpublic information that are accessible to, or held by, third-party service providers. Ensure that these policies and procedures address:
  - The identification and risk assessment of third-party service providers
  - Minimum cybersecurity practices that third-party service providers are required to meet to do business with you
  - Due diligence processes used to evaluate the adequacy of cybersecurity practices of such third-party service providers
  - Periodic assessment of such third-party service providers based on the risk they present and the continued adequacy of their cybersecurity practices
- **Disposal of data.** Ensure the cybersecurity program addresses the periodic secure disposal of certain nonpublic information that is no longer necessary for business operations or for other legitimate business purposes, except where either:
  - You are otherwise required to retain such information by law or regulation.
  - Targeted disposal is not reasonably feasible due to the way you maintain the information.
- **Implement a training and monitoring program.** Implement risk-based policies, procedures, and controls designed to monitor the activity of authorized users and detect unauthorized access or use of, or tampering with, nonpublic information by such authorized users. In addition, you should provide regular cybersecurity awareness training for all personnel that is updated to reflect risks identified in your risk assessment.
- **Encrypt nonpublic information.** Implement controls, including encryption, to protect nonpublic information held or transmitted by your company both in transit over external networks and at rest.
- **Develop an incident response plan.** Establish a written incident response plan designed to promptly respond to, and recover from, any cybersecurity event materially affecting the confidentiality, integrity, or availability of your information systems or the continuing functionality of any aspect of your operations.

  The incident response plan should address:
  - The internal processes for responding to a cybersecurity event
  - The goals of the incident response plan
  - Identifying roles, responsibilities, and levels of decision-making authority
  - External and internal communications and information sharing
  - Remediating any identified weaknesses in information systems and associated controls
  - Documenting and reporting cybersecurity events and related incident response activities
  - Evaluating and revising as necessary the incident response plan following a cybersecurity event. L

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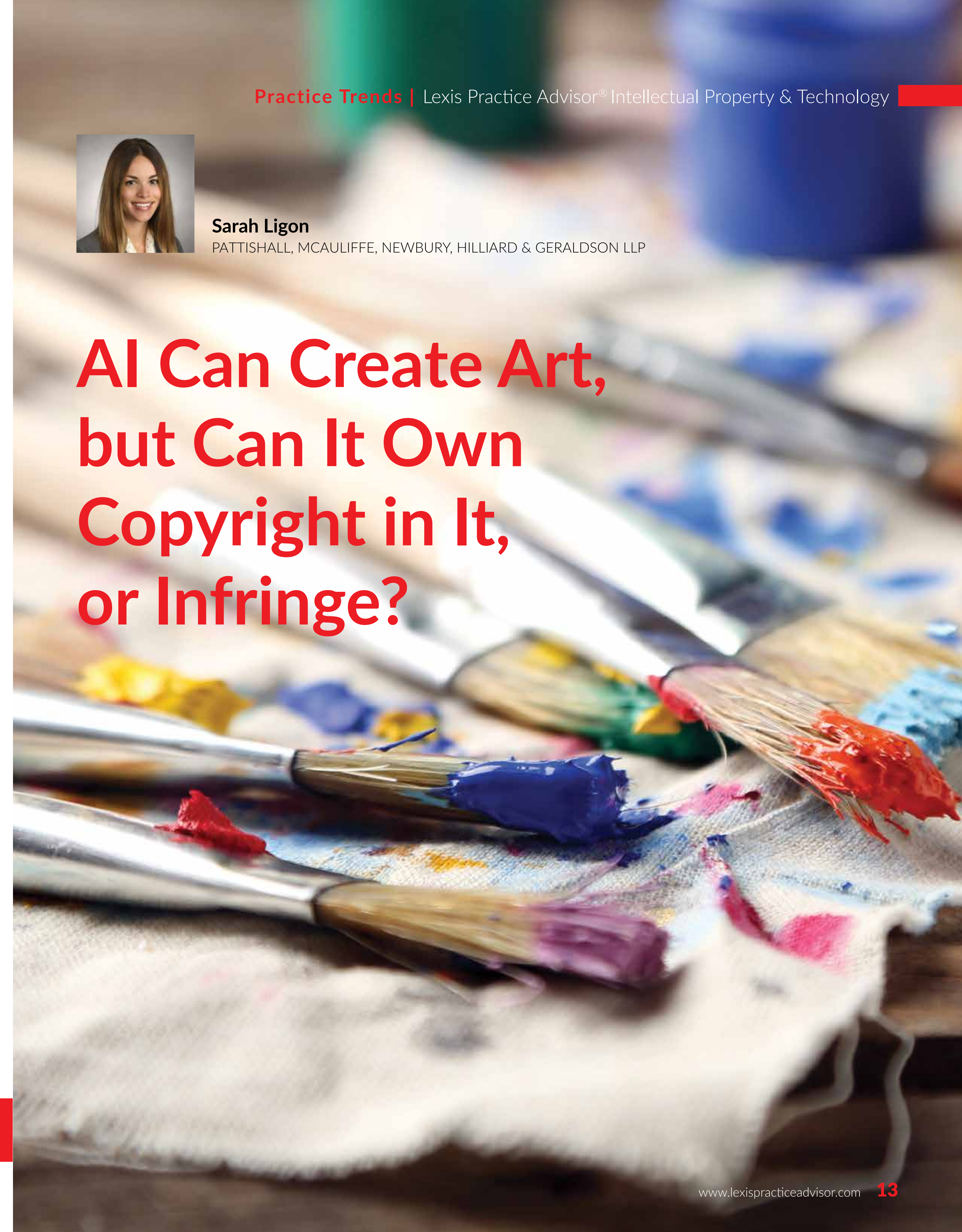
RESEARCH PATH: Data Security & Privacy > Data Breaches > Planning > Practice Notes



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AI Can Create Art, but Can It Own Copyright in It, or Infringe?

A 17-year-old bet his high school programming club that artificial intelligence (AI) could outperform human beings. To prove it, Robbie Barrat developed a program that could write its own rap lyrics using 6,000 Kayne West lyrics.[1] He is not the only one creating art using AI. Major news organizations like *The Washington Post* are integrating AI into their business models.[2] In addition, a painting created by Obvious using AI was recently auctioned off by Christie's for almost a half of a million dollars.[3]

THE RISE IN AI-ART HAS RAISED FUNDAMENTAL questions in copyright law that authors and companies are struggling to address, including questions of copyrightability, ownership, and infringement.

How Does AI Create Art?

To answer these questions, it is important to understand how AI creates art. As explained by self-taught programmer turned AI-artist, Barrat AI-artists use two neural networks that consist of algorithms called a generator and a discriminator to create AI-art.[4]

For example, Barrat would feed the generator paintings and the generator would create rules based on those paintings in order to produce its own version of them.[5] The discriminator would then look at both the real paintings and the AI-versions to determine which painting is "real."[6] Like a game, the generator tries to trick the discriminator into believing that its new paintings are "real."[7] The fascinating part of this process is that the resulting AI-work can sometimes be beautiful and quite different from the underlying artwork on which it is based.

Can AI-Art be Copyrighted and Who (or What) is the Author?

AI-artists like Barrat input data into these neural networks, but it is the computer program that actually creates the art and, in theory, could be the author of the work. Copyright ownership "vests initially in the author or authors of the work."[8] Although Section 101 of the Copyright Act fails to define an author, recent case law suggests that the author cannot be a computer.

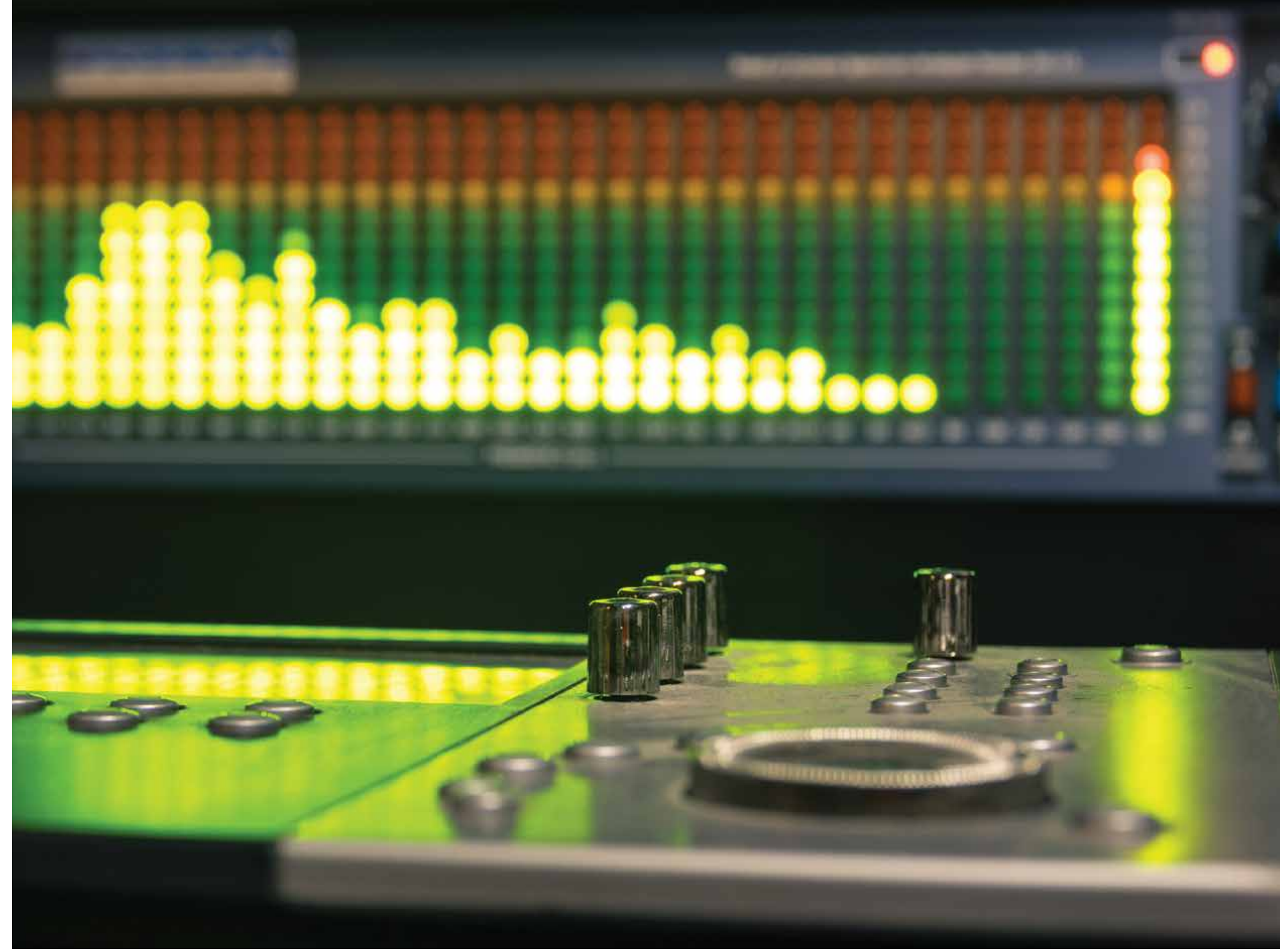
In the widely publicized "Monkey Selfie" case, *Naruto v. Slater*, a crested macaque named Naruto picked up a photographer's camera and clicked photographs of himself.[9] The photographer, David Slater, and Wildlife Personalities, Ltd. published the "Monkey Selfies" in a book and claimed copyright ownership in the photographs.[10] People for the Ethical Treatment of Animals (PETA) and Dr. Antje Engelhardt sued as next friends on behalf of Naruto, claiming Naruto was the author of the photographs and that Slater and Wildlife Personalities infringed Naruto's copyright.[11]

Naruto's claim was dismissed, and the U.S. Court of Appeals for the Ninth Circuit affirmed, holding that Naruto lacked standing to sue under the Copyright Act because animals cannot sue for infringement.[12] The court reasoned that "[t]he Copyright Act does not expressly authorize animals to file copyright infringement suits under the statute", and other sections of the Copyright Act, which refer to "children" and "widow," for example, imply that the author must be a human being.[13] Although corporations can own copyrights and sue under the Copyright Act, the court noted that corporations are considered "persons" under U.S. Supreme Court precedent and, unlike animals, these entities "are formed and owned by humans."[14]

The U.S. Copyright Office likewise will not grant a registration unless the author is a human being.[15] It relies on old Supreme Court precedent that "copyright law only protects 'the fruits of intellectual labor' that 'are founded in the creative powers of the mind.'"[16] The Copyright Office's position is that this does not include "works produced by a machine or mere mechanical process that operates randomly or automatically without any creative input or intervention from a human-author."[17]

Thus, it appears Barrat's rapping robot cannot be an author that owns a copyright, but this does not foreclose AI-artists like Barrat from claiming some element of authorship in the resulting work. A computer program cannot create the work without the artist's initial input, and AI-artists arguably exercise some degree of originality in the selection of the underlying works that form a basis for the AI-created work. Some other countries already protect such works. For example, the U.K. grants copyright protection to the person that makes arrangements for the computer to create the work.[18] Given that the purpose of the Copyright Act is to provide an incentive for artists to create art, it may not be long before the United States follows suit.

1. Dave Gershgorn, "A West Virginia teen taught himself how to build a rapping AI using Kanye West lyrics," *Quartz* (March 17, 2017), https://qz.com/920091/a-west-virginia-teen-taught-himself-how-to-build-a-rapping-ai-using-kanye-west-lyrics/. 2. Corinna Underwood, "Automated Journalism – AI Applications at New York Times, Reuters, and Other Media Giants," *Emerj* (last updated November 29, 2018), https://emerj.com/ai-sector-overviews/automated-journalism-applications/. 3. Jimmy Im, "This portrait made by A.I. just sold for $432,000 — that's 40 times the original estimate," *CNBC Make It* (October 25, 2018), https://www.cnbc.com/2018/10/25/portrait-made-by-artificial-intelligence-sold-for-432k-at-christies.html. 4. Joe Dworetzky, "Q&A: Robbie Barrat on training neural networks to create art," *The Stanford Daily* (June 12, 2018), https://www.stanforddaily.com/2018/06/12/qa-robbie-barrat-on-training-neural-networks-to-create-art/. 5. *Id*. 6. *Id*. 7. *Id*. 8. 17 U.S.C.S. § 201. 9. Naruto v. Slater, 888 F.3d 418, 420 (9th Cir. 2018). 10. *Id*. 11. *Id*. 12. *Id*. at 426. 13. *Id*. 14. *Id*. at n. 9. 15. COMPENDIUM OF U.S. COPYRIGHT OFFICE PRACTICES III, § 306 (2017). 16. *Id*. (quoting Trade-Mark Cases, 100 U.S. 82, 94 (1879)). 17. *Id*. at § 313.2. 18. Andres Guadamuz, "Artificial Intelligence and copyright," *WIPO Magazine* (October 2017), http://www.wipo.int/wipo_magazine/en/2017/05/article_0003.html.



What is the Line Between Fair Use and Infringement for AI-Created Works?

Apart from whether AI-artists like Barrat can claim copyright ownership in the resulting work, can the likes of Kayne West stop him from selling or displaying his work? New artists often build upon existing art, but the line between inspiration and appropriation is not always clear. In the AI-world where a computer program is literally fed copies of existing art to try to recreate it, the line would seem non-existent. Prior appropriation art cases, however, suggest that some uses may be protected by fair use if the result is sufficiently transformative from the underlying work.

In *Graham v. Prince*, a photographer sued the well-known appropriation artist Richard Prince for infringement when Prince took a screenshot of a third-party's Instagram post of Graham's photograph that Prince commented on and later displayed the post, along with Prince's comment, in an art exhibit featuring a collection of screenshots of social media posts with nonsensical comments by Prince.[19] Prince moved to dismiss on the basis of fair use, claiming that his work was transformative because a "reasonable viewer" would interpret his art as conveying a number of messages that are distinct from the underlying art.[20]

The district court disagreed, holding that Prince's reproduction of the photograph in its entirety with "*de minimis* cropping" and "a cryptic comment" is not transformative as a matter of law.[21] Unlike Prince's prior appropriation art that the U.S. Court of Appeals for the Second Circuit previously held was insulated from infringement under the fair use defense, "Prince has not materially altered the 'composition, presentation, scale, color palette, and media' originally used by" Graham.[22]

19. Graham v. Prince, 265 F. Supp. 3d 366, 370-73 (S.D.N.Y. 2017). 20. *Id*. at 380. 21. *Id*. at 380-82. 22. *Id*. at 381 (quoting Cariou v. Prince, 714 F.3d 694, 706 (2d. Cir. 2013)).

Related Content

For more information on the requirements for the granting of a copyright, see

> **AUTHORSHIP AND OWNERSHIP OF COPYRIGHT**

RESEARCH PATH: *Intellectual Property & Technology > Copyright > Copyright Counseling & Transactions > Practice Notes*

For a detailed discussion on the categories of works that may be entitled to copyright protection, see

> **COPYRIGHT FUNDAMENTALS**

RESEARCH PATH: *Intellectual Property & Technology > Copyright > Copyright Counseling & Transactions > Practice Notes*

For a review of the exclusive rights that are controlled by an owner of a copyrighted work, see

> **EXCLUSIVE RIGHTS OF COPYRIGHT OWNERS**

RESEARCH PATH: *Intellectual Property & Technology > Copyright > Copyright Counseling & Transactions > Practice Notes*

For an analysis of the fair use defense to a claim of copyright infringement, see

> **FAIR USE CONSIDERATIONS**

RESEARCH PATH: *Intellectual Property & Technology > Copyright > Copyright Counseling & Transactions > Practice Notes*

So, if an AI-artist sells or displays AI-art that is substantially similar to the underlying work, it is unlikely the AI-artist will be able to rely on fair use. If, however, Barrat's rapping robot, for example, produced lyrics that are quite different in composition and presentation from the original Kanye West lyrics, then Barrat could plausibly assert fair use, bearing in mind that the defense is typically more difficult to successfully assert earlier on in a dispute.[23] Thus, risk averse AI-artists who wish to avoid the murky waters of fair use or high costs of discovery can rely solely on public domain works, obtain a license, or commission the underlying works.

The key takeaway from these cases is that AI-artists should not only document the creative process when selecting and inputting the underlying art, AI-artists should also consider evaluating the resulting AI-work to determine whether it is sufficiently transformative before releasing it to the public to mitigate any potential claims of infringement.

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RESEARCH PATH: *Intellectual Property & Technology > Copyright > Copyright Counseling & Transactions > Articles*

23. *Id.* at 377 ("Due to the fact-sensitive nature of the inquiry, courts generally do not address the fair use defense until the summary judgment phase.").


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Biosimilars and The Biologics Price Competition and Innovation Act (BPCIA)

The Biologics Price Competition and Innovation Act (BPCIA) provides an abbreviated pathway for companies to bring biologic drugs to market that are biosimilar to previously approved branded reference products by relying on clinical studies that were performed by the reference product sponsor (RPS).

THIS ARTICLE INTRODUCES BIOSIMILARS AND THE LITIGATION process set up by the BPCIA to facilitate resolution of patent disputes between RPSs and biosimilar manufacturers, and touches on related trends, such as the potential use of inter partes review proceedings by biosimilar manufacturers as an alternative to or in addition to litigation.

Background

Four out of the five top-selling prescription drugs in 2017 were biologics. Conventional drugs, like Tylenol® (acetaminophen), Nexium® (esomeprazole magnesium), and Advair® (fluticasone propionate), generally have fully characterized chemical structures, and are assembled through a sequence of chemical reaction and purification steps. Biologics, in contrast, tend to be complex mixtures of much larger proteins, polysaccharides, or nucleic acids that may not be fully structurally characterized and are produced by biotechnology methods that can result in variation between lots. Examples include:

- Antibodies (proteins that target (e.g., proteins expressed by cancer cells to trigger the body's immune response)) such as Herceptin® (trastuzumab)
- Growth factors (proteins that affect the growth of a cell) such as Regranex® (becaplermin)
- Enzymes (proteins that speed up biochemical reactions) such as Fabrazyme® (agalsidase beta)
- Immunomodulators (agents that affect immune response) such as Orencia® (abatacept)[1]

In 1984, Congress modified the Food, Drug, and Cosmetic Act and the Patent Act to permit generic manufacturers of conventional drugs to apply for marketing approval through an abbreviated process by relying on clinical studies performed by the sponsor of the reference brand name drug. It was not until March 2010 that the BPCIA created an abbreviated pathway for companies to bring biologic drugs to market that are biosimilar to previously approved branded reference products by relying on clinical studies that were performed by the RPS.

Approaching a decade later, there are now more than 10 FDA-approved biosimilars in the United States, and the Food and Drug Administration (FDA) is working to facilitate further biosimilar development and market access. The number of biosimilars is expected to increase in coming years as companies become more familiar with the legal framework and major biologics begin to lose patent protection and marketing exclusivity.

What Are Biosimilars?

Biologics

Section 351(i) of the Public Health Service Act (PHS) defines a "biological product" as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."[2] Marketing of a new biologic product requires filing a biologics license application (BLA) pursuant to Section 351(a) of the PHS.[3]

Abbreviated Biologics License Applications: Demonstration of Biosimilarity and Interchangeability to the Reference Product

The BPCIA modified Section 351(k) of the PHS to allow for licensure of biosimilar products through an abbreviated BLA (aBLA).

A biosimilar is "highly similar to the reference product notwithstanding minor differences in clinically inactive components" and has "no clinically meaningful differences" from the reference product in terms of "safety, purity, and potency."[4] Biosimlarity is based on analytical studies; animal studies, including toxicity assessments; and a clinical study or studies, including assessments of immunogenicity and pharmacokinetics or pharmacodynamics.[5] The biosimilar must have the same dosage form, strength, mechanism of action, and conditions of use as the approved reference product.[6] An interchangeable is a biosimilar for which it has been further demonstrated that the proposed product is "expected to produce the same clinical result as the reference product in any given patient" and that the risk of alternating between the proposed interchangeable and the reference product "is not greater than the risk of using the reference product without such alteration or switch."[7] As the name suggests, the demonstration

1. *See* U.S. Food & Drug Administration, *FDA 101: Regulating Biological Products* (https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048341.htm). 2. 42 U.S.C.S. § 262(i)(1). 3. 42 U.S.C.S. § 262(a). 4. 42 U.S.C.S. § 262(i)(2). 5. 42 U.S.C.S. § 262(k)(2)(A)(i)(I). 6. 42 U.S.C.S. § 262(k)(2)(A)(i)(II)–(IV). 7. 42 U.S.C.S. § 262(k)(4).

of interchangeability means that the FDA has concluded that it may be substituted for the reference product without consulting the prescriber.[8] Whether a product may be automatically substituted, or consent must be sought from the patient or prescriber, is governed at the state level. As of mid-2018, 41 states and Puerto Rico had laws relating to substitution.[9] In addition, the first interchangeable product, but not the first biosimilar, is entitled to up to one year of market exclusivity as against other interchangeable products.[10]

Regulatory Exclusivities

No 351(k) application for a biosimilar can be filed for four years after the date the reference product was first licensed for approval.[11] Reference products also have 12 years of marketing exclusivity before approval of a biosimilar can be made effective.[12] These periods of exclusivity can be extended an additional six months for pediatric exclusivity if the RPS completes FDA-requested pediatric studies within the allotted time frame, and the FDA completes its review and accepts the study report more than nine months before the original exclusivity would expire.[13] Reference products may be separately entitled to a seven-year period of "orphan drug" exclusivity for an approved indication for treating a condition affecting fewer than 200,000 in the United States (or more but with no hope of recovering costs).[14]

Biosimilar vs. Generic Version of Conventional Drug

While biosimilars are sometimes described as generic versions of biologics, there are important differences between biosimilars and generic versions of conventional drugs. Because of the complexity and biosynthetic preparation, biosimilars are not exact copies of the reference active component and require additional testing to demonstrate similarity than for conventional generic drugs.[15] As a result, biosimilars are significantly more expensive and time-consuming to develop than generic small molecule drugs.[16] Marketing costs are also expected to be higher for biosimilar products, at least for those that are not granted the interchangeable stamp.

In addition, unlike for generic drugs, biosimilars have their own proprietary and non-proprietary names. The FDA has issued guidances requiring the non-proprietary name to be a combination of the core name of the reference product and a suffix of four lowercase letters that is devoid of meaning.[17] In general, biologics are protected by larger patent portfolios than small molecules. These patent portfolios may include patents covering the active component itself, variations thereof, manufacturing processes, formulations, and methods of treatment. Unlike conventional drugs, for which the RPS has the opportunity to identify patents covering a product or an approved method of use by way of FDA Forms 3542/a,[18] which the FDA then publishes in the FDA's Orange Book,[19] there is no equivalent listing mechanism for biologics. This can make it difficult to determine how many and what patents an RPS could potentially assert against a 351(k) applicant.

Biosimilar Litigation

The BPCIA contains a framework that contemplates various exchanges of information between the RPS and the 351(k) applicant and two rounds of patent litigation, often referred to as the patent dance. The U.S. Supreme Court confirmed that this patent dance is not required, and the 351(k) applicant can choose to opt out of the various exchanges.[20] This gives the 351(k) applicant control over how and when litigation transpires.

Patent Dance: Phase I

Section 271(e)(1) of the Patent Act[21] excludes from patent infringement liability certain actions taken in connection with seeking approval from the FDA to market a new drug or biologic. As discussed below, additional provisions of 35 U.S.C.S. § 271(e) set forth conditions of constructive patent infringement following submission of an aBLA. Prior to satisfaction of conditions set forth in Section 271(e), however, no case or controversy may exist supporting a declaratory judgment action.[22]

351(k) Applicant Provides aBLA

The first phase of litigation may be initiated when, within 20 days of the aBLA being accepted for review, the 351(k) applicant provides the aBLA to the RPS and "such other information that describes the process or processes used to manufacture" the proposed biosimilar or interchangeable.[23] Disclosure of the aBLA is limited to designated outside counsel and one in-house attorney who do not engage in patent prosecution "relevant or related to the reference product."[24] If the aBLA is timely provided, neither the RPS nor the 351(k) applicant may file a declaratory judgment action until the 351(k) applicant provides notice of commercial marketing.[25]

RPS Provides Patent List

Within 60 days of receipt of the aBLA, the RPS provides to the 351(k) applicant a list of patents for which the RPS believes a claim of patent infringement could reasonably be asserted "if a person not

8. 42 U.S.C.S. § 262(i)(3).**9.** *See* National Conference of State Legislatures, *State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars* (Oct. 22, 2018) (http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx). **10.** 42 U.S.C.S. § 262(k)(6). **11.** 42 U.S.C.S. § 262(k)(7)(B). **12.** 42 U.S.C.S. § 262(k)(7)(A). **13.** 42 U.S.C.S. § 262(m). **14.** 21 U.S.C.S. §§ 360bb, 360cc. **15.** *See* U.S. Food & Drug Administration, *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* (Apr. 2015) (https://www.fda.gov/downloads/drugs/guidances/ucm291128.pdf); *Considerations in Demonstrating Interchangeability With a Reference Product* (Jan. 2017) (https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537135.pdf). **16.** *See* Pfizer, *Let's See How Biosimilars Are Developed* (https://www.pfizerbiosimilars.com/biosimilars-development) (estimated at $100 million over five to nine years for development of a biosimilar versus $1–2 million over two years for a conventional generic drug); Erwin A. Blackstone & P. Fuhr Joseph, *The Economics of Biosimilars*, 6(8) AMER. HEALTH & DRUG BENEFITS 469–78, 470–71 (2013) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031732/). **17.** *See* U.S. Food & Drug Administration, Nonproprietary Naming of Biological Products (Jan. 2017) (https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf). **18.** https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048345.pdf. **19.** https://www.accessdata.fda.gov/scripts/cder/ob/. **20.** Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1669, 1673–74 (2017). **21.** 35 U.S.C.S. § 271(e)(1). **22.** *See* Sandoz Inc. v. Amgen Inc., 773 F.3d 1274, 1278–80 (Fed. Cir. 2014). **23.** 42 U.S.C.S. § 262(l)(2). **24.** 42 U.S.C.S. § 262(l)(1)(B). **25.** 42 U.S.C.S. § 262(l)(9)(A).

licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological" product that is the subject of the 351(k) application as well as a list of such patents that the RPS "would be prepared to license."[26] Failure to timely list a patent by the RPS means the RPS cannot sue the 351(k) applicant on that patent under 35 U.S.C. S. § 271(e). Thus, the RPS may not be able to sue on that patent until the 351(k) applicant commercially markets.[27] Given the relatively short notice, to the extent possible, the RPS should be prepared with its patent lists in advance of the four-year date on which an aBLA may be submitted. Likewise, the RPS should also include patents that could potentially be infringed; the U.S. Court of Appeals for the Federal Circuit found no Rule 11 (Fed. R. Civ. P. 11) problem listing patents for which additional discovery might be needed beyond the aBLA to determine potential infringement.[28]

351(k) Applicant Provides Counter-List and Detailed Statement

Within 60 days of receiving the patent lists, the 351(k) applicant "may" provide to the RPS a list of patents that the 351(k) applicant believes could be reasonably asserted by the RPS pursuant to 42 U.S.C.S. § 262(l)(3)(A), and "shall" provide (1) for each of the patents identified by the RPS and the 351(k) applicant, a detailed statement on a claim-by-claim basis of the factual and legal bases for any assertion of invalidity, unenforceability, and noninfringement; and (2) a response regarding each patent identified by the RPS for potential licensing.[29] Within 60 days of receiving these materials from the 351(k) applicant, the RPS provides a detailed statement on a claim-by-claim basis of the factual and legal bases for allegations of infringement and responses to the assertions of validity and unenforceability.[30] Statements in these letters may be party admissions, and therefore great care should be taken in drafting.[31]

The Parties Negotiate

After the exchange of patent lists and detailed statements, the parties then negotiate which patents should be the subject of immediate infringement litigation.[32] If the parties cannot reach an agreement within 15 days, the 351(k) applicant tells the RPS the number of patents that the applicant will provide, and the parties subsequently exchange respective lists with that number of patents for immediate litigation.[33] This gives the 351(k) applicant significant control over the scope of phase I litigation. If the 351(k) applicant lists no patents, the RPS is still permitted to list a single patent.[34] Given the relatively short time frame for negotiation, both parties should be prepared as early as practicable with strategies regarding which patents to litigate at this stage.

26. 42 U.S.C.S. § 262(l)(3)(A). **27.** 35 U.S.C.S. § 271(e)(6)(C). **28.** Amgen Inc. v. Hospira, Inc., 866 F.3d 1355, 1362–63 (Fed. Cir. 2017). **29.** 42 U.S.C.S. § 262(l)(3)(B). **30.** 42 U.S.C.S. § 262(l)(3)(C). **31.** *See* Amgen Inc. v. Apotex Inc., 2017 U.S. App. LEXIS 22638, at *9 (Fed. Cir. Nov. 13, 2017). **32.** 42 U.S.C.S. § 262(l)(4). **33.** 42 U.S.C.S. § 262(l)(5). **34.** 42 U.S.C.S. § 262(l)(5)(B)(ii)(II).

> Inter partes reviews (IPRs) against patents covering biologics have increased significantly since 2016, but still represent a relatively small percentage of IPRs on biopharmaceutical patents...of those IPRs against biologic drug patents that have gone to a final written decision, more than 70% have found at least some claims unpatentable.

RPS Brings Suit

Within 30 days of agreeing to a list of patents for immediate resolution or within 30 days after the exchange of lists when no agreement can be reached, the RPS shall bring an action for patent infringement with respect to each implicated patent.[35] Section 271(e)(2)(C)(i) of the Patent Act makes the filing of the 351(k) application an artificial act of infringement of these patents. Phase I litigation may result in injunctive relief or damages due to any commercial manufacture, use, offer for sale, or sale within the United States not protected by the safe harbor provision of 35 U.S.C.S. § 271(e)(1).[36] For example, a jury in the District of Delaware recently awarded $70 million in damages for patent infringement even though the biosimilar had not yet been approved by the FDA because the jury found the manufacture of the product was not "solely for uses reasonably related to" seeking FDA approval.[37] At the time of writing, motions for judgment as a matter of law were pending. 351(k) applicants that manufacture product or store product in the United States should be ready to demonstrate a nexus to FDA approval.

Injunctive relief is granted ("the court shall order a permanent injunction") for any patents on which the RPS is successful during phase I litigation where the reference product has time remaining in the 12-year period of market exclusivity.[38] Failure to file an infringement suit within the applicable 30-day window (see above) limits a successful RPS to a reasonable royalty; no injunctive relief will be available.[39]

For patents that issue or are exclusively licensed after the first exchange of lists, the RPS has 30 days to provide a supplemental list with these patents to the 351(k) applicant.[40] These later issued patents will be included in second phase of litigation.[41]

Patent Dance: Phase II

The second phase of litigation is initiated when the 351(k) applicant provides notice of intended commercial marketing, which must occur at least 180 days before marketing first occurs.[42] This notice can be provided even prior to FDA approval.[43] After receiving that notice, the RPS "may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement" of any patent included in the lists of patents provided by the RPS and 351(k) applicant in the previous exchanges that were not the subject of phase I litigation[44]. Because the 351(k) applicant is not statutorily required to notify the RPS of the actual launch date, the RPS has little choice but to make best use of the 180-day window post-notice to file any infringement action and seek injunctive relief.

No Patent Dance

The 351(k) applicant is not required to provide the aBLA to the RPS, and the RPS cannot compel its production.[45] If the aBLA is not provided, 35 U.S.C.S. § 271(e)(2)(c) makes the filing of the 351(k) application an artificial act of infringement "for a patent that could be identified" by the RPS in phase I of the patent dance, and 42 U.S.C.S. § 262(l)(9)(C) permits declaratory judgment claims "of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."[46] If the 351(k) applicant initiates phase I by providing the aBLA but then fails to take an action required in phase I of the patent dance or to provide notice of commercial marketing, the RPS but not the 351(k) applicant "may bring" an action for declaratory judgment "of infringement, validity, or enforceability of any patent" included on the RPS's initial list of patents.[47] Thus, if the 351(k) applicant fails to comply with the patent dance procedure, the RPS gains significant control over the scope and timing of litigation.

Biosimilars and Inter Partes Review

The America Invents Act (AIA) created the inter partes review (IPR) as a quicker and less expensive avenue for third parties to challenge the validity of patents on 35 U.S.C.S. §§ 102 or 103 grounds based on prior art patents or printed publications in a trial proceeding conducted before a panel of administrative patent law judges.[48] The AIA also created procedurally similar post-grant review proceedings that allow third parties to challenge patents issuing under the new first-to-file system (effective priority date on or after March 16, 2013) within nine months of issuance, which can include additional grounds of invalidity not available in IPRs such as lack of written description or enablement.[49] IPRs are generally completed within 18 months of initial petition, with a six-month period for the Patent Trial and Appeal Board (PTAB) to decide whether to institute a trial if the patent owner files a preliminary response to the petition and a one-year period to issue a final written decision.[50]

Patent challengers can only file an IPR if they have not already filed a declaratory judgment action challenging the validity of the patent.[51] However, if the patent owner sues the patent challenger for patent infringement, there is a one-year window for the challenger to file an IPR.[52] 351(k) applicants should consider early whether it is preferable to file an IPR instead of seeking a declaration of invalidity.

In an IPR, the patent is not presumed valid, and accordingly, the challenger has the burden of proving unpatentability by a mere preponderance of the evidence, instead of the clear and convincing evidence standard of district court litigation.[53] At the time of writing, in contrast to the *Phillips* claim construction standards that apply in district court litigation, the PTAB applies the broadest reasonable construction in light of the specification.[54] The standards of construction, however, may become aligned.[55]

In further contrast to district court litigation, the patent owner in an IPR has an opportunity to amend the challenged claims by canceling them or proposing substitute claims.[56] The U.S. Court of Appeals for the Federal Circuit sitting en banc recently held that under the current rules, the burden of proving patentability does not rest with the patent owner, upending a standard that had been relied on to deny claim amendments.[57] It remains to be seen whether this burden shifting will result in more successful claim amendments.

It has been common for multiple IPRs to be filed against single patents covering biologics.[58] The PTAB, however, has warned petitioners against filing serial or follow-on petitions challenging patents that have already been challenged in a previously unsuccessful IPR.[59] Such petitions may be denied institution under 35 U.S.C.S. §§ 314(a), 325(d), and 37 C.F.R. § 42.108(a) to prevent petitioners from waiting to file the best challenges until they receive guidance from the PTAB and/or the patent owner's preliminary response. It is therefore a risk to file a single IPR, wait to see if it is instituted, and then file a subsequent IPR on the same patent with different art without having an explanation as to why the subsequent IPR could not have been brought sooner.

Unlike Article III court litigation, there is no standing requirement to bring an IPR challenge.[60] Accordingly, companies have used IPRs early in an attempt to knock-out patents before there would be declaratory judgment jurisdiction. While IPRs appear to be a convenient and easier way to invalidate a patent, there are risks for the petitioner. If unsuccessful at the final written decision stage, the petitioner is estopped from making further arguments in another IPR or district court proceeding that were already raised or could have been raised during the first IPR trial.[61] An unsuccessful patent owner also faces estoppel from taking action inconsistent with an adverse judgment, including seeking a patent claim that is "not patentably distinct" from a finally refused or canceled claim.[62]

35. 42 U.S.C.S. § 262(l)(6). 36. 35 U.S.C.S. § 271(e)(4). 37. Amgen Inc. v. Hospira, Inc., 232 F. Supp. 3d 621 (D. Del. 2017). 38. 35 U.S.C.S. § 271(e)(4)(D). 39. 35 U.S.C.S. § 271(e)(6)(B). 40. 42 U.S.C.S. § 262(l)(7). 41. *Id*. 42. 42 U.S.C.S. § 262(l)(8). 43. *Sandoz Inc*., 137 S. Ct. at 1677; Amgen Inc. v. Apotex Inc., 827 F.3d 1052, 1054–55 (Fed. Cir. 2016). 44. 42 U.S.C. § 262(l)(8)(B). 45. *Sandoz Inc*., 137 S. Ct. at 1674–77; Amgen Inc. v. Sandoz Inc., 877 F.3d 1315, 1327–30 (Fed. Cir. 2017). 46. 42 U.S.C.S. § 262(l)(9)(C). 47. 42 U.S.C.S. § 262(l)(9)(B). 48. 35 U.S.C.S. §§ 311–319.

49. 35 U.S.C.S. §§ 321–329. 50. 35 U.S.C.S. § 314(b); 42 37 C.F.R. § 42.100(c). 51. 35 U.S.C.S. § 315(a). 52. 35 U.S.C. S.§ 315(b). 53. 35 U.S.C.S. §§ 282(a), 316(e). 54. 37 C.F.R. § 42.100(b); Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc). 55. *See* 83 Fed. Reg. 21, 221 (May 9, 2018). 56. 35 U.S.C.S. § 316(d). 57. Aqua Products v. Matal, 872 F.3d 1290, 1296, 1327–28 (Fed. Cir. 2017). 58. *See* Venable LLP, *Biologics HQ*, *Biologic Drug IPR Challenges* (2018) (https://biologicshq.com/stats_entry/biologic-drug-ipr-challenges/). 59. *See*, *e.g*., General Plastic Indus. Co. v. Canon Kabushiki Kaisha, IPR2016-01357, Paper 19 at 16–19 (P.T.A.B. Sept. 6, 2017) (precedential). 60. *See*, *e.g*., 35 U.S.C.S. § 311(a). 61. 35 U.S.C.S. § 315(e). 62. 37 C.F.R. § 42.73(d).

Related Content

For a discussion of the approval process for prescription drugs, see

> **HATCH-WAXMAN ACT FUNDAMENTALS**

RESEARCH PATH: *Intellectual Property & Technology > Patents > Patent Litigation > Practice Notes*

For an overview of the safe harbor provision in the Hatch Watchman Act, see

> **HATCH-WAXMAN SAFE HARBOR CHECKLIST**

RESEARCH PATH: *Intellectual Property & Technology > Patents > Patent Litigation > Checklists*

For practical guidance on seeking inter partes review, see

> **INTER PARTES REVIEW — DRAFTING AN IPR PETITION**

RESEARCH PATH: *Intellectual Property & Technology > Patents > Patent Litigation > Practice Notes*

For information on the requirements and strategic considerations for responding to a petition for inter partes review, see

> **PATENT OWNER'S PRELIMINARY RESPONSE TO A PETITION FOR INTER PARTES REVIEW**

RESEARCH PATH: *Intellectual Property & Technology > Patents > PTAB Proceedings > Practice Notes*

While in at least some circumstances, the Federal Circuit has held that estoppel does not apply to grounds that were not instituted, district courts have split on how narrow the estoppel provision is, and the scope of estoppel has not been clearly established.[63] Further, to seek review of a PTAB decision upholding a patent claim on appeal to the Federal Circuit, Article III standing must be demonstrated.[64] In a pending case before the Federal Circuit (No. 17-1694), Momenta Pharmaceuticals is seeking to establish standing in its appeal of a final written decision finding challenged claims patentable where no aBLA has been filed because Momenta had spent money developing a biosimilar to Orencia®. However, there is a risk that an unsuccessful early petition will leave the challenger unable to seek relief from the Federal Circuit and estopped from making similar arguments in later litigation.

IPRs against patents covering biologics have increased significantly since 2016, but still represent a relatively small percentage of IPRs on biopharmaceutical patents.[65] As of March 31, 2018, the institution rate for biologic drug IPRs was 53%, which is slightly less than the 60% institution rate for IPRs against Orange Book-listed patents and the 62% institution rate for IPRs against biopharmaceutical patents reported by the U.S. Patent and Trademark Office.[66] Of those IPRs against biologic drug patents that have gone to a final written decision, more than 70% have found at least some claims unpatentable.[67] Thus, when instituted, IPR challenges to patents covering biologics have been successful to date. L

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RESEARCH PATH: *Intellectual Property & Technology > Patents > Patent Litigation > Practice Notes*

63. Compare Shaw Indus. Group, Inc. v. Automated Creel Sys., Inc., 817 F.3d 1293, 1300 (Fed. Cir. 2016) with HP Inc. v. MPHJ Tech. Investments, LLC, 817 F.3d 1339, 1347–48 (Fed. Cir. 2016); *see also* Biscotti Inc. v. Microsoft Corp., 2017 U.S. Dist. LEXIS 144164, at *15–21 (E.D. Tex. May 11, 2017) (recognizing differing interpretations by district courts). **64.** Phigenix, Inc. v. Immunogen, Inc., 845 F.3d 1168, 1172–76 (Fed. Cir. 2017). **65.** *See* Venable LLP, *Biologics HQ, Bio/Pharma IPR Petitions Filed by Fiscal Year* (2018) (https://biologicshq.com/stats_entry/bio-pharma-ipr-petitions-filed-fiscal-year/), Venable LLP, *Biologics HQ, IPRs Filed to Date* (2018) (https://biologicshq.com/stats_entry/iprs-filed-as-of-february-28-2018/). **66.** *See* Venable LLP, *Biologics HQ, Institution Outcomes: Biologic and Orange Book Drug IPRs* (2018) (https://biologicshq.com/stats_entry/institution-outcomes-biologic-and-orange-book-drug-iprs/); *see also* U.S. Patent and Trademark Office, *Trial Statistics, IPR, PGR, CBM*, slide 8 (Mar. 2018) (https://www.uspto.gov/sites/default/files/documents/trial_statistics_20180331.pdf). **67.** *See* Venable LLP, *Biologics HQ, FWD Outcomes: Biologic and Orange Book Drug IPRs* (2018) (https://biologicshq.com/stats_entry/fwd-outcomes/).

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Considerations when Marketing Alternative Investment Funds if a "Hard Brexit" Occurs

This article addresses common questions and concerns regarding the marketing of alternative investment funds in the European Economic Area (EEA), should a "hard Brexit" occur. Hard Brexit is a scenario in which the United Kingdom (UK) fully exits the single market and leaves full access to the customs union along with its membership in the European Union (EU). In contrast, a "soft Brexit" would keep the UK's access to the European single market (as part of the EEA) and remain within the EU customs union, meaning that there would be no border checks for UK exports, among other benefits.

THE ALTERNATIVE INVESTMENT FUND MANAGERS DIRECTIVE (Directive 2011/61/EU) of the European Parliament and of the Council of June 8, 2011, on Alternative Investment Fund Managers[1] currently permits EEA-domiciled alternative investment funds (EEA AIFs) to be marketed throughout the EEA to EEA-domiciled or incorporated professional clients on a passported basis, but only if the alternative investment fund manager (AIFM) of the alternative investment fund (AIF) is fully regulated as an AIFM by an EU regulator. Note that the third-country passports under AIFMD for non-EEA AIFs and/or non-EEA AIFMs have not been activated yet.

A non-EEA fund manager (such as a U.S. manager) that is not regulated in the EEA as an AIFM typically actively promotes (as opposed to relying on reverse solicitation) its EEA-domiciled AIFs to EEA professional investors in one of three ways:

1. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32011L0061.

(1) Registering its AIFs under the national private placement regime (NPPR) of each target EEA country

(2) Appointing an AIFM Platform, which means that an EEA regulated AIFM is appointed by the EEA AIF with the U.S./non-EEA manager ceasing to be the AIFM (which would enable the AIF to be passported throughout the EEA) and either (i) managing the AIF's assets on a delegated basis or (ii) providing advice to the EEA AIFM, which then makes investment decisions

(3) By forming an EEA-co-owned or subsidiary entity which itself is fully regulated as an EEA AIFM by the EEA regulator of the country in which it is formed (the Subsidiary Model)

If Brexit were to occur without a formal withdrawal agreement or transitional arrangements being put into place by the remaining EEA states in respect of the UK, then UK AIFMS and UK AIFs will lose their passporting rights in respect of the EEA (and of course the reverse would apply). This will impact non-EEA managers using the AIFM Platform and Subsidiary Models where the AIFMs manage EU AIFs that are passported into or out of the UK.

Consultation and Proposed Interim Legislation on a Hard Brexit

The Treasury laid before Parliament, in July 2018, The EEA Passport Rights (Amendment, etc., and Transitional Provisions) (EU Exit) Regulations 2018 [2] in draft form, which seeks to create a temporary permissions regime (TPR), among other things, for inbound passported AIFMs and AIFs.

The UK Financial Conduct Authority (the FCA) issued a consultation paper[3] on October 10, 2018, which sought responses by December 7, 2018, to its TPR rules, which would apply on a hard Brexit (which would come into force if the UK does not negotiate a withdrawal agreement with the EU before 11:00 p.m. on March 29, 2019, called "exit day" in the draft regulations).

On the legislative front, the UK Treasury under the European Union (Withdrawal) Act 2018 published draft statutory instruments[4] (The Alternative Investment Fund Management (Amendment) (EU Exit) Regulations 2018 (the Draft AIF Regulations) and The Collective Investment Schemes (Amendment etc.) (EU Exit) Regulations 2018 (which seek to amend the UK Alternative Investment Fund Managers Regulations 2013 and UCITS implementation laws respectively)) on October 8, 2018, which would come into force on exit day in a hard Brexit scenario and would repeal the existing EEA passporting regimes.

> On acceptance of a temporary permissions regime (TPR) firm, the Financial Conduct Authority (FCA) will notify that firm of the three-month time period or landing slot by which time it expects to receive a formal FCA authorization application from the TPR firm.

What Does the Temporary Permissions Regime Do?

Without a form of TPR, EEA incoming managers would need to formally apply for and receive FCA authorization on or before exit day to continue conducting UK-regulated activities on and from exit day. The AIF marketing passport will likewise fall away on exit day (as would the national private placement regime requirements under AIFMD as they apply to the UK), so EEA-domiciled AIFs would need to be re-registered by their AIFMs with the FCA under the UK national private placement regime (or receive recognized fund status under Section 272 of the UK Financial Services and Markets Act 2000) prior to that date to enable seamless marketing from exit day.

Broadly, (1) EEA AIFMs may opt into the TPR if they qualify for authorization under the existing passporting regime and notify the FCA of that fact before exit day (more on the notification procedure below); and (2) EEA AIFMs may opt into their (i) EEA-domiciled AIFs and (ii) third-country AIFs into TPR, provided that EEA AIFs are eligible to be marketed via the existing AIFMD passport into the UK, or the third-country AIF is marketed under Article 36 of AIFMD (already registered under the UK national private placement regime) prior to exit day. By definition then, the TPR does not apply to UK-authorized funds (UK UCITS or UK non-UCITS retail schemes).

The effect from 11:00 p.m. on exit day on firms that opt into the TPR is that they will be treated as being authorized by the FCA and so (1) the FCA will supervise those TPR firms, and (2) UK laws and regulations will apply to those firms together with UK-implemented EU directives which are currently enforced by their home state regulator (including regulatory notifications and other obligations), which contrasts with the existing passporting regime where the compliance burden predominantly falls on the home state regulator of the incoming EEA AIFM. An EEA AIFM that opts into the TPR will be

2. https://www.legislation.gov.uk/ukdsi/2018/9780111172421/contents. 3. Consultation Paper CP18/29: Temporary permissions regime for inbound firms and funds, https://www.fca.org.uk/publications/consultation-papers/cp18-29-temporary-permissions-regime-inbound-firms-and-funds. 4. https://www.gov.uk/government/publications/draft-eu-exit-sis-for-investment-funds-and-their-managers

able to market its AIFs in the UK without having the financial promotion approved by an FCA-authorized firm.

Firms opting into the TPR should note that the FCA Principles for Business will apply to TPR firms in full (aside from Principle 4, financial prudence, which deals with capital adequacy) because from 11:00 p.m. on exit day, there will be no home/host state regulatory split. Firms that have not previously been authorized by the FCA should note in particular that Principle 11 requires all firms to be open and cooperative with the FCA and are required to notify the FCA of any matter or issue of which the FCA would reasonably expect notice, regardless of whether there is a specific rule, for example, which requires notification to a home state regulator. TPR firms will need to adjust their compliance and reporting procedures accordingly.

How Long Will the TPR Run and What Are Landing Slots?

The TPR is intended to run for three years (which may be extended by the Treasury); however, in practice, the actual period will vary. On acceptance of a TPR firm, the FCA will notify that firm of the three-month time period or landing slot by which time it expects to receive a formal FCA authorization application from the TPR firm. Given that the first landing slot period is envisaged to be September–December 2019, the actual transitional period will differ between firms depending on their landing slots.

Similarly, for AIFs the FCA will notify the AIF of its landing slot for submission of an application for recognized fund status under FSMA Section 272. The alternative for the AIF will be to register under the UK national private placement regime, which may not give it access to the same categories of investor.

The FCA expects to enforce the landing slots, so it is likely that it will have the power to remove a firm or AIF from the TPR if that firm or AIF does not make its application during its allocated landing slot. If a firm is refused authorization by the FCA, then its TPR permissions will terminate.

When and How Will Notification Be Made?

When? The FCA will open the notification window in early 2019, which will terminate on exit day. If a firm or AIF does not make a notification on time, it will lose its right to opt into the TPR.

How? The FCA envisages that firms opting in will make the notification for a temporary permission by using the FCA Connect system and will in due course publish a guide to the notification process on its website.

Can a Firm in the TPR Vary Its FCA Permissions?

No, the firm would have to apply for full authorization and include the varied permission as part of its application. Firms applying for the TPR will need to take care in determining which permissions they will notify the FCA of when opting into the TPR. Similarly, TPR firms will not be able to vary the categories of investor from those for which they had permission to market before exit day.

How Does This Apply to Umbrella Funds?

Only those umbrella funds and their specific sub-funds that received a passport before exit day and that opted into the TPR will be eligible to continue marketing after exit day. New sub-funds of an existing umbrella structure or new stand-alone funds will need to be registered under the UK national private placement regime or apply for recognized fund status.

What about Marketing UK AIFs to the EU?

Without a similar regime to the TPR or a general transition period granted by the EU, UK AIFMs will lose their right to passport UK AIFs and EEA AIFs into the EEA while UK AIFMs will also lose their AIFMD management passport.

Non-EEA managers using the AIFM Platform Model or Subsidiary Model should therefore consider what impact a hard Brexit would have on the marketing of their AIFs. For example, assuming no EEA transition period or TPR equivalent, a non-EEA manager using a UK AIFM Platform Model or a UK Subsidiary would not be able to market EEA AIFs managed by the UK Platform AIFM on a passported basis from exit day. It may also be the case that the UK AIFM Platform or Subsidiary AIFM would lose the right to manage EEA AIFs from exit day.

UK AIFMs marketing EEA AIFs into the UK will be able to avail themselves of the TPR.

What about UCITS?

This article has focused on AIFs; however, it should be noted that a similar TPR regime applies to UCITS.

Assuming no transition period or EEA TPR equivalent, EEA UCITS will become AIFs, and, therefore, if they do not avail themselves of the TPR, they will be subject to NPPR/recognized fund applications to market into the UK (and will lose the automatic right to market to UK retail investors). The same mechanisms apply as for AIFs (so future sub-funds or funds/sub-funds not eligible to passport prior to exit day will not be eligible under the TPR).

Assuming no EEA equivalent to the TPR, UK UCITS will become AIFs on exit day while UK UCITS managers will cease to have the right to perform the UCITS management function in relation to EEA UCITS.

UK UCITS, UK-authorized Non-UCITS Retail Schemes, and UK Qualified Investor Schemes do not need to opt into the TPR.

Conclusion

Given impending Brexit, it is unlikely that the EU will activate the third-country AIF/AIFM management passports anytime soon, so non-EEA fund sponsors will continue to consider forming EEA-regulated AIFM subsidiaries or using EEA-regulated AIFM platforms to access the EU market.

Non-EEA managers who do not access the EEA market but do access the UK market may be less concerned as they will continue to market their AIFs to UK investors under the UK national private placement regime or, where appropriate, will apply for UK recognized fund status. L

Related Content

For an overview of the Alternative Investment Fund Managers Directive (AIFMD), see

> AIFM DIRECTIVE

RESEARCH PATH: *Private Equity & Investment Management > Fund and Manager Compliance > Practice Notes*

For further information on the AIFMD private placement regime, see

> AIFMD PRIVATE PLACEMENT REGIME: PROMOTION OF NON-EU FUNDS IN THE EUROPEAN UNION

RESEARCH PATH: *Private Equity & Investment Management > Fund Marketing > Practice Notes*

For a discussion of issues faced by new funds in raising capital, see

> PRIVATE EQUITY FUND LAUNCH CONSIDERATIONS

RESEARCH PATH: *Private Equity & Investment Management > Private Fund Formation > Private Equity Fund Formation > Practice Notes*

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RESEARCH PATH: *Private Equity & Investment Management > Trends and Insights > Practice Notes*

Data Analytics in the Insurance Industry

Data analytics is at work every time Amazon tells a customer he or she may want to buy a product, each time Facebook recommends a resource page, and when a life insurance company assesses risk and set rates for potential policyholders. It's an area governed by layers of laws and rules that are impacting the highly regulated insurance industry in a significant way.

THIS ARTICLE PROVIDES PRACTICAL GUIDANCE FOR ATTORNEYS on managing data analytics in the insurance industry. It focuses on data related to complaints, claims, call centers, privacy, and security. Rules and regulations on how companies need to keep specific types of data are also discussed.

Rules and Regulations

The Health Insurance Portability and Accountability Act, the New York Department of Financial Services Rule Cyber Security Rule, and the General Data Protection Regulation speak to an insurer's obligation to make sure that data is protected from cybersecurity threats and that breaches of data are properly and timely reported. Specific types of data that are governed by these rules include protected health information (PHI), personally identifiable information (PII), and personal financial information (PFI). These rules and regulations do not speak to the collection of data or how an insurer may use the data.

Although legislators and regulators have addressed these issues, they are beyond the scope of this article. Insurance companies analyze their data and look for ways to provide a better customer service experience, streamline processes, create efficiencies, reduce claims and complaints, and detect and reduce fraud.

A consistent, repeatable process should be outlined and defined to clearly articulate the process for collecting data and to help ensure data that is collected may be accurately measured, analyzed, and assessed. If all employees charged with collecting and reporting on data are not following the same process and data is not collected on a regular basis and for a specified period of time (e.g., quarterly or monthly), then measuring and analyzing the data will not work. Specificity, clear definitions, and a consistent, repeatable process are imperative.

A centralized reporting system and a complaints policy that clearly defines a complaint and complainant are essential, especially if you are looking to provide metrics on complaints data.

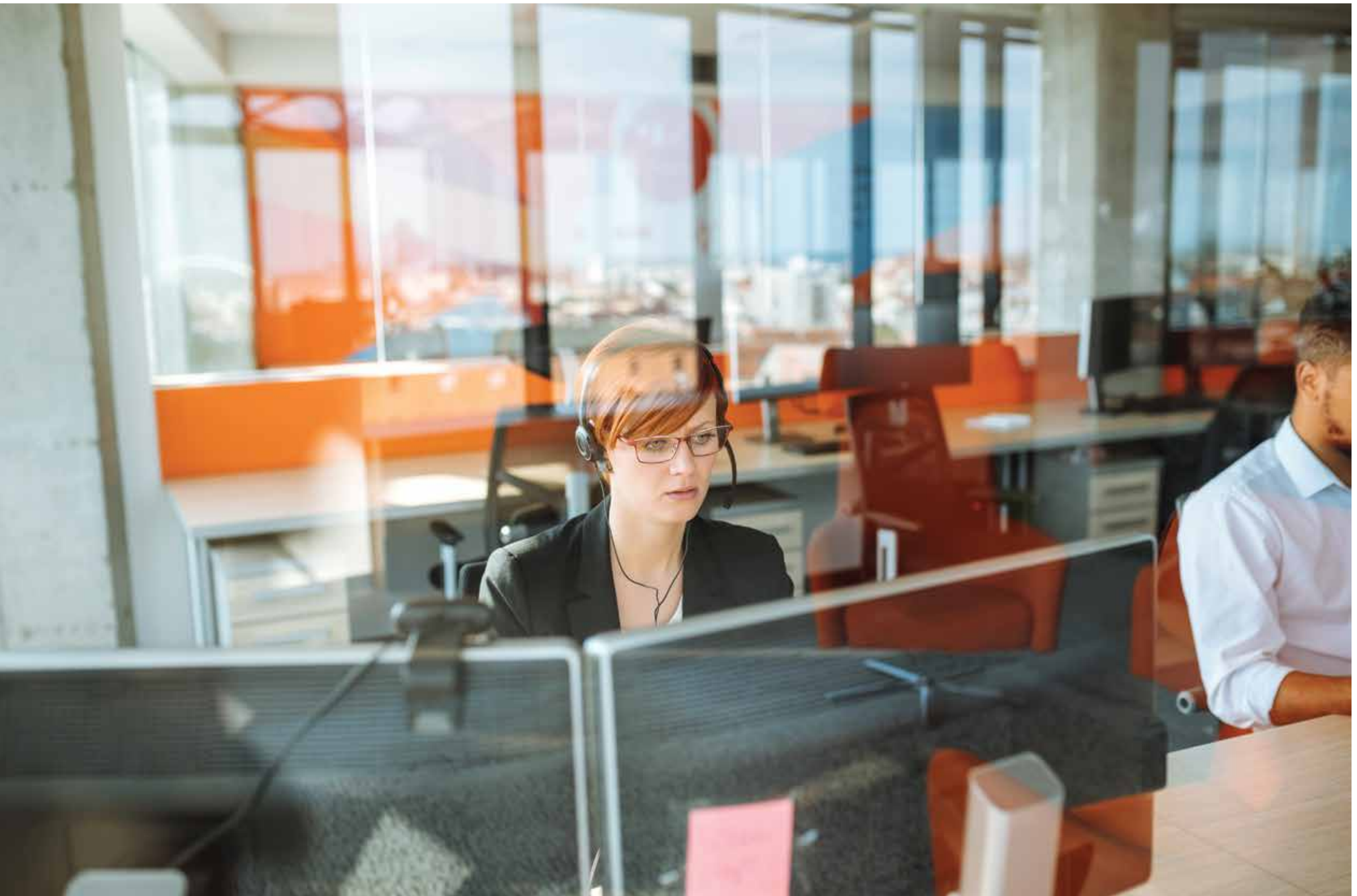
Complaints

State rules and regulations require authorized insurance companies to maintain a complaints policy and procedure and designate a department within the company to manage complaints. Management of customer complaints by the designated department should also include management of complaints data. Analyzing complaints can speak to broader issues and concerns with respect to company processes, complaint response timeliness, claim denials, and overall customer service and satisfaction.

The most effective way to analyze complaints data is by outlining a clear and consistent repeatable process.

A complaint must be defined and then universally agreed upon by all business areas. All communications meeting the definition of a complaint are then reported using a centralized database. Database reports are generated regularly using specific categories. The results are reviewed and analyzed, helping to identify trends that may provide insight into the company, its policies, and procedures.

Adding a data analyst proficient in Structured Query Language (SQL) will help to assist the department in organizing and outlining how complaints data will be gathered, reviewed, and analyzed. SQL is a programming language used to run analytical queries and manage relational databases.



Categories for organizing complaints data for review and analysis include:

- Amount of time since complaint was logged
- Age of complainant (if available)
- Gender of complainant (if available)
- State
- Region
- Line of business
- Agent/broker
- Claim denials
- Claim appeals
- Origin of complaint:
  - Executive complaints
  - Department of Insurance
  - Website inquiries
  - Social media
  - Call centers

Analyzing these fields may help identify trends in the way the company handles complaints in addition to targeting where greater resources may need to be provided. Examples of discoveries made during data analysis can include:

- A decrease in call center complaints and an increase in social media complaints may mean the company needs to dedicate more resources to the team responding to social media complaints.
- A large number of complaints from a specific state may speak to an issue with a policy issued in that state.
- A number of complaints from complainants of a certain age may speak to a policy coverage issue related to that demographic.

A centralized reporting system and a complaints policy that clearly defines a complaint and complainant are essential, especially if you are looking to provide metrics on complaints data. Analyzing data and providing metrics without a centralized approach and clear policy will not add value and will not provide accurate data or reliable insights.

In addition to reviewing and analyzing customer complaints, you should also look at internal complaints received through human resources (HR) and through an ethics hotline and/or portal. HR complaints should be centralized with a policy on reporting HR complaints. HR complaints should be categorized by fields including age, gender, nature of the complaint including harassment, and employee terminations. A series of complaints related to a specific individual may speak to employee behavior that violates company policy.

A policy on sexual harassment and a system for reporting such complaints is essential. Analyzing that data may speak to broader concerns with the company culture. The data may only be effectively analyzed if the system for reporting this data is consistent and repeatable.

Claims

If you would like to measure claim denials and appeals, a centralized policy for reporting claim denials and appeals should be established. Claim denials and appeals may be categorized by:

- State
- Geographic region
- Line of business
- Reason for claim denial:
  - Coverage policy denial
  - Failure to timely appeal

These are just a few of the categories the claims team may wish to use for collecting and analyzing data. For this data to be properly scrubbed, reviewed, and analyzed, the process for collecting and reporting the claims data must be consistent and repeatable. Adding a data analyst proficient in SQL will assist the department in organizing and outlining how claims data will be gathered, reviewed, and analyzed.

Examples. Many claim denials in a specific geographic area over a certain period of time may speak to a coverage concern (e.g., was a policy incorrectly issued). Many complaints related to how the claim was handled may speak to the claims analyst's ability and knowledge. This may prompt the company to look at its training program and perhaps provide additional training and education to ensure claims analysts understand the policy, coverage, and how to adjust claims.

Call Centers

Call center employees should be trained, and data received through the call center should be centralized and collected consistently and repeatedly. Call center employees must operate under the same definitions and processes. Call center data may be categorized in several ways including by:

- State
- Geographic region
- Customer service representative
- Nature of the call

Adding a data analyst proficient in SQL will assist the department in organizing and outlining how call center data will be gathered, reviewed, and analyzed.

Examples. If a large number of calls are reported shortly after the new year and related to the issuance of a new policy, the calls may speak to a processing or coverage error. Repeated calls regarding a customer call center representative may speak to the call center representative's professionalism and/or lack of product understanding. Both scenarios afford the company an opportunity to address the expressed concerns before the matter gains external traction—perhaps preventing a matter from trending and thus mitigating company reputational harm.

Privacy

A privacy breach is the loss of, unauthorized access to, or disclosure of personal information. Privacy breaches occur when personal information is lost, stolen, or inadvertently shared. A privacy breach can also happen because of faulty business procedures or operational breakdowns. Like the processes outlined for complaints and call centers, privacy data reporting should follow a consistent and repeatable process. Questions you should ask include:

- What is the company's privacy-incident response plan?
- Is a privacy incident clearly defined?
- Is a privacy breach clearly defined?
- Do employees know and understand when to advise of a privacy incident or privacy breach?
- Is the company operating under a set of clearly defined privacy definitions, protocols, and processes?

Collecting privacy data consistently and repeatedly over a specified period will allow the incidents and breaches to be accurately analyzed and interpreted. Adding a data analyst proficient in SQL will assist the privacy department in organizing and outlining how privacy data will be gathered, reviewed, and analyzed. If a number of reports from a specific region surface, you may be able to assess why the privacy incident or breach occurred and take corrective action quickly. Privacy incidents and breaches should be reported through a centralized repository. The categories for privacy incidents and breaches may include:

- State
- Geographic region
- Line of business
- Type of incident (e.g., misdirected emails or mail)
- Type of breach (e.g., PFI, PHI, PII)

Related Content

For information about responding to complaints, see

> **COMPLAINT RESPONSE**

RESEARCH PATH: *Insurance > Conducting Insurance Company Operations > Practice Notes*

For step-by-step guidance on handling complaints, see

> **COMPLAINT RESPONSE CHECKLIST**

RESEARCH PATH: *Insurance > Conducting Insurance Company Operations > Checklists*

For a discussion of coverage for data breaches, see

> **CYBER INSURANCE AND COVERAGE FOR DATA BREACH RISK**

RESEARCH PATH: *Insurance > Assessing Claims and Coverage > Types of Insurance > Practice Notes*

For information about the regulation of innovation in the insurance industry, including data analytics, see

> **HISTORY OF INSURANCE REGULATION**

RESEARCH PATH: *Insurance > Interacting with Regulators and Responding to Investigations > Secondary Materials*

For forms to use when handling complaints from policyholders, see

> **COMPLAINT INTAKE FORM (CUSTOMER CALLS), COMPLAINT/COMMENT/INQUIRY ACKNOWLEDGMENTS (SOCIAL MEDIA),** AND **COMPLAINT RESPONSE (EMAIL AND US MAIL)**

RESEARCH PATH: *Insurance > Conducting Insurance Company Operations > Forms*

Example. If you received many complaints claiming a breach of PII from the same geographic region and yet there is no indication of any type of systematic error leading to a privacy breach, the breach may be an internal one by a rogue employee. The company may need to look at the security controls around the data and who has access and who should have access to information.

Security

Unlike a privacy breach, which involves personal information, a security breach or security violation is an act from inside or outside an organization that bypasses or contravenes security policies, practices, or procedures. Security incidents should follow the same process for collection of data. Is there a clearly defined policy for reporting security incidents with a clear definition of a security incident? Do employees know where and how to report security incidents? The incidents should be reported on a consistent basis through a centralized repository. Adding a data analyst proficient in SQL will assist the department in organizing and outlining how security data will be gathered, reviewed, and analyzed. Categories for security incidents may include:

- Internal security incident
- External security incident
- Cybersecurity threats
- Fraud

A data analyst should produce reports on the data on a regular basis to allow the security data to be analyzed and assessed.

Conclusion

Data may be used to analyze and assess company policies and efficiencies, company behavior, and patterns of conduct. Clearly drafted data analysis policies can help to ensure that the approach to the collection of data is consistent, thereby yielding data that may be analyzed for trends and broader company issues and concerns. A company best practice is to utilize a data analytics specialist to collate the data and present the findings on an agreed-upon regular basis for further analysis and assessment. Companies may try to standardize collection of data across the company, enabling the company to paint an even broader picture and allowing the company to, over time, follow and address trends.

Attorneys managing data need to understand how data can assist companies in providing greater efficiencies, helping to reduce claims and complaints, detect fraud, and curtail privacy and security incidents. The key is creating a successful program and implementing a consistent repeatable process. Data can only be analyzed and used to create metrics if the process is the same each time and collected on a regular basis. L

RESEARCH PATH: *Insurance > Trends and Insights > Practice Notes*

Managing Data Analytics Checklist

This checklist will help insurance companies manage data analytics related to complaints, claims, call centers, privacy, and security.

Insurers should outline policies and include definitions in each of these areas. A data analyst proficient in Structured Query Language should categorize, collect, and analyze data. Other units must help the analyst understand the business to ensure that the categories, collection, and analyzation of data is accurate and adds value.

Complaints

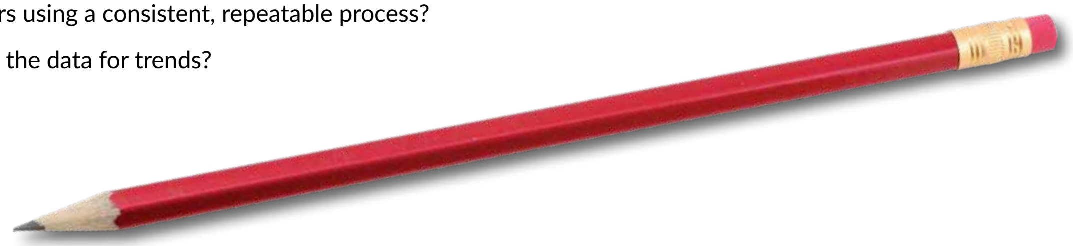
- ✓ Do you have a centralized reporting system for complaints?
- ✓ Do you require that complaints, not centralized, be reported at specified time frames?
- ✓ Have you set up monthly, semiannually, or yearly reporting?
- ✓ Have you clearly outlined categories for complaints data?
- ✓ Are you using a consistent repeatable process for managing complaints?
- ✓ Have you provided training to those individuals charged with managing complaints and collecting data from complaints?
- ✓ Are you reporting on complaints on a regular basis?
- ✓ Are you analyzing the data for trends?

Claims

- ✓ Are claims centralized?
- ✓ If claims have not been centralized, how are you collecting the claims data in order to analyze the data?
- ✓ Have you clearly outlined categories for claims data?
- ✓ Are you using a consistent repeatable process for managing claims?
- ✓ Have you provided training to those individuals charged with managing claims and claims data?
- ✓ Are you reporting on claims findings on a consistent basis?
- ✓ Are you analyzing the data for trends?

Call Centers

- ✓ Are the call center representatives trained?
- ✓ Do they have clear definitions of matters that come in to the call center to ensure information is accurately captured and reported?
- ✓ Are the call centers using a consistent, repeatable process?
- ✓ Are you analyzing the data for trends?



Privacy

- ✓ Have you clearly defined what constitutes a privacy incident and a privacy breach and do employees understand when to report possible privacy violations?
- ✓ Have you clearly outlined categories for collecting and reporting privacy data?
- ✓ Are you using a consistent repeatable process for collecting privacy data?
- ✓ Have you provided training to those individuals charged with managing privacy and privacy data?
- ✓ Are you analyzing the data for trends?

Security

- ✓ Have you clearly outlined categories for security data?
- ✓ Are you using a consistent repeatable process for managing security incidents?
- ✓ Have you provided training to those individuals charged with managing security and security data?
- ✓ Are you analyzing the data for trends?

RESEARCH PATH: *Insurance > Trends and Insights > Checklists*

Timothy Murray MURRAY HOGUE & LANNIS

The Misunderstood but Critically Important Merger Clause

ONE TIME IN AN ARBITRATION, THE PLAINTIFF CLAIMED that my client, the defendant, breached an alleged oral agreement that my client denied entering into. It was undisputed that after the alleged oral agreement, the parties entered into a written contract that dealt with the same subject matter but that omitted the rights and obligations of the supposed oral agreement. The written contract contained a merger clause making it the complete and exclusive statement of the terms of the agreement. The simple legal question for the arbitrators was whether the written contract discharged the alleged earlier oral agreement.

I cross-examined the plaintiff's previous attorney, a seasoned commercial lawyer who was a witness to the supposed oral agreement. When I showed him the merger clause, I'll never forget his reaction.

"That's a standard clause!" he spat out with a scorn dismissing any suggestion that the clause was even remotely pertinent to the dispute. I actually thought I could hear his eyes rolling. He didn't bother to explain why the clause was impertinent—presumably merger clauses are tacked onto contracts solely because clients are impressed by fancy legalese that few people understand.

The arbitrators found the "standard clause" to be conclusive and held that the alleged oral agreement was not binding.

For too many attorneys, these standard clauses are the epitome of boilerplate and unworthy of a second thought. The fact is, they are not only overlooked but often misunderstood, and that's unfortunate because they can be among the most important provisions in the entire contract. Misunderstanding merger clauses can expose our clients to unnecessary and, at times, staggering risk. It's time to demystify them.

The Dreaded Parol Evidence Rule in a Nutshell

We can't clear away the haze surrounding merger clauses without traversing that dark and twisted alleyway of contract law known as the parol evidence rule, a subject most of us thought we'd never have to think about again after the bar exam. The fact is, the parol evidence rule hovers over every contract we enter into even if we dare not speak its name.

And even that name—parol evidence rule—is a puzzle because it's not a rule of evidence at all but of substantive law, and that's the least of its riddles. One of the chief reasons it is so terribly misunderstood is that it is encrusted with an arcane language all its own.

The idea behind it is simple enough. Attorneys and clients alike understand the necessity of reducing most agreements to a final writing that will embody the parties' whole deal. The purpose behind the parol evidence rule "is to prevent parties to a written contract from seeking to vary its terms by reference to side agreements, or tentative agreements reached in preliminary negotiations."[1]

Integration: Partial or Complete?

If the parties intend their writing as a final expression of one or more terms of an agreement, the agreement is said to be integrated—a word that continues to have vitality in the parlance of contract law despite its analytical uselessness. To make matters worse, there are two kinds of integration:

- A partially integrated agreement is intended by the parties as a final expression of some, but not all, terms of their agreement. It discharges prior or contemporaneous agreements that contradict the subsequent writing. However, it does not discharge prior or contemporaneous agreements that contain consistent additional terms that do not contradict the writing.
- A completely integrated agreement is intended by the parties as a complete and exclusive statement of the terms of the agreement. Like partially integrated agreements, it discharges any prior or contemporaneous agreements that contradict the writing. Unlike partially integrated agreements, it also discharges any prior or contemporaneous agreements that are within the scope of the agreement—even consistent additional terms that don't contradict the writing are excluded.[2]

If the alleged prior or contemporaneous oral agreement contradicts the terms of the subsequent written contract, the prior oral agreement is inadmissible regardless of whether the written agreement is partially or completely integrated. The difficult cases—the ones that erupt into litigation—are those where there is no contradiction between the prior oral agreement and the subsequent written contract. Determining whether the prior oral agreement is admissible hinges on whether the written contract is completely or partially integrated. But how do courts make this determination?

Courts parrot various tests to decide whether a writing is partially or completely integrated, but the dominant one is the natural omission test: would reasonable parties in this situation naturally and normally include the terms of the prior oral agreement in the written contract? If so, the written agreement is completely integrated, and the prior oral agreement is inadmissible. If not, the written agreement is partially integrated, and the prior oral agreement is admissible.[3]

For contracts for the sale of goods, the official comments to the Uniform Commercial Code (UCC) suggest a variation of the natural omission test: the subsequent written agreement is completely integrated if the prior oral agreement "would certainly have been included in the" subsequent writing.[4] This is a more stringent

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1. Herzog Contracting Corp. v. McGowen Corp., 976 F.2d 1062, 1070 (7th Cir. 1992) (Posner, J.). 2. *See, e.g.*, Restatement (Second) of Contracts §§ 210, 213, 215, and 216 (1981). 3. *See, e.g.*, 1-25 Corbin on Contracts Desk Edition § 25.06[4] (2017). *See also* Restatement (Second) of Contracts § 216 (1981). 4. U.C.C. § 2-202, cmt. 3. *See, e.g.*, Druckzentrum Harry Jung GmbH & Co. KG v. Motorola Mobility LLC, 774 F.3d 410 (7th Cir. 2014).

> Merger clauses—sometimes called integration or zipper clauses—are contractual provisions stating in all sorts of different ways "that there are no representations, promises or agreements between the parties except those found in the writing."

standard than the common law test—it means that if the written contract is governed by the UCC, it is more difficult to find that it is completely integrated, and it is more likely that the prior oral agreement will be admissible. This is consistent with the UCC's progressive Corbin-esque philosophy.

The parol evidence rule is sometimes mistakenly regarded as an aid to interpreting contracts. It is nothing of the kind. The parol evidence rule "only determines which terms of the agreement a court will deem to constitute 'the contract' between the parties. It is not a rule of interpretation. Rather, it defines the subject matter of interpretation."[5]

Merger Clauses

How do so-called merger clauses fit into all this? Merger clauses—sometimes called integration or zipper clauses—are contractual provisions stating in all sorts of different ways "that there are no representations, promises or agreements between the parties except those found in the writing."[6]

A merger clause can act as a sort of silver bullet that automatically transforms a partially integrated agreement into a completely integrated agreement. Including a merger clause in the contract is "likely to conclude the issue whether the agreement is completely integrated."[7] This means that with a merger clause, "[c]onsistent additional terms may then be excluded even though their omission [from the written agreement] would have been natural in the absence of such a clause."[8] As one court put it: "The purpose of a merger clause is to require the full application of the parol evidence rule in order to bar the introduction of extrinsic evidence to alter, vary or contradict the terms of the writing . . . ."[9]

Drafting Merger Clauses

Include a Merger Clause

The most important rule about merger clauses is to have one. In the event of a dispute, failing to have a merger clause can open the door to the admission of all manner of evidence about side agreements and extra-contractual promises that your client likely intended to omit from the contract. This could give a court license to ferret through the drafting history of the contract (e.g., the emails and text messages exchanged by the parties prior to contract formation). This is something that might be difficult to explain to a client.

Courts often justify the admission of evidence about side agreements by noting that the written contract lacks a merger clause—a clear signal to the party opposing the admission of this evidence that his or her lawyer had a drafting lapse.

It is a blunder that is easily avoided. On your checklist of essential clauses, merger clauses are among the most important.

Use the Language Recognized by the Courts

If parties want the written contract to constitute a complete integration, they should just come out and say that the agreement is "completely integrated."[10] Why on earth would they not do so?

They should not characterize the writing as merely containing the entire or the final agreement of the parties.[11] They should use the language used by the courts. For example: "The parties intend this statement of their agreement to constitute the complete, exclusive, and fully integrated statement of their agreement. As such, it is the sole expression of their agreement, and they are not bound by any other agreements of whatsoever kind or nature."

If that suggested language offends the style-mavens as inelegant or ham-handed overkill, tell it to the judges. This is not an English essay contest. We need to draft so that the clause is given effect by using language that tracks the precedents. Contracts are drafted not only for the parties but also for a hypothetical judge who might someday be called upon to resolve disputes over the language.

A drafter might very well get away with using language that does not track the precedents—it happens all the time. If, however, the merger clause becomes an issue in a dispute between the parties, it might be a significant problem. Why take that risk?

5. 1-24 Corbin on Contracts Desk Edition § 24.04 (2017). 6. Restatement (Second) of Contracts § 216 cmt. e (1981). A merger clause states "that the writing constitutes the sole and exclusive repository of the parties' agreement and somewhat redundantly [adds that the parties] do not intend to be bound by any other agreement, understanding or negotiation of whatsoever kind or nature." Murray on Contracts § 85 (5th ed. 2011). 7. Restatement (Second) of Contracts § 216 cmt. e (1981). 8. *Id.* 9. Jarecki v. Shung Moo Louie, 95 N.Y.2d 665, 669 (2001) (citation omitted). 10. "[T]he contract drafter is wise to recite that the agreement is completely integrated if it is meant to be so regarded." David G. Epstein, Adam L. Tate, and William Yaris, *Fifty: Shades of Grey - Uncertainty About Extrinsic Evidence and Parol Evidence After All These UCC Years*, 45 Ariz. St. L.J. 925, 933 (2013). 11. Middletown Concrete Prods. v. Black Clawson Co., 802 F. Supp. 1135 (D. Del. 1992); Gem Corrugated Box Corp. v. Nat'l Kraft Container Corp., 427 F.2d 499, 503 (2d Cir. 1970).

Drafting in Case Merger Clauses Are Not Conclusive under the Applicable Law

Merger clauses are not everywhere deemed to be conclusive on the issue of whether the writing is a completely integrated agreement. Courts in some jurisdictions hold them to be conclusive[12] or "generally conclusive,"[13] while other courts say they are not conclusive but may be a significant factor on the question of integration depending on the facts.[14] The Restatement (Second) of Contracts says that such clauses are "likely to conclude the issue whether the agreement is completely integrated."[15]

Since the parol evidence is a rule of substantive law, the parties ought to be free to control whether their merger clause is given conclusive effect by designating in their choice of law provision a state that makes merger clauses conclusive (provided that the choice of that state's law is otherwise enforceable).[16] Truth be told, attorneys often insist on the law of a particular state for less practical reasons (often it's because they claim they are comfortable with the law of a jurisdiction where their client has a presence—even if they don't really know how that law differs from the law of other states).

12. E.g., "[T]he parties' insertion of the merger clause into the settlement agreement is conclusive evidence of their intent to create a fully integrated contract." Bonner v. City of New Haven, 2018 Conn. Super. LEXIS 1285, *11 (June 22, 2018). Benvenuti Oil Co. v. Foss Consultants, Inc., 64 Conn. App. 723, 781 A.2d 435 (2001) (conclusive, so long as parties are of equal bargaining power). *See also* Custom Pack Sols., Inc. v. Great Lakes Healthcare Purchasing Network, Inc., 2018 Mich. App. LEXIS 333 (Feb. 22, 2018); Green Acres Mall, L.L.C. v Sevenfold Enters., LLC, 936 N.Y.S.2d 58 (Dist. Ct. 2011). 13. IIG Wireless, Inc. v. Yi, 22 Cal. App. 5th 630, 640 (2018). 14. Bonfire, LLC v. Zacharia, 251 F. Supp. 3d 47 (D.D.C. 2017). Amplatz v. AGA Med. Corp., 2012 Minn. Dist. LEXIS 200 (May 21, 2012) (merger clause a "significant" factor). "[T]he force accorded to an integration clause is dependent upon the facts. Corbin § 25.8[A] at 70 (observing that an integration clause 'should be given weight based on the circumstances under which it was adopted, including the complexity and sophistication of the contract and the parties' . . . ." Jacobson v. Hofgard, 168 F. Supp. 3d 187, 202 (D.D.C. 2016). 15. Restatement (Second) of Contracts § 216 cmt. e (1981). 16. The choice of law provision "includes application of the parol evidence rule, which is a rule of substantive law." Ng v. Schram, 2013 U.S. Dist. LEXIS 141046, *20 (S.D.N.Y. Sept 30, 2013).

But even if the contract is governed by the law of a state that does not deem merger clauses to be conclusive, the parties can enhance their chances of having their contract construed to be a completely integrated agreement by the way they draft, as explained below.

Don't Rely Solely on Merger Clauses to Make Your Writing Fully Integrated

In many instances, the parties should not solely rely on a merger clause—they can draft the contract in other ways to enhance the likelihood that a writing will be construed as a complete integration.

Courts seek to fulfill the parties' intentions. If those intentions are spelled out with clarity, a court will have little room to find an agreement that does not comport with them. For example, if the parties have other dealings that are related to or arguably within the scope of the agreement at issue, if possible, the parties should expressly refer to those other dealings in the agreement and explicitly state that the agreement does not alter any rights or obligations except to the extent expressly stated in the agreement. This should preclude the admission of any evidence of alleged side agreements relating to those other dealings.

Make it clear that any agreements creating obligations between the parties—without exception—either are set forth in the present writing or are not being altered by the present writing. Don't rely on a cookie cutter merger clause. This requires a little more work in the drafting phase, but it is a prudent investment of your time.[17]

Drafting Merger Clauses to Exclude Trade Usage and Course of Dealing

There are invisible terms that are part of every agreement: trade usage, course of dealing (a sequence of conduct between the parties in previous transactions), and course of performance (a sequence of conduct between the parties in the present transaction). People often confuse the latter two. For contracts for the sale of goods governed by the UCC, and even for common law contracts in some jurisdictions, evidence of trade usage and course of dealing may be admitted despite the parol evidence rule, even for completely integrated agreements.[18] Evidence of course of performance, as discussed below, should not be barred by the parol evidence rule under any law.

Under the UCC, parties are permitted to carefully negate trade usage and course of dealing.[19] This requires words in addition to a garden-variety merger clause.[20] If the parties desire to negate trade usage and course of dealing, in the contract's merger clause the caption of the merger clause should include a clear reference to the negation of trade usage and course of dealing, and something akin to the following sentence should be added to the merger clause: "The parties also intend that this agreement may not be supplemented, explained, or interpreted by any evidence of trade usage or course of dealing."

17. Courts are naturally more skeptical of boilerplate provisions than of terms specifically drafted for the present transaction. The chief architect of the UCC, Karl Llewellyn, said that "there is no assent at all" to such terms. Karl Llewellyn, The Common Law Tradition: Deciding Appeals 370 (1960). **18.** U.C.C. §§ 1-201(b)(3), 1-303; Restatement (Second) of Contracts § 209 cmt. (a) (1981); Restatement (Second) of Contracts §§ 221-224 (1981). C-Thru Container Corp. v. Midland Mfg. Co., 533 N.W.2d 542 (Iowa 1995) (UCC); TDN Money Sys. v. Everi Payments, Inc., 2017 U.S. Dist. LEXIS 183223 (D. Nev. Nov. 6, 2017) (non-UCC); Diponio Contr. v. City of Howell, 2015 Mich. App. LEXIS 706 (Apr. 14, 2015) (non-UCC). *But see* Hamilton Secs. Advisory Servs. v. United States, 2004 U.S. Claims LEXIS 147 (Fed. Cl. 2004) (merger clause bars evidence of such terms under common law). **19.** U.C.C. § 2-202 cmt. 2. **20.** Precision Fitness Equip., Inc. v. Nautilus, Inc., 2011 U.S. Dist. LEXIS 13576 (D. Colo. Feb. 2, 2011).

Related Content

For assistance in creating merger clauses, see

> MERGER CLAUSE AND FORCE MAJEURE CLAUSE DRAFTING

RESEARCH PATH: *Commercial Transaction > Supply of Goods and Services > Contract Formation, Breach, and Remedies under the UCC > Practice Notes*

For guidance in drafting a merger clause, see

> MERGER, SURVIVAL, AND NOTICE CLAUSES

RESEARCH PATH: *Commercial Transaction > General Commercial and Contract Boilerplate > Contract Boilerplate and Clauses > Practice Notes*

For tips on how to avoid mistakes in drafting contracts for the sale of goods, see

> SALE OF GOODS AGREEMENTS: AVOIDING COMMON PITFALLS

RESEARCH PATH: *Commercial Transaction > Supply of Goods and Services > Contract Formation, Breach, and Remedies under the UCC > Practice Notes*

For a discussion on the issues to consider when drafting or reviewing a commercial contract, see

> COMMERCIAL CONTRACT DRAFTING AND REVIEW

RESEARCH PATH: *Commercial Transaction > General Commercial and Contract Boilerplate > Contract Boilerplate and Clauses > Practice Notes*

For a sample integration or merger clause, see

> BOILERPLATE CLAUSES (CORPORATE AGREEMENTS; COMMERCIAL AGREEMENTS)

RESEARCH PATH: *Commercial Transaction > General Commercial and Contract Boilerplate > Contract Boilerplate and Clauses > Forms*

Note that course of performance technically cannot be negated since it involves conduct that occurs post-contract formation.[21] This raises a simple but fundamental point about merger clauses and the parol evidence rule: they only apply to things that happen prior to or contemporaneous with contract formation.[22] Even a well-drafted

Merger and asset-purchase agreements…often contain anti-reliance clauses. The idea behind these clauses is that a party should not be permitted to rely on an alleged representation that is expressly contradicted by the plain words of the contract.

merger clause does not preclude a post-formation modification. Generally, "[p]arties to a contract cannot, even by an express provision in that contract, deprive themselves of the power to alter or vary or discharge it by subsequent agreement."[23] This is not to say that no-oral-modification clauses are invariably useless—some laws make them effective, at least to some degree.[24] But no-oral-modification clauses are sometimes tacked onto merger clauses as if they are part and parcel of the same legal concept. They are not, and to avoid confusion, merger clauses and no-oral-modification clauses should be set forth in separate provisions.

Drafting Merger Clauses to Exclude Fraud

Generally, evidence of fraud is admissible even in the face of a completely integrated agreement containing a garden-variety merger clause. But if the contract contains an anti-reliance clause stating "that the parties to the contract did not rely upon statements or representations not contained within the document itself,"[25] apparently most—but not all—jurisdictions that have ruled on the issue hold that claims of fraud in the inducement are barred.[26]

Merger and asset-purchase agreements, among other kinds of complex agreements, often contain anti-reliance clauses. The idea behind these clauses is that a party should not be permitted to rely on an alleged representation that is expressly contradicted by the plain words of the contract. Such language should be included in every merger clause.

Seeking Complete Integration in International Contracts

Most of the world's major trading nations, including the United States, have adopted the United Nations Convention on Contracts for the International Sale of Goods (CISG). Unless the parties have agreed to opt out of CISG (per Article 6), it applies to contracts for the sale of goods made by parties with their principal places of business in different CISG countries.

21. U.C.C. § 2-202 cmt. 2; K. Rowley, Contract Construction and Interpretation: From the "Four Corners" to Parol Evidence (and Everything in between), 69 Miss. L.J. 73, 331 (1999) (course of performance cannot be "carefully negated"); 1 William D. Hawkland, Uniform Commercial Code Series § 2-208:3, at 2-306 (1998) (no provision in U.C.C. to negate course of performance). **22.** E.g., Beal Bank S.S.B. v. Krock, 1998 U.S. App. LEXIS 22051 (1st Cir. Sept. 3, 1998). **23.** 8 Corbin on Contracts § 40.13. **24.** E.g., N.Y. Gen. Oblig. Law § 15-301 and U.C.C. § 2-209. **25.** Billington v. Ginn-LA Pine Island, Ltd., LLLP, 192 So. 3d 77, 80 (Fla. App. 2016). **26.** *Id*. The *Billington* case contains an excellent discussion of anti-reliance clauses.

There are many important differences between the UCC and the CISG (and a lot of similarities), but perhaps the most important difference is that there is no parol evidence rule under the CISG. In addressing how a court should determine the intent or understanding of a reasonable person, Article 8 provides that "due consideration is to be given to all relevant circumstances of the case including the negotiations, any practices which the parties have established between themselves, usages and any subsequent conduct of the parties." Such negotiations can include any prior promises, agreements, or understandings—so all of these could be admissible into evidence.

Does a merger clause make a contract completely integrated under the CISG to discharge any prior or contemporaneous agreements that are within the scope of the written agreement? It is not altogether clear, but merger clauses probably are not the silver bullet that they are in many American jurisdictions. Even with a merger clause, there is authority that the extrinsic evidence should not be excluded unless the parties actually intended the merger clause to have that effect. To make that determination, evidence of all relevant facts and surrounding circumstances must be examined.[27]

Practitioners steeped in the law of the United States, including the UCC, appreciate the utility of setting forth the parties' entire deal in a writing. The absence of a parol evidence rule under the CISG is one legitimate reason to opt out of the CISG. But to opt out of the CISG, the parties cannot rely on an ordinary choice of law provision that states, for example, that the law of a particular state in the United States shall apply—that's because the law in the United States includes CISG, so to opt out of CISG, it is necessary to choose the law of a jurisdiction and then expressly add that the parties also agree to opt out of the CISG.[28]

Putting It All Together

Parties should not rely solely on a generic merger clause to ensure that their agreement is completely integrated. They should also reference the parties' other dealings and spell out that the writing is not altering any rights or obligations except to the extent expressly stated in the writing.

To draft a merger clause, here is a start:

> The parties intend this statement of their agreement to constitute the complete, exclusive, and fully integrated statement of their agreement. As such, it is the sole expression of their agreement, and they are not bound by any other agreements of whatsoever kind or nature. The parties also intend that this agreement may not be supplemented, explained, or interpreted by any evidence of trade usage or course of dealing. The parties did not rely upon statements or representations not contained within the document itself.

If the CISG might apply, and if the parties want to opt out of it because of the absence of the parol evidence rule or otherwise, in their choice of law provision they should designate a jurisdiction and add something like this: "The parties hereby agree that the United Nations Convention on Contracts for the International Sale of Goods will not apply to this contract." L

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RESEARCH PATH: *Commercial Transactions > General Commercial and Contract Boilerplate > Contract Boilerplate and Clauses > Articles*

27. Cedar Petrochemicals, Inc. v. Dongbu Hannong Chem. Co., 2011 U.S. Dist. LEXIS 110716 (S.D.N.Y. Sept. 28, 2011). 28. *See, e.g.*, 1-83 Corbin on Contracts Desk Edition § 83.02[4] (2017).

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Restrictive Covenant and Trade Secret Misappropriation Claims: Key Initial Considerations and Tips for Seeking TROs and Preliminary Injunctions

This article provides guidance on substantive and procedural considerations involved in pursuing temporary restraining orders (TROs) and preliminary injunctive relief to help protect employer trade secrets and enforce restrictive covenants against former employees.

FOR EMPLOYERS, RESTRICTIVE COVENANTS HAVE BECOME a vital tool for protecting confidential information, trade secrets, client goodwill, and other important business interests. Just as vital is knowing how to effectively protect those interests through litigation if necessary. Successfully enjoining restrictive covenant breaches or misappropriations of trade secrets (or both) requires a coherent litigation strategy and careful consideration of numerous procedural and substantive issues.

This article addresses the following considerations regarding TROs and preliminary injunctions in connection with restrictive covenants and trade secret misappropriation:

- Strategies for determining whom to sue and where to do it
- Insights into whether and how to seek injunctive relief (including TROs and preliminary injunctions (PIs))

This article does not supply an exhaustive discussion of the similarities and differences between state laws with respect to the enforceability of restrictive covenants or protection of trade secrets. This article also does not comprehensively explore state law distinctions for drafting enforceable restrictive covenants or protecting employer trade secrets.

Strategies for Determining Whom to Sue and Where to Do It

Choosing Your Defendant(s)

The Former Employee

It perhaps goes without saying that your complaint should name the person you suspect has breached a restrictive covenant or misappropriated your trade secrets—the former employee. Review your records to ascertain the employee's full name and last known address.

The New Employer

A frequent topic of debate in this area is whether to also name the new employer as a defendant. The answer hinges on a variety of factors, not all of which apply to every situation. In determining whether to sue the new employer in a restrictive covenant or trade secret litigation, you should consider the following issues:

- **The new employer's role in the underlying misconduct.** Do you have evidence the new employer was aware of your former employee's covenants? Was it aware of acts he took that may be in breach of those covenants, such as bringing your clients or trade secrets to the new employer? A misbehaving ex-employee's new employer may be involved in a number of ways and subject to a number of claims. Carefully review the results of your investigation.
- **The new employer's finances and litigation track record.** One additional consideration is an evaluation of the new employer's financial resources vis-à-vis the former employer's finances. Does naming the new employer as a defendant risk a lawsuit longer and more expensive than the former employer is prepared to litigate? Another factor is the new employer's litigation history. Has your research shown that the new employer has a propensity for litigating cases to the mat? Would including the new employer invite potential counterclaims, aggressive discovery tactics, and other potential downsides?
- **The new employer's relationship with the employee.** More nuanced considerations may also come into play. Have you received any indication of whether the new employer is prepared to indemnify the employee? If not, and your primary defendant (i.e., the employee) has to financially go it alone, ponder whether you might be able to coax an early settlement by naming only the former employee without involving his or her deeper-pocketed employer.
- **The need to send a message to the new employer.** Another consideration is the extent to which the business we have been referring to as the new employer has been involved in previous episodes of foul play involving your former employees. Do you sense a pattern? Is the former employee you are considering suing just the latest in a string of employees who left to join that business and violated their covenants (or the law) on the way out the door? Do you have reason to believe that by not naming the new employer as a defendant, you may be encouraging it to lure other employees to leave and try to bring your clients and trade secrets with them? Naming the new employer as a defendant may send a message that it should think twice before hiring your employees or sharing in their misdeeds at your expense.

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Other Potential Defendants

While the former employee and his or her new employer may be the most likely defendants in a lawsuit involving restrictive covenant or trade secret misappropriation claims, they are hardly the only potential defendants.

Do you have reason to believe other former employees are participating or have helped the employee? Did your investigation turn up names of other individuals at the new employer who may be helping the former employee solicit your clients? Has the former employee already incorporated a new business that you should name as defendant (in addition to the former employee individually)? While less likely, what about a now-former client who breached its existing contract with you to follow the employee to his or her new business?

You may be able to exert additional pressure on the former employee by identifying third parties who have assisted in his or her wrongdoing.

Choosing Your Forum

Intertwined with the who question is the where question. Where do you sue and how do you decide? Sometimes making this determination is as simple as checking the agreement. Other times it may require research of state law and analysis of various practical, strategic considerations. Below are just a few of these considerations:

- **Relevant clauses in the parties' agreement.** It is possible that the former employee's restrictive covenant agreement will indicate the proper forum for litigation. Accordingly, you should first check to see if the agreement has any provisions addressing venue, forum, or dispute resolution procedures. Such a provision might require that all claims be brought in a specific venue, such as the U.S. District Court for the District of New Jersey, or in a specific jurisdiction, such as the federal or state courts of New York. A word of caution: forum and venue clauses are not always enforced by courts, no matter how ironclad they might appear on paper. You will need to research applicable law to determine how courts in your jurisdiction have interpreted similar forum selection clauses in prior cases.
- **The location of the parties and witnesses.** Whether or not the agreement contains a provision that addresses forum, you should not ignore the facts on the ground in deciding where to file your complaint. Where are your offices located? Where does the former employee currently reside? Where was the former employee located while working for you? Where was the former employee's supervisor located? Where is the new employer located? The clients he or she may have improperly solicited? These questions are important from a few perspectives. First, you, of course, will need to establish proper jurisdiction over your defendants and comply with court venue rules. Second, you should keep in mind whether relevant witnesses or documents will be available and are within the forum's subpoena power. Third, say your agreement does contain a choice of forum clause; courts in many states enforce such clauses only if the chosen forum bears a sufficiently close relationship to the transaction at issue and does not offend public policy.[1]
- **Consider whether certain forums are more favorable than others.** In analyzing the objective considerations addressed above, do not overlook the potential favorability of some courts over others. For example, have judges in the forum you are considering shown a propensity for granting or denying requests for injunctive relief (a topic we will discuss below)? What about relative docket speed—is there a risk that a judge may not rule on your claims in a particular venue for months, if not years? Have you developed a certain expertise in litigating in one court or another?

Insights into Whether and How to Seek Injunctive Relief (Including TROs and PIs)

Do not take lightly a decision to commence legal action against an employee, former employee, and/or a former employee's new employer. If an employer has actual evidence, or a good-faith reason to believe, that an employee (or former employee) has violated restrictive covenants and/or common-law obligations that threaten the employer's confidential information, client and employee relationships, or other legitimate business interests, the employer should strongly consider filing an action that includes a request for injunctive relief to put a stop to the harm or potential imminent harm to the employer.

Common Forms of Requested Injunctive Relief (TROs and PIs)

The most common forms of requested injunctive relief are TROs and PIs.

TROs

On a TRO application, the movant is seeking short-term temporary relief from a court until the court has an opportunity to consider an evidentiary record and a fuller opposition from the opposing party(ies). If the employer has hard evidence or a good-faith reason to believe that an employee has engaged in conduct that poses an imminent risk of misappropriation

1. *See, e.g.*, Guardian Fiberglass, Inc. v. Whit Davis Lumber Co., 509 F.3d 512, 515 (8th Cir. 2007) ("Arkansas courts will honor a choice of law provision, provided that the law selected is reasonably related to the transaction and does not violate a fundamental public policy of the state") (internal quotation marks omitted); Outside Television, Inc. v. Murin, 977 F. Supp. 2d 1, 13–14 (D. Me. 2013) (noting Maine's "strong presumption in favor of [employer's] choice of forum and . . . forum selection clause" and enforcing forum selection clause where employer had "a non-trivial presence within Maine" and where former employee failed to show "that any public policy would be offended by enforcement of the forum selection clause"); Stryker Corp. v. Ridgeway, 2014 U.S. Dist. LEXIS 98455, at *5–6 (W.D. Mich. July 21, 2014) (applying Michigan law to enforce Michigan choice of law and forum provisions where former employer was "based in Michigan and Michigan has an interest in enforcing its employers' non-compete agreements and forum selection clauses," and because enforcement of forum selection clause would not be fundamentally contrary to public policy of Louisiana where former employee lived).

> An employer's failure to promptly seek a temporary restraining order and/or permanent injunction could make it more difficult to demonstrate to a court that the employer faces a situation warranting emergency relief.

of confidential information, loss of key clients, or some other imminent harm to the business, the employer should seek a TRO as soon as practicable. A TRO application, which the movant files along with a complaint, will generally require a proposed order to show cause outlining the injunctive relief sought, a sworn emergency affidavit from a person with knowledge of the facts, and a supporting memorandum of law. The sworn affidavit should explain to the court how and why the employer faces an imminent risk of harm (e.g., the employer has evidence that the employee downloaded sensitive company files the day before he or she resigned) such that the court should temporarily enjoin the employee or another entity from engaging in certain conduct until the court holds a more fulsome PI hearing.

TRO applications in employment disputes are generally not made ex parte. That is, unless the employer can demonstrate that providing notice to the opposing party would lead to further irreparable harm, a movant generally must give the opposition reasonable notice of the movant's intent to make a TRO application.

PIs

While TROs are generally intended to secure short-term temporary relief prior to any evidentiary hearings, PIs are typically sought to preserve a status quo based on a limited evidentiary record pending a full trial at the end of the case. That is, a PI enjoins a party from taking a particular action throughout the duration of the case until a full trial on the merits. Because lawsuits may last months (if not years), securing a PI is often critical to protecting the employer's interests.

Like TROs, attorneys generally seek PIs by written application to the court. In fact, attorneys often seek PIs through the same initial application as a TRO. For instance, an employer might file a complaint accompanied by an application for a TRO and a PI, with the application supported by motion papers such as a memorandum of law, one or more sworn affidavits from witnesses with knowledge of relevant facts, and a proposed order to present to the court. A court presented with a TRO/PI application typically will issue an order granting or denying the relief requested in the TRO application and set a date for an in-court hearing on the PI application. In scheduling the PI hearing, the court also will likely set a briefing schedule under which the opposing party (here, the employee) may file a memorandum of law and proffer its own evidence in opposition to the employer's application.

Successfully obtaining a PI generally requires that an employer satisfy several factors, such as a demonstration that it will likely succeed on the merits of its underlying claims and that it will suffer irreparable harm if the court were to deny its PI application. We discuss these and the other factors typically required for obtaining injunctive relief below.

Avoid Delays When Seeking TROs and PIs

An employer's failure to promptly seek a TRO and/or PI could make it more difficult to demonstrate to a court that the employer faces a situation warranting emergency relief.[2]

To Seek or Not to Seek a TRO or PI?

Whether to seek a TRO or PI against a former employee involves both legal and practical considerations and may turn on the specific employee and the suspected misconduct. For example, say that an employer learns that a non-unique former employee with a covenant not to compete accepts employment with a direct competitor to work in a similar position, but there is no evidence that the employee has taken any of the employer's confidential information or trade secrets. Should the employer still seek to enjoin the employee based on the covenant not to compete, and if so, will the employer succeed?

2. *See, e.g.*, Southtech Orthopedics, Inc. v. Dingus, 428 F. Supp. 2d 410, 420 (E.D.N.C. 2006) ("[T]he six to nine week delay between plaintiff's discovery of defendant's competitive activities and its filing suit weighs against injunctive relief."); Embarcadero Techs., Inc. v. Redgate Software, Inc., 2017 U.S. Dist. LEXIS 191317, at *14 (W.D. Tex. Nov. 20, 2017) ("If the harm Plaintiffs feared were indeed irreparable, it is unclear why they, knowing all of the primary facts forming the basis for their claims by April at the latest, filed the complaint on May 11, did not request a hearing or file a brief supporting their application for a preliminary injunction until June 12, and, once the Court set a hearing for July 25, requested that the hearing be moved to early September."). See below for factors courts consider, including that movant would suffer irreparable harm in the absence of injunctive relief. The TRO or PI application may also include a request for expedited discovery so that the employer can quickly learn the full extent of the potential breaches and/or tortious conduct.

The answer to both questions depends on the facts and circumstances and the applicable law. Even without evidence of actual misappropriation of trade secrets or confidential information, the employer still may have one or more protectable interests warranting protection through an injunction preventing the employee from breaching the non-compete.

Employer's Interest in Customer Goodwill and Relationships

In many jurisdictions an employer has a protectable interest in its customer goodwill and relationships. For instance, in Grp. Health Sols., Inc. v. Smith, 2011 N.Y. Misc. LEXIS 4402, at *14 (N.Y. Sup. Ct., N.Y. Cnty. Aug. 5, 2011), despite no evidence of misappropriation, the court denied defendant former employee's motion to dismiss a breach of non-compete claim because of the employer's "legitimate interest in protecting [its] relationships and goodwill." The former employee had interacted with former employer's customers during employment and then allegedly subsequently used these business relationships to compete with his former employer.[3]

Inevitable Disclosure Doctrine

Depending on the employee's prior role and position, the employer may also have an interest in preventing him or her from misusing competitively valuable confidential information he or she did not take by, for example, downloading files or printing documents, but still possesses by virtue of having received or been exposed to such information. In several jurisdictions, the inevitable disclosure doctrine may allow for injunctive relief against a former employee whose acceptance of competing employment threatens disclosure of his or her former employer's trade secrets, even though the employee did not actually misappropriate the employer's trade secrets or confidential information.

For example, in Payment Alliance Int'l., Inc. v. Ferreira, 530 F. Supp. 2d 477, 482 (S.D.N.Y. 2007), the court enjoined a former executive from working for "a direct competitor" where the executive "possesse[d] detailed knowledge" of "non-public information" regarding the former employer's "customers and marketing strategies [that] would undeniably be of value to one of its direct competitors." The court explained that "even if [the former executive] acted with the best of intentions, he may unintentionally transmit information gained through his association with [his former employer] during his day to day contact with his new employer" and that "[the former executive's] employment with [the new employer] creates the risk that disclosure of [the former employer's] trade secrets is inevitable."[4] In IBM Corp. v. Papermaster, 2008 U.S. Dist. LEXIS 95516, at *25 (S.D.N.Y. Nov. 21, 2008), the court enforced a covenant not to compete where a former employee had access to "sensitive and confidential information through his

3. 2011 N.Y. Misc. LEXIS 4402, at *15. 4. 530 F. Supp. 2d at 482 (internal quotations omitted).

work" concerning former employer's "strategic plans, product development, technical recruitment, and long-term business opportunities." The court found that the "likely inevitability of even inadvertent disclosure is sufficient to establish a real risk of irreparable harm to IBM."[5]

In short, depending on the particular circumstances and applicable law, there may be multiple grounds on which an employer can obtain injunctive relief against a former employee for breaching a restrictive covenant even without evidence of a smoking gun.

Factors for Obtaining Injunctive Relief

As a general matter, to succeed on a TRO (or PI) application, the movant must demonstrate each of the following:

- A likelihood of success on the merits of the claim(s)
- Irreparable harm to the movant if the court denies injunctive relief
- A balance of equities in the movant's favor

In federal court, the movant must also demonstrate that an injunction is in the public interest.[6]

At a hearing on a TRO/PI application, the assigned judge will generally give the movant and the opposing party each an opportunity to present their case. As addressed below, the movant must be prepared to articulate how it satisfies each of the TRO/PI factors.

Likelihood of Success on the Merits

Likelihood of success on the merits on a claim of breach of a restrictive covenant agreement generally hinges on whether the agreement at issue is enforceable. Each state has its own statutory or common law governing the enforceability of restrictive covenants. For example, in New York, courts will enforce restrictive covenants that (1) are reasonable in time and space, (2) protect legitimate interest(s) of the employer, (3) do not impose an undue hardship on the employee, and (4) are not injurious to the public.[7] For misappropriation of trade secret or confidential information claims, an employer may demonstrate likelihood of success by, among other things, advising the court of the nature of the information that an employee has wrongfully retained, the steps the company took to preserve the confidentiality of such information, and how the employee has already used such information, or may use such information to harm the business.[8]

Irreparable Harm if the Court Does Not Grant Injunctive Relief

For the irreparable harm prong, the employer should demonstrate to the court that, should the employee's conduct remain unchecked, the employer is in danger of serious harm to the employer's business interests for which money damages are not sufficient. The employer's restrictive covenant agreement with the employee may contain an acknowledgment from the employee that a breach or threatened breach would result in irreparable harm to the employer.

Case law in the jurisdiction in which the employer seeks injunctive relief should also provide helpful guidance. In New York, for example, violations of restrictive covenants that result in the misuse of confidential information or loss of client relationships or goodwill may satisfy the irreparable harm standard.[9]

Balance of Equities in the Movant's Favor

When an employer seeks to enforce a restrictive covenant, courts will weigh the potential hardship to an employee should the court grant the requested injunctive relief against the harm to the employer if the court denies the injunctive relief. The restrictive covenant at issue may contain an acknowledgment from the employee agreeing not to contend hardship if the employer seeks to enforce the restrictive covenants, because, for example, the employee remains free to engage in certain business activities that will enable the employee to continue to earn a livelihood.

The movant should also look at precedent in the applicable jurisdiction. Courts in some jurisdictions have found that any hardship to an employee from enforcing the restrictive covenant agreement is ameliorated by the employee's informed acceptance of such an outcome when he executed the agreement, and, ultimately, chose to violate it.[10]

Potential Outcomes and Implications

Standing on Success

If the company is successful on a TRO application, the court will enjoin the defendant(s) from engaging in certain conduct until the PI hearing, at which time the court may consider live witness testimony and additional documentary evidence. Depending on the court, the PI hearing could take place anywhere from a week to over a month after the date of issuance of the TRO. From the movant's perspective, the longer the period of time between the TRO and PI hearing, the more leverage the movant may have to negotiate a settlement with the opposition.

5. 2008 U.S. Dist. LEXIS 95516, at *34. *But see* DGM Servs., Inc. v. Figueroa, 2016 Tex. App. LEXIS 13808, at *14 (Tex. Ct. App. Dec. 29, 2016) (concluding "that the inevitable disclosure doctrine has not been adopted by Texas courts"). **6.** *See* Winter v. Natural Res. Def. Council, Inc. 555 U.S. 7, 20–22 (2008). **7.** *See, e.g.*, BDO Seidman v. Hirshberg, 93 N.Y. 2d 382, 388–89 (1999) (partially enforcing non-compete). **8.** *See, e.g.*, Marcone APW, LLC v. Servall Co., 85 A.D.3d 1693 (N.Y. App. 4th Dept 2011) (determining that customer names, contacts, and business information was a trade secret that must be protected from misuse). **9.** *See, e.g.*, Second on Second Café v. Hing Sing Trading, 66 A.D.3d 255, 272–73 (N.Y. App. 1st Dept 2009) (holding that the loss of the goodwill of a viable, ongoing business can "constitute irreparable harm warranting the grant of preliminary injunctive relief"); FTI Consulting, Inc. v. PricewaterhouseCoopers LLP, 8 A.D.3d 145, 146 (N.Y. App. 1st Dept 2004) (finding breach of restrictive covenants constitutes irreparable harm where the loss of goodwill is not readily quantifiable); Chertoff Diamond & Co. v. Fitzmaurice, 234 A.D.2d 200, 203 (N.Y. App. 1st Dep't 1996) (holding "it clearly shown that plaintiff would suffer irreparable harm should its clients terminate their relationships with it to use defendants' services"); Alside Div. of Associated Materials Inc. v. Leclair, 295 A.D.2d 873, 874 (N.Y. App. 3d Dept 2002) ("[I]f defendants are permitted to compete unfairly by using plaintiff's confidential and proprietary pricing information to underbid it, plaintiff will not only lose business, but will also suffer a dilution of the good will it has developed with its customers. Such a loss of customer good will can constitute irreparable harm for preliminary injunction purposes."); Aon Risk Servs., N.E. v. Cusack, 2011 N.Y. Misc. LEXIS 6392, at *59 (Sup. Ct. N.Y. Cnty. Dec. 20, 2011) (stating that "under New York law, it is clear that the continuing violations of restrictive covenants that result in the loss of customer goodwill or proprietary information constitute irreparable harm, incapable of being measured monetarily at the time injunctive relief is requested"). **10.** *See* DAR Assoc., Inc. v. Uniforce Services, Inc., 37 F. Supp.2d 192, 200 (E.D.N.Y. 1999); Jiffy Lube International, Inc. v. Weiss Bros. Inc., 834 F. Supp. 683, 693 (D.N.J. 1993) ("To the extent that the defendants suffer significant . . . damage from the granting of the preliminary injunction, this harm is a predictable consequence of their willful breach of contract and their misconduct. As such, it is not the type of harm from which we seek to protect a defendant . . . [and] is not a basis for denying a plaintiff the relief to which it is legally entitled.").

Preliminary Injunction Hearing

Should the matter proceed to a PI hearing, the court may order expedited discovery prior to the hearing to enable the parties to more fully present their cases. Nevertheless, a PI hearing is not a full-blown trial, and the court generally will limit the parties' presentations to determine whether the movant can satisfy the PI factors, which we discussed previously in this article.

Depending on the jurisdiction, the PI hearing typically involves a mix of presentation of evidence and legal argument. Evidence presented at a PI hearing generally takes the form of live testimony and documentary evidence such as witness affidavits or documents and communications related to the suspected breach. Should it elect (or be ordered) to present live testimony, an employer moving for a PI might call the following witnesses:

- The defendant-employee's former supervisor to testify to any sensitive non-public information the employee was privy to
- A former coworker of the defendant-employee who might testify to the client relationships and goodwill the employee had access to
- Even an existing client to testify to any solicitations it has received from the defendant-employee and which may be in violation of one or more restrictive covenants

Whether to rest on written affidavits or present live testimony (and if so, which witnesses and on what subjects) will vary depending on the jurisdiction, court rules, the judge presiding over the case, and the nature of the evidence. For example, presenting live witness testimony may assist the court in understanding the context and importance of written evidence such as emails or documents that the employer submitted in its written application.

Regardless of whether or not it elects to present live testimony, an employer seeking a PI should be prepared to articulate how the requisite PI factors tilt in its favor and warrant injunctive relief. In particular, the movant should brush up on the relevant agreement and the restrictive covenants at issue and be prepared to demonstrate how the employer will be irreparably harmed (e.g., through misappropriation of trade secrets and/or confidential information and/or the loss of client goodwill) if the court does not grant the requested relief.

Effect of Obtaining a Preliminary Injunction

Should the movant succeed in obtaining a PI, the injunctive relief will remain in effect until a full-blown trial on the merits. In some jurisdictions, the trial may not begin for over a year from the date of the PI order. Moreover, the court's order on a PI application may telegraph how the court is likely to rule were the case to proceed to trial. Accordingly, parties may look to resolve the matter following the PI order but prior to trial, often leaving the PI hearing as the final litigated part of the dispute. A movant's success at the PI hearing often bodes well for these settlement discussions.

Dealing with Denial

Denial of TRO Application

If a court denies a TRO application, the employer may wish to press for a PI hearing to be scheduled as soon as possible, so as to mitigate any adverse effects of the employee's ability to continue his or her contested actions prior to the PI hearing. Before doing so, the employer should consider whether expedited prehearing discovery would improve its chances of securing a PI; it may be the case that important documents or communications lie solely in possession of the departed employee and that obtaining such documents or communication would bolster the employer's case at the PI hearing. And, of course, the employer should heed any guidance or remarks that the court made during the TRO hearing to possibly improve its chances at obtaining a PI.

Denial of PI

If a court denies a PI, the employer will have to weigh the costs and risks of trial against the benefits of a potential positive outcome following trial. The employer should typically push for an expedited trial date so that it can seek to obtain the requested injunctive relief before too much additional time passes. If the court's order on the PI application expressly states or impliedly suggests that the court is denying injunctive relief because money damages could satisfy the harm at issue, if proven, then the employer may still have some leverage to seek a resolution short of trial. L

Related Content

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RESEARCH PATH: *Labor & Employment > Non-competes and Trade Secret Protection > Restrictive Covenants > Practice Notes*

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Extraterritorial Reach of U.S. Antitrust Laws

This article addresses the extraterritorial reach of U.S. antitrust laws—that is, their application to international trade or commerce—specifically discussing the interplay between the Sherman Act, which prohibits anticompetitive conduct, and the Foreign Trade Antitrust Improvements Act (FTAIA), which defines the Sherman Act's extraterritorial application.

GENERALLY, THE FTAIA PROVIDES THAT THE SHERMAN ACT does not apply to purely foreign activity, but the Sherman Act could apply to partially foreign activity. This article outlines significant considerations to help you understand when U.S. antitrust law reaches foreign conduct.

Why Is the FTAIA Needed?

Section 1 of the Sherman Act,[1] declares illegal every "contract, combination . . . or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations." Thus, by its own terms, the Sherman Act has extensive reach and would apply to any agreement that (unreasonably) restrains trade or commerce involving a foreign nation. To limit the reach of the Sherman Act, U.S. courts developed a set of guidelines to determine when, in fact, the Sherman Act reached foreign conduct.

In *United States v. Aluminum Co. of America*, Judge Learned Hand of the U.S. Court of Appeals for the Second Circuit fashioned an effects test to determine whether U.S. antitrust law applies to foreign conduct.[2] Under the effects test, Judge Hand held, U.S. law would apply to foreign business activity (1) "intended to affect" U.S. commerce, and (2) "shown actually to have had some effect upon" U.S. commerce. Subsequent courts followed

Judge Hand's general guidance but disagreed significantly as to when the Sherman Act applied to foreign conduct.

In response to this disagreement, Congress enacted the FTAIA in 1982.[3]

1. 15 U.S.C.S. § 1. 2. 148 F.2d 416 (2d Cir. 1945). 3. 15 U.S.C.S. § 6a.

> Absent compelling evidence that the foreign activity involved minimal commerce, courts will generally find that the foreign activity had a substantial effect on U.S. commerce.

Why Is the FTAIA Relevant?

The FTAIA defines when U.S. antitrust law reaches foreign or international operations, purchases, and conduct. Thus, the FTAIA has special importance for companies that buy or sell goods or services outside the United States. For example, U.S. companies that purchase goods from foreign sellers may hold those sellers accountable under U.S. antitrust laws for anticompetitive practices, so whether the FTAIA bars U.S. antitrust claims would be relevant to those U.S. companies. Relatedly, foreign companies that sell goods or services knowing that those goods or services will be imported into the United States have an interest in knowing when and the extent to which U.S. law applies to those sales.

When Does the FTAIA Apply?

Courts often speak of the FTAIA in terms of whether it applies or not. That is because if the FTAIA applies, then it bars the application of the Sherman Act. By contrast, if the FTAIA does not apply, then the Sherman Act theoretically reaches the conduct at issue. Accordingly, courts will often analyze whether the FTAIA applies.

The FTAIA states a general principle—the Sherman Act does not apply to foreign trade or commerce—and then states the exceptions to that general principle. By its own terms, the FTAIA does not apply (and, thus, U.S. antitrust law may apply) in two cases:

- The conduct involves import trade or commerce
- The conduct involves non-import trade or commerce (i.e., U.S. exports, trade between or within foreign countries) that has a direct effect on U.S. commerce and that effect gives rise to a Sherman Act claim

The FTAIA's Application to Import Commerce

The FTAIA does not apply to direct imports. For example, courts have held that the following activities involve U.S. imports:

- Sales billed to entities within the United States regardless of where the products were ultimately delivered
- Sales billed to a foreign entity but still delivered to an entity inside the United States
- A conspiracy targeting U.S. import commerce regardless of whether the conduct involved a direct import into the United States

Courts also consider who imported the products. For example, courts have often found no U.S. import when the plaintiff, as opposed to the defendant, imported the product into the United States.[4]

Practice Tip. Courts consider conduct to involve U.S. import commerce not only when the defendant physically imported the product into the United States, but also when the defendant's conduct was directed at an import market, meaning that the conduct must target import goods or services.[5] For example, where foreign travel agents sued airlines for an alleged fixing of commission rates paid to foreign travel agents, the conduct was not directed at an import market because the airlines' alleged conduct targeted a foreign market, and any importing of the fixed rates into the United States occurred as a result of the plaintiff travel agents' own activities and not the actions of the defendant airline companies.

The FTAIA's Application to Non-import Commerce

The FTAIA does not bar Sherman Act claims based on foreign activity where that activity causes a direct, substantial, and reasonably foreseeable effect on U.S. commerce and the effect rises to the level of a Sherman Act claim. U.S. law applies to foreign conduct only when the conduct satisfies both conditions.

When Foreign Activity Has a Direct, Substantial, and Reasonably Foreseeable Effect

The first prong of the non-import commerce condition requires that the foreign activity have a (1) direct, (2) substantial, and (3) reasonably foreseeable effect.

Determining Whether the Foreign Activity Has a Direct Effect

Appellate courts disagree about what constitutes a direct effect. The U.S. Courts of Appeal for the Seventh and Second Circuits ask whether the "injury is within the reasonably proximate causal nexus of the anticompetitive behavior."[6]

4. *See* Kruman v. Christie's Int'l PLC, 284 F.3d 384, 395 (2d Cir. 2002). 5. Animal Sci. Prods. v. China Minmetals Corp., 654 F.3d 462, 470 (3rd. Cir. 2011). 6. Minn-Chem, Inc. v. Agrium, Inc., 683 F.3d 845, 856 (7th Cir. 2012); Lotes Co. v. Hon Hai Precision Indus., 753 F.3d 395 (2d Cir. 2014).

The Department of Justice's Antitrust Division agrees with this approach.[7] The U.S. Court of Appeals for the Ninth Circuit, on the other hand, asks whether the "immediate consequence of the anticompetitive behavior" caused the injury.[8] The Ninth Circuit's interpretation has been described as a stricter test because it requires a more direct causal connection than the Seventh and Second Circuits.[9]

Illustrations of these standards follow below:

- **Proximate Causal Nexus Test**
  - **Effect is not direct.** The effect is not direct when many layers come between the injury and the foreign anticompetitive conduct.

    Example. Foreign companies agree to supply reductions in foreign markets. The supply reductions lead to increases in the price of the product. The product is then sold to multiple intermediary purchasers before being imported into the United States at a higher price. The alleged injury is the higher price paid for the product in the United States. The supply reductions do not proximately cause the injury, because too many intermediate layers come between the conduct and the U.S. effect.[10]
  - **Effect is direct.** The effect is direct when an anticompetitively priced item indirectly imported into the United States causes the injury.

    Example. Technology manufacturers in a foreign country conspire to raise the price of LCD panels. They sell the anticompetitively priced panels to a technology company that incorporates the panel into a finished product. The technology company then imports the product into the United States. The alleged injury is the higher price paid for the finished product due to the higher panel price. The raised LCD panel prices proximately caused the injury because there was only one intermediary between the panel manufacturers and the plaintiff.[11]
- **Immediate Consequence Test**
  - **Effect is not direct.** The effect is not direct when the injury caused by the alleged anticompetitive depends on uncertain, intervening developments.

    Example. A foreign company bans the sale of specially modified seeds into the United States. The alleged injury is the loss of potential innovations that U.S. companies might create if they could buy the seeds. The injury is not an immediate consequence of the banned sale of the seeds because U.S. companies might not produce new innovations.[12]
  - **Effect is direct.** The effect is direct when an anticompetitively priced item indirectly imported into the United States causes the injury.

    Example. Technology manufacturers in a foreign country conspire to raise the price of LCD panels. They sell the anticompetitively priced panels to a technology company that incorporates the panel into a finished product. The technology company then imports the product into the United States. The alleged injury is the higher price paid for the finished product due to the higher panel price. The injury is an immediate consequence of the raised LCD panel prices because the finished product passes on the substantial price of the panels.[13]

Practice Tip. While commentators often discuss the difference between the two tests, as a practical matter the two tests will often reach similar outcomes because they both ultimately require a causal relationship between the defendant's conduct and the plaintiff's injury. Thus, even though the Ninth and Seventh Circuits reached apparently different results in *Hui Hsiung* and *Motorola Mobility*, those results turned not on the "direct" prong of the FTAIA, but on whether the *Illinois Brick* rule bars civil (but not criminal) claims.[14]

Determining Whether the Foreign Activity Has a Substantial Effect

Absent compelling evidence that the foreign activity involved minimal commerce, courts will generally find that the foreign activity had a substantial effect on U.S. commerce.[15]

Practice Tip. Whether the foreign activity has a substantial effect is rarely an issue that affects a court's determination of whether the FTAIA applies.

Determining Whether the Foreign Activity Has a Reasonably Foreseeable Effect

The reasonably foreseeable requirement incorporates an objective standard into the FTAIA. The test is "whether the alleged domestic effect would have been evident to a reasonable person making practical business judgments."[16]

Practice Tip. Given the overlay with the direct prong, this factor is often not seriously discussed by courts.

7. *See* Makan Delrahim, *Drawing the Boundaries of the Sherman Act: Recent Developments in the Application of the Antitrust Laws to Foreign Conduct*, 61 N.Y.U. Ann. Surv. Am. L. 415, 430 (2005). 8. United States v. LSL Biotech., 379 F.3d 672, 680 (9th Cir. 2004). 9. *Minn-Chem*, 683 F.3d at 857. 10. *See Minn-Chem*, 683 F.3d at 859. 11. *See* Motorola Mobility LLC v. AU Optronics Corp., 775 F.3d 816, 819 (7th Cir. 2015). 12. *See LSL Biotech.*, 379 F.3d at 681. 13. *See* United States v. Hui Hsiung, 778 F.3d 738, 759 (9th Cir. 2015). 14. Ill. Brick Co. v. Illinois, 431 U.S. 720 (1977). 15. *Compare Minn-Chem*, 683 F.3d at 856 (finding the sale of 5.3 million tons of potash to be substantial) with United Phosphorus, Ltd. v. Angus Chem. Co., 131 F. Supp. 2d 1003, 1012 (N.D. Ill. 2001), *aff'd*, 322 F.3d 942 (7th Cir. 2003) (finding the sale of only 500 grams of a chemical not substantial). 16. *Animal Sci. Prod.*, 654 F.3d at 471 (3d Cir. 2011).

Determining Whether the Effect Gives Rise to a Sherman Act Claim

The second prong of the non-import commerce condition requires that the effect rise to the level of a Sherman Act claim. If it does not rise to that level, then the FTAIA applies and bars the application of U.S. antitrust law.

The Supreme Court has held that the gives rise to prong prevents foreign purchasers from bringing a Sherman Act claim where the price-fixing activity is foreign but causes both injury in the United States and independent foreign injury.[17] In that circumstance, the independent foreign harm rather than the domestic harm gives rise to the plaintiff's claim. Only if the foreign harm from the price-fixing had given rise to a domestic injury could a plaintiff fit into the FTAIA domestic injury exception. Courts have found that the give rise to prong requires a showing of proximate causation, not just but-for causation.[18] Notably, the parties that are injured in the United States by the same foreign price-fixing fit into the FTAIA exception and therefore may bring a Sherman Act claim.

Only personally incurred injuries give rise to Sherman Act claims. For example, Motorola claimed that its foreign subsidiaries bought anticompetitively priced LCD panels during an alleged price-fixing scheme. The subsidiaries integrated the panels into larger products and sold those products to Motorola in the United States. Motorola brought claims against the LCD manufacturers on behalf of its subsidiaries, but the FTAIA barred those claims. Though directly affected by the manufacturers' actions, Motorola was an indirect purchaser, so the effect did not rise to the level of a Sherman Act claim.[19]

Practice Tip. Motorola's status as an indirect purchaser constituted a standalone, related flaw under *Illinois Brick* that independently defeated Motorola's claim. Direct purchasers pay increased prices on the immediate subjects of a cartel. Indirect purchasers buy goods from direct purchasers. *Illinois Brick* stands for the proposition that indirect purchasers generally have no standing under the Sherman Act—even if direct purchasers passed on their price increases to the indirect purchasers. As a result, the *Motorola Mobility* court held that *Illinois Brick* independently barred Motorola's antitrust claims.[20] Notably, the Department of Justice (DOJ) has taken the position that this judicial doctrine does not apply in criminal actions, which explains the difference between the results in *Motorola* and *Hui Hsuing*.

FTAIA also bars claims brought by Motorola's subsidiaries under U.S. antitrust law. The Seventh Circuit held that Motorola's subsidiaries—as non-U.S. entities—had to seek relief under the laws of the countries where either they or the LCD manufacturers had incorporated.[21] For a foreign plaintiff's injury to give rise to a U.S. antitrust law claim, the injury must arise from conduct that directly affected U.S. commerce.[22] As an example, foreign companies agreeing to boycott U.S. exports—reducing supply and in turn raising foreign prices—constitutes an acceptable chain of injury that would enable a foreign plaintiff to sue under U.S. antitrust law.

17. *See* F. Hoffmann-La Roche Ltd. v. Empagran S.A., 542 U.S. 155, 158–59 (2004). 18. *See, e.g.*, Empagran S.A. v. F. Hoffmann-LaRoche, Ltd., 417 F.3d 1267 (D.C. Cir. 2005); *In re* Dynamic Random Access Memory (DRAM) Antitrust Litig. v. Micron Tech., Inc., 546 F.3d 981, 987 (9th Cir. 2008); *In re* Monosodium Glutamate Antitrust Litig. Inquivosa SA v. Ajinomoto Co., 477 F.3d 535, 538 (8th Cir. 2007). 19. *Motorola Mobility*, 775 F.3d at 820. 20. *Motorola Mobility*, 775 F.3d at 823. 21. *Motorola Mobility*, 775 F.3d at 820. 22. *F. Hoffmann-La Roche*, 542 U.S.at 164.

Related Content

For background on the required effect on interstate commerce for domestic conduct, see

> **EFFECT ON COMMERCE IN FEDERAL ANTITRUST CASES**

RESEARCH PATH: *Antitrust > Civil Antitrust Litigation > Pleadings > Practice Notes*

For a discussion of the issue of whether an antitrust plaintiff has standing to sue, including a discussion of the antitrust injury doctrine, see

> **STANDING IN ANTITRUST CASES**

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For an overview of considerations related to application of the Foreign Trade Antitrust Improvements Act (FTAIA), see

> **FOREIGN TRADE ANTITRUST IMPROVEMENTS ACT (FTAIA) CHECKLIST**

RESEARCH PATH: *Antitrust > Civil Antitrust Litigation > Pleadings > Checklists*

For basic information on antitrust law, see

> **ANTITRUST LAW FUNDAMENTALS**

RESEARCH PATH: *Antitrust > Antitrust Fundamentals > Practice Notes*

Practice Tip. As suggested by *Motorola*, the foreign subsidiary of a U.S. company will have difficulty bringing a claim for a foreign injury under U.S. antitrust law.

The FTAIA and Criminal Law

The DOJ may still pursue criminal enforcement actions against foreign companies when private plaintiffs may not otherwise pursue antitrust claims. As discussed above, in *Motorola Mobility*, the U.S. Court of Appeals for the Seventh Circuit found that Motorola was barred from bringing its civil claims because the defendants' conduct did not give rise to an antitrust remedy for Motorola because of the *Illinois Brick* rule prohibiting claims by indirect purchasers. Judge Richard Posner, writing for the Seventh Circuit, observed, however, that the government could pursue criminal charges based on the same underlying conduct because there was no analog to the *Illinois Brick* rule in criminal proceedings. Indeed, Judge Posner acknowledged that the government's charges in *Motorola Mobility* were appropriate because the government was not limited by *Illinois Brick*.[23]

The FTC Act and the FTAIA

The FTAIA also limits the scope of the FTC's antitrust enforcement authority under Section 5 of the FTC Act, which prohibits unfair methods of competition. Thus, the limitations imposed by FTAIA on the Sherman Act apply similarly to the FTC's enforcement authority under Section 5 of the FTC Act.[24]

Comity

Because the FTAIA regulates foreign conduct, courts often consider comity when applying it. Comity is the principle that nations or states respect one another's sovereignty and laws. Courts may bar the application of U.S. antitrust law if, for example, its application would cause a foreign company to violate domestic law.[25] Notably, U.S. courts assume that the U.S. government's claims do not violate principles of comity.[26] L

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RESEARCH PATH: *Antitrust > Civil Antitrust Litigation > Pleadings > Practice Notes*

23. *See Motorola Mobility*, 775 F.3d at 825. 24. 15 U.S.C.S. § 45(a)(3). 25. *See* Hartford Fire Ins. Co. v. California, 509 U.S. 764, 798 (1993). U.S. courts determine for themselves, though, whether such a conflict exists. *See* Animal Sci. Prod., Inc. v. Hebei Welcome Pharm. Co., 138 S. Ct. 1865, 1870 (2018) (finding that the Chinese government's interpretation of Chinese law is not dispositive for determining whether Chinese law compelled Chinese manufacturers' price-fixing). 26. *F. Hoffmann-La Roche*, 542 U.S. at 171.

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Restrictions on Bank Affiliate Transactions:

Federal Reserve Act §§ 23A and 23B and Regulation W

This article covers Sections 23A and 23B of the Federal Reserve Act (FRA), which establish certain quantitative limits and other prudential requirements for loans, purchases of assets, and certain other transactions between a member bank and its affiliates. Regulation W, promulgated by the Board of Governors of the Federal Reserve System (Federal Reserve), implements Sections 23A and 23B of the FRA.

Overview of Sections 23A and 23B of the Federal Reserve Act

The term member bank, as used in Sections 23A and 23B, includes national banks, state-chartered banks, trust companies, and institutions that are members of the Federal Reserve. Member banks also include state-chartered banks that are not members of the Federal Reserve as the Federal Deposit Insurance Act[1] applies Sections 23A and 23B to insured state nonmember banks in the same manner and to the same extent as if they were Federal Reserve member banks.

The principal regulatory policy behind these restrictive provisions is to reduce the risk exposure of member banks, which take deposits that are insured, up to a $250,000 limit, by the Federal Deposit Insurance Corporation (FDIC) to the balance sheet and activities of their non-FDIC-insured affiliates. The regulatory objective, in other words, is to shield the taxpayer-funded deposit insurance fund from potential losses that may result from activities of insured depository institutions that may enter into transactions with their affiliates without due regard to conflicts of interest-related concerns.

1. 12 U.S.C.S. § 1828(j) .

A low-quality asset includes an asset that is classified or treated as “special mention” or “other transfer risk problems” in an examination report or pursuant to the bank’s or the affiliate’s own internal asset classification system...

Overview of Section 23A

Section 23A prohibits a bank from entering into a “covered transaction” with an affiliate if, after the transaction, (1) the aggregate amount of the bank’s covered transactions with that particular affiliate would exceed 10% of the bank’s capital stock and surplus, or (2) the aggregate amount of the bank’s covered transactions with all of its affiliates would exceed 20% of the bank’s capital stock and surplus.

Covered transactions include loans and other extensions of credit to an affiliate, investments in the securities of an affiliate, purchases of assets from an affiliate, and certain other transactions that expose the bank to the risks posed by its affiliates. A bank’s “capital stock and surplus” means the sum of the bank’s tier 1 and tier 2 capital under the risk-based capital guidelines, plus the balance of the allowance for loan and lease losses (ALLL) not included in tier 2 capital, based on the bank’s most recent Call Report.[2]

Section 23A requires all covered transactions between a bank and its affiliate to be on terms and conditions consistent with safe and sound banking practices (Safety and Soundness Requirement), subject to certain exemptions discussed later in this article, and prohibits a bank from purchasing a low-quality asset from an affiliate.

A low-quality asset includes an asset that is classified or treated as “special mention” or “other transfer risk problems” in an examination report or pursuant to the bank’s or the affiliate’s own internal asset classification system, an asset in a nonaccrual status, or an asset on which payments are more than 30 days past due. In addition, an asset whose terms have been renegotiated or compromised as a result of the obligor’s deteriorating financial condition, and any asset acquired through foreclosure, repossession, or otherwise in satisfaction of a debt previously contracted that has not been satisfactorily reviewed in an examination or inspection, are included within the definition of a “low-quality asset.”[3]

Extensions of credit to an affiliate and guarantees, letters of credit, and acceptances issued on behalf of an affiliate (credit transactions) must be secured by a statutorily defined amount of collateral, ranging from 100% to 130% of the covered transaction amount. Securities issued by an affiliate and low-quality assets are not acceptable collateral for any credit transaction with an affiliate.

Overview of Section 23B

Section 23B of the FRA requires that certain transactions, including all covered transactions, be on market terms and conditions (Market Terms Requirement). In addition to covered transactions, the Market Terms Requirement applies to:

- Any sale of assets by a bank to an affiliate
- Any payment of money or furnishing of services by a bank to an affiliate
- Any transaction in which an affiliate acts as agent or broker for the bank or any other person if the bank is a participant in the transaction
- Any transaction by a bank with a third party if an affiliate has a financial interest in the third party or if the affiliate is a participant in the transaction

In the absence of comparable transactions for identifying market terms, the bank must use terms (including credit standards) that are at least as favorable to the bank as those that would be offered in good faith to nonaffiliated companies.

If you are representing a bank that is engaged in what is, or may be, a covered transaction with one of its affiliates, you should consider carefully on behalf of your client the Safety and Soundness Requirement, the Market Terms Requirements, and other limitations applicable to such transaction under FRA Sections 23A and 23B and Federal Reserve Regulation W.

As noted later in this article, severe civil money penalties may be imposed for violating the aforementioned provisions, not only on the bank itself but also on an “institution-affiliated party” (IAP), as such term is defined under 12 U.S.C.S. § 1813(u), which can include an attorney who knowingly or recklessly counsels, or aids or abets, a violation.

2. *See* 12 C.F.R. § 223.3(d). 3. *See* 12 C.F.R. § 223.3(u).

Who and What Are Covered by Regulation W Restrictions?

Two threshold questions need to be answered in determining whether a transaction is subject to FRA Section 23A/23B and Regulation W. The first question is whether the transaction is between a bank and an "affiliate" of the bank. The second question is whether the transaction is a "covered transaction."

Definition of Affiliate

Regulation W applies to covered transactions between a bank and a bank affiliate. The definition of affiliate for purposes of Regulation W, set forth in Section 223.2, is broad and includes, among other things:

- Any company that controls the bank
- Any company that is controlled by a company that controls the bank
- Any company that is controlled, directly or indirectly, by or for the benefit of shareholders who beneficially or otherwise control, directly or indirectly, by the bank or any company that controls the bank
- Any company, including a real estate investment trust, that is sponsored and advised on a contractual basis by the bank or an affiliate of the bank
- Any registered investment company for which the bank or any affiliate of the bank serves as an investment adviser
- Any unregistered investment fund for which the bank or any affiliate of the bank serves as an investment adviser, if the bank and its affiliates own or control in the aggregate more than 5% of any class of voting securities or more than 5% of the equity capital of the fund
  - *Note that private equity funds, foreign investment funds, and commodities funds that currently escape treatment as an affiliate because they are not registered under the Investment Company Act of 1940 (1940 Act) may be covered under this definition.*
- An insured depository institution that is a subsidiary of the bank
- Any subsidiary of the bank that is an employee stock option plan or similar entity established for the benefit of the shareholders, partners, members, or employees of the bank or an affiliate of the bank
- Any subsidiary of the bank, if affiliates (other than insured depository institution affiliates) or controlling shareholders of the bank also control the subsidiary through a nonbank chain of ownership
- Subject to certain safe harbors, any portfolio company in which a holding company of the bank owns or controls, directly or indirectly, or through one or more other persons, 15% or more of the equity capital of the company under the merchant banking or insurance company investment authority of the Financial Services Modernization Act of 1999, also known as the Gramm-Leach-Bliley Act (GLBA)[4]
- Any company that the Federal Reserve (or other appropriate federal banking agency) determines to have a relationship with the bank or an affiliate of the bank such that covered transactions by the bank with the company may have a detrimental effect on the bank[5]

Definition of Covered Transaction

Once a determination has been made that a bank indeed proposes to enter into a transaction with an affiliate, then the next step is to see whether the transaction is covered under Section 23A or 23B and under Regulation W.

Under Section 223.3(h) of Regulation W, a covered transaction includes:

- An extension of credit to an affiliate
- A purchase of, or investment in, a security issued by an affiliate
- A purchase of an asset from an affiliate, including an asset subject to recourse or an agreement to repurchase
- The acceptance of a security issued by an affiliate as collateral for an extension of credit to any person or company
- The issuance of a guarantee, acceptance, or letter of credit, including an endorsement or standby letter of credit, on behalf of an affiliate; a confirmation of a letter of credit issued by an affiliate; and a cross-affiliate netting arrangement (cross-affiliate netting arrangements are defined in Section 223.3(j) of Regulation W as arrangements among a bank, one or more affiliates of the bank, and one or more nonaffiliates, where the nonaffiliate is permitted to deduct obligations of the affiliate to the nonaffiliate in settling its obligations to the bank, or a bank is required or permitted to add affiliate obligations to a nonaffiliate when determining the bank's total obligations to the nonaffiliate)

An extension of credit to an affiliate is broadly defined in Section 223.3(o) of Regulation W as the making or renewal of a loan, the granting of a line of credit, or the extending of credit in any manner whatsoever (examples include advance to an affiliate by means of an overdraft, cash item, or otherwise; a sale of federal funds to an affiliate; a lease that is the functional equivalent of an extension of credit to an affiliate; an acquisition by purchase, discount, exchange, or otherwise of a note or other obligation, including commercial paper or debt securities, of an affiliate; any increase in the amount of, extension of the maturity of, or adjustment to the interest rate term or other material term of an extension of credit to an affiliate; and any other similar transaction as a result of which an affiliate becomes obligated to pay money or its equivalent), including on an intraday basis, to an affiliate.

A bank's purchase of a debt security issued by an affiliate is an extension of credit by the bank to the affiliate for purposes of Section 23A. Keepwell agreements, under which a bank commits to maintain the capital levels or solvency of an affiliate, also are considered guarantees for purposes of FRA Section 23A and Regulation W. The regulatory presumption here is that credit risk incurred by the bank in such arrangements is similar to the risk incurred by the bank when it issues a guarantee on behalf of an affiliate.

Valuation and Timing Rules

Sections 223.21 through 223.24 of Regulation W set forth valuation and timing rules that are designed to determine the amount of a covered transaction subject to the quantitative limitations and collateral requirements of the rule and the time at which a transaction becomes subject to such limitations and requirements.

Valuation Rules for Credit Transactions

Credit transactions with affiliates generally are valued at the greatest of:

- The principal amount of the transaction
- The amount owed by the affiliate to the bank under the transaction
- The sum of the amount provided to, or on behalf of, the affiliate in the transaction and any additional amount the bank could be required to provide to, or on behalf of, the affiliate under the terms of the transaction

The value of a loan to an affiliate purchased by the bank from a nonaffiliate is the total amount of consideration given by the bank in exchange for the loan and any additional amount the bank could be required to provide to, or on behalf of, the affiliate. Although a bank's purchase of, or investment in, a debt security issued by an affiliate is considered an extension of credit to the affiliate, these transactions are not valued like other extensions of credit. Purchases of, or investments in, securities issued by an affiliate are valued at the greater of the bank's purchase price or the carrying value of the securities.

Special Timing Rules for Credit Transactions

A bank is deemed to enter into a credit transaction with an affiliate at the time during the day that the bank becomes legally obligated to enter into the transaction, not at the end of the day on which the loan agreement is signed or the loan is funded. Credit transactions with nonaffiliates generally become covered transactions when the nonaffiliate becomes an affiliate of the bank. If the nonaffiliate becomes an affiliate within one year after the bank has entered into the credit transaction with it, the bank must ensure that the collateral requirements of Regulation W are met promptly after the nonaffiliate becomes an affiliate. In all cases, the transaction must meet the Market Terms Requirement. However, leeway provided by the promptly standard is not available if the credit transaction is made in contemplation of the nonaffiliate becoming an affiliate of the bank.

Related Content

For an overview of bank lending limits and related regulatory restrictions, see

> LENDING LIMITS AND RESTRICTIONS

RESEARCH PATH: *Financial Services Regulation > Financial Services Transactions > Bank M&A, Asset Sales, and Bank Failure > Practice Notes*

For a checklist concerning affiliate transactions and compliance with Regulation W, see

> AFFILIATE TRANSACTIONS CHECKLIST FOR INSURED DEPOSITORY INSTITUTIONS

RESEARCH PATH: *Financial Services Regulation > Bank Activities and Regulatory Enforcement Actions > Regulatory Examinations and Interfacing with Federal Agencies > Checklists*

For a general discussion of Section 23 of the Federal Reserve Act, see

> 1 BANK HOLDING COMPANY COMPLIANCE MANUAL §7.01

RESEARCH PATH: *Financial Services Regulation > Secondary Materials*

For information about the FDIC, see

> FEDERAL DEPOSIT INSURANCE CORPORATION

RESEARCH PATH: *Financial Services Regulation > Bank Activities and Regulatory Enforcement Actions > Regulatory Examinations and Interfacing with Federal Agencies > Practice Notes*

4. 106 P.L. 102. 5. For a complete definition of Affiliate, please see the full practice note in Lexis Practice Advisor under Financial Services Regulation > Bank Activities and Regulatory Enforcement Actions > Holding Company Regulation and Intercompany Transactions > Practice Notes.

Loans Secured by Affiliate Securities

Loans by a bank to a third party that are secured exclusively by affiliate securities are valued at the lesser of:

- The total amount of the extension of credit
- The fair market value of the pledged affiliate securities, if they have publicly available price quotes

On the other hand, loans by a bank to a third party that are secured by both affiliate and nonaffiliate securities are valued at the lesser of:

- The total amount of the extension of credit, minus the fair market value of nonaffiliate
- The fair market value of the pledged affiliate securities, if they have publicly available price quotes (Under this valuation rule, the maximum amount that the bank must count against Regulation W's quantitative limits is the difference between the full amount of the loan and the fair market value of the nonaffiliate collateral.)

Securities of an eligible affiliated mutual fund are not considered securities issued by an affiliate for purposes of this valuation rule, subject to certain conditions designed to ensure liquidity and minimize the use of the exemption as a method of funding affiliates.

Eligible affiliated mutual fund securities are securities issued by an open-end investment company registered with the SEC under the 1940 Act if both of the following are true:

- The securities have publicly available price quotes.
- The bank and its affiliates do not own more than 5% of the fund's shares, excluding shares held in good faith in a fiduciary capacity.

Furthermore, the bank may not exclude affiliated mutual fund securities if it knows, or has reason to know, that the proceeds of the extension of credit will be used to purchase the affiliated mutual fund shares serving as collateral or otherwise will be used to benefit an affiliate.

Valuation Rules for Purchases of Assets from an Affiliate

Purchases of assets by a bank from an affiliate generally are valued at the total consideration given, including liabilities assumed, by the bank in exchange for the asset. The value may be reduced after the purchase to reflect amortization or depreciation of the asset, consistent with GAAP.

Regulation W provides a special valuation rule for a bank's purchase of a line of credit or loan commitment from an affiliate. A bank must value such an asset at the purchase price paid, plus any additional amount that the bank is obligated to provide under the credit facility. Without this special rule, a company would be able to transfer substantial amounts of unfunded obligations to its affiliated bank without being subject to Section 23A's quantitative limitations.

Valuation Rules for Purchases of or Investments in Affiliate Securities

As noted above, purchases of or investments in securities issued by an affiliate are valued at the greater of the bank's purchase price or carrying value of the securities. This approach reflects the risk of continuing exposure to an affiliate through an investment in securities, even if that investment was made at a price below the carrying value of the securities. On the other hand, if the carrying value of the investment declines below the purchase price as the affiliate's financial condition worsens, the rule limits the ability of the bank to provide additional funding as the affiliate approaches insolvency.

A bank may acquire securities of an affiliate in a transaction that results in the affiliate becoming an operating subsidiary of the bank. These transactions are treated as a purchase of assets and assumption of liabilities of an affiliate. The covered transaction amount for these transactions is the total amount of consideration given by the bank for the shares, plus the total liabilities of the transferred company. The value of the covered transaction may be subsequently reduced to reflect amortization or depreciation of the assets of the transferred company consistent with GAAP and sales of assets of the transferred company.

Various Limitations and Requirements

Quantitative Limitations

A bank may not engage in a new covered transaction with an affiliate if the aggregate amount of covered transactions between the bank and the affiliate would be in excess of 10% of the bank's capital stock and surplus after consummation of the new transaction. Aggregate covered transactions between the bank and all affiliates are limited to 20% of the bank's capital stock and surplus.

Consistent with GLBA, transactions between a bank and a financial subsidiary of the bank are not subject to the 10% limitation. This exemption from the 10% limit applies to investments by the bank in its own financial subsidiaries. Investments by the bank in the financial subsidiaries of affiliated depository institutions are subject to the 10% limitation. Aggregate covered transactions with all financial subsidiaries and other affiliates of the bank are subject to the 20% limitation.

Consistent with existing interpretations of Section 23A, Regulation W does not require the unwinding of transactions if a bank's capital declines such that the 10% or 20% quantitative limitation is exceeded. However, new transactions would be forbidden until the quantitative limits could be met.

Collateral Requirements

Any credit transaction between a bank and its affiliate must be secured with the statutorily required amount of collateral.

Under Section 223.14 of Regulation W:

- A credit transaction must be secured by collateral having a market value equal to at least:
  - 100% of the amount of the transaction if the collateral is:
    - Obligations of the United States or its agencies
    - Obligations fully guaranteed by the United States or its agencies as to principal and interest
    - Notes, drafts, bills of exchange, or bankers' acceptances that are eligible for rediscount or purchase by a Federal Reserve Bank
    - A segregated, earmarked deposit account with the bank that exists for the sole purpose of securing credit transactions between the bank and its affiliates and is identified as such
      - 110% of the amount of the transaction if the collateral is obligations of any state or political subdivision thereof
      - 120% of the amount of the transaction if the collateral is other debt instruments, including loans or other receivables
      - 130% of the amount of the transaction if the collateral is stock, leases, or other real or personal property
  - The following types of collateral are ineligible collateral under Regulation W:
    - Low-quality assets
    - Securities issued by any affiliate
    - Equity securities issued by the bank and debt securities issued by the bank that represent regulatory capital of the bank
    - Intangible assets, unless specifically approved by the Federal Reserve
    - Guarantees, letters of credit, and similar instruments

In addition, a bank must maintain a perfected security interest in collateral securing credit transactions. The security interest must be enforceable under applicable law, including in the event of bankruptcy or similar default.

If the bank does not have a first priority security interest in the collateral, it must deduct from the value of the collateral the lesser of:

- The amount of any security interest in the collateral that is senior to the bank's interest
- The amount of credit secured by the collateral that is senior to the bank's position (any retired or amortized collateral must be replaced with additional eligible collateral over the life of the credit transaction)

Note that some transactions are exempt from the collateralization requirements. These include:

- An acceptance that is already fully secured either by attached document, or other property with an ascertainable market value that is involved in the transaction
- The unused portion of an extension of credit to an affiliate if the bank does not have any legal obligation to advance additional funds until required collateral is posted
- Purchases of affiliate debt securities by the bank from a nonaffiliate in a bona fide secondary market transaction

Applicability to U.S. Branches and Agencies of Foreign Banks

Section 223.61 of Regulation W applies Sections 23A and 23B only to transactions between a U.S. branch or agency of a foreign bank and affiliates of the branch or agency engaged directly in the United States in the following activities: full-scope securities underwriting and dealing, non-credit-related insurance underwriting, merchant banking, and insurance company investments. Regulation W also applies Sections 23A and 23B to transactions between a U.S. branch or agency of a foreign bank and any portfolio company controlled by the foreign bank under GLBA's merchant banking or insurance company investment authorities. Regulation W does not apply to transactions between a U.S. branch or agency of a foreign bank and other affiliates or to transactions between the foreign bank's non-U.S. offices and its U.S. affiliates.

Special Rules and Exemptions under Regulation W

Special Rules for Derivatives Transactions

Under Section 223.33 of Regulation W, a bank must establish policies and procedures reasonably designed to manage the credit exposure arising from its derivatives transactions with each affiliate and all affiliates in the aggregate. Specifically, the policies and procedures must at a minimum provide for:

- Monitoring and controlling the credit exposure arising at any one time from the bank's derivatives transactions with each affiliate and all affiliates in the aggregate
- Ensuring that the bank's derivatives transactions comply with the Market Terms Requirement of Section 23B

In particular, a bank must:

- Have in place credit limits on its derivatives exposures to affiliates that are at least as strict as those imposed on unaffiliated companies engaged in similar businesses and substantially equivalent in size and credit quality
- Monitor its derivatives exposure to affiliates in a manner at least as rigorous as used to monitor exposure to comparable unaffiliated companies
- Price, and require collateralization of, affiliate derivatives transactions in a way that is at least as favorable to the bank as pricing and collateralization of unaffiliated transactions

Monitoring and controlling the credit exposure from derivatives transactions includes, at a minimum, imposing appropriate credit limits, mark-to-market requirements, and collateral requirements. The limits and requirements imposed by a bank should reflect the nature, volume, and complexity of its derivatives transactions, and should be approved by the board of directors of the bank or an appropriate board committee.

Under Section 223.33(c) of Regulation W, a credit derivative between a bank and a nonaffiliate in which the bank provides credit protection to the nonaffiliate with respect to an obligation of an affiliate of the bank is considered a guarantee by a bank on behalf of an affiliate and, as such, would be a covered transaction. Such derivatives include:

- An agreement under which the bank, in exchange for a fee, agrees to compensate the nonaffiliate for any default of the underlying obligation of the affiliate
- An agreement under which the bank, in exchange for payments based on the total return of the underlying obligation of the affiliate, agrees to pay the nonaffiliate a spread over funding costs plus any depreciation in the value of the underlying obligation of the affiliate

Special Rules for Financial Subsidiaries

Regulation W treats financial subsidiaries of a bank as affiliates of the bank, in contrast to the general treatment of subsidiaries of a bank as nonaffiliates. A financial subsidiary is any subsidiary of a national or state bank that engages in activities (whether as principal or agent) not permissible for national banks to conduct directly.

Regulation W exempts from the definition of a financial subsidiary a subsidiary of a state bank that engages only in activities permissible for the state bank to conduct directly or activities lawfully conducted prior to December 12, 2002, the date of publication of final Regulation W. However, neither of these exemptions is available for a financial subsidiary

of a state bank that engages in principal activities that GLBA requires a national bank to conduct in a financial subsidiary. For example, a subsidiary of a state bank that is underwriting and dealing in bank-ineligible securities would be a financial subsidiary.

A bank's investment in securities issued by its own financial subsidiary is valued at the greater of:

- The total amount of consideration given by the bank in exchange for the security
- The carrying value of the security as of the date of acquisition (The carrying value of the bank's investment for purposes of this valuation rule is not adjusted going forward for any earnings retained or losses incurred by the subsidiary after the bank's investment.)

Exemptions from the Attribution Rule

Regulation W provides certain exemptions from the general rule that treats a transaction with any person as an affiliate transaction to the extent that the proceeds of the transaction are used for the benefit of, or transferred to, an affiliate. Notwithstanding these exemptions, these transactions are subject to the Safety and Soundness and Market Terms Requirements of Regulation W. Please refer to the [complete practice note] in Lexis Practice Advisor for a comprehensive explanation of exemptions from the Attribution Rule, including:[6]

- Exemption from the Attribution Rule for General Purpose Credit Cards
- Exemption from the Attribution Rule for Agency Transactions
- Exemption from the Attribution Rule for Riskless Principal Transactions
- Exemption from the Attribution Rule for Preexisting Lines of Credit

Exemptions from the Quantitative Limits and Collateral Requirements

- Sister Bank Transactions
- Exemption for Purchases of Marketable Securities
- Exemption for Internal Corporate Reorganizations
- Exemption for Nonrecourse Loan Purchases

Exemptions from the Quantitative Limitations, Collateral Requirements, and Low-Quality Asset Purchase Prohibition[7]

- Exemption for Intraday Credit to Affiliates
- Exemption for Riskless Principal Transactions
- Exemption for Purchases of Municipal Securities from a Securities Affiliate
- Exemption for Nonrecourse Loan Purchases

Additional Transactions Exempt from the Quantitative Limitations, Collateral Requirements, and Low-Quality Asset Purchase Prohibition include the following:[8]

- Purchases of loans subject to repurchase
- Purchases of securities of a servicing affiliate
- Purchases of liquid assets
- Purchases of assets by a newly formed bank
- Mergers and acquisitions (12 U.S.C.S § 1828(c))
- Correspondent banking deposits
- Giving credit for uncollected items
- Transactions secured by cash or U.S. government securities

6. Exemptions from the Attribution Rule are listed and explained in the full practice note in Lexis Practice Advisor under Financial Services Regulation > Bank Activities and Regulatory Enforcement Actions > Holding Company Regulation and Intercompany Transactions > Practice Notes. 7. For additional explanation of Exemptions from the Quantitative Limitations, Collateral Requirements, and Low-Quality Asset Purchase Prohibition, see the full practice note in Lexis Practice Advisor under Financial Services Regulation > Bank Activities and Regulatory Enforcement Actions > Holding Company Regulation and Intercompany Transactions > Practice Notes. 8. For additional explanation of transactions exempt from the quantitative limitations, collateral requirements, and low-quality asset purchase prohibition, see the full practice note in Lexis Practice Advisor under Financial Services Regulation > Bank Activities and Regulatory Enforcement Actions > Holding Company Regulation and Intercompany Transactions > Practice Notes.

Exemption from the Prohibition on Purchases of Low-Quality Assets

The general prohibition on purchases of low-quality assets from affiliates does not apply to certain situations in which a bank seeks to protect its interest in a distressed loan participation. Under Section 223.15(b) of Regulation W, the prohibition does not apply to the renewal of, or extension of additional credit with respect to, a bank's participation in a loan to a nonaffiliate that was originated by an affiliate of the bank, if all of the following are true:

- The loan was not a low-quality asset at the time the bank purchased its participation.
- The renewal or extension of additional credit is approved as necessary to protect the bank's investment by the board of directors of the bank.
- The participating bank's share of the renewal or extension of additional credit does not exceed its proportional share of the original transaction by more than 5%, unless the bank obtains the written approval of its appropriate federal banking agency.
- The bank provides its appropriate federal banking agency with written notice of the renewal or extension of additional credit within 20 days.

Penalties for Violations

Section 29 of the FRA[9] provides for civil money penalties for any member bank, as well as any IAP with respect to such member bank, that violates Section 23A or 23B of that Act. IAPs are defined broadly to include a director, officer, employee, or agent of a member bank, as well as (under certain circumstances) a consultant or joint venture partner who participates in the conduct of the affairs of the bank, and an independent contractor (including any attorney, appraiser, or accountant) who knowingly or recklessly participates in such violation.

The term violate includes any action (alone or with another or others) for or toward causing, bringing about, participating in, counseling, or aiding or abetting a violation.

- **First tier penalties.** Any member bank which, and any IAP with respect to such member bank who, violates any provision of Section 23A or 23B, or Regulation W, shall forfeit and pay a civil penalty of not more than $5,000 for each day during which such violation continues.
- **Second tier penalties.** Any member bank which, and any IAP with respect to such member bank who, in committing such violation:
  - Recklessly engages in an unsafe or unsound practice in conducting the affairs of such member bank
  - Breaches any fiduciary duty; and which violation, practice, or breach:
    - Is part of a pattern of misconduct
    - Causes or is likely to cause more than a minimal loss to such member bank
    - Results in pecuniary gain or other benefit to such party, shall forfeit and pay a civil penalty of not more than $25,000 for each day during which such violation, practice, or breach continues
- **Third tier penalties.** Any member bank which, and any IAP with respect to such member bank who knowingly:
  - Commits any such violation
  - Engages in any unsafe or unsound practice in conducting the affairs of such member bank
  - Breaches any fiduciary duty; and knowingly or recklessly causes a substantial loss to such member bank or a substantial pecuniary gain or other benefit to such party by reason of such violation, practice, or breach, shall forfeit and pay a civil penalty of not more than $1 million (or 1% of the total assets of such member bank, whichever is lesser) for each day during which such violation, practice, or breach continues

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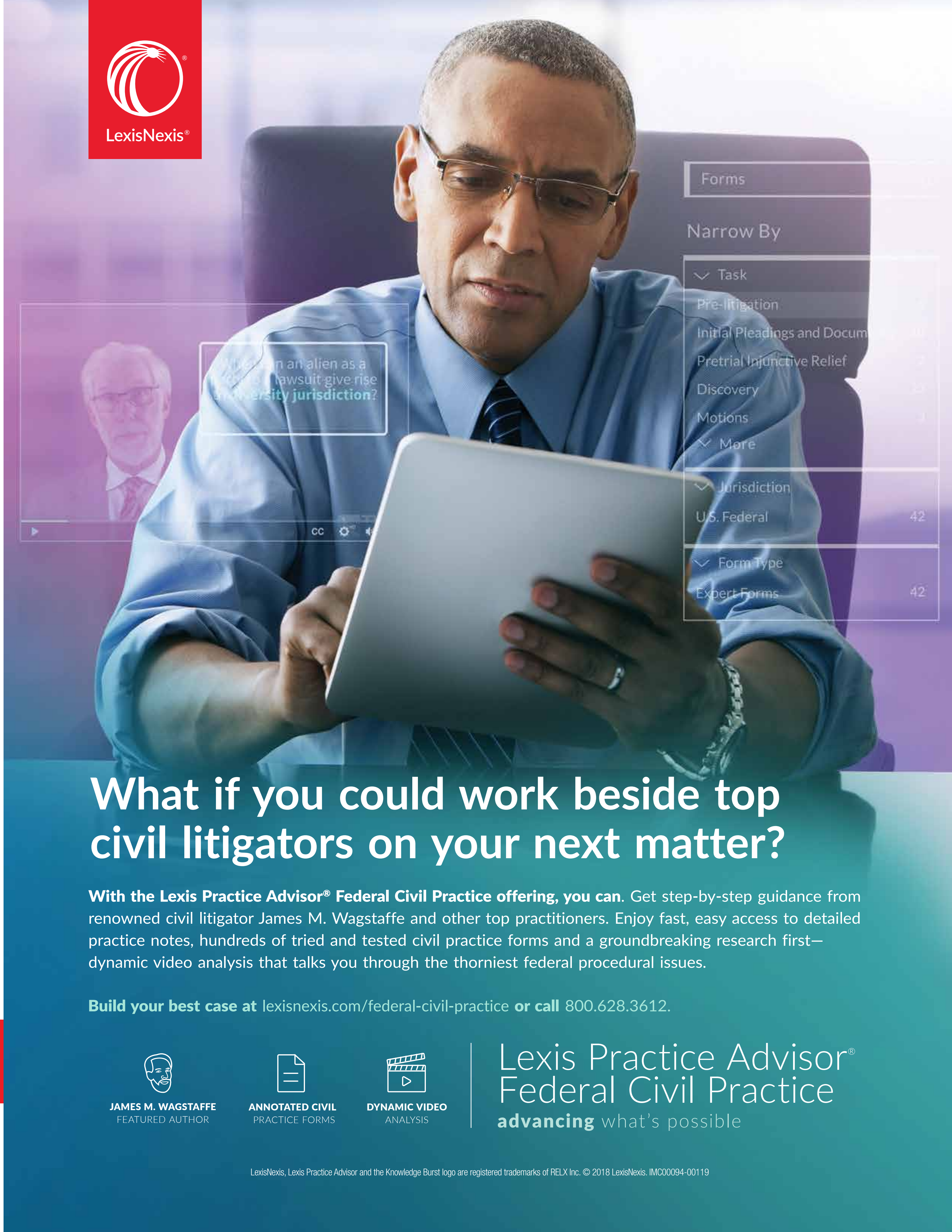
RESEARCH PATH: Financial Services Regulation > Bank Activities and Regulatory Enforcement Actions > Holding Company Regulation and Intercompany Transactions > Practice Notes

9. 12 U.S.C.S. § 504

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Market Trends: Employee Stock Ownership Plans

This market trends article covers employee stock ownership plans (ESOPs), which are a combination of a tax-qualified retirement plan and a corporate finance tool, and addresses recent trends in ESOPs relating to the design and structuring of the transaction, setting the price of the ESOP shares, and governing the post-ESOP company. Although sometimes misunderstood, ESOPs can be a very effective form of exit strategy and corporate succession structure for family-owned and closely-held businesses in the United States.

AN ESOP IS A FORM OF EMPLOYEE RETIREMENT BENEFIT plan governed by the Internal Revenue Code (IRC) and the Employee Retirement Income Security Act of 1974 (ERISA)[1] that is designed to invest primarily in securities issued by the employee's company or the sponsoring company. Although an ESOP transaction is not always considered by closely-held business owners ready to sell, studies show ESOPs have significant potential to create economic stability, provide significant retirement benefits for employees, and increase corporate growth, while at the same time providing business owners a gradual exit and source of liquidity. Provisions of the IRC give businesses and employees major tax incentives to establish ESOPs.

Deal Structure and Process

Benefits of ESOPs

According to the non-profit National Center for Employee Ownership (NCEO), which tracks economic trends in employee ownership:

- ESOP companies are 25% more likely to stay in business.
- Employee-owners were four times less likely to be laid off during periods of recession.
- Employees in ESOP companies may have greater retirement accounts.
- Wages may be up to 5%–12% higher in ESOP companies.

1. 29 U.S.C.S. § 1001.

It should also be noted that unlike other defined contribution plans governed by ERISA (like 401(k) plans), retirement benefits under ESOPs are 100% company-funded and employees do not invest any of their own funds.

The majority of ESOP companies are not public companies and thus do not file Securities and Exchange Commission (SEC) reports. In view of this lack of ongoing public disclosure, their structures may be less well known than businesses sold in the public arena. Due to the ESOP's perceived and actual complexity, the M&A professional community and the middle-market business sector have often discounted or ignored the potential opportunities offered by an ESOP. Although economic data positively correlates employee-ownership, corporate growth, productivity, and sustainability, recent studies show that ESOP buyouts and stock purchases account for possibly as little as 1% of the business owner exit/M&A market in the United States.

The opportunities afforded by an ESOP may be overlooked in succession planning and exit discussions, due to the lack of knowledge about ESOPs other than by a relatively select group of financial and legal professionals. Given the potential for significant tax efficiencies in the transaction for the sponsoring company, the sellers, and employees, and the potential for long-term corporate growth, employee retention, and satisfaction, an ESOP should be discussed as an exit strategy alternative in any conversation involving succession planning or a sale.

Leveraged ESOP Structure

In the typical ESOP transaction, the ESOP trustee (trustee) serves as the buyer, with the often closely-held group of founders or the company serving as sellers of the corporate stock. NCEO statistics provide that 75.4% of ESOP-owned companies used a leveraged financing structure, meaning borrowed funds were utilized to acquire employer shares held by the ESOP trust. In a leveraged ESOP purchase, the funds for the trustee to purchase shares are often borrowed from the company's existing senior lender or a private equity lender, with the selling shareholders providing additional subordinated debt financing of the purchase price through the ESOP trust's issuance of notes in favor of the sellers. The ESOP trust does not have the means to repay the loans to the senior lender, mezzanine lender, or sellers for the purchase of the employer stock other than through internal loans and contributions funded from the sponsoring company. Thus, the company will make cash contributions to the ESOP trust over the life of the loan to enable the ESOP to make principal and interest payments on the funds borrowed to purchase the employer shares. The sponsoring company often later assumes the debt the ESOP trust owes to the selling shareholders through a refinancing of the seller notes. The senior lender releases the purchased shares used as collateral as the debt is repaid and shares are then allocated to the accounts of participating employees over time. This is only one example of a typical leveraged ESOP financing structure. In a non-leveraged ESOP structure, the shares or cash are contributed from the employer company to the ESOP trust.

Trends in ESOPs

ESOP transactions and governance involve specialized processes whose structures and operations must comply with the IRC, ERISA, and the oversight of the Department of Labor (DOL) and the Internal Revenue Service (IRS). Over the last several years, as the size of ESOP transactions has increased, some of the processes related to ESOPs have undergone change due to an increase in DOL proceedings against ESOP trustees, private litigation, and intensified DOL reviews of sponsoring employer securities valuations.

ESOPs 2017–2018 and Beyond —Recent Statistics

An advocate of employee ownership, the NCEO estimates there are approximately 6,669 employee stock ownership plans covering around 14 million employees, holding total assets of an estimated $1.3 trillion. NCEO further estimates that employees in the United States beneficially control about 8% of corporate equity. Recent data reveals that the slight majority of ESOPs (3,477 companies) are C corporations (C Corp) with the remaining (3,192) as subchapter S corporations (S Corp).

Recent Trends in ESOP Structuring

Timeline

For calendar fiscal year-end companies, many ESOP transactions are third and fourth quarter transactions with closings during December to enable a clean fiscal-year end transition from management ownership to ESOP ownership. Businesses and sellers can receive significant tax benefits in the year a company implements an ESOP transaction, which also ties into year-end planning.

Ideally, the transaction timeline should provide four to six months (or additional time dependent on complexity) from beginning to end. The timeline begins with initial planning stages, selection of the financial advisory firm to the company which performs financial modeling, the selection of a law firm with ESOP experience, the design of the retirement plan provisions, and an independent trustee interview process with a number of candidates and engagement of the trustee. A thorough careful process is very important and requires the allocation of sufficient time to enable the trustee to select its own valuation advisor and legal counsel and to conduct due diligence. Significant time is also needed to design the ESOP and complete the ESOP transaction.

If the transaction involves a tender offer, corporate restructuring, or other corporate redemption of shares, the timeline should be expanded.

Deal Terms

Uptick in 100%-Owned ESOP Transactions

There is a recent trend towards implementing a 100% buyout of the selling shareholders by the ESOP either in one stock purchase and/or a stock redemption transaction or in multiple stages over time. One major reason for this trend is that because of the financial magnitude of the complete 100% buyout, there is a greater need for new sources of capital. Private equity firms are becoming more interested in ESOP transactions to provide additional mezzanine capital for larger transactions, and management sellers often participate in junior lending or mezzanine financing through the issuance of debt. The other major reason for the trend towards 100% owned ESOPs is that an S Corp that is 100% owned by an ESOP will be exempt from paying federal income taxes.

Synthetic Equity

In a typical ESOP transaction, the trustee is an independent passive investor and must rely on the continuity of current management to run the company. Retaining key management is thus very important. Management incentive plans, providing in some cases stock appreciation rights with deferred cash payouts, are commonly implemented at the time of adoption of the ESOP to provide additional upside to key members of management in 100%-owned structures. These deferred compensation plans are typically granted to both retain key employees and provide incentive for performance in a reasonable percentage tied to outstanding equity on a fully diluted basis.

Warrants in ESOP Transactions

Redeemable warrants with company-elected call features are most often used to provide sellers additional value for providing debt financing to the transaction. The terms of the warrants should be carefully designed to avoid overly dilutive terms affecting shareholder plan valuations. Providing warrants to selling shareholders aligns their incentive for company growth with the ESOP and saves the company important cash flow immediately following the closing.

Call Right upon Notice of Exercise

Warrants most often give the ESOP-owned company the ability to call the warrant upon exercise by the warrant holder. The reacquisition of equity by the warrant holder through the exercise of the warrant, although theoretically possible, is generally not intended in typical ESOP structures.

Call Right upon Debt Retirement

The warrants may often contain a right triggered at the time that the company has repaid in full its senior bank loan. Upon the bank repayment trigger, the company would have a window of opportunity, for a specified period, to pay the warrant holders in cash the excess of the fair market value of the equity at the time over the warrant strike price.

Corporate Governance Trends

A common misperception of employees (and some members of management) new to the ESOP-owned structure is that the employees, as participants in the plan, will self-govern the company. In reality, the exiting founder and majority shareholder along with the existing management team often continue to manage the company immediately following the sale transaction, while also continuing to participate in governance at the board of directors' level. However, as ESOP companies mature, many companies increase the involvement of employee-owners through participation on committees.

> The lowered corporate tax rate beginning in 2018 will be beneficial to ESOPs which are C Corps by potentially increasing available cash.

Essential Governing Board and Committees

Following the close of the ESOP sale transaction, more formalized corporate governance procedures and practices should be implemented. Although ESOP company governance is dissimilar in many aspects from public company governance, the trend is clearly for an increase in governance when compared to the pre-transaction operations of these closely held companies. Conscious design and recruiting for the corporate boards and committees may likely be occurring for the first time in the history of the company, especially in the case of a family-owned business or sole shareholder sale to the ESOP where informality has prevailed (though likely due to necessary resource allocation and without fault of the prior owners).

Trustee as Stockholder Representative

One of the trustee's primary responsibilities as shareholder representative is voting the ESOP shares to select the ESOP company board of directors. In addition, the trustee is responsible for managing the assets of the ESOP trust and establishing, based on the recommendation of an independent valuation advisor, the annual ESOP stock price.

The legal landscape is shifting toward the trustee negotiating additional contractual provisions to facilitate expanded involvement and discretion in the election of directors including the ability to nominate director candidates. Whether trustees will in practice exercise such discretion and interact in the annual meeting elections process remains to be seen.

Board of Directors' Composition

Use of independent or outside directors on ESOP boards has been required for some time by trustees through contractual provisions. Although not a new concept, increasing the use or number of outside directors on the ESOP company board may be gaining favor generally in view of recent DOL and private class action litigation, as will be discussed later in this article. Outside directors with no family relationship with former management or employment history with the ESOP company will be viewed more favorably by the DOL during an ESOP investigation. Outside directors will likely be most effective if they are experienced in or familiar with the ESOP company's specific industry. The independent director should support the concept of an employee-owned company. Independent directors enhance the credibility of boards and build trust among the management and employee constituents, providing additional resources to the corporate boards overall.

ESOP Committee

The ESOP committee may consist of members of the board of directors and non-board members of management. In some cases, however, state corporate statutes addressing committee composition and formation may not allow non-board members to serve on or cast votes on a committee of the board.

The ESOP committee may initially include sellers of securities to the ESOP and will ideally include the board member closest to the corporate treasury and financial department with a reasonable understanding of the inner workings of the ESOP. The committee should also include a board member with an open line of communication to the human resources department and rapport with plan participants generally. The ESOP committee is often the plan administrator (a requirement under ERISA), thereby having plan operation duties and other responsibilities as outlined in guidelines or a charter which vary by company. Most often, they include the responsibility for delivery of a summary description of the plan, an annual report on account balances, and reports on amendments to the plan, and completing the annual government filing (Form 5500). The ESOP committee is also usually responsible for communications to plan participants and employees' introduction and orientation to the ownership plan.

In practice, the ESOP committee is the board's and executive management's governing body and interacts on an ongoing basis with the plan participants. Thus, the members of this committee are vital to the existence of the ownership structure.

Compensation Committee

There is also a trend for boards of ESOP companies to create compensation committees. The compensation committee of the board of directors in many ESOP structures is a contractual requirement imposed by the trustee in a shareholders' agreement among the trustee, the sponsoring company, and the company sellers. The committee is commonly charged with managing an incentive plan, the sellers' future compensation, and the management team's compensation in a manner that ensures that executive compensation is reasonable and aligns the executive team and the plan participants to maximize share value.

Members of the compensation committee are usually members of the full board tasked with compensatory decision making. Consideration should be given to inclusion of independent, non-executive management members on this committee. Independent members of the compensation committee will be viewed more favorably by the DOL and may also satisfy lending requirements.

Nominating Committee and Audit Committee

The nominating committee and the audit committee are most often formed in public companies filing disclosure reports with the SEC. ESOP companies should also consider forming nominating and audit committees to select candidates, enhancing the independence of boards and eliminating conflicts of interest with the past members of management who may continue to hold senior or mezzanine debt. Audit committees in ESOP companies will ideally focus on the ESOP financial reporting requirements under ERISA.

ESOP company nominating and audit committee guidelines and charters are not driven by stock exchange requirements, generally, if the company is not publicly traded. Naming an outside director as chair of the nominating and audit committees, however, will eliminate actual or perceived conflicts of interest.

Industry Insights

NCEO publicly available data indicates that while ESOPs are represented in many industries, approximately 50% are in the services (28%) and manufacturing (22%) industries. Other industries notably represented with ESOP plans include finance/insurance/real estate (an aggregate of 17%), construction (11%), wholesale trade (9%), and retail trade (6%).

Legal and Regulatory Trends

New Tax Act Considerations

The Tax Cuts and Jobs Act[2] (Tax Act) was signed into law by President Donald J. Trump on December 22, 2017. Under the Tax Act, the nominal corporate tax rate was reduced to 21% for tax years after Dec. 31, 2017, eliminating higher rates up to 35%. The Tax Act will have some effect on how ESOP companies administer their plans, although the Tax Act did not otherwise make significant changes to the regulation of ESOPs. Most significantly, the Tax Act preserves the ESOP tax exemption for S Corps from income and unrelated business income taxes.

2. 115 P.L. 97, 131 Stat. 2054.

Post-Tax Act, More ESOPs May Elect to Remain C Corps or Convert

The lowered corporate tax rate beginning in 2018 will be beneficial to ESOPs which are C Corps by potentially increasing available cash. A lower C Corp tax rate could result in a greater net profit, assuming other performance metrics are otherwise equal. The greater net profit has the potential to increase the value of the shares owned by the C Corp ESOP and the value of the individual ESOP participants' accounts.

With the Tax Act's lower corporate rate, it is possible that more newly structured ESOP-owned companies are likely to remain a C Corp at the transaction or convert from an S Corp to a C Corp in an attempt to enhance the company's share value, while affording Section 1042[3] tax treatment to shares sold by the company's selling shareholders, where available.

Repurchase Obligations Will Be Monitored

The Tax Act's lower corporate tax rate could increase the sponsor company's stock value which, in turn, may affect a company's ESOP repurchase obligation or the requirement that ESOP employee stockholders have their ownership redeemed for cash due to retirement, death, disability, age diversification, and other triggering events. In light of the new tax rate, management may consider whether ESOP repurchase obligation studies will need to be updated to ensure that sufficient cash is available to meet the repurchase obligations to employees.

Main Street Employee Ownership Act

The Main Street Employee Ownership Act was signed by President Trump on August 13, 2018. This law is a confirmation of strong bipartisan congressional support for ESOPs. It is designed to make it easier for small companies to use the Small Business Administration to finance the transition to ESOP ownership.

DOL ESOP Litigation

During the last several years, the DOL has been involved in litigation scrutinizing valuations of employer securities and fiduciary standards of due diligence in sales to an ESOP. In 2017 alone, the DOL participated in at least 23 proceedings, specifically analyzing and criticizing the valuation of employer securities, which were compiled and summarized by the Plan Benefits Security Division. Further, in the exercise of its oversight, the DOL regularly audits newly-adopted ESOP company books and records and may examine fiduciary independence issues, valuation process issues, and the trustee's engagement in the valuation due diligence process as a determinant for purchase price.

Related Content

For an overview of fiduciary duties under ERISA, see

> **ERISA FIDUCIARY DUTIES**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Health and Welfare Plans > ERISA and Fiduciary Compliance > Practice Notes*

For additional information on fiduciary liability issues, see

> **EMPLOYER SECURITIES AND REAL PROPERTY ERISA INVESTMENT RULES**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Retirement Plans > ERISA and Fiduciary Compliance > Practice Notes*

To learn about designing a compliant employee stock ownership plan, see

> **EMPLOYEE STOCK OWNERSHIP PLAN DESIGN AND COMPLIANCE**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Incentive and Equity-Based Compensation > Equity-Based Compensation > Practice Notes*

For a sample employee stock ownership plan for a U.S. privately-held company, see

> **EMPLOYEE STOCK OWNERSHIP PLAN (PRIVATE COMPANY)**

RESEARCH PATH: *Employee Benefits & Executive Compensation > Retirement Plans > Design and Implementation > Forms*

A challenge for ESOP companies is that the DOL has not issued meaningful regulations or consistent guidance on ESOPs for many years. The closest thing the ESOP community has to such guidance is the DOL's position in litigation or settlement agreements. This was the case in 2014 when the DOL set forth a trustee's proper fiduciary process in its seminal settlement with GreatBanc Trust Company (GreatBanc).

The 2014 settlement between the DOL and GreatBanc became the standard operating procedure for parties in an ESOP sale transaction in which the ESOP is purchasing or selling employer securities that are not publicly traded. The standard procedures are set forth below.

3. 26 U.S.C.S. § 1042.

Hire a Qualified Valuation Advisor

In all purchase and sale transactions, the trustee should hire a qualified valuation advisor; prudently investigate the valuation advisor's qualifications; take reasonable steps to determine that the valuation advisor receives complete, accurate, and current information necessary to value the employee securities; and prudently determine that its reliance on the valuation advisor's advice is reasonable before entering into any transaction in reliance on the advice.

Document Valuation and Reasonableness

Under the *GreatBanc* standard, the trustee must request that the valuation advisor document in the valuation reports certain items (including reasonableness of the company's projections) in light of the company's five-year historical averages and the five-year historical averages or medians of peer public companies.

Obtain Financial Statements

The trustee must request that the company provide the trustee and valuation advisor with audited unqualified financial statements prepared by a certified public accountant for the preceding five fiscal years. In the event that audited unqualified financial statements are not available for any of the preceding five fiscal years, the trustee must determine whether is advisable to rely on the unaudited or qualified financial statements and the risk posed by such reliance.

Ensure No Conflicts of Interest

The trustee should engage a valuation advisor free from conflicts of interest (i.e., consider the valuation professional's prior engagements for the company undertaking the ESOP transaction). The trustee should prepare a written analysis addressing the reason for selecting the valuation advisor; a list of the valuation advisors the trustee considered and discussion of the qualifications the trustee considered; a list of references checked and discussion of the references' views on the valuation advisors; a summary of any potential valuation advisor's involvement in prior criminal or civil proceedings; and an explanation of the bases for concluding that the trustee's selection of the valuation advisor was prudent.

Evaluate the Valuation Report

The trustee should engage in a fiduciary review process related to documentation of its reliance on the valuation report, including comparing the valuation report with the due diligence information in its possession and determining whether conclusions are consistent with the available data and analyses.

Restrict Leverage

The trustee must not cause an ESOP to engage in a leveraged stock purchase under circumstances in which the principal amount of the debt financing the transaction exceeds the fair market value of the stock acquired which that debt, without regard to the interest rate or other terms of the debt used to finance the transaction.

Consider Claw-Back Arrangement or Purchase Price Adjustment

The trustee should consider in its evaluation whether it is appropriate to request a claw-back arrangement or other purchase price adjustment to protect the ESOP against possible adverse consequences in the event of significant corporate events or changed circumstances.

Create and Preserve Records

Finally, under the *GreatBanc* standard, the trustee should create and preserve records of the negotiated transaction to be maintained for a period of six years. These records should include how each member of the trustee's fiduciary committee voted on the proposed transaction and be signed and certified by each member of the voting committee and other trustee personnel who made any material decision in connection with the proposed transaction.

Recent Valuation Cases—First Bankers' Trust and Reliance Trust Settlements

More recently, subsequent to *GreatBanc*, the DOL has continued to express concerns that valuations must not rely on overly aggressive growth projections, which could lead to the employee ownership plan overpaying for shares of employer stock. Four recent DOL settlements with trustees have expanded and delineated fiduciary processes, especially with respect to hiring a valuation firm to evaluate the ESOP sponsor's securities, the trustee's due diligence, and analysis of the plan sponsor's business risks and projected financial performance. In 2017, the DOL entered into settlement agreements to resolve three lawsuits with First Bankers Trust Services Inc. (FBTS), the trustee of three ESOP-owned companies, alleging that FBTS violated ERISA and breached its fiduciary duties when it approved stock purchases by three ESOPs.

Risk Factors Must Be Analyzed and Commercially Reasonable Term considered

As part of the FBTS settlement agreements, the trustee defendant agreed to pay $15.75 million to the plans and to design procedures to enhance and ensure proper compliance in the future for handling ESOP transactions, including due diligence procedures. These FBTS settlement agreements provide that in selection and oversight of a valuation advisor the trustee must document the steps it takes to receive complete, accurate, and current information from the valuation advisor. Furthermore, the settlement agreements require (1) additional oversight of the valuation advisor's analysis, (2) a description of the risks factors and uncertainties facing the ESOP company which could cause the financial performance to fail to meet projections relied on by the valuation advisor, and (3) an analysis of whether the terms of the ESOP loan are as favorable as the terms of any loan between the company and any executive of the ESOP company made within the two years preceding the transaction.

In the wake of private litigation and enforcement activity alleging that indemnification contracts benefiting trustees are void as against public policy under ERISA, there appears to be a decreasing and narrowed use of indemnification provisions for trustees.

Critical Analysis of Company Projections

The FBTS settlement agreements require the trustee to perform additional critical analysis of the company's financial projections and to request new and reasonable projections from management, or reject the transaction.

Additional Due Diligence of Prior Management Transactions

Further, the FBTS settlement agreements provide that the trustee is required to ensure that in the course of due diligence the valuation advisor will obtain information about any transaction by the sellers in company stock and any prior defaults within the past five years by the company under its financing arrangements. The trustee must also obtain management letters and valuation-related information provided to the IRS within the prior five years.

Trustee Indemnification

In September 2018, Reliance Trust Company entered into a consent judgment with the DOL[4] representing a complete settlement, based on the DOL's claim that the trust overpaid for ESOP shares in the purchase of Tobacco Rag Processors. The consent judgment makes it clear that Reliance Trust cannot seek indemnification from either the ESOP or the company for any fees or expenses they incurred in defending the litigation or the DOL investigation.

Private Litigation

In addition to DOL enforcement activity, private litigation activity in the past two years has focused on the valuation process. In a recent case,[5] the district court ruled that the Constellis Group ESOP overpaid for the private company, causing damage to the ESOP for which the trustee was held liable for $30 million. The district court stressed in its memorandum opinion that ERISA fiduciaries cannot blindly rely on valuation professionals they hire without a significant level of investigation. The court's decision rested on outlined allegations that the trustee in this case did not adequately investigate the ESOP transaction valuation advisor's report and overlooked earlier valuation reports prepared by other advisors and the disparity in stock value between the two reports, thus failing to discharge its duty to ensure that the sale was for "adequate consideration" defined in ERISA as the fair market value of the asset as determined in good faith by the trustee. The trustee in the Constellis case has filed an appeal which is pending on the date of this article.

Additional Trends in ESOP Transactions

In the wake of private litigation and enforcement activity alleging that indemnification contracts benefiting trustees are void as against public policy under ERISA, there appears to be a decreasing and narrowed use of indemnification provisions for trustees. It may be the case that an indemnity payment to a trustee for defense costs to settle disputes, where wrongdoing may not be admitted or denied in the settlement, will become the subject of litigation and demanded to be voided. Recent court decisions voiding indemnification clauses have driven an increase in fiduciary insurance liability coverage integrated into transaction documents.

The authors further note there appears to be an increase in use of representation and warranty insurance in ESOP transactions, which may be highly beneficial to both the seller and buyer. This increase may be related to an overall increase and acceptance of this insurance product in acquisitions generally resulting from new insurers entering the market, and more competitive terms. The use of reps and warranties insurance is intended to enable the transaction parties to eliminate the seller indemnity for prolonged periods or altogether, subject to carve-outs for certain types of liabilities, including tax liabilities. This insurance can provide a highly streamlined

4. Acosta v. Reliance Trust Co., Inc., No.5:17-CV- 00214-D (E.D. N.C. Sept. 18, 2018). 5. Brundle v. Wilmington Trust N.A., 258 F.Supp. 3d (E.D. Va. 2017).

process for the buyer processing claims expeditiously with limited seller involvement.

Finally, there is a trend towards a longer and more detailed trustee selection process also driven by the plaintiff's bar litigation and enforcement activity given that trustees are increasingly litigation targets. Thus, trustees are currently revisiting their roles with their current ESOP company clients with a view to litigation risk and loss exposure analysis, and ESOP-owned companies are reviewing existing engagements with their trustees reassessing the role and responsibilities the trustee will play in the company, including the appointing and electing members of the board of directors and voting the ESOP shares.

Market Outlook

The market outlook for ESOPs is highly favorable as comprehensive studies continue to evidence that ESOP companies have a distinct advantage over non-ESOP companies in longer company life cycles, increasing sales, longer employment periods, and increased employee benefits. The M&A professional community is expected to react and evolve in light of the recent increase in DOL and private litigation in several ways in the future. Trustee engagement agreements will likely begin to place additional conditions on providing the trustee with the limited ability to exercise greater oversight and responsibility even in instances of a directed trustee and afford the trustee some discretionary decision making in limited circumstances. The trustee will be inclined to more vigorously negotiate indemnification agreements and insurance provisions to the extent allowable within the limits of ERISA and DOL case precedent, although such agreements may not absolve trustees from their fiduciary responsibilities under ERISA by holding trustees harmless from breaches of fiduciary duty. ESOP companies will gradually begin to implement more formalized corporate governance procedures, including more formalized annual meetings and annual meeting documentation. Trustees will become more involved in nominations of board of director members and committee members, while trustee liability insurance coverage will expand to cover potential litigation costs. Specifically, trustees moving forward will be likely to consider procedures to avoid a contractual ceding of shareholder control and more carefully accept engagements outlining their involvement in the board of director governance, director selection, and elections process. L

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Jim Wagstaffe AND THE WAGSTAFFE GROUP

Seven Summary Judgment Survival Skills

In federal and state court cases, the litigator's survival kit frequently has as its principal tool motions for summary judgment. For defendants, the winning case strategy frequently involves executing the summary judgment escape plan to survive the costs and risks of litigation. Conversely, for plaintiffs, staying alive for settlement and trial is quite often all about surviving the inevitable defense motion for summary judgment.

THEREFORE, SUMMARY JUDGMENT SURVIVAL SKILLS ARE CRUCIAL for litigators young and old. What follows are my seven sure-fire skills for winning or avoiding case-dispositive summary judgment rulings.

1 Stay Abreast of the Very Most Recent Summary Judgment Case Law

The case law on summary judgment is ever-evolving. And if you file your summary judgment papers unaware of that controlling hot new case, unlike Tom Hanks in the movie *Castaway*, you will be stranded in your losing case position unaware of recent developments.

For example, if you represent government officials and the summary judgment motion raises questions of qualified immunity, you'd better be familiar with District of Columbia v. Wesby, 138 S. Ct. 577 (2018) and the U.S. Supreme Court's totality of the circumstances protection for law enforcement officials who make reasonable inferences about allegedly unlawful conduct.[1]

Your summary judgment life raft can be found in Chapters 43 and 44 of The Wagstaffe Practice Guide: Federal Civil Procedure Before Trial (Lexis Nexis 2018). And access to the saving graces of hot developments in this area is right at your fingertips with our companion Current Awareness online feature that captures the hot new case decisions on summary judgment and all other procedural areas, available weekly.

1. *See also* McCoy v. Meyers, 887 F.3d 1034 (10th Cir. 2018) (qualified immunity—yes); Strand v. Minchuk, 908 F.3d 300 (7th Cir. 2018) (qualified immunity—no).

2 Plan the Summary Judgment Escape Route

Great litigators plan for summary judgment before filing or defending their state or federal lawsuits. This means lawyers at the outset must painstakingly evaluate the evidence and proof (or lack thereof) necessary to prevail when the ultimate summary judgment motion is presented.

The survival trick is the early outlining of the claims and defenses, while actually drafting on Day 1 the jury instruction setting forth the required elements for the case. Toward this end, you should design your discovery to obtain the necessary evidence to prevail on the anticipated summary judgment motion.

By way of example, let's suppose there is a statute of limitations question in the case. The moving party defendant will perform summary judgment case planning at the outset, plead the affirmative defense, and then have defense counsel lead the plaintiff at deposition to acknowledge his or her actual or constructive knowledge of the alleged wrongdoing beyond the statutory period. There often is no better way to obtain summary judgment than through the sworn testimony of the potentially unsuspecting (or unprepared) plaintiff at his or her own deposition.[2]

By the same token, to avoid summary judgment in this example, the plaintiff's lawyers not only will research the governing statute(s) and, if necessary, plead a tolling element (e.g., delayed discovery or fraudulent concealment), they will map out the plan (through interviews, written discovery and deposition) to provide oppositional evidence to be presented later on summary judgment. Know where the landmines are located, plan allegations and present honest sworn testimony accordingly—all in service of surviving the big defense litigation moment called summary judgment.[3]

Bottom line: you wouldn't take a trip without knowing your destination and the same is true when approaching surviving the summary judgment process. And you've got the perfect "summary judgment GPS" in Chapter 44 of my Lexis Nexis Practice Guide as it provides detailed road maps in the application of summary judgment motions in a large variety of substantive areas of law.

2. *See, e.g.*, Migliaro v. Fidelity Nat. Indem. Ins. Co., 880 F.3d 660 (3d Cir. 2018) (rejection of proof of loss claim leading to filing of suit triggers bar of statute of limitations). 3. *See, e.g.*, Soto v. Sweetman, 882 F.3d 865 (9th Cir. 2018) (court rejects equitable tolling of civil rights claim against government).

> Too many lawyers forget that on summary judgment the evidence submitted needs to be presented in an admissible form or with a showing that it will be admissible at trial.

3 Master the Most Favorable Light Rule

You'll never win the summary judgment game if you think it is a substitute for trial or somehow a vehicle for educating your judge. After all, you don't get summary judgment unless there is nothing for the jury to do—meaning the evidence, given the most favorable light for the other side, shows no genuine issue of material fact.[4]

Thus, the most important rule for summary judgment is that all inferences, the weight of all evidence, and each credibility determination are to be made in favor of the non-moving party. This is what the Supreme Court calls the "axiom" of summary judgment—the judge's function on summary judgment is not to weigh the evidence but to view it in the light most favorable to the non-moving party.[5]

Survival for proponents and opponents of summary judgment, therefore means having more than the proverbial strong case. To the contrary, it must be plain that the moving party wins even if all inferences, weight, and credibility are given to the other side. To ignore this survival tip means a lot of wasted time and expense, to say nothing of what one can read every day: appellate decisions reversing lower court grants of summary judgment.[6]

4 Play Family Feud Summary Judgment

In the game show Family Feud, host Steve Harvey seeks a focus on the successful answer most given to the posted question. Applied to summary judgment motions, the Family Feud inquiry aims at the Number One ground for prevailing on such motions: if possible formulate your motion around a dispositive question of law and tell the court why its resolution compels victory for your client.

Judges naturally favor jury determinations of fact questions and, therefore, are most open to summary judgment motions when framed as a question of law. Frankly, those are the questions judges—not juries—decide in the first instance.

As a survival tip and if possible, therefore, identify and raise questions of law when making summary judgment motions. Here are some examples of dispositive questions that are routinely resolved on summary judgment:

- Res judicata
- Statute of limitations
- Statute of frauds
- Meaning of unambiguous contract
- Plaintiff's status as a public figure

Following this Family Feud approach flows from the prism through which all such motions are viewed—to wit, is the moving party entitled to judgment as a matter of law.[7] So, for example, the question whether the plaintiff is an "employee" under the Fair Labor Standards Act is one of law, therefore, authorizing the court on summary judgment to evaluate the statutory balancing factors.[8]

5 Imagine Your Summary Judgment Evidence is on the Witness Stand

Too many lawyers forget that on summary judgment the evidence submitted needs to be presented in an admissible form or with a showing that it will be admissible at trial.[9] So, my fifth survival tip on summary judgment is to imagine that the declarations, affidavits, discovery excerpts, and exhibits are being introduced on the witness stand at a live hearing.

This discipline reminds you that, as if at a testimonial hearing, objections can and should be made to evidence that is not properly authenticated or inadmissible. This will emphasize to each side they must have fully contained evidentiary submissions, and also should make page and line written objections to the other side's evidence.

This survival skill is vital on multiple levels as seen in many exemplar cases in recent years. These include the following:

- Conclusory declarations are subject to objection on summary judgment.[10]
- Authentication and a proper foundation for evidence are also required on summary judgment.[11]

4. *See* Fed. R. Civ. P. 56(a). 5. Tolan v. Cotton, 572 U.S. 650 (2014). 6. *See, e.g.*, Strothers v. City of Laurel, 895 F.3d 317 (4th Cir. 2018) (manager's prior expressed wish to hire someone of another race supports inference of Title VII violation); Minarsky v. Susquehanna Cty., 895 F.3d 303 (3d Cir. 2018) (explanation for plaintiff's failure to report alleged harassment could be believed by jury). 7. Fed. R. Civ. P. 56(a). 8. Xuedan Wang v. Hearst Corp., 877 F.3d 69 (2d Cir. 2017). 9. *See* Wagstaffe Prac. Guide: Fed. Civil Proc. Before Trial § 43-VI[B][3]. 10. *See, e.g.*, Mancini v. City of Providence, 2018 U.S. App. LEXIS 32962 (1st Cir. 2018) (conclusory assertion of disability); Montgomery v. Risen, 875 F.3d 709 (D.C. Cir. 2017) (conclusory recitation of falsity in defamation suit). 11. *See, e.g.*, Orr v. Bank of America, 285 F.3d 764 (9th Cir. 2002) (attorney declaration without court reporter certificate insufficient to authenticate deposition transcript). 12. *See, e.g.*, Daubert v. NRA Group, 861 F.3d 382 (3d Cir. 2017).

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RESEARCH PATH: *Civil Litigation > Motions > Dispositive Motions > Practice Notes*

For more information on submitting summary judgment motions in federal court, see

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For a detailed explanation on how to oppose summary judgment in a federal court case, see

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> **SUMMARY JUDGMENT: SUBMITTING EVIDENCE IN SUPPORT OF THE MOTION (FEDERAL)**

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- Sham affidavits, which are ones containing statements that inexplicably contradict prior sworn testimony, are subject to being stricken on summary judgment.[12]
- Evidence not properly disclosed in discovery can be excluded on summary judgment.[13] And if imagining is hard, actually read your evidence out loud with a colleague at the ready to object as if at the evidentiary hearing. Be alert to all sorts of proper objections (e.g., hearsay, lack of personal knowledge, etc.) and then fix the evidence before submission. You can also try this out loud technique with the other side's evidence, converting it to written objection when justified.

6 Don't Count on Changing Horses in Middle of Summary Judgment Stream

It is vital to understand that, unlike a motion to dismiss, courts routinely rule on summary judgment motions without giving leave to amend either the pleading or factual record. In other words, don't count on surviving summary judgment by changing the then-existing case template.

This don't change horses survival skill conforms to established and recent case law holding that summary judgment generally cannot be avoided by seeking to add new and different factual or legal theories of the case.[14]

By the same token, unless the motion is filed prematurely (e.g., well before close of discovery or when moving party is failing to comply with outstanding discovery), courts often will not continue the motion simply to allow further discovery.[15]

If, on the other hand, you find yourself behind the survival curve, you can ask the court to amend the complaint (if no unreasonable delay or prejudice) or alternatively for specified discovery that could not have been presented through due diligence.[16]

However, despite some potential openings, parties making and opposing summary judgment motions should proceed as if the factual and legal record is set. This is why pre-planning at an early stage (see above) is critical.

7 Ensure that the Motion and/or Opposition Are User-Friendly for the Court and Staff

It is a fundamental survival skill on summary judgment to make the motion user-friendly for the court and its staff. This is best accomplished by being absolutely clear in citations to the docket and ensuring that the referenced exhibits and evidence are in the record and readily accessible.

The case law makes it clear that the court, when addressing summary judgment motions, has no duty to scan the record to find information and evidence.[17] Moreover, even the moving party cannot rely on unsupported generalizations, but rather must direct the court to the non-moving party's lack of sufficient evidence.[18]

In making your motion user-friendly for the court, think about what it will be like to read the briefs and evidence. Try locating the supporting documents and references yourself, and if it's hard for you it will be even harder for busy judges and their clerks. Remember that winning at the motion level has two vital elements: (1) tell the court how you win, and (2) persuade the court why you ought to win. Clear and accessible briefs and supporting evidence will get these jobs done effectively.

Conclusion

The seven tips in this article will help you survive the summary judgment process and with greater efficiency and clarity. And through the use of The Wagstaffe Group Practice Guide and Current Awareness you can not only survive, you just might prevail. L

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13. *See, e.g.*, Vanderberg v. Petco, 906 F.3d 698 (8th Cir. 2018) (failure to disclose expert testimony results in exclusion on summary judgment); Karum Holdings LLC v. Lowe's, 895 F.3d 944 (7th Cir. 2018) (same). **14.** *See* Chessie Logistics Co. v. KRINIS Holdings, Inc., 867 F.3d 852 (7th Cir. 2017) (court can deny summary judgment if non-moving party relies on facts beyond complaint). **15.** Hodgin v. UTC Fire & Sec. America's Corp., 885 F.3d 243 (4th Cir. 2018) (court rejects request for further discovery). **16.** *See* Fed. R. Civ. P. 15, 56(d); *see also* Jacobson v. U.S. Department of Homeland Sec., 882 F.3d 879 (9th Cir. 2018) (plaintiff makes showing discovery could result in triable issue); BRC Rubber & Plastics, Inc. v. Continental Carbon Co., 900 F.3d 529 (7th Cir. 2018) (new legal theory could be pursued). **17.** *See, e.g.*, Carlson v. Bos. Sci. Corp., 856 F.3d. 320 (4th Cir. 2017) (opponent's a failure to cite to evidence allows granting of motion); TWG, sec 43-VIII[E][2]. **18.** Nick's Garage, Inc. v. Progressive Cas. Co., 875 F.3d 107 (2d Cir. 2017).

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