

The **LEXIS PRACTICE ADVISOR** Journal™

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EMERGING BIOMETRIC INFORMATION LAWS

**Economic Advantages
for Existing Owners in
Opportunity Zones**

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Disputes**



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Eric Bourget, Editor-in-Chief

USING BIOMETRIC INFORMATION IS becoming a hot-button issue for companies and employers as well as a privacy concern for individuals. Individuals are concerned that using, collecting, and storing this personal data is intrusive, and two recent actions have moved toward imposing greater restrictions in this area and could potentially expose companies and employers involved in collecting this personal data to greater risk. A recent Illinois Supreme Court decision found that someone who had suffered no specific harm following a violation of the Illinois Biometric Privacy Act could still be considered an aggrieved party. The City of San Francisco passed an ordinance banning the use of facial recognition technology to identify

individuals by any city agencies, including the police department. In this edition of the Lexis Practice Advisor Journal, we offer guidance to employers and businesses that use or collect biometric information, along with a summary of related laws and restrictions under consideration across the country.

Another important topic for employers is determining whether to mediate employment disputes. Some courts mandate or strongly encourage this method of resolution over litigation, and many employment agreements require mandatory mediation before a dispute may proceed to arbitration. This edition discusses the advantages and disadvantages of utilizing mediation, outlines the process, and provides a checklist with steps involved in mediating employment disputes and sexual harassment claims.

Our drafting practice tips section in this issue focuses on common mistakes made when drafting sale of goods agreements and how to avoid these mistakes. Express warranties can include some of the most important provisions in sale of goods agreements. Unfortunately, the meaning of "express warranty" is amorphous, and laws governing these warranties can be confusing and loaded with pitfalls. Our practice tips on sale of goods agreements offer guidance for writing sound express warranty provisions to best protect your clients' interests.

Also, in this edition we take a look at debt securities commonly issued by companies in U.S. debt capital markets where we provide a review of the offering process and list key

Letter From The Editor

characteristics of different transaction types. This article includes cautionary warnings for issuers, investors, and underwriters about the significant number of additional legal terms and issues that should be considered in advance of issuing these tradeable instruments.

The Tax Cuts and Jobs Act of 2017 created Opportunity Zones that are designed to encourage investments in economically-distressed communities by providing preferential tax treatment for such investments. These tax benefits are not only for new investments—existing owners of property in Opportunity Zones can enjoy some of the preferential tax treatment; however, the process can be quite complicated. This article offers guidance for existing property owners on ways to reap some of the tax benefits and perhaps qualify for funds to develop their properties.

This issue of the Lexis Practice Advisor Journal should help you stay on top of current trends and will undoubtedly serve as an entry point into practical guidance and deep legal research, ultimately saving you time, so you can focus on obtaining new business or perhaps carving out some time to unwind over the summer months.

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.



SAN FRANCISCO ADOPTS ORDINANCE BANNING CITY'S USE OF FACIAL RECOGNITION TECHNOLOGY

SAN FRANCISCO HAS BECOME THE FIRST CITY IN THE United States to ban the use of facial recognition technology to identify individuals. As a result, city agencies, including the police department, will be prohibited from using the technology in the course of their governmental activities. The ordinance does not apply to individuals, businesses or federal agencies, such as those which operate the San Francisco Airport and the Port of San Francisco.

The ordinance was passed by the city's Board of Supervisors by an 8-1 vote on May 14. A second reading of the ordinance was expected within a week and Mayor London Breed was expected to sign it into law. In general findings included in the text of the ordinance, the Board of Supervisors cited its concern with the impact of the technology on civil liberties.

"Whenever possible, decisions relating to surveillance technology should occur with strong consideration given to the impact such technologies may have on civil rights and civil liberties, including those rights guaranteed by the First, Fourth, and Fourteenth Amendments to the United States Constitution as well as Sections 1, 2, and 13 of Article I of the California Constitution," the board said. Use of the technology has affected the privacy rights of the public at large, the board said, but "surveillance efforts have historically been used to intimidate and oppress certain communities and groups more than others, including those that are defined by a common race, ethnicity, religion, national origin, income level, sexual orientation, or political perspective. The propensity for facial recognition technology to endanger civil rights and civil liberties substantially outweighs its purported benefits, and the technology will exacerbate racial injustice and threaten our ability to live free of continuous government monitoring."

In addition to banning use of facial recognition technology, the ordinance requires that city agencies disclose to the Board of Supervisors for approval any surveillance technology in use or expected to be in use in the future along with a proposed policy for use of the equipment.

The ordinance is not without its critics. In a statement, the grassroots group Stop Crime SF said, "Instead of an outright ban, we believe a moratorium would have been more appropriate. We agree there are problems with facial recognition ID technology, and it should not be used today. But the technology will improve, and it could be a useful tool for public safety when used responsibly and with greater accuracy. We should keep the door open for that possibility. Especially when facial recognition technology can help locate missing children, people with dementia and fight sex trafficking."

Similarly, the Information Technology and Innovation Foundation, a D.C.-based non-profit think tank, said in a statement, "There are plenty of legitimate concerns about government surveillance, but the right approach is to implement safeguards on the use of technology rather than prohibitions. Good oversight and proper guidance can ensure that police and other government agencies use facial recognition appropriately."

Counsel working in the data privacy practice area should be aware of developments in their state legislatures dealing with limitations on the gathering of personal information, including biometric information. The City of Oakland is currently considering an ordinance similar to that adopted by San Francisco and other cities are expected to follow suit.



RESEARCH PATH: [Data Security > Industry Compliance > Public Sector > Articles](#)

RIDE SHARE SERVICE DRIVERS ARE INDEPENDENT CONTRACTORS, NLRB RULES



DRIVERS FOR THE RIDE-SHARING SERVICE UBER ARE independent contractors, not employees, for purposes of coverage under the National Labor Relations Act (NLRA), the National Labor Relations Board (NLRB) has decided. The NLRB's memo serves as guidance for the various regional offices to apply in processing unionization bids and adjudicating unfair labor practice allegations.

The memorandum is the second in several weeks to find that so-called "gig workers" are not employees within the meaning of the NLRA and could signal a trend in how the NLRA is interpreted by the current members of the NLRB.

The memorandum was issued by Associate General Counsel Jayme L. Sophir in response to an inquiry by Jill Coffman, director of NLRB Region 20, located in San Francisco, seeking clarification following the filing of three charges in Regions 14, 13, and 29, raising the issue of Uber drivers' employment status. Two of the cases involved termination of Uber's relationships with drivers working in the UberX service category. The third alleged that Uber provided unlawful assistance to a labor organization representing Uber drivers in the UberX and UberBLACK service tiers.

Finding that the drivers are independent contractors, not employees, under the NLRA, Sophir applied the reasoning set forth in the NLRB's Jan. 25 opinion in *SuperShuttle DFW Inc. and Amalgamated Transit Union Local 1338*, NLRB, 2019 NLRB LEXIS 15 (Jan. 25, 2019). In *SuperShuttle*, the Board found that franchisees who operated shared-ride vans for SuperShuttle Dallas-Fort Worth are independent contractors and therefore ineligible to organize with the Amalgamated Transit Union. In so ruling, the Board, in a 3-1 opinion, applied a 10-part test to determine the workers' entrepreneurial opportunity or ability to impact their income.

Relying on the NLRB's reasoning in *SuperShuttle*, Sophir found that the UberX drivers were independent contractors because they control their schedules, cars, work locations and have the

ability to work for competitors, and that UberBLACK drivers control their economic opportunity in addition to being free to hire other drivers to work on their behalf, choosing to receive both UberX and UberBLACK assignments, and contracting with Uber as business entities, not individuals.

Several weeks before issuance of the Uber ruling, the Department of Labor's Wage and Hour Division found that gig workers for an unnamed company were independent contractors. The DOL applied a six-factor test to the company's business model in concluding that the workers were economically independent from the company. In so ruling, the DOL emphasized the status of the company as a virtual marketplace company and the ability of the workers to accept or reject assignments. U.S. Department of Labor, Wage and Hour Division, FLSA2019-6.

Initial Guidance

The decisions by the NLRB and the DOL provide important protection (and guidance) to employers hiring workers in a gig economy. Although the traditional multifactor tests used to determine whether a worker is an employee, or an independent contractor, were not designed to address such workers, certain aspects of those tests (as highlighted by the NLRB and DOL decisions) can provide employers guidance when deciding how to classify their workers. For example, the NLRB relied upon the fact that the workers could simultaneously work for other employers and had control over their schedules and opportunities. The DOL also relied upon the workers' independence and ability to reject or accept assignments. That said, employers should continue to be cautious in their classification of workers as employees or contractors because the penalties for violating the NLRA can be significant and state agency and court decisions in this area are not uniform. In addition, companies should strongly consider including arbitration agreements with class and collective action waivers in their agreements with their gig economy workers. Although class and collective action waivers were frequently subject to legal challenge, in *Epic Systems Corp. v. Lewis*, 138 S. Ct. 1612 (2018), the U.S. Supreme Court upheld their enforceability and found that they do not violate the NLRA. By including an arbitration agreement and class and collective action waiver, a company facing a challenge to its classification of independent contractors can move to dismiss such claims and compel arbitration on an individual basis.



RESEARCH PATH: [Labor & Employment > Wage and Hour > Independent Contractors > Articles](#)

AMENDMENTS TO CALIFORNIA CONSUMER PRIVACY ACT MOVING THROUGH STATE LEGISLATURE

THE CALIFORNIA ASSEMBLY COMMITTEE WITH JURISDICTION over consumer protection legislation has voted out several bills that would amend the California Consumer Privacy Act (CCPA), the nation's most wide-ranging state law of its kind.

Governor Edmund G. Brown Jr. signed the original bill on June 28, 2018. The law gives consumers greater control over how businesses use their personal information. Under the new law, which takes effect on January 1, 2020, consumers will have the right to request that businesses disclose how their personal information is used and to ask that personal information be deleted under some circumstances.

The law was fast-tracked by the legislature in return for a pledge by consumer advocates to abandon their campaign to place an initiative bearing the same name on the November 2018 ballot.

At the time of the bill's signing, legislators conceded that amendments would be necessary to address concerns raised by consumer advocacy and business groups. In fact, Gov. Brown signed a so-called cleanup bill containing a number of minor amendments in September 2018.

The recently proposed amendments, voted out by the committee after an April 23 hearing, are more substantive in nature and largely address industry-backed concerns. The proposed amendments are:

2019 Cal. A.B. 25 would modify the statute's definition of consumer to exclude job applicants whose personal information is used solely for the purposes of the job application.

2019 Cal. A.B. 846 would allow businesses to offer consumers different levels of service and charge varying prices based on financial incentives such as participation in loyalty or reward programs.

2019 Cal. A.B. 873 would revise the term deidentified to mean "information that does not reasonably identify or link, directly or indirectly, to a particular consumer, provided that the business makes no attempt to reidentify the information and takes reasonable technical and administrative measures designed to ensure that the data is deidentified, publicly commits to maintain and use the data in a deidentified form, and contractually prohibits recipients of the data from trying to reidentify it."

2019 Cal. A.B. 874 would revise the definition of personal information to exclude deidentified or aggregate consumer information and define publicly available to mean "information that is lawfully made available from federal, state, or local records," while deleting language stating that data is not publicly available if it is used for certain purposes.

2019 Cal. A.B. 981 would exempt from the CCPA insurance institutions, agents, and support organizations to which the Insurance Information and Privacy Protection Act applies.

2019 Cal. A.B. 1146 would exempt from the CCPA vehicle information shared between a new motor vehicle dealer and the vehicle's manufacturer, if the information is shared pursuant to, or in anticipation of, a vehicle repair relating to warranty work or a recall.

2019 Cal. A.B. 1564 would change the requirement that businesses make available to consumers two or more designated methods for submitting requests for information, including a toll-free number and a web address, to provide a toll-free number or email address and to make available the URL for the company's website, if any.

The bills must now be considered by the full Assembly and sent to the California Senate.

 **RESEARCH PATH:** [Data Security & Privacy > State Law](#)
[Surveys and Guidance > State Guidance > Articles](#)

ARBITRATION OF CLASS ACTION CLAIMS MUST BE EXPLICITLY STATED IN CONTRACT, SUPREME COURT RULES

EMPLOYEES CANNOT SEEK ARBITRATION OF EMPLOYMENT- related claims on a class-wide basis unless their arbitration agreement with their employer explicitly provides for such relief, the U.S. Supreme Court ruled on April 24 in *Lamps Plus Inc. v. Varela*, 203 L. Ed. 2d 636 (2019). The decision means employers can compel individual arbitration and avoid the risk of class arbitration—unless they specifically agree to it.

The Court reversed a ruling by the U.S. Court of Appeals for the Ninth Circuit, *Varela v. Lamps Plus Inc.*, 701 Fed. Appx. 670 (9th Cir. 2017), compelling the employer to arbitrate class claims that the company did not adequately protect employees' personal data.

Frank Varela filed suit in the U.S. District Court for the Central District of California on his own behalf and that of his co-workers, alleging that the employer released personal information in response to a phishing scam. The employer moved to compel arbitration of plaintiff's individual claims under an arbitration agreement between the employer and its employees. The district court compelled arbitration of both the individual and class claims, finding that the arbitration agreement constituted a contract of adhesion and that the agreement was ambiguous as to class arbitration.

On appeal, the Ninth Circuit affirmed, finding that because the agreement was capable of two reasonable constructions, the lower court correctly found ambiguity and construed the agreement against the employer.

Reversing in a 5-4 ruling, the high court cited its own ruling in *Stolt-Nielsen S.A. v. Animal Feeds Int'l Corp.*, 559 U.S. 662 (2010), where it found that mutual agreement in the form of a contractual provision was required in order to compel class-wide arbitration of an antitrust claim.

Writing for the majority, Chief Justice John G. Roberts Jr. said, "Our reasoning in *Stolt-Nielsen* controls the question we face today. Like silence, ambiguity does not provide a sufficient basis to conclude that parties to an arbitration agreement agreed to 'sacrifice[] the principal advantage of arbitration.'"

In a clear victory for employers, the ruling extends the holding in *Stolt-Nielsen*—that silence on the issue in an arbitration agreement is insufficient to allow for class arbitration—to situations in which the arbitration agreement is ambiguous on the issue. The holding severely limits, if not removes, employees' ability to seek redress of employment-based claims on anything but an individual basis.

The holding makes clear the need for employers to draft arbitration agreements carefully and for employees to be cognizant of the terms and their significance before signing arbitration agreements. Counsel for employers would be well served to review their clients' arbitration agreements, many of which have not been updated for many years, and to provide periodic reviews as the law in this area is refined.

 **RESEARCH PATH:** [Labor & Employment > Employment](#)
[Contracts > Waivers and Releases > Articles](#)



THE SAFE BANKING ACT TO INCREASE ACCESS TO BANKING FOR LEGAL MARIJUANA-RELATED BUSINESSES

ON JUNE 5, 2019, THE U.S. HOUSE FINANCIAL SERVICES Committee approved an updated version of the Secure and Fair Enforcement Banking Act of 2019, H.R. 1595, 116th Cong. (Mar. 7, 2019) (SAFE Banking Act). While passage in the U.S. Senate is unclear, the SAFE Banking Act is supported by numerous financial-services trade groups.

Banks, credit unions, and insurance companies have been reluctant to provide banking and financial services for cannabis-related businesses due to the significant regulatory and compliance costs under the federal Bank Secrecy Act of 1970 (BSA), 31 U.S.C. § 5311 et seq., and related anti-money laundering (AML) regulations. The SAFE Banking Act would prohibit federal financial regulatory agencies from undertaking federal actions against financial institutions, including adverse or corrective supervisory actions, in connection with providing services to a “cannabis-related legitimate business,” which is defined as a business handling cannabis products

in compliance with applicable state laws and regulations. Specific protections under the SAFE Banking Act include:

- A provision that prohibits penalizing a depository institution or a service provider for authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments for a cannabis-related legitimate business for payments made by any means, including a credit, debit, or other payment card, an account, check, or electronic funds transfer.
- The development of specific Financial Crimes Enforcement Network (FinCEN) guidance related to suspicious activity reports (SARs) for cannabis-related legitimate businesses and service providers, consistent with the legislative intent of the SAFE Banking Act, which does not discourage institutions from providing financial services to such companies.
- A provision requiring a government study regarding diversity in the cannabis market and a study of the effectiveness of SARs for cannabis-related businesses and service providers.

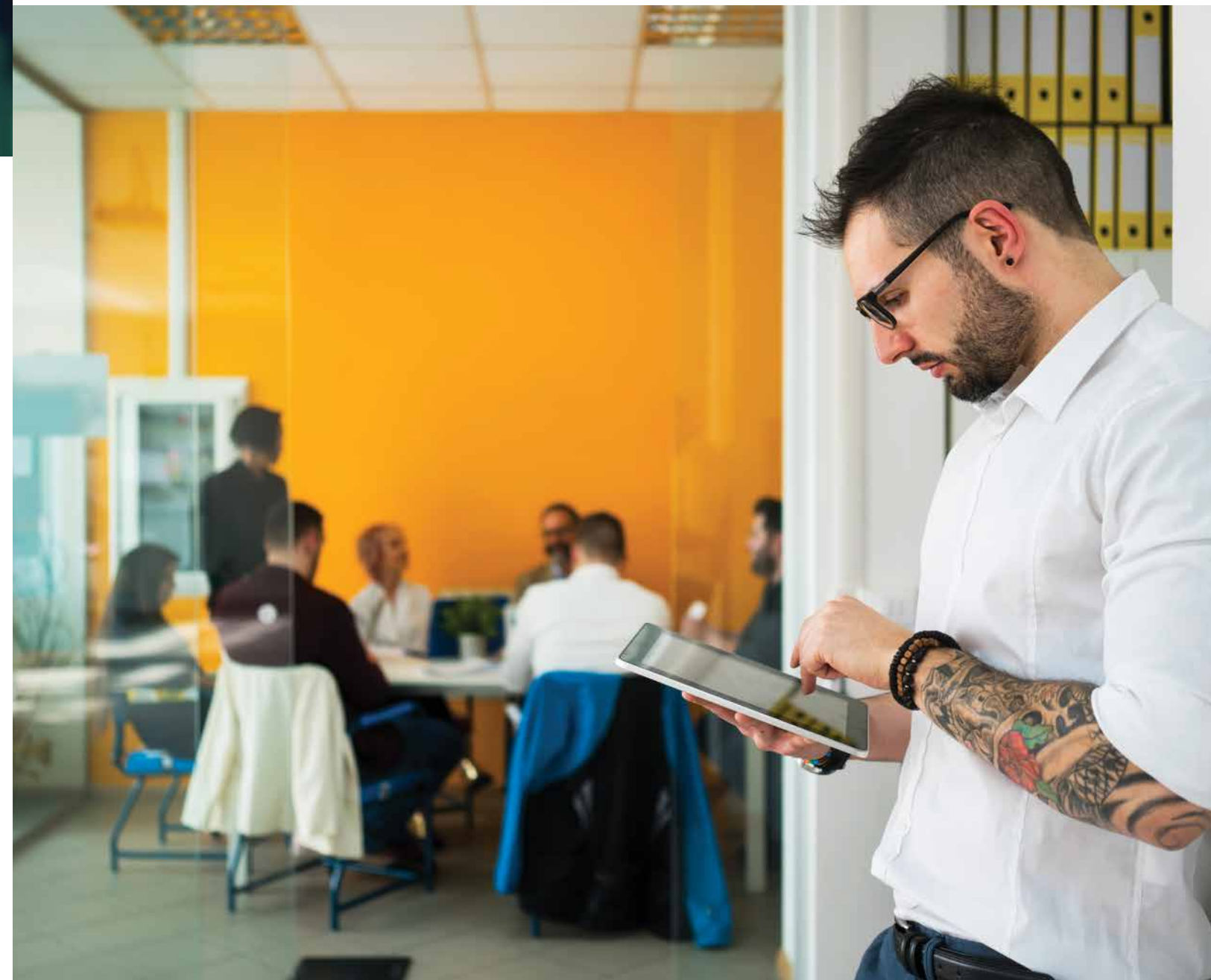
- Provisions streamlining regulatory expectations, reporting, and examination guidance for institutions providing banking and financial services to cannabis-related businesses and service providers to ensure that all institutions could offer services subject to similar regulatory requirements.
- A provision protecting depository institutions, service providers, and insurers, together with their officers, directors, and employees, from prosecution under federal law solely on the basis of providing such financial services to a cannabis-related business or further investing any income derived from such financial services.

The SAFE Banking Act does not preempt state laws. As a result, financial institutions and their service providers should confirm

whether their customers are complying with applicable state laws and regulations related to cannabis.

The SAFE Banking Act would expand competition in the cannabis industry and enable financial services companies to treat legitimately formed and operated cannabis businesses as similarly situated, high-risk businesses entitled to protections from federal prosecution and BSA/AML compliance responsibilities. Cannabis-related businesses receiving banking services will undoubtedly be subject to enhanced due diligence standards, as well as regulatory reporting and examination guidance issued by FinCEN and the Federal Financial Institutions Examination Council.

 RESEARCH PATH: [Financial Services Regulation > Trends & Insights > Market Trends > Articles](#)



FEDERAL CIRCUIT HOLDS FIRM ON LACK OF DEFERENCE TO PTO ELIGIBILITY GUIDANCE

A RECENT U.S. COURT OF APPEALS FOR THE FEDERAL Circuit ruling reinforces the court's long-held position that deference need not be given to patent examiner guidance issued by the U.S. Patent and Trademark Office (PTO).

The ruling in *Cleveland Clinic Found. v. True Health Diagnostics*, 2019 U.S. App. LEXIS 9451 (Fed. Cir. Apr. 1, 2019), cites a May 2016 guidance, but also calls into question the viability of recent guidances, including a January 2019 guidance for patent examiners to follow when considering applications that contain abstract ideas.

The court invalidated two patents related to diagnostic tests for cardiovascular disease, rejecting Cleveland Clinic's argument that the May 2016 guidance on patent eligibility was entitled to deference. The lower court had found the patents invalid as directed to natural law and lacking inventive concept.

"While we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance," the circuit court said. "And, especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law."

The PTO has issued guidances for the application of the *Alice/Mayo* test for eligibility under Section 101 of the Patent Act (35 U.S.C.S. §101). In *Alice Corp. v. CLS Bank*, 573 U.S. 208 (2014), 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 January 2019 guidance lists three categories of inventions deemed to constitute abstract ideas 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.

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

Members of Congress, including Sens. Thom Tillis (R-N.C.) and Chris Coons (D-Del.), have addressed the uncertainty on the eligibility issue by releasing a memorandum that provides four guiding principles for reform of Section 101, including a statement that "diagnostic and life sciences should be eligible for patent protection *per se*, subject to meeting the other existing statutory requirements, and should not be considered a law of nature, natural phenomena, or otherwise patent ineligible subject matter."

 **RESEARCH PATH:** [Intellectual Property & Technology > Patents > Patent Litigation > Articles](#)



SUPREME COURT TO HEAR TRIO OF CASES ON DISCRIMINATION AGAINST LGBT EMPLOYEES

THE U.S. SUPREME COURT WILL ADDRESS THE ISSUE OF discrimination against LGBT employees in the workplace in its next term after granting review in three cases—two brought by gay employees and the third by a transgender worker.

The three cases raise the issue of whether the anti-discrimination provisions of Title VII of the Civil Rights Act of 1964¹ extend to discrimination on the basis of sexual orientation and gender identity.


In *Altitude Express Inc. v. Zarda* (No. 17-1623, U.S. Sup.), the justices will review an en banc decision of the U.S. Court of Appeals for the Second Circuit holding that Title VII applies in the case of a skydiving company employee who alleged that he was fired because he was gay. The appeals court found that discrimination based on sexual orientation "is a subset of sex discrimination."²

The arguments in the *Zarda* case will be consolidated with those for *Bostock v. Clayton County, Ga.* (No. 17-1618, U.S. Sup.), in which the U.S. Court of Appeals for the Eleventh Circuit affirmed a ruling by the U.S. District Court for the Northern District of Georgia dismissing a suit brought by a county employee who contended

that his firing for financial mismanagement was a pretext for his termination after the county discovered that he was gay.³

The third case, *R.G. & G.R. Harris Funeral Homes Inc. v. EEOC* (No. 18-107, U.S. Sup.), was filed by Aimee Stephens, a transgender woman who presented as a male at the time of her hiring by a funeral home and was fired when she revealed six years later that she identified as a woman and wished to dress in women's clothing. The Equal Employment Opportunity Commission (EEOC) filed a wrongful termination suit on Stephens' behalf in the U.S. District Court for the Eastern District of Michigan, which entered summary judgment for the funeral home. On appeal, the U.S. Court of Appeals for the Sixth Circuit reversed and entered summary judgment for Stephens and the EEOC.⁴

The cases will be heard during the high court's upcoming term, which begins on October 7.

 **RESEARCH PATH:** [Labor & Employment > Discrimination, Harassment, and Retaliation > EEO Laws and Protections > Articles](#)

¹ 42 U.S.C.S. § 2000e. ² *Zarda v. Altitude Express Inc.*, 883 F.3d 100 (2d Cir. 2018). ³ *Bostock v. Clayton Cty. Bd. of Comm'rs*, 723 Fed. Appx. 964 (11th Cir. 2018). ⁴ *EEOC v. R.G.*, 884 F.3d 560 (6th Cir. 2018).





Patrick J. Lamparello and Noa M. Baddish PROSKAUER ROSE LLP

Mediating Employment Disputes



This article explains the process of mediating employment disputes, describes the contexts in which it may arise, and articulates the advantages and disadvantages of this process. Mediation is a non-binding, informal, and confidential negotiation in which a neutral third party actively promotes a mutually acceptable settlement.

PARTIES OFTEN ATTEMPT TO RESOLVE EMPLOYMENT LAW disputes through mediation to reduce the uncertainty and expense inherent in litigation. The mediator facilitates negotiations between the two parties, while the parties retain complete control over the dispute and resolution. This article advises how best to prepare for a mediation and offers best practices on how to achieve a favorable settlement.

How and When Mediations Arise

Mediations can be mandatory (or strongly encouraged) by a tribunal or arise at the parties' own initiative. They also can occur at various junctures in the timeline of a claim.

Often, a court mandates or strongly encourages the parties to mediate their dispute. For example, in the U.S. District Court for the Southern District of New York, the Court's rules mandate that all employment discrimination claims be automatically referred to mediation upon the filing of the answer.¹ In addition, Fair Labor Standards Act (FLSA) cases assigned to certain judges in the Southern District of New York are automatically referred to mediation.² Moreover, some employers may require mandatory mediation in their employment agreements with employees that require the parties to attempt to resolve the dispute before proceeding to arbitration.

Government agencies also may initiate mediation. The Equal Employment Opportunity Commission (EEOC) has a mediation process, known as conciliation, which occurs after it issues a probable cause finding on a charge. Conciliation with the EEOC is an informal, confidential, and voluntary process. Employers may consider settling with the EEOC early in the process instead of after the EEOC has filed a lawsuit. Also note that although the process of mediation with the EEOC is confidential, the ultimate settlement and/or its terms may not be.

In addition, in the wake of the #MeToo movement, many state and local governments have enacted legislation that either discourages or prohibits confidentiality of sexual harassment claims and/or settlements unless certain conditions are met (e.g., it is the employee's preference to maintain confidentiality). For example, New York law states that an agreement to resolve a claim of sexual harassment may not include a section mandating the confidentiality or nondisclosure of the underlying circumstances of the claim, unless the employee prefers confidentiality.³

Parties increasingly turn to mediation voluntarily to resolve employment disputes. Such voluntary mediations achieve their best results when the parties are reasonable and willing to cooperate and compromise. On many occasions, it may be helpful for the parties to exchange some limited discovery for purposes of the mediation. This can help manage each party's expectations and set a realistic tone for the mediation. It also may be important, particularly in employment discrimination cases, that each party feel like they received the opportunity to tell their story and be heard. With respect to timing, perhaps the best opportunity for a successful mediation occurs early in a matter before the parties have developed an acrimonious relationship and incurred substantial expenses. Thus, employers should consider mediation upon receipt of a demand letter or complaint. That said, parties also frequently attempt mediation much later in a matter's timeline or try mediation several times over the course of a matter. For example, a defendant-employer may be more open to mediation after losing summary judgment. A plaintiff-employee may want to discuss settlement after receiving notice for his or her deposition or after being deposed.

To Mediate or Not to Mediate?

This section will help you make an informed decision about whether to embark on mediation of an employment dispute. In particular, it addresses the advantages and disadvantages of using mediation as a settlement tool.

Pros

- **Cost savings.** Mediation can result in significant cost savings because it increases the prospects for settling a dispute at an early stage. Moreover, mediated settlements may involve non-monetary relief, thereby increasing the potential for settlement and perhaps reducing the monetary amount. A successful mediation also generally results in lower attorney's fees due to avoiding or curtailing discovery as well as other case preparation and presentation (as compared to a trial).
- **Faster resolution.** The benefits of a swift resolution to a dispute transcend cost savings. It also enables the former employee to move on and minimizes the amount of management time and energy that is diverted from the employer's business to deal with the case.

1. See *In re: Cases Assigned to Mediation by Automatic Renewal*, No. 11 Misc. 003 (S.D.N.Y. 2015). 2. See *In re: FLSA Pilot Program, Mediation Referral Order for Cases that Include Claims under the Fair Labor Standards Act 29 USC § 201 et seq.* (S.D.N.Y. 2016). See also *Mediation/ADR*, (S.D.N.Y.). 3. N.Y. Gen. Oblig. Law § 5-336; N.Y. C.P.L.R. § 5003-b.



In employment disputes, parties should select a mediator who has expertise on the relevant employment laws and judicial standards and a reputation as a fair and neutral professional who will work hard to find common ground between or among the parties.

■ **Confidentiality.** Parties can share information with the mediator in confidence that the mediator will not disclose to the opposing party without the disclosing party's consent. Moreover, communications during a mediation generally are privileged and inadmissible as evidence in a later proceeding. Additionally, if mediation occurs prior to the filing of a claim, a party is likely to be able to resolve a dispute privately, off the docket sheet. Whether or not this concept applies to FLSA claims is an open question because while the U.S. Court of Appeals for the Second Circuit held in *Cheeks v. Freeport Pancake House, Inc.*⁴ that court or government agency approval is required to secure an enforceable settlement of FLSA claims, at least one district court has held that *Cheeks* does not apply to pre-litigation claims.⁵ Additionally, there are limits on confidentiality of discrimination and harassment settlements. For example, if the EEOC facilitates a mediation, it may not agree to confidentiality of the settlement or its terms. In addition, as explained above, due in large part to the #MeToo movement, many state and local governments have developed laws that either discourage or ban making sexual harassment claim settlements confidential.

■ **Flexibility.** Mediation also presents the opportunity to craft a remedy that would not be available through the litigation process. Beyond money damages, an employee may find appealing a wide range of non-monetary relief. For example, non-monetary relief in a mediated settlement may include references, outplacement services, arrangements for additional pension accrual, extended group insurance benefits, or changing a policy or practice at the company. Tailoring a settlement to include such other types of relief may cost the employer less.

■ **Expectations-setting.** Mediation allows a neutral third party to examine the claims and set realistic expectations for parties as they move forward in litigation. This may benefit a party that has a particularly strong claim or defense. For instance, if a party believes it has a strong case and the opposing party disagrees, a well-respected mediator may help the parties correctly view and evaluate their respective cases.

■ **Education.** Even if the parties fail to reach a settlement through mediation, the mediation process can benefit the parties by educating them about the potential risks and liabilities in their positions.

Cons

- **Mediation expense.** Although successful mediations reduce a party's litigation expenses, unsuccessful mediations drive up costs. It can be expensive to effectively prepare for and participate in mediation. Thus, it may frustrate employers if no settlement results.
- **Counterproductive distraction.** If the parties bring a dispute to mediation and it does not settle, the dispute may end up in court, thus giving an employee two bites at the apple. Indeed, some parties may not want to mediate as it gives the opposing party an opportunity for free discovery. Depending on when the mediation occurs in litigation, it also may distract the employer and its counsel from other time-sensitive tasks that would move the litigation forward. It also would not make sense to pursue mediation if you represent a party that categorically refuses to settle.

Logistics

Agreeing on Fee Payment

Parties should work out with each other whether one party will cover the cost of the mediation or whether and how the parties will share such costs. Both the American Arbitration Association and Judicial Arbitration & Mediation Services (JAMS) charge administrative fees, and the mediators associated with those organizations charge for their time. In some cases, the parties share the cost of mediation fees equally. However, many employers offer to pay most (or all) of the administrative fee and the mediator's first day of fees as an incentive to the employee to participate in the mediation process. The parties should confirm their fee agreement in writing.

Selecting a Mediator

Generally, mediations have one mediator. The mediator must be impartial, devoid of decision-making power, and acceptable to both parties. In employment disputes, parties should select a mediator who has expertise on the relevant employment laws and judicial standards and a reputation as a fair and neutral professional who will work hard to find common ground between or among the parties.

A number of agencies offer mediation administration services and a source of trained mediators. For example, JAMS offers retired judges as mediators as well as lawyers who are trained in mediation. JAMS

and other similar alternative dispute resolution firms offer a panel of mediators from which the parties may choose. The parties also may request a specific mediator with whom they are familiar from prior experience or reputation. There are also mediators who are not affiliated with agencies. The nature and quality of their services vary.

If you are unfamiliar with a suggested mediator, research the mediator's background and experience with similar cases and issues by soliciting the views of knowledgeable attorneys.

Scheduling the Mediation

Mediations often take longer than anticipated. Thus, when scheduling a mediation, overestimate the amount of time you feel may be necessary to reach a resolution.

When selecting a mediation date, ensure that a company representative is available to attend the mediation. Either this individual should have settlement authority or a person with settlement authority should be readily available by phone. The presence (or lack thereof) of the company representative may send a message about the employer's position or take on the plaintiff's case. Employers should therefore consider the effect of the company representative's attendance.

The mediator may request that the parties submit mediation statements or other written materials before the conference. Depending on the parties' and the mediator's preferences, the parties may either provide the mediation statements to the mediator only or may share them with the mediator and the other parties participating in the mediation. If mediation statements are shared with other parties, a party often may choose to submit additional information for the mediator's eyes only. If you do not want the mediator to share your mediation statement with the opposing party, you should clearly label it "for the mediator's eyes only." You should also emphasize in your covering correspondence to the mediator that the mediator should not disclose it or its contents.


Mediation statements typically contain the material facts, a discussion of liability issues, damages calculations, the history of the dispute, any settlement negotiations, and a statement of expectations. You should draft the mediation statement with an eye toward educating the mediator about the procedural posture of the case and the strengths of your client's case. If the mediation statement is not only for the mediator, you should of course also

4. 796 F.3d 199 (2d Cir. 2015). 5. See Gaughan v. Rubenstein, 261 F. Supp. 3d 390, 402 (S.D.N.Y. 2017).

Related Content

For more information on resolving FLSA claims, see

> [SETTLEMENTS AND RESOLUTIONS OF FLSA CLAIMS AND POTENTIAL FLSA VIOLATIONS](#)

 **RESEARCH PATH:** [Labor & Employment > Employment Contracts > Waivers and Releases > Practice Notes](#)


For a checklist on mediating employment matters, see

> [MEDIATING EMPLOYMENT DISPUTES CHECKLIST \(INCLUDING SEXUAL HARASSMENT CLAIMS\)](#)

 **RESEARCH PATH:** [Labor & Employment > Discrimination, Harassment, and Retaliation > Claims and Investigations > Checklists](#)


For an overview of the EEOC conciliation process, see

> [CONCILIATING EEOC CHARGES](#)

 **RESEARCH PATH:** [Labor & Employment > Discrimination, Harassment, and Retaliation > Claims and Investigations > Practice Notes](#)

For a review of New York discrimination, harassment, and retaliation laws, see

> [DISCRIMINATION, HARASSMENT, AND RETALIATION \(NY\)](#)

 **RESEARCH PATH:** [Labor & Employment > Discrimination, Harassment, and Retaliation > EEO Laws and Protections > Practice Notes](#)

The Mediation Conference

No set format exists for a mediation conference, and the mediator's and/or the parties' preferences generally guide its process.

The conference typically—although not always—begins with an informal joint session involving all principals to the dispute and their lawyers. The mediator describes general procedures, including ground rules for presentations by the parties and the confidentiality of proceedings.

In many mediations, each party may then present its view of the dispute in the presence of the other side. Presentations to the other side do not occur in every mediation, and, again, this process generally is driven by the preferences of the mediator and the parties. Parties may be more likely to agree to have opening presentations when the plaintiff is not familiar with the mediation and litigation process and/or when the litigation is at an early stage when the parties are not familiar with each other's positions and the employer's attorney may have had limited or no contact with the plaintiff. There has been a trend towards having fewer opening presentations at mediations where the parties are sophisticated and/or where the litigation is at a late stage (e.g., after depositions are complete or before trial) and the parties are already intimately familiar with each other's positions. In these mediations, the parties often go directly into caucus sessions with the mediator.

If presentations are made to the other side, you need to strategically decide how to handle your client's presentation. For example, you will need to decide whether it would be better for you to present your client's position or for the employer's representative to present the employer's position him- or herself. It could make a more impactful and positive impression on the mediator and the opposing party if your client makes this initial presentation him- or herself. On the other hand, if there is tremendous animosity between the parties, it might be more productive for you to make the initial presentation. You may decide that a show of strength of your client's position will help obtain a favorable settlement. On the other hand, in more sensitive or volatile situations, a more conciliatory approach may lead to more fruitful negotiations.

After the mediator's introductory remarks and the parties' respective presentations (if they make opening presentations), the parties will typically go to separate rooms. The mediator then meets with each party separately in what are called caucuses. In the caucuses, which involve a sort of shuttle diplomacy, the mediator clarifies each party's version of the facts, priorities, and positions, attempts to loosen rigid stances, elicits demands and offers, explores alternative solutions, and seeks possible tradeoffs. Although the mediator will have gathered facts about the dispute from the mediation statements and the preliminary presentations (if any), during caucuses the mediator also tries to understand each party's perceptions, positions, and interests.

be judicious about not including information that you do not want your adversary to know or that may unnecessarily derail settlement discussions. Even if the mediation statement is only for the mediator, you should remain cautious about what you disclose.

Regardless of whether the mediator requests a mediation statement, you should prepare for the mediation by strategizing with your client and taking stock of the strengths and weaknesses of the case as well as the potential liabilities and damages. Additionally, you, your client, and, if applicable, the client's insurance company, should determine what would constitute an acceptable settlement. You should also discuss whether your client would consider any non-monetary relief as part of the settlement (e.g., changing a policy or practice). Mediations often provide a good opportunity to work out creative solutions to disputes.




Unlike judges, mediators actively facilitate communication between the parties. They candidly discuss the strengths and weaknesses of each party's position as well as possible means of resolution. During these caucuses, each party may share information with the mediator that the party specifies may not be shared with the other side. If you do not wish the mediator to share certain information, you should clearly state that limitation.

Each party is led to think through its views and demands in response to the other party's arguments and the mediator's reactions, which can serve as a surrogate for those of a judge, arbitrator, or jury. Ideally, the mediation will create an environment for the parties to assess realistically the alternatives of continuing the dispute or resolving it. This process helps the parties move toward tradeoffs and acceptable accommodations; in short, toward a workable resolution.

When the parties reach an agreement, the mediator may hold a final joint session to verify the terms of settlement. The mediator may make certain the settlement is agreeable to the parties and resolves all aspects of the dispute. The mediator may also assist the parties in reducing the terms to writing during that session or in subsequent communications. If the parties do not reach a settlement, the parties should consider whether they wish to try another day of mediation

with the same mediator, switch to another mediator, or discontinue mediation altogether. If the parties choose to discontinue mediation altogether, the parties remain free to explore resolution of the matter on their own. **L**

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Mediating Employment Disputes Checklist (Including Sexual Harassment Claims)

This checklist highlights the main points for attorneys to consider when pursuing the mediation of employment disputes, including sexual harassment claims. Parties may wish to pursue mediation to resolve conflicts rather than engage in costly litigation. Mediation—a non-binding, informal, and confidential negotiation—facilitates a mutually-acceptable settlement while allowing parties to retain control over the process and outcome.

Prepare for the Mediation

The following steps are recommended in determining whether to mediate and how to prepare for mediation. The benefits of mediation are addressed in the section below entitled “Pros of Employment Mediation.”

- ✓ **Determine the appropriate parties for mediation.** All principals involved in the dispute (both the employer’s representative and the employee) and their attorneys should participate in mediation. The employer will need to have a representative with settlement authority available and in attendance at the mediation conference. It is critical that the parties and their representatives appear in person and not by phone.
- ✓ **When to mediate.** Parties may derive greater benefits from mediation at the outset of the dispute, before they become entrenched in their positions; however, mediation is a viable tool to resolve disputes in litigation, especially with a change in circumstances (e.g., summary judgment, management change, or impending trial). Sexual harassment claims are particularly appropriate for mediation due to their emotional and confidential nature. In emotionally charged disputes, consider co-mediation as an option (i.e., where two mediators work together to resolve the conflict).
- ✓ **Address fees with the other side.** Parties should work out whether one party will cover the mediation costs or whether and how the parties will split the costs. Optimally, both parties will bear the cost of mediation. Mediators want all parties to be invested in the process.
- ✓ **Select a mediator.** In employment disputes, mediators should be impartial and educated in labor and employment laws and regulations. Several companies offer mediation services, including the American Arbitration Association, Judicial Arbitration & Mediation Services, and Effective Employment Mediation, LLC. It is important to know your mediator. Inquire as to his or her training, the number of mediations conducted, and—where appropriate—a willingness to co-mediate the dispute. Make sure the mediator discusses mediation training as a part of his or her experience, as opposed to seminars on substantive law. Mediation training focuses on the mediation process; it is not the same as attending a continuing legal education seminar on mediations. Also inquire as to the mediator’s memberships in national or state mediation organizations and his or her commitment to the process of mediation.



Although most states have minimal requirements for designating oneself as a mediator, many states have no such requirements. Mediators who claim they are certified often satisfy only the minimal certification requirements of their local counties. Mediators frequently claim to be certified because they have a certificate attesting to completion of introductory mediation training. A certificate is not in any way an official credentialing.

While knowledge of the underlying law is essential, it is not as important as the mediator’s conflict management skills. Mediators weak on mediation skills but strong on substantive law may turn out to be very directive and evaluative—in effect, deciding the case for the parties and thereby extinguishing one of the benefits of mediation: self-directed outcomes. Also, don’t assume that a retired judge who had a distinguished career on the bench is necessarily a good mediator. Judges are accustomed to telling people what the outcome is or should be. Mediators have no such authority and it is not their place to direct the outcome in a mediation.

- ✓ **Schedule the mediation.** When scheduling the mediation, always overestimate the time needed to complete mediation, as the process often takes longer than expected.



Draft the Mediation Statement

Consider the following issues when drafting a mediation statement or submission prior to mediation:

- ✓ **When to submit a statement.** The mediator may request a mediation statement (or other written materials) from each party prior to the mediation conference.
- ✓ **Contents.** Mediation statements generally contain material facts, liability issues, damages, a summary of any previous settlement negotiations, the particulars of any employment practices liability coverage, and the party's mediation expectations. To avoid the parties becoming contentious or entrenched in positions, consider requesting that any mediation submissions be for the mediator's eyes only and not shared with the opposition.
- ✓ **Goal of the statement.** The mediation statement should educate the mediator on the procedural posture of the matter and the strengths of the party's case. It also helps the party to analyze the strengths and weaknesses of the case (along with potential liabilities and damages), so as to be better prepared for the mediation conference.
- ✓ **Potential cons of mediation statements.** Experienced mediators know that the actual issues or conflict are not necessarily reflected in mediation submissions. As a result, some experienced mediators prefer to take the case cold, because this tends to elicit a more nuanced statement of the actual matters in dispute. Mediation statements may result in a party becoming more entrenched in his or her position. The more a party identifies with the position, the more difficult it becomes to move the party off that position to a compromised resolution without losing face. Mediation statements also may reinforce unrealistic expectations on the part of the client and serve as reminders of an adversarial proceeding.

Best Practices for the Mediation Conference

Consider the following issues when participating in the mediation conference:

- ✓ **Focus.** Parties control the outcome of the mediation; mediators control the process. Good mediators tailor the process to the particular circumstances.
- ✓ **Format.** The parties' preferences generally guide the flow of the mediation conference. Typically the conference begins with the mediator outlining the procedures and rules of the proceeding. Sometimes the parties (or their attorneys) will then present opening statements to the opposing parties and the mediator. When used, opening statements should not amount to a legal argument of the case. Parties should exude civility and open-mindedness and avoid falling into the adversarial mode (which could escalate the conflict and impede resolution).
- ✓ **Caucuses.** Caucuses are private meetings between the mediator and a party. In a caucus, the mediator often works to better understand the party's position and to help move that party toward an amicable settlement.

Poorly trained mediators often rely extensively on the caucus to dissipate anger or avoid highly-charged situations. But experienced mediators will tell you that joint sessions are where the real communication takes place and where movement off of positions occurs. If the mediator is just shuttling between rooms, the best opportunities may be lost. Mediators who rely almost exclusively on shuttle are usually engaging in a glorified settlement conference, rather than mediating. They also are engaging in positional negotiations rather than in integrative negotiations which, unfortunately, fail to address the parties' real interests. In positional bargaining, one party starts with a high demand and the other party makes a low offer. The mediator is reduced to shuttling between rooms, cajoling the party with the low offer to come up, and pushing the party with the high demand to come down. Professional mediators do not consider this to be mediation. Mediators committed to the mediation process strive to engage the parties in integrative negotiations, a more sophisticated form of negotiation (expanding the pie, not arguing over how big a piece each one gets). Integrative negotiation results in increased party satisfaction and more creative and reasoned outcomes.



- ✓ **Settlement.** If mediation is successful, the parties will move toward resolution and may achieve a settlement of the dispute. If the parties do not reach a settlement at mediation, the dialogue which began at the mediation often results in a subsequent settlement. If no settlement is reached in a single session, the parties may resume the mediation at a later date or pursue other means of resolving their conflict (typically through arbitration or litigation).

Key Considerations in Sexual Harassment Mediations

Attorneys should consider the following issues when participating in mediations involving sexual harassment claims:

- ✓ **Don't only focus on the legal merits of the sexual harassment claims and defenses.** Mediation allows employers to cost-effectively address (and stop) inappropriate workplace behavior, even if it fails to meet the legal definition of a sexually hostile work environment. The parties should not only address the technical merits of any claims or defenses asserted, but they should also focus on the mediation process and the challenged behavior and reactions to it.
- ✓ **Consider noneconomic solutions.** Mediation preserves the employment relationship in a sexual harassment case. It permits both the complainant and the alleged harasser—if the employer feels it would be productive to bring the alleged harasser to the mediation session—to be heard in a confidential and safe environment without public disparagement or judgment. It further allows for creative, noneconomic solutions that may be more important to the resolution of the alleged sexual harassment claims than monetary relief, including:
 - An apology
 - Transfer or discipline of the alleged harasser
 - Promotion of a complainant who claims that he or she was denied a promotion when he or she objected to his or her supervisor's alleged sexual harassment
 - Meaningful changes to the employer's sexual harassment policies and procedures
- ✓ **Give the complainant a chance to tell his or her story.** Because the complainant in a sexual harassment case often feels violated or abused, it is important that he or she have an opportunity to tell his or her story, either to the mediator privately in a caucus or to all mediation participants in an open session. The best approach for allowing the complainant to explain what happened depends on the circumstances of the particular case, but the importance of allowing the story to be told cannot be overstated.



Pros of Employment Mediation

Among the benefits of mediation are the following:

- ✓ **Cost savings.** Mediation may result in cost savings for the parties; quick resolutions can result in a reduced or even no monetary award and may avoid litigation costs and expensive fees. Also, mediation frees up management and other personnel to focus on their work, not on answering interrogatories, assembling documents, or attending depositions or hearings. Mediation, likewise, permits employees to move forward with their lives and careers.
- ✓ **Faster resolution.** Mediation often results in a quicker resolution, minimizing the time spent by the parties on the claim.
- ✓ **Confidentiality.** Information shared during mediation is confidential and generally inadmissible in any later proceeding, which reduces the likelihood of adverse repercussions (such as a tarnished reputation or media coverage) to both employers and employees. Confidentiality is of heightened concern in sexual harassment cases.
- ✓ **Flexibility.** Parties may agree to various types of remedies—beyond monetary damages—that litigation generally would not allow. Mediation, thus, permits creative solutions that a court cannot order or that a jury cannot award. If the mediator is falling back on exclusive use of caucus, don't be afraid to request more joint meetings. You can (and should) object to evaluative, directive efforts by the mediator in favor of a more self-directed approach.
- ✓ **Expectations-setting or reality-testing.** Mediators can assist parties in exploring possible outcomes and the likelihood of attaining one or more outcomes. Mediators often help parties explore their BATNA (Best Alternative to a Negotiated Agreement), their WATNA (Worst Alternative to a Negotiated Agreement), and their MLATNA (Most Likely Alternative to a Negotiated Alternative). However, mediators should not profess to know how a judge or jury would decide the case; such statements impede the process.
To facilitate the process, mediators should give attorneys an opportunity to confer with their clients from time to time. This may occur during a caucus with the other party, but also can be built into the process without shuttle.
- ✓ **Positive client perceptions.** Even if mediation does not result in a settlement, the client will understand (if so educated) that you attempted to reduce emotional and financial costs, maintain confidentiality, and preserve relationships. The latter two issues are often of paramount concern in sexual harassment cases.
- ✓ **Preserving relationships.** Because mediation is designed to achieve interest-based outcomes and manage conflict, a mediation may salvage and, in fact, strengthen ongoing employment relationships.
- ✓ **Education.** Mediation educates parties as to the potential risks and benefits of moving forward with litigation.
- ✓ **Finality.** Mediation offers the parties finality. Moving beyond the dispute and avoiding “being sucked into” the adversarial process has considerable value.

Cons of Employment Mediation

There are not many negative aspects to mediation if the process is respected.


- ✓ **Employee frustration.** In litigation, employers generally benefit from having more money and resources to spend, which wears down employees with a lengthy process. Because of this, employers may perceive that mediation—which moves more quickly—is a detriment or undermines their strategic advantage, but this is more a function of perception than reality.
- ✓ **Mediation expense.** Unsuccessful mediation can drive up costs, especially if the parties must proceed to trial without a settlement, but when compared with litigation, mediation costs are minimal.
- ✓ **Distraction.** Mediation may distract attorneys and parties from other tasks needed to prepare for litigation, especially if one party is adamantly opposed to settlement. But, again, if one party is opposed to settlement, a good mediator may help the party realize and achieve the benefits of a confidential resolution of the controversy. **L**

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Related Content


For more information on strategies and steps for attorneys to consider when mediating employment disputes, see

> [MEDIATING EMPLOYMENT DISPUTES](#)

 **RESEARCH PATH:** [Labor & Employment > Discrimination, Harassment, and Retaliation > Claims and Investigations > Practice Notes](#)


For an overview of the Equal Employment Opportunity Commission (EEOC) conciliation process, see

> [CONCILIATING EEOC CHARGES](#)

 **RESEARCH PATH:** [Labor & Employment > Discrimination, Harassment, and Retaliation > Claims and Investigations > Practice Notes](#)

For a discussion of state laws governing discrimination, harassment, and retaliation in the workplace, see

> [DISCRIMINATION, HARASSMENT, AND RETALIATION STATE PRACTICE NOTES CHART](#)

 **RESEARCH PATH:** [Labor & Employment > Discrimination, Harassment, and Retaliation > Policies and Procedures > Practice Notes](#)

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Timothy Murray MURRAY HOGUE AND LANNIS

Drafting Landmines: Warranties for the Sale of Goods

The word warranty isn't just mired in confusion; it leaps, dives, and wallows in it. It means so many different things that the great Karl Llewellyn, the chief architect of the Uniform Commercial Code (U.C.C.), said that “the sane course is to discard the word from one's thinking.”¹

LLEWELLYN AND COMPANY BOWED TO TRADITION AND included the word in the U.C.C. but wisely kept § 2-313, the express warranty provision, straightforward. An express warranty is the description of, or statement of fact or promise about, the goods that become part of the basis of the bargain, conveyed by words or other means (including models, samples, technical specifications, and blueprints). It's what “the seller has in essence agreed to sell.”²

When it comes to contracts for the sale of goods, is there any provision more important than the express warranty? Yet when it comes to drafting express warranties for the sale of goods, attorneys typically rely on the client to do the heavy lifting—the client almost always knows the product better than the lawyer, and product descriptions are often very laden with technical language beyond the pay grade of most attorneys.

Little time is typically devoted to drafting warranties because warranty is one of those concepts that a lot of us assume is too simple to worry much about—after all, what can go wrong with a warranty?

The answer is plenty. The law governing warranties is riddled with landmines, and lawyers need to be familiar with them. Even if the client is the primary drafter of the warranty, that doesn't absolve attorneys of their responsibility to ensure that the warranty is done right.



The Other Warranties

Aside from express warranties, there are also implied warranties—of merchantability (§ 2-314) and fitness for a particular purpose (§ 2-315)—and there is a warranty of title and against infringement (§ 2-312). As a matter of course, sellers try to exclude from the contract the implied warranties of merchantability and fitness for a particular purpose. The latter is a specialty warranty premised on the buyer's reliance on the seller's skill or judgment in selecting the product.

Of greater concern to sellers is the implied warranty of merchantability, but that warranty only offers limited protections to buyers. It requires that the goods will be of “fair average quality” and that they are “fit for the ordinary purposes for which such goods are used” It's not a useless warranty, but buyers should not rely on the implied warranty of merchantability to provide them the protections they need. Buyers need a clear and precise express warranty describing the product and what it is supposed to do.

A well-drafted express warranty displaces the implied warranty of merchantability. Under the U.C.C., the buyer can't claim a breach of the implied warranty of merchantability if it is inconsistent with the express warranty.³

Express Warranties: The Not-So-Uniform Uniform Commercial Code

Despite its name, the Uniform Commercial Code is not always applied in a uniform fashion. Proof of this is the absence of consensus over whether reliance is an element of an express warranty claim under § 2-313:

[A] slim majority of courts considering the issue have held that reliance is not an element of an express warranty claim At the other end of the spectrum, a number of courts have required proof of specific reliance on a seller's statements to recover for breach of express warranty Finally, various jurisdictions have taken a middle ground approach, holding that a seller's affirmations relating to goods create a rebuttable presumption that the statements were part of the basis of the bargain, which the seller may rebut by “clear affirmative proof” to the contrary.⁴

Sellers: Do Not Try to Disclaim Express Warranties

Sometimes the seller will insist on a provision that purports to exclude not just implied warranties but express warranties, too. Disclaimers of implied warranties are expressly allowed by the U.C.C. and routinely upheld by the courts, but courts generally don't look kindly on contracts that try to undo express warranties with general exclusions.

Consider *Dakota Style Foods, Inc. v. SunOpta Grains & Foods, Inc.*⁵ SunOpta recalled the sunflower kernel products that it sold to Dakota Style due to the potential presence of listeria monocytogenes. Dakota Style sued SunOpta for breach of express warranty. The product specification stated that

“[t]he product shall be manufactured in accordance with Good Manufacturing Practice 21 CFR, Part #110”; “shall conform in every respect with the provisions of the Federal Food, Drug and Cosmetic Act, as amended, and to all applicable State and Local Regulations”; and “shall meet the Kashruth requirements of the Union of Orthodox Jewish Congregations of America.” It provided nutritional data, a flavor profile, and indicated that the sunflower kernels are “[n]utritionally-dense whole food.”

But SunOpta claimed that the product description—the express warranty—had no legal effect because it was disclaimed by the following general statement in the contract: “This information is presented in good faith, and great care was used in its preparation. However, no warranty, guarantee, or freedom from patent infringement is implied or intended. This information is offered solely for your consideration and verification.”

The court rejected SunOpta's argument. Despite some wobbly language in U.C.C. § 2-316(1) suggesting the possibility that express warranties can be negated,⁶ the court followed U.C.C. § 2-313 comment 4, which states that a general disclaimer of warranties designed “to reduce the seller's obligation with respect to [a product] description” simply “cannot be given literal effect” SunOpta's disclaimer was ineffective.⁷

In another case, the brand name of defendant's One A Day vitamin gummies created a warranty that one pill alone contained the recommended daily vitamin dosage. This warranty could not be undone by “miniscule” print on the back of the bottle announcing that two-a-day are actually needed.⁸

These cases underscore the near-sacrosanct status of the description of the product in contracts for the sale of goods. Your client cannot both give an express warranty, then negate it with a general or inconspicuous disclaimer.

Puffery, Puffery, Puffery

Sellers sometimes lard their sales contracts with vague assertions of quality or superiority about the products, replete with needless boasts lifted from ads or marketing brochures. To my everlasting horror, I've seen more contracts than I care to think about that actually incorporated marketing materials.

General assertions of quality⁹ or superiority¹⁰ usually are not legally binding. “The common theme that seems to run through cases considering puffery . . . is that consumer

1. K. Llewellyn, *Cases and Materials on the Law of Sales* 210 (1930). Judge Learned Hand provided one of the more coherent definitions: “A warranty is an assurance by one party to a contract of the existence of a fact upon which the other party may rely. It is intended precisely to relieve the promisee of any duty to ascertain the fact . . . ; it amounts to a promise to indemnify the promisee for any loss if the fact warranted proves untrue” *Metropolitan Coal Co. v. Howard*, 155 F.2d 780, 784 (2d Cir. 1946). 2. U.C.C. § 2-313, cmt. 4.

3. U.C.C. § 2-317. 4. *Michael v. Wyeth, LLC*, 2011 U.S. Dist. LEXIS 56157, *26-27 (S.D. W.Va. May 25, 2011). 5. 329 F. Supp. 3d 794 (D. S.D. 2018). 6. An early draft of the U.C.C. flatly stated that express warranties cannot be disclaimed. The language added later that became § 2-316 as it exists today—which has been called “obfuscation”—was tacked on to appease people who did not understand the earlier language. John E. Murray, Jr., *Amended Article Two: Reversing the Curse? Revised Article 2: Eliminating the “Battle” and Unconscionability*, 52 S. Tex. L. Rev. 593, 598 (2011). 7. See *Raatz v. Dealer Trade Inc.*, 261 F. Supp. 3d 997, 1002 (D. Ariz. 2017) (“The disclaimer language relied on by Defendant is contained in fine print at the bottom of the [Retail Buyer's Order]. It clearly was not bargained for and is inconsistent with the express representation, earlier on the same page, that the Vehicle had 35,648 miles.”) “Express” warranties rest on “dickered” aspects of the individual bargain, and go so clearly to the essence of that bargain that words of disclaimer in a form are repugnant to the basic dickered terms.” U.C.C. § 2-313 cmt. 1. 8. *Brady v. Bayer Corp.*, 26 Cal. App. 5th 1156 (2018). But another court disagreed: “The ‘ONE A DAY’ brand does not strike the Court as a warranty; and coupled with the open and obvious two-gummies-a-day serving information, no actionable express warranty was created.” *Howard v. Bayer Corp.*, 2011 U.S. Dist. LEXIS 161583, *5 (E.D. Ark. July 22, 2011). 9. *Bunn v. Navistar, Inc.*, 2019 U.S. Dist. LEXIS 12390, *6 (M.D. Tenn. Jan. 24, 2019). 10. *Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv.*, 911 F.2d 242 (9th Cir. 1990).

Depending on the context, a vague assertion may be unenforceable puffery in one instance and an enforceable express warranty in another.

reliance will be induced by specific rather than general assertions. Advertising which merely states in general terms that one product is superior is not actionable. However, misdescriptions of specific or absolute characteristics of a product are actionable.”¹¹

But suggesting that there are bright-lines in this area is perilous. Too often, marketing-type assertions touting a product’s purported superiority lie in a shadow land between unenforceable puffery and legally binding warranty. There is a staggering amount of litigation over the question of where the one ends and the other begins.

[R]epresentations that a product is as good as or better in all respects than a competitor’s is not always puffery as a matter of law. As observed by leading commentators on the topic, “. . . anyone who claims always to be able to tell a ‘puff’ from a warranty is (we will not hold back) a fool or a liar.”¹²

Depending on the context, a vague assertion may be unenforceable puffery in one instance and an enforceable express warranty in another. In one case, buyer bought a car advertised as “Mechanically A-1.” Right after buyer took possession of the vehicle—in fact, while he was driving it home—it stalled and was inoperable up to the time of trial. The court concluded that whatever “A-1” might mean in other contexts, it was not puffery here. The car “should have lasted at least long enough for the [buyer] to get [it] home.”¹³ But in another case, the buyer, an expert in tractors, was aware of problems with a tractor he purchased, so the contract’s description that the tractor was “in A-1 condition” was not part of the basis of the bargain.¹⁴

General characterizations of quality and superiority have no place in a contract’s description of the product. The description should be precise, thorough, and limited to assertions that can be objectively verified.

By the same token, clients ought to assume that whatever they say about the product—including an assertion that might look like puffery—is going to constitute an enforceable warranty. The U.C.C.’s official comments warn that all statements about the product are presumed to be part of the basis of the bargain “unless good reason is shown to the contrary.”¹⁵ To the extent an assertion is in the nature of general touting of a product’s superiority, the seller runs the risk that it might be found to bind the seller to all sorts of things that he or she never intended.

In addition, when assertions have the patina of deception, “the possibility is left open that a remedy may be provided by the law relating to fraud or misrepresentation.”¹⁶

Pre-Warranty Puffery: Make Sure You Have a Merger Clause

But what about assertions made prior to and separate from contract formation? These, too, can form part of the basis of the bargain. In negotiated contracts between merchants, the seller can often limit the effect of such assertions with a well-drafted merger clause.¹⁷ Merger clauses are not everywhere deemed to be conclusive on the question of complete integration.¹⁸

Of course, sellers make pre-contract fraudulent statements at their peril. Some jurisdictions hold that “a contractual agreement to ‘forego reliance on any prior false representation and limit . . . reliance to the representations . . . expressly contained in the contract’ has the binding effect of negating an action based on fraud in the inducement.”¹⁹ But not all jurisdictions agree that non-reliance clauses can whitewash pre-formation fraudulent statements.²⁰ For consumer transactions, robust federal and state laws protect against deceptive advertising.

Warranties Extending to Future Performance

Generally, warranties warrant that goods will do certain things or be a certain way at the time of delivery. Thus, “[a] breach of warranty occurs when tender of delivery is made.”²¹ This means that the statute of limitations starts to run from the date of delivery, not from the time a problem with the product manifests itself.



Buyers, of course, would prefer to have the statute of limitations start to run at the time a breach manifests itself as opposed to the time of delivery. Depending on how the warranty is worded, it can extend to future performance and delay the start of the statute of limitations to the time that a breach is or should have been discovered—possibly for many years, even decades. “[F]or a warranty to explicitly extend to future performance, the warranty ‘must expressly provide a guarantee that the product will perform as promised in the future.’”²²

The most extreme kinds of warranties of future performance are promises of a “lifetime warranty” and that a product will work satisfactorily “at all times.”²³

In one case, a tombstone was purchased and installed in 2003. If the tombstone had had a garden-variety warranty, the statute of limitations would have expired in 2007. But the seller’s literature stated that its tombstones were guaranteed to “last forever” and were “backed by a perpetual warranty.”

Unspecified “issues with the stone and the engraving” were later discovered, and suit was not filed until 2013. The court held that because of the language in seller’s literature, the warranty extended to future performance, and the cause of action did not accrue until the problem was or should have been discovered. It was the tombstone seller’s burden to establish at trial that the claim was time-barred under this standard.²⁴

But does anything really last forever? It’s certainly possible that the tombstone seller knew exactly what it was doing by making such a warranty—that it wanted to stand behind its product come hell or high water. But there is a nagging suspicion that a lot of sellers who are not terribly sophisticated do not appreciate that statements such as “last forever” can vastly extend their legal obligations far beyond what the law otherwise requires—in the case of the tombstone, from four years to . . . forever. It’s a boon for buyers, but sellers’ attorneys need to ensure that their clients understand the rights they are giving up.

11. Viggiano v. Hansen Nat. Corp., 944 F. Supp. 2d 877, 894-95 (C.D. Cal. 2013) (citations omitted). 12. SFEG Corp. v. Blendtec, Inc., 2017 U.S. Dist. LEXIS 12413, *46-47 (M.D. Tenn. Jan. 30, 2017) (quoting 1 White, Summers, & Hillman, Uniform Commercial Code § 10:12 (6th ed.)). 13. Jones v. Kellner, 5 Ohio App. 3d 242, 243 (1982). 14. Beckett v. Bauer, 1976 Ohio App. LEXIS 8356 (Apr. 22, 1976). 15. U.C.C. § 2-313 cmt. 8. 16. *Id.* 17. See Pure Bioscience v. Ross Sys., 2008 U.S. Dist. LEXIS 28454, *14-15 (S.D. Cal. Apr. 4, 2008); Martino v. MarineMax Northeast, LLC, 2018 U.S. Dist. LEXIS 201582 (E.D.N.Y. Nov. 28, 2018). 18. E.g., Bonfire, LLC v. Zacharia, 251 F. Supp. 3d 47 (D.D.C. 2017). 19. Billington v. Ginn-LA Pine Island, Ltd., LLLP, 192 So. 3d 77, 80 (Fla. App. 2016). 20. *Id.* 21. U.C.C. § 2-725(2). See, e.g., Repasky v. Jeld-Wen, Inc., 81 Pa. D. & C. 4th 495 (C.P. Adams 2006); Horsmon v. Zimmer Holdings, Inc., 2012 U.S. Dist. LEXIS 15650 (W.D. Pa. Feb. 8, 2012).

22. Leprino Foods Co. v. DCI, Inc., 2017 U.S. Dist. LEXIS 800 (D. Colo. Jan. 3, 2017) (citation omitted). In one case, the instruction manual of a humidifier stated, under the heading “1 YEAR LIMITED WARRANTY,” that the product was warranted “for a period of one year from the date of purchase” to be “free from defects in material and workmanship.” The statement qualified as an express warranty that extended to future performance because it related to the quality of the product and guaranteed that the humidifier would be free from defect for a certain period of time in the future. Singer v. Sunbeam Prods., 2016 U.S. Dist. LEXIS 56455 (N.D. Ill. Apr. 28, 2016). 23. See Tolen v. A.H. Robins Co., 570 F. Supp. 1146 (N.D. Ind. 1983); Rawls v. Associated Materials, LLC, 2011 U.S. Dist. LEXIS 84366, *6 (S.D. W.Va. Aug. 1, 2011). 24. Hoctor v. Polchinski Mems., Inc., 23 N.Y.S.3d 796 (App. Term 2015).

Warranties Created or Modified After Contract Formation

It's probably true that after the sales contract is entered into, no one usually looks at it until it's time to renew, one of the parties wants to terminate, or a problem arises. But it's a mistake to think that express warranties are set in stone just because the contract is signed. A lot can happen after contract formation to change existing warranties and create new ones. It's the lawyer's job to educate clients about the dangers this poses.

The U.C.C. contemplates the possibility of post-formation warranties: "The precise time when words of description or

affirmation are made or samples are shown is not material. . . . If language is used after the closing of the deal (as when the buyer when taking delivery asks and receives an additional assurance), the warranty becomes a modification, and need not be supported by consideration if it is otherwise reasonable and in order (Section 2-209)."²⁵

Important warranties can be created or modified in a matter of seconds with just a few words in a simple email or text message—without adequate deliberation and without the guidance of an attorney. Clients need to be counseled about the contractual significance of such actions and about the wisdom of having a more formal memorial of their rights and obligations.


²⁵ U.C.C. § 2-313, cmt. 7. "Warranties may be binding on the parties even if the buyer does not receive the details before the transaction is completed." *Rosa v. Am. Water Heater Co.*, 177 F. Supp. 3d 1025, 1041 (S.D. Tex. 2016). See also *Liberty Lincoln-Mercury, Inc. v. Ford Motor Co.*, 171 F.3d 818 (3d Cir. 1999).



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The parties' post-formation course of performance can also supplement and modify the warranty. *Bayer Chems. Corp. v. Albermarle Corp.*²⁶ is a cautionary tale. Albermarle agreed to supply 100 percent of Bayer's requirements of a C16–C18 compound, alkenyl succinic anhydride (ASA). The contract defined the ASA compound in this manner: "C16–C18 alkenyl succinic anhydride (hereinafter referred to as 'PRODUCT')."

²⁶ 171 Fed. App'x 392 (3d Cir. 2006) (the author was one of the attorneys for Bayer).



The precise percentages of C16 and C18 were nowhere mentioned in the contract, but from 1997 to 2003, the formulation of the "PRODUCT" that was actually supplied was 65% C16 and 35% C18.

Section 1.7 of the contract stated that if Bayer decided to "reformulate" the "PRODUCT," the parties would enter into good faith negotiations—but if an agreement was not reached, Bayer had the right to seek the supply of the reformulated "PRODUCT" from a third party. With two years remaining on the contract, Bayer notified Albermarle that it wanted to reformulate the "PRODUCT" by changing the percentages from 65% C16 and 35% C18 to 75% C16 and 25% C18. Albermarle argued that this was not a reformulation—the written contract did not establish any percentages of either component, so Bayer's proposal was already within the contract's definition of "PRODUCT."

The U.S. Court of Appeals for the Third Circuit disagreed and sided with Bayer. Despite the contract's broad description of "PRODUCT," the formula supplied since 1997 via the parties' course of performance—65% C16 and 35% C18—became the contract description that was every bit as binding as if it had been spelled out in the written contract. Bayer's change in the formulation was thus a reformulation, and Bayer was permitted to invoke the reformulation clause.

The lesson is sobering. Clients need to be forewarned that their post-formation conduct can supplement and modify the warranty—the very basis of the bargain—without ever putting it in writing. **L**

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Aravind Swaminathan, David T. Cohen, Rochelle Swartz, and Nicholas Farnsworth
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Emerging Biometric Laws: Considerations for Employers and Companies Collecting Data

A recent decision from the Supreme Court of Illinois heightens the risks faced by companies collecting biometric information by holding¹ that an individual who is the subject of a violation of Illinois' Biometric Information Privacy Act (BIPA)—but who suffered no separate harm from the violation—is an “aggrieved party” with a cause of action under the statute.

THIS DECISION WILL ONLY FURTHER EMBOLDEN PLAINTIFFS' lawyers to bring biometric privacy suits, and the risk to companies collecting biometric information will likely increase as newly enacted and proposed legislation comes into effect. This article discusses what happened, what is on the horizon, and some steps to consider.

Overview of the Illinois Biometric Information Privacy Act

The BIPA regulates private entities' (defined broadly) collection, use, storage, and disposal of an individual's “retina or iris scan, fingerprint, voiceprint, or scan of hand or face geometry” (defined as “biometric identifiers”) or any information “based on an individual's biometric identifier used to identify an individual” (defined as “biometric information”). BIPA imposes several obligations on private entities in possession of biometric identifiers or biometric information, including requiring:

- The development of a written biometrics retention and destruction policy
- The disclosure of the content and purposes for which the biometric identifiers or biometric information are collected and used
- The procurement of a written release for the collection and use of biometric identifiers and biometric information
- The implementation of safeguards meeting “the reasonable standard of care within the private entity's industry”

Private entities failing to comply with their obligations under the statute may face litigation based on BIPA's private right of action available to persons “aggrieved” by such statutory violations and could be liable for actual damages or, if greater, liquidated damages of \$1,000 per negligent violation and \$5,000 per intentional or reckless violation of the law.

Preliminary Challenges in Biometric Privacy Litigation

In BIPA and other privacy and cybersecurity litigation, defendants have two separate and independent ways to attack plaintiffs' injury allegations:

- Challenge the plaintiff's standing through either a federal court Article III challenge or a state court equivalent
- Argue that the plaintiff failed to plead or prove the injury redressable by the cause of action in question (e.g., that the plaintiff was not aggrieved by a violation of BIPA)

An example of a successful standing challenge is *Rivera v. Google*.² There, two individuals asserted that Google violated BIPA by applying its face-recognition program to images of them without their knowledge or consent. The U.S. District Court for the Northern District of Illinois held that the plaintiffs failed to demonstrate that they suffered a concrete injury from Google's alleged collection or retention of the biometric data. It therefore concluded that the plaintiffs failed to establish a “case or controversy” under Article III of the U.S. Constitution, and that consequently federal courts lacked power to hear the suit.³ Notably, however, this decision did not permanently terminate the litigation. The plaintiffs from *Rivera* have refiled their claims against Google in the Circuit Court of Cook County, Illinois,⁴ where Google may argue that the plaintiffs likewise fail to satisfy the Illinois state constitution's equivalent of Article III.

Impact of the *Rosenbach* Decision

The Supreme Court of Illinois in *Rosenbach* did not address Article III standing nor the Illinois state constitution equivalent, but rather focused on the circumstances in which a plaintiff can satisfy the injury requirement contained in BIPA itself—that is, the requirement that the plaintiff be “aggrieved.” In *Rosenbach*, a mother filed suit on behalf of her 14-year-old son, claiming that the fingerprinting practices of Six Flags in connection with their repeat-entry pass enrollment process violated BIPA⁵ by collecting the son's fingerprints without informing him or his mother of “the specific purpose and length of term for which his fingerprint had been collected” and without obtaining either his or his mother's written release or consent. In addition to other defenses, Six Flags argued that the plaintiff “had suffered no actual or threatened injury” and, as a result, wasn't an aggrieved person eligible for the BIPA private right of action.

¹ *Rosenbach v. Six Flags Entm't Corp.*, 2019 Ill. LEXIS 7 (Jan. 25, 2019). ² 238 F. Supp. 3d 1088 (N.D. Ill. 2017). ³ In so holding, the court departed from the conclusion of an analogous case, *Patel v. Facebook, Inc.*, 290 F. Supp. 3d 948 (N.D. Cal. 2018), which upheld the Article III standing of consumers who alleged that Facebook applied facial-recognition software to create facial templates without consent. The *Patel* litigation is now pending in the U.S. Court of Appeals for the Ninth Circuit. ⁴ *Rivera v. Google LLC*, No. 2019CH00990 (Ill. Cir. Ct.). ⁵ According to the complaint, the fingerprinting process for the repeat-entry passes to the park is as follows: When individuals sign up for repeat-entry passes, Six Flags' system “scans pass holders' fingerprints; collects, records and stores 'biometric' identifiers and information gleaned from the fingerprints; and then stores that data in order to quickly verify customer identities upon subsequent visits by having customers scan their fingerprints to enter the theme park.”



Although Illinois is currently the only biometric information statute with a private right of action, the risks for entities collecting biometric information are increasing...

Emphasizing the importance of proper notice and the right to refuse consent, the court explained that “[w]hen a private entity fails to adhere to the statutory procedures . . . ‘the right of the individual to maintain [his or] her biometric privacy vanishes into thin air. The precise harm the Illinois legislature sought to prevent is then realized.’” Therefore, the court held that no actual injury, beyond a violation of BIPA, is required for a person to qualify as an aggrieved person and be entitled to seek liquidated damages and injunctive relief.

Takeaways

The *Rosenbach* decision has several important takeaways for businesses that collect or use personally identifiable information, including biometric identifiers and biometric information.

- **Liability risks for alleged mishandling of biometric information are increasing.** Several additional states have laws on the books, or are considering legislation, for biometric information. Although Illinois is currently the only biometric information statute with a private right of action,⁶ the risks for entities collecting biometric information are increasing, particularly if other jurisdictions use similar “aggrieved” language and adopt the *Rosenbach* rationale.
- **The California Consumer Privacy Act of 2018 (CCPA).** The CCPA introduced sweeping changes to the U.S. privacy landscape by granting California residents enhanced rights in relation to their personal information (which includes biometric information), as well as a private right of action for certain breaches of personal information.
- **The proposed Massachusetts Senate Bill 341.** The proposed bill would add a Consumer Data Privacy chapter to the Massachusetts General Laws, which would grant Massachusetts consumers similar rights to those provided under the CCPA in relation to personal information (which may include biometric

- information). Unlike the CCPA, the proposed bill would create a private right of action for a consumer who has “suffered [any] violation” of the bill and specifically states the intent that a violation of the bill “shall constitute an injury in fact to the consumer . . . and the consumer need not suffer a loss of money or property . . . to bring an action for a violation.”⁷
- **The proposed Washington Privacy Act, Senate Bill 5376 (WPA).** The proposed WPA would create a new overarching privacy law in Washington state. The proposed law would create an enumerated set of consumer rights in relation to personal data (which includes biometric data) similar to those provided under the CCPA. Although the proposed law does not include a private right of action for aggrieved consumers, a violation of its provisions could result in enforcement by the attorney general.⁸
- **The proposed New York Biometric Privacy Act, Senate Bill 1203 (BPA).** The proposed BPA would create a new biometric-specific privacy law in New York similar to BIPA. The proposed law would create a private right of action for “[a]ny person aggrieved by a violation” of the statute.⁹
- **Understanding which biometric identifiers/information are collected/used.** Businesses across industries increasingly are (or are considering) using biometrics more frequently, including in relation to:

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- For additional information on the *Rosenbach* decision, see
- > [NO ACTUAL INJURY NEEDED FOR SUIT UNDER BIOMETRIC PRIVACY LAW, ILLINOIS HIGH COURT RULES](#)
 - RESEARCH PATH: [Data Security & Privacy > State Law Surveys and Guidance > State Guidance > Articles](#)
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- For guidance on complying with the European Union’s data protection requirements, see
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- For a list of state laws that regulate the protection of personal information, see
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 - RESEARCH PATH: [Data Security & Privacy > Industry Compliance > Public Sector > Practice Notes](#)
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- For a discussion on the design and operation of wellness programs, which may include biometric screening, see
- > [WELLNESS PROGRAM DESIGN AND COMPLIANCE](#)
 - RESEARCH PATH: [Employee Benefits & Executive Compensation > Health and Welfare Plans > Fringe Benefit and Other Welfare Plans > Practice Notes](#)

- User verification (such as mobile device fingerprint authentication)
- Workforce management (such as fingerprint-based time clocks)
- Personal identification (such as facial recognition in photographs and video)

⁶ The biometrics laws of both Texas (Tex. Bus. & Com. Code Ann. § 503.001) and Washington state (Wash. Rev. Code § 19.375.030) do not create a private right of action for individuals impacted by an entity’s violation of the statutes. However, both statutes grant the attorney general the power to enforce the statutory provisions, including through the imposition of civil fines and penalties.

⁷ <https://malegislature.gov/Bills/191/SD341>. ⁸ <https://app.leg.wa.gov/billssummary?BillNumber=5376&Initiative=false&Year=2019>. ⁹ <https://legislation.nysenate.gov/pdf/bills/2019/S1203>.



complying with the procedures afforded to avoid the significant litigation risk. Once in place, companies can begin to revise notice, collection, use, and retention practices accordingly. Companies that don't have the resources to undertake a data mapping effort should (at a minimum) understand whether they're collecting biometrics and review privacy policies and terms of service to identify risks and take basic steps to manage them.

■ **Alternative defenses remain.** Despite the *Rosenbach* decision being favorable to plaintiffs, defendants still have other defenses that can be raised in BIPA litigation. These include, but are not limited to:

- **Standing.** It remains to be seen whether the Illinois Supreme Court will be open to dismissing BIPA litigation on constitutional standing grounds where the plaintiff suffers no harm apart from the alleged statutory violation. And, as noted above, Article III standing challenges may be viable in federal court.
- **Statutory interpretation.** There are several terms and concepts under the biometric statutes that are still open to interpretation, such as the meaning of biometric identifiers; what conduct qualifies as the collection of biometric information; and whether practices are considered negligent, reckless, or intentional under BIPA. In addition, businesses may be able to argue that some of their obligations under the statute are satisfied by implicit messaging provided through the context of the process involved in the collection of biometric identifiers or biometric information.
- **Procedural defenses.** Defendants are still able to assert the procedural defenses available to them in all lawsuits, including a failure to meet class certification requirements, improper venue, and lack of personal jurisdiction, among others. **L**

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RESEARCH PATH: [Data Security & Privacy > State Law Surveys and Guidance > State Guidance > Articles](#)

With potential liability in private actions or state attorney general enforcement proceedings for mere procedural violations, such as failure to provide adequate disclosure or obtain necessary release/consent, entities using (or considering using) biometrics should take steps to gain a deeper understanding of a business's actual collection, use, storage, and disposal practices relating to biometrics. In that regard, many businesses would benefit from conducting a data mapping exercise and/or information audit to identify the information and practices that would be subject to privacy and cybersecurity laws, such as BIPA. Only with this kind of solid understanding can companies undertake to comply with the patchwork of laws that are emerging and ensure that they are

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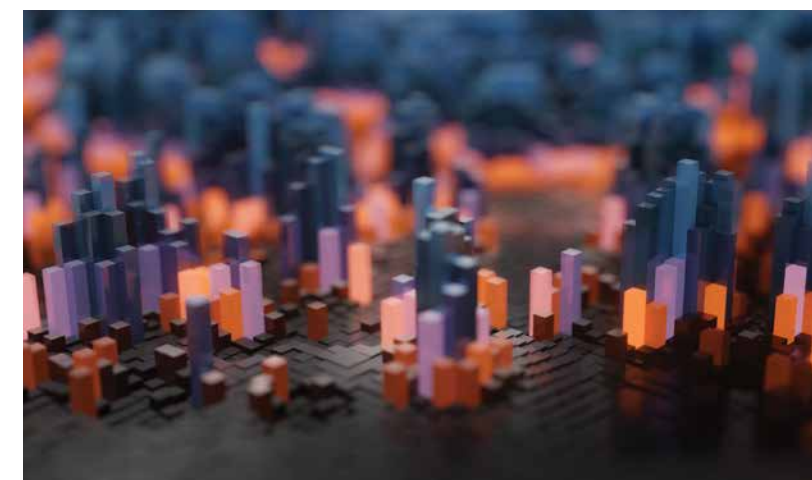
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Business Development Companies

Increasing numbers of asset managers are evaluating the potential benefits of including a business development company (BDC) within their suite of managed funds and accounts. A BDC is a hybrid of an investment company and a traditional operating company and, as a result, their operations are subject to a unique and complex adaption of various federal securities laws. Below are 10 practice tips that will help you navigate the BDC space without panicking.

Origins

BDCs were established under the Small Business Investment Incentive Act of 1980 as a type of closed-end investment company designed to provide capital to small, developing, and financially troubled companies lacking access to public capital markets, financial and operational management expertise, and miscellaneous forms of traditional equity and debt capital. BDCs elect, pursuant to Section 54 of the Investment Company Act of 1940, as amended (the 1940 Act), to be subject to Sections 55 to 65 and certain other provisions of the 1940 Act. In addition, BDCs are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act), and file Forms 10-K, 10-Q, and 8-K. The common stock of BDCs can be listed on a national securities exchange (e.g., Nasdaq or the New York Stock Exchange), although there are a number of large BDCs that have been offered to institutional investors or through certain retail channels that are not listed. Prior to 2003, the largest BDCs were internally managed, meaning that the BDC manages its assets through its own employees, who are compensated directly by the BDC. Since that time, however, a meaningful majority of new BDCs have been externally managed, meaning that the BDC engages an investment adviser registered under the Investment Advisers Act of 1940, as amended (the Advisers Act), to manage its



assets under the supervision of a board of directors. This has allowed a number of large asset managers to offer a BDC to their clients as part of a wide array of products across a number of strategies. Asset managers considering entry into the BDC space should give careful consideration to the proposed investment strategy and how a BDC will fit within the existing platform (including with respect to legal, operations, and other resources necessary to ensure compliance with regulatory restrictions).

In the case of BDCs engaging in formation transactions, care must be taken with respect to the structuring, sequencing, and timing of the transactions to ensure that they do not run afoul of the 1940 Act's restrictions on transactions with affiliates...

Formation Transactions

Over the past several years, it has become increasingly difficult for a BDC to complete an initial public offering (IPO) as a blind pool. As a result, most BDCs either (1) operate as a private vehicle and build up a portfolio of assets prior to commencement of an IPO (e.g., Bain Capital Specialty Finance, Inc.; TCG BDC, Inc.; and Goldman Sachs BDC, Inc.) or (2) engage in a series of formation transactions pursuant to which they acquire a pool of assets prior to commencement of the IPO (e.g., Golub Capital BDC, Inc. and Garrison Capital Inc.). In the case of BDCs engaging in formation transactions, care must be taken with respect to the structuring, sequencing, and timing of the transactions to ensure that they do not run afoul of the 1940 Act's restrictions on transactions with affiliates (which take effect at the time a company elects status as a BDC).

Eligible Portfolio Companies

A BDC is generally prohibited from acquiring assets other than qualifying assets unless, after giving effect to any acquisition, at least 70% of its total assets are qualifying assets. Qualifying assets generally include securities of eligible portfolio companies, cash, cash equivalents, U.S. government securities, and high-quality debt instruments maturing in one year or less from the time of investment. As a general matter, a company is an eligible portfolio company if it (1) is organized under the laws of any U.S. state and has its principal place of business in the United States; (2) is not an investment company or a company that would be an investment company except for the exclusions under Section 3(c) of the 1940 Act; and (3) either (a) does not have any class of securities listed on a national securities exchange or (b) has an aggregate market value of its voting and non-voting equity securities of less than \$250 million. Subject to certain limitations on investing in securities and insurance-related businesses, the remaining 30% of a BDC's total assets can be invested opportunistically, including in non-U.S. issuers, joint ventures, aircraft finance businesses, and unsecured consumer loans. Asset managers should ensure that they expect to have access to an appropriate level of qualifying assets following completion of the launch of a BDC.

Fee Structure

Externally managed BDCs typically pay their investment advisers a base management fee and an incentive fee, although the rates can vary meaningfully depending on the BDC's investment strategy, the year in which the BDC was launched, and whether the BDC is listed or unlisted. Fee structures are often a significant negotiation point at the time of any BDC IPO, as the underwriters and management review and assess market comparables. Fee structures have changed over the past several years, and managers considering establishing a BDC, or taking a private BDC public, should be certain to evaluate fee arrangements within the current market.

The base management fee is typically paid at an annual rate of between 1% and 2% of gross assets (often calculated excluding cash and cash equivalents) and is generally paid quarterly in arrears. The incentive fee typically has two parts: one based on the BDC's income and the second based on capital gains. The income-based component of the incentive fee is typically between 15% and 20% of the BDC's net investment income (calculated before payment of the incentive fee) over a specified annual rate of return (hurdle) of between 6% and 8% and is generally paid quarterly in arrears. The capital gains component of the incentive fee is typically between 15% and 20% of a BDC's realized gains over a period, less its realized losses and unrealized capital depreciation over the same period, and is paid annually. The capital gains component of the incentive fee is subject to a statutory cap of 20% of realized gains less realized losses and unrealized capital depreciation. By contrast, the base management fee and the income-based component of the incentive fee are not subject to any statutory maximum.

Over the past several years, many BDCs have incorporated caps on their incentive fees such that they are not payable to the investment adviser absent certain returns to stockholders over a period of time (often three years). In addition, many BDCs have incorporated limitations on the income-based component of the incentive fee such that it is payable only on amounts received by the BDC in cash. Asset managers should carefully consider market trends in BDC fee structures as well as fees across other investment vehicles they offer in connection with

fixing the fee structure for any new BDC, especially as the asset manager will be limited in its ability to adjust the fee structure without approval of the BDC's stockholders.

Approval of Investment Advisory Agreements

The initial investment advisory agreement between a BDC and its investment adviser may have a term of no more than two years from its date of execution and must be approved by (1) a majority of the BDC's board of directors; (2) a majority of the directors who are not interested persons (within the meaning of the 1940 Act) of the BDC (at an in-person meeting called for that purpose); and (3) the holders of a majority of the outstanding voting securities of the BDC (which means the affirmative vote of the lesser of (a) 67% or more of the shares of the BDC present or represented by proxy at a stockholder

meeting if the holders of more than 50% of the outstanding shares are present or represented by proxy at such meeting or (b) more than 50% of the outstanding shares). The initial stockholder approval is typically accomplished before the BDC accepts money from outside investors. However, any subsequent modification to the investment advisory agreement (other than fee reductions) will generally require that the BDC seek stockholder approval of such modification.

Following an initial two-year term, the investment advisory agreement will remain in effect from year to year thereafter if approved annually by the BDC's board of directors or by the affirmative vote of the holders of a majority of outstanding voting securities of the BDC, and, in either case, a majority of the directors who are not interested persons of the BDC (at an in-person meeting called for that purpose).





In connection with their consideration of the investment advisory agreement, the directors of the BDC must request and evaluate (and the BDC's investment adviser must provide) such information as may reasonably be necessary to evaluate the terms of the investment advisory agreement. The resulting analysis should focus on a number of items, including (1) the nature, extent, and quality of services performed by the investment adviser; (2) the investment performance of the BDC and the investment adviser; (3) the costs of providing services to the BDC; (4) the profitability of the relationship between the BDC and its investment adviser, including realized and potential economies of scale; and (5) comparative information on fees and expenses borne by other comparable BDCs or registered investment companies and other advised accounts. No single factor in this analysis is required to be dispositive.

Given the technical nature of the requirements for the approval of an investment advisory agreement and the amount of

information provided to directors as part of the approval process, asset managers should carefully set the fee structure such that amendments will not be required except in extreme circumstances and consider the timings of required approvals and plan accordingly.

Termination of Investment Advisory Agreements; Section 15(f)

The 1940 Act requires that the holders of a majority of the outstanding voting securities of a BDC be able to terminate the investment advisory agreement at any time without penalty upon not more than 60 days' written notice to the investment adviser. In addition, the investment advisory agreement must provide that it terminates automatically in the event of its assignment. For purposes of the 1940 Act, the acquisition by any person of greater than 25% of the voting securities in an investment adviser will generally constitute an assignment,

as will the failure of any greater than 25% holder to continue holding greater than 25% of the voting securities of the investment adviser. As a result, a change of control transaction of the investment adviser to a BDC will generally require that the BDC seek stockholder approval of the investment advisory agreement, regardless of whether economic terms are changing.

As a general matter, Section 15(f) of the 1940 Act prohibits an investment adviser from receiving compensation or other benefit in connection with the sale of an interest in the investment adviser that results in an assignment unless (1) during the three-year period following the consummation of a transaction, at least 75% of the BDC's board of directors are not interested persons of the new investment adviser or predecessor adviser; and (2) an unfair burden is not imposed on the BDC as a result of the transaction relating to the sale of such interest, or any of its applicable express or implied terms, conditions, or understandings. The term unfair burden includes any arrangement during the two-year period after the transaction whereby the investment adviser (or predecessor or successor adviser), or any interested person of such an investment adviser, receives or is entitled to receive any compensation, directly or indirectly, from the investment company or its stockholders (other than certain advisory and services fees) or from any person in connection with the purchase or sale of securities or other property to, from, or on behalf of the investment company (other than certain underwriting compensation).

Asset managers evaluating change of control transactions should take care to ensure that no party inadvertently takes action that would result in the assignment of an investment advisory agreement prior to receipt of appropriate stockholder approvals and also address as part of the transaction documentation appropriate allocation of responsibility for ensuring compliance with Section 15(f).

Co-investment

The 1940 Act prohibits a BDC from knowingly participating in certain types of transactions with its affiliates without prior approval of its directors who are not interested persons and, in some cases, prior approval by the Securities and Exchange Commission (SEC). These restrictions generally prohibit a BDC from engaging in joint transactions with other entities that share the same investment adviser (or investment adviser controlling, controlled by, or under common control with such adviser). Certain types of co-investments across a platform of affiliated funds, including a BDC, could constitute such a prohibited joint transaction. The staff of the SEC has granted no-action relief permitting purchases of a single class of privately placed securities provided that the investment

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adviser negotiates no term other than price and certain other conditions are met. However, many BDCs and their investment advisers seek exemptive orders from the SEC in order to permit greater flexibility to negotiate the terms of co-investments. Under the terms of this relief, a required majority, as defined in the 1940 Act, of the BDC's board of directors would be required to make certain conclusions in connection with any negotiated co-investment transaction, including that the terms of the proposed transaction do not involve overreaching by the BDC or its stockholders and that the transaction is consistent with the BDC's investment strategies and policies. Asset managers should consider whether the strategy for their BDC overlaps with that of other funds and accounts and, if so, whether the ability to co-invest on originated or other negotiated transactions is important to the successful implementation of the investment strategy across relevant accounts.

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Asset Coverage

The 1940 Act contains asset coverage requirements that limit the ability of BDCs to incur leverage. Until March 2018, a BDC was generally only allowed to borrow amounts by issuing debt securities or preferred stock (collectively referred to as senior securities) if its asset coverage, as defined in the 1940 Act, equaled at least 200% (equivalent to a 50% debt-to-total capital ratio) after such borrowing. For purposes of the 1940 Act, asset coverage means the ratio of (1) the total assets of a BDC, less all liabilities and indebtedness not represented by senior securities, to (2) the aggregate amount of senior securities representing indebtedness (plus, in the case of senior securities represented by preferred stock, the aggregate involuntary liquidation preference of such preferred stock). Since March 2018, BDCs have been able to increase the maximum amount of leverage that they are permitted to incur, so long as the BDC meets certain disclosure requirements and obtains certain approvals. Under these modified asset coverage requirements, a BDC will be able to incur additional leverage, as the asset coverage requirements for senior securities (leverage) applicable to the company pursuant to Sections 18 and 61 of the 1940 Act will be reduced to 150% (equivalent to a 66-2/3% debt-to-total capital ratio). Effectiveness of the reduced asset coverage requirement to a BDC requires approval by either (1) a required majority of such BDC's board of directors with effectiveness one year after the date of such approval or (2) a majority of votes cast at a stockholder meeting of such BDC's stockholders at which a quorum is present, which is effective the day after such stockholder approval. In addition, a BDC which does not have its common stock listed on a national securities exchange must offer each stockholder of record on the approval date of the reduced asset coverage requirements the opportunity for the BDC to repurchase such stockholder's securities held on such date. The BDC then must repurchase, by tender offer or otherwise, 25% of the securities held by electing stockholders of record on the approval date in each of the four succeeding calendar quarters following the quarter during which the reduced asset coverage ratio was approved.

BDCs can incur leverage through a variety of means, including traditional senior secured credit facilities, collateralized loan

obligations, warehouse credit facilities, institutional notes offerings, retail (baby bond) notes offerings, debentures from the Small Business Administration, and preferred stock. In the current environment, many BDCs have established both debt facilities that provide for revolving borrowings at a floating rate above the London Interbank Offered Rate (LIBOR) (or an equivalent) and debt facilities (or notes offering) that provide for term borrowings at a fixed rate.

Asset managers entering the BDC space should consider carefully the desired asset coverage requirement to which the BDC will be subject and also evaluate the types of leverage that fit best with the intended investment strategy.

Compliance Function

BDCs are required to adopt and implement written policies and procedures reasonably designed to prevent violations of the federal securities laws by the BDC, including policies and procedures that provide for the oversight of compliance by the BDC's investment adviser, administrator, transfer agent, and any principal underwriters. These policies and procedures are required to be approved by the BDC's board of directors on a finding that the policies and procedures are reasonably designed to prevent violations of the federal securities laws. Adequacy of the policies and procedures must be reviewed at least annually. BDCs are also required to have a chief compliance officer, whose designation and compensation are approved by the BDC's board of directors, including a majority of the directors who are not interested persons. This individual must deliver, no less than annually, a written report to the board of directors addressing the operation of the compliance program and any material compliance matters and meet in executive session with the directors who are not interested persons no less frequently than annually. The investment adviser to a BDC is also required to comply with its own regulatory requirements under the Advisers Act and compliance manuals and policies.

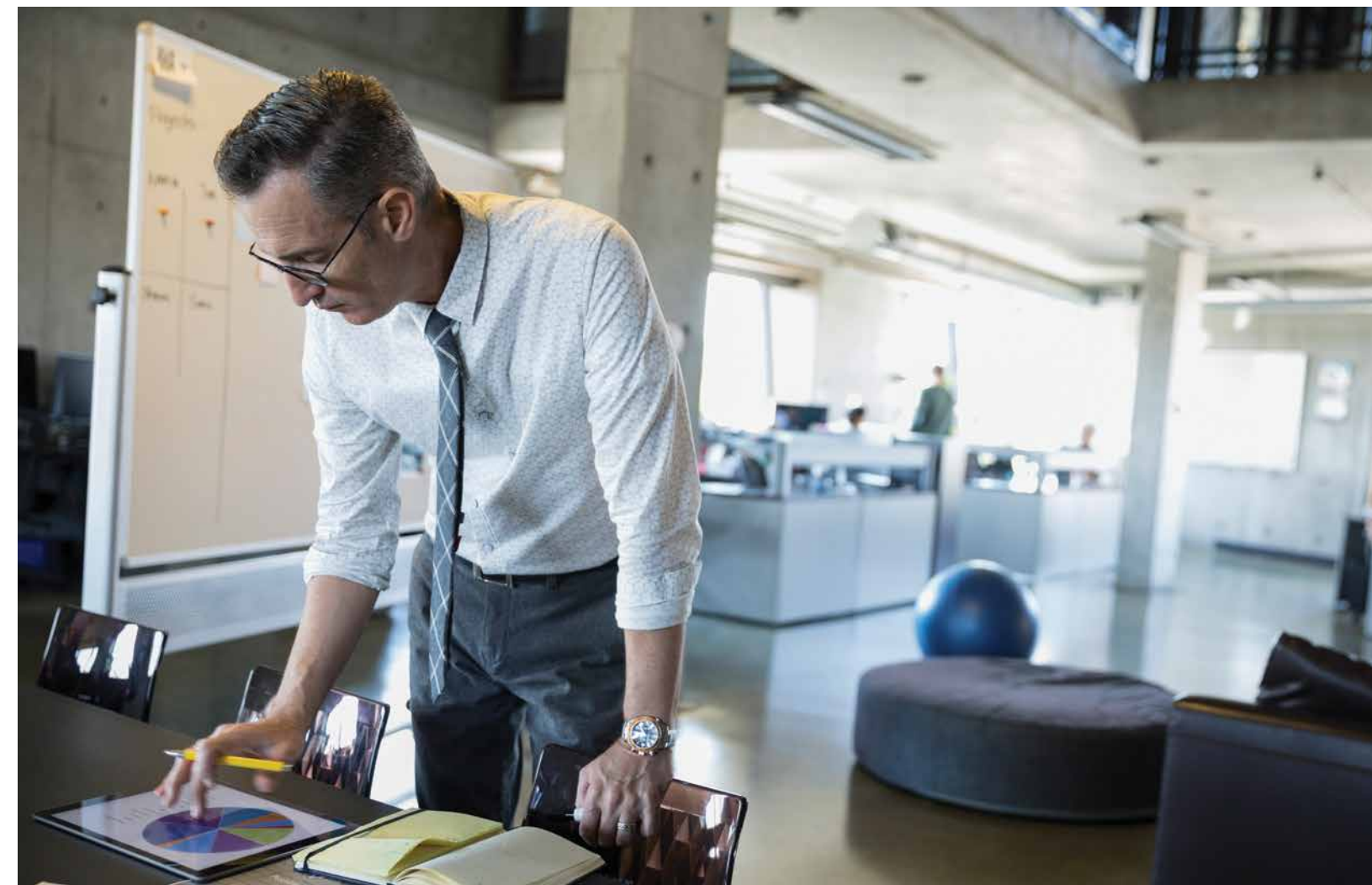
Asset managers entering the BDC space should ensure that the existing compliance team has sufficient bandwidth for the new product or consider whether additional resources (whether at the asset manager or through retention of a third party) will be necessary.

Consolidation and M&A Transactions

As the BDC industry has grown and become an attractive vehicle for asset managers, it has experienced a number of novel consolidation transactions. Consolidation transactions could be an attractive and efficient way for asset managers to gain access to the BDC market whether through acquiring another asset manager (or the books and records related to managing the BDC), which may be an ideal option as certain asset managers evaluate succession planning, or purchasing the investment advisory contract directly from the stockholders. In addition, existing BDCs may be able to gain scale through the acquisition of BDCs managed by other asset managers and/or through the consolidation of multiple BDCs across the same platform. Any of these structures require careful analysis of a number of difficult issues ranging from 1940 Act restrictions to tax planning to securities laws. Asset managers evaluating the BDC space should consider whether a consolidation or M&A transaction might be a more efficient means of gaining access to capital, as compared to raising capital in a newly formed BDC or otherwise acquiring the resources to expand its platform. **L**

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Preparing for Patent Litigation Against **Generic Drug Companies**

This article addresses how counsel for a generic drug company should prepare for patent litigation under the Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch-Waxman Act.¹ It examines strategies that you should review with your client and actions that you should take in advance of Hatch-Waxman litigation. Careful pre-suit preparation increases the likelihood of a favorable result, whether through litigation or settlement, and minimizes the small, but real, risk of a fees award against your client that may result from insufficient attention to pre-suit issues.²

THE FOCUS OF THIS ARTICLE IS PREPARATION FOR A Hatch-Waxman suit based on the filing of an Abbreviated New Drug Application (ANDA). However, many of the same considerations apply to Hatch-Waxman suits based on the filing of a 505(b)(2) application.

Hatch-Waxman Recap

The Hatch-Waxman Act affords a generic drug company an abbreviated path to approval of a generic version of a brand-name drug. It also provides a special patent litigation scheme that enables patent infringement and validity issues to be determined before the generic drug is launched on the market. Originally conceived to be an incentive to challenge patents that blocked generic versions of brand-name drugs, the Act promised a potentially lucrative 180-day marketing exclusivity to the first generic drug company to file an ANDA and successfully challenge the brand's patent. Over time, changes in patent law and amendments to the Hatch-Waxman Act, as well as developments in the pharmaceutical marketplace, have



significantly altered the typical Hatch-Waxman litigation. In particular, the promise of a single generic company obtaining a 180-day marketing exclusivity has become elusive. The sharing of the 180-day marketing exclusivity among more than 20 ANDA applicants is not uncommon.

Other changes have exacerbated the complexity of the strategic considerations in a Hatch-Waxman suit. These include the

¹ 21 U.S.C.S. § 355. ² The terms generic drug company and brand-name drug company are used in this article to denote the parties' respective positions in relation to a particular drug, rather than defining each company's overall business. (A generic drug company may innovate and own patents, and a brand-name drug company may have a generic drug division). For convenience, the generic drug company may sometimes be referred to as "the generic," and the brand-name drug may be referred to as "the brand."



availability of concurrent Patent Trial and Appeal Board (PTAB) validity challenges and the evolving case law on the proper venue for a Hatch–Waxman suit under *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*.³

The following summarizes the essential concepts and important features of Hatch–Waxman litigation.

New Drug Application (NDA)

A drug company seeking government approval to market a new drug must submit an NDA establishing the drug’s safety and efficacy to the Food and Drug Administration (FDA). The NDA must also identify each patent claiming the drug, or a use of the drug, which could reasonably be asserted against a person not authorized to engage in the manufacture, use, or sale of the drug. The patent information and any marketing exclusivities covering the approved drug product are provided in the FDA publication entitled *The Approved Drug Product with Therapeutic Equivalence Evaluations* (the Orange Book).

Abbreviated New Drug Application (ANDA)

The Hatch–Waxman Act provides generic companies with an abbreviated route to FDA approval of a generic drug, piggybacking on the NDA’s safety and efficacy data. Instead of filing a full NDA, the generic drug company need only demonstrate in an ANDA that the generic product is bioequivalent to the reference-listed drug (RLD) (i.e., the approved NDA drug). Also, for each Orange Book patent, the ANDA applicant must make one of the following four certifications: (1) no patent information has been provided,

(2) the patent has expired, (3) the applicant will not market the drug until the patent has expired, or (4) the patent is invalid or will not be infringed by the generic drug (the latter is referred to as a Paragraph IV certification).⁴

Orange Book Listed Patents

Only certain types of patents can be listed in the Orange Book and thus require a patent certification by the generic company. The listed patents are those claiming the active pharmaceutical ingredient (API), product or formulation, composition, treatment or method of use, drug delivery system (e.g., inhalers), and polymorphs, as well as product-by-process patents. Patents that claim other aspects of the product, such as metabolites, intermediates, and methods of manufacture, cannot be listed in the Orange Book. The ANDA filer makes no certification with respect to any unlisted patent.

Paragraph IV Certification

If the ANDA includes a Paragraph IV certification, the applicant must provide notice of the certification to the patent owner and the NDA holder. Under the Hatch–Waxman Act, the filing of an ANDA with a Paragraph IV certification as to any Orange Book patent is an artificial act of patent infringement.⁵ The infringement under Section 271(e)(2) is termed artificial because it is not based on any allegedly infringing use, sale, or offer for sale but rather is designed to provide federal courts with subject matter jurisdiction over an infringement dispute. Infringement litigation (along with any invalidity counterclaims) may then proceed contemporaneously with the

FDA approval process. As sales of the generic product have not yet begun at this point, the ANDA filer can litigate the validity and infringement issues without being exposed to a potential award of damages for patent infringement.

30-Month Stay of FDA Approval

If the patent owner files a patent infringement suit against the ANDA filer within 45 days of receiving notice of the Paragraph IV certification, the FDA stays approval of the ANDA for 30 months. This 30-month period is meant to approximate the duration of the patent infringement litigation and can be shortened or extended, but only based on a party’s failure to reasonably cooperate in expediting the action.⁶

180-Day Marketing Exclusivity for First Generic Filer with a Paragraph IV Certification

The ANDA applicant who is first to file an ANDA with a Paragraph IV certification against an Orange Book patent is entitled to a 180-day marketing exclusivity, excluding other generic drug companies from the market for the generic drug for the 180-day period. Should more than one ANDA applicant file a Paragraph IV certification on the same patent on the same day, the applicants will share the 180-day exclusivity period. The exclusivity can be forfeited if the applicant fails to obtain FDA approval or market its product within certain time periods. Also, an authorized generic will not be blocked by the 180-day exclusivity period. Note that the 180-day exclusivity is not granted for 505(b)(2) applications; it applies only to ANDAs with a Paragraph IV certification.

Section VIII Carve-Out

If the Orange Book lists a method-of-use patent that does not cover the use for which the ANDA seeks approval, the ANDA must contain a statement to this effect (a so-called Section VIII carve-out or skinny label).⁷ This statement allows the ANDA applicant to avoid having to litigate the applicable method of use patent.

Preparing to File an ANDA

The decision to pursue FDA approval for a particular generic drug requires analysis of related economic, scientific, and legal factors. A generic drug company must balance the economic potential of the product with the costs and the difficulties of obtaining FDA approval. The latter can include both product development and legal issues.

Choosing a Generic Product

In choosing which generic drugs to pursue, generic drug companies try to predict the number and identity of likely

competitors and use this information to help estimate future profits. A generic drug company may gather the relevant business, technical, and manufacturing facts for this analysis by taking the following actions:

- Analyze business intelligence on brand-name drug companies and generic competitors
- Monitor NDA approvals by the FDA
- Track sales of brand-name drugs
- Research the availability and cost of the APIs for drugs of interest, including the number of suppliers
- Investigate formulation and testing issues, including the complexity and likely cost of the required bioequivalence studies and the ability to produce a consistently stable formulation

Marketing exclusivities that may attach to the brand-name drug will also inform the choice of which generic drug to pursue and the timing of an ANDA filing. Such exclusivities may preclude the filing of an ANDA or prevent approval of a generic version of the drug for certain time periods. The types of marketing exclusivities that commonly attach to a brand-name drug are the following:

- **New chemical entity (NCE) exclusivity.** NCE exclusivity applies to an active ingredient not previously approved by the FDA. A generic drug company cannot file an application for approval of a generic version of the NCE drug for five years following the approval of the NCE application. The exclusivity period is reduced to four years if the generic drug application includes a Paragraph IV certification (four and a half years if there is pediatric exclusivity).
- **Orphan drug exclusivity.** The FDA may grant orphan drug exclusivity for a drug approved to treat a disease or condition affecting fewer than 200,000 people in the United States (or more if there is no hope of recovering the drug company’s costs). Orphan drug exclusivity lasts seven years from FDA approval, limited to the approved indication.
- **Pediatric exclusivity.** Pediatric exclusivity may apply if the new drug sponsor conducts and submits pediatric studies of the active ingredient. It does not exist as an independent period but rather adds six months to another exclusivity period.
- **New clinical investigation exclusivity.** This exclusivity applies to a new indication or dosage, that requires new clinical investigations to obtain FDA approval, providing a three-year exclusivity period from the date of approval.

3. 137 S. Ct. 1514 (2017). 4. See 21 U.S.C.S. § 355(j)(2)(vii)(I)–(IV). 5. See 35 U.S.C.S. § 271(e)(2).

6. See 21 U.S.C. § 355(j)(5)(B). 7. See 21 U.S.C.S. § 355(j)(2)(A)(viii).

Absent an NCE exclusivity, which blocks the ANDA filing (not merely the approval), an ANDA may be filed at any time after NDA approval. If another exclusivity applies, your client should consider filing its ANDA in the timeframe before the expiration of the exclusivity period, calculated based on the time that it typically takes for the FDA to approve an ANDA. Recent information indicates that the median time to tentative approval is 30 months, but it may be as short as 15 months.

If a new clinical investigation exclusivity applies, your client should consider limiting its ANDA to the reference listed drug as previously approved (excluding the new indication or formulation). Because the exclusivity applies only to the new indication or formulation, this may avoid the three-year wait.

As counsel, you should ensure that your client has sufficient information about the relevant patents before it makes its final choice of which drug to pursue. In particular, the strength or weakness of the patents may effectively narrow your client's choice. Ultimately, the overall assessment of the benefit and risk will be your client's business decision, but you should ensure that your client carefully considers critical patent issues in making its determination.

Analyzing the potential patent issues includes taking the following steps:

- Check the status of any Orange Book listed patents directed to the API and the formulation
- Search for any pending applications on the API or formulation
- Search for any pertinent patents not listed in the Orange Book, as well as pending applications that may be directed to:
 - Methods of use
 - Manufacturing methods
 - Methods of treatment
- Study the most important patents and assess the strength of any non-infringement and invalidity arguments

Defining the Objective and Choosing the Procedural Path

When choosing the product to pursue, your client should decide on its ultimate goal, which may or may not be qualifying for the 180-day marketing exclusivity. Consider and discuss with your client which procedural path to take.

Among the possible objectives and procedural options are the following:

- **File early.** File your ANDA at the earliest possible date to try to obtain the first filer 180-day marketing exclusivity and litigate the patent infringement and validity issues through trial and appeal.
- **Delay filing.** Wait to file your ANDA until after the first filer lawsuits have begun and litigate in a second round. During the first round of litigation, the patent(s) may be invalidated, or the issues may be narrowed, potentially saving your client legal and expert fees.
- **Settle.** Settle with the brand for payment, or to obtain early entry into the market as an authorized generic. Note as follows:
 - While reverse payment settlements (also known as pay-for-delay) must pass muster with the Federal Trade Commission and the U.S. Department of Justice under antitrust laws, such a settlement may be lucrative for your client.⁸
 - A deal that allows your client to enter the generic market for the drug ahead of other generic competitors offers a valuable first-mover advantage.
- **Sell.** Sell your ANDA to another generic who is in litigation with the brand, or to a third party.
- **Partner with other generics.** Partner with one or more ANDA filers on the same patent(s) to reduce legal expenses (e.g., in one ANDA litigation a single law firm was listed as representing seven generics on the appeal). Note as follows:
 - This may be an attractive option if there are a large number of ANDA filers, and your client is not the first ANDA applicant to file and is, thus, not eligible for the 180-day marketing exclusivity.
 - Be sure that the arguments of the other ANDA applicants on infringement and validity are not in conflict with those of your client.
 - Enter into a joint defense agreement, including a provision addressing the potential conflicts that arise if one ANDA applicant settles, but others do not.
- **File a PTAB proceeding.** Initiate an inter partes review (IPR) before the PTAB to challenge the validity of one or more of the Orange Book patents or any blocking patents not listed in the Orange Book. In evaluating when and whether to pursue an IPR, consider the following factors:
 - An IPR affords the ability to challenge the validity of a patent before you file an ANDA (and during any NCE exclusivity period barring an ANDA filing).



- As with district court litigation, you may effectively decrease the costs of an IPR by partnering with other generics which are interested in challenging the patent, or you may join an existing IPR.
- An IPR is a faster and less expensive procedure for challenging patent validity than a district court litigation, although discovery in an IPR is more limited.
- If the PTAB proceeding is instituted early, a district court will generally grant a stay of any pending Hatch-Waxman suit on the same patent until the PTAB's final written decision. However, note that the stay does not toll the statutory 30-month stay of ANDA approval.⁹
- The standard of proof of invalidity in an IPR (preponderance of the evidence) is lower than that used in a district court (clear and convincing evidence).
- An IPR may make it easier to settle with a brand that is reluctant to fight in two venues.
- Be aware that an IPR is limited to invalidity challenges for obviousness and anticipation based on prior art patents and publications. If you have a strong non-infringement position or a strong non-prior based invalidity position, it may be better to focus all your resources instead on the district court litigation.
- An IPR is not an effective substitute for a first-filed ANDA with a Paragraph IV certification as it does not provide the benefit of the 180-day marketing exclusivity.
- Note that there is an appeal (*BTG International Ltd. v. Amneal Pharmaceuticals LLC*, Case No.19-1147) pending before the U.S. Court of Appeals for the Federal Circuit in which the Patent Office seeks to preclude a defendant from raising in the district court the same invalidity arguments that were successfully raised in the IPR proceeding.¹⁰
- If your client is not the first ANDA applicant to file, you may consider filing an IPR to get a judgment of invalidity and to attempt to cause the first ANDA filer to forfeit its 180-day marketing exclusivity. Note as follows:
 - If the first ANDA filer is not ready to launch its generic drug within 75 days after the date of a final decision that the patent is invalid or not infringed, it could forfeit its exclusivity (see Timing Considerations for 180-day Exclusivity below).
 - However, this forfeiture provision was written contemplating a final decision in federal court litigation, not a PTAB proceeding. Accordingly, it remains unclear whether a PTAB final written decision, even when affirmed by the Federal Circuit, qualifies as a final decision for forfeiture purposes.
- Note that an ANDA applicant has standing to pursue an IPR to invalidate a patent even if its ANDA has a Paragraph III certification as to that patent.¹¹

Your client's chosen objective and preferred procedural options should inform its regulatory and legal strategy. They will also

⁸ See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1112, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003).

⁹ See, e.g., *Alcon Labs., Inc. v. Akorn, Inc.*, 2016 U.S. Dist. LEXIS 2182 (D.N.J. Jan. 8, 2016); *Eli Lilly & Co. v. Accord Healthcare, Inc.*, 2015 U.S. Dist. LEXIS 166106 (S.D. Ind., Dec. 11, 2015). ¹⁰ See *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 2018 U.S. Dist. LEXIS 91703, n. 13 (D.N.J. 2018). ¹¹ See *Amerigen Pharms. Ltd. v. UCB Pharma GmbH*, 913 F.3d 1076 (Fed. Cir. 2019).



The most important witnesses, whether on summary judgment motions or trial, are the experts. It is not uncommon to find that there are only a limited number of litigation (or litigation-friendly) experienced technical experts in a highly specialized field.

impact the amount of legal and expert fees incurred. A particular objective may require that certain actions be taken at some stage before the litigation begins (e.g., contacting possible generic partners (i.e., potential co-defendants) in advance of litigation and preparing for a PTAB proceeding). It is, therefore, essential that you review the various options with your client and analyze how they impact your litigation strategy in sufficient time to avoid foreclosing a preferred option.

Early Input from Patent Counsel and Outside Experts

Because of the complexities of Hatch-Waxman litigation and the interrelationship of regulatory, patent, and litigation considerations, it is best to involve both outside counsel and technical experts in the process as early as possible to the extent that your client's budget permits this.

The importance of technical experts in Hatch-Waxman litigation cannot be overstated. The most important witnesses, whether on summary judgment motions or trial, are the experts. It is not uncommon to find that there are only a limited number of litigation (or litigation-friendly) experienced technical experts in a highly specialized field. Considering that Hatch-Waxman actions can involve scores of generic companies as defendants (e.g., Celgene initiated patent litigations against 25 defendants in New Jersey on the drug Otezla), delaying retention of an expert may result in your

chosen experts having a conflict. If it proves impossible to engage a knowledgeable and capable expert, you might even want to advise your client to reconsider its strategy.

Effective preparation includes the following:

- **Pre-filing expert input.** Consider retaining a technical expert to assist you with the pre-ANDA filing analysis and the preparation of the Paragraph IV certification and notice letter. Note that this may not be the same expert ultimately retained to testify in the litigation. Early input from both patent counsel and an outside technical expert may suggest modifications to the ANDA product that in-house scientists may not have considered, such as a potentially effective formulation design-around, or a labeling change that can carve out a particular method of use to avoid a problematic patent.
- **ANDA and related communications with the FDA.** Be aware that the contents of the ANDA and related communications with the FDA will be disclosed during discovery. Consideration of litigation strategy and consultation with patent litigation counsel in formulating important communications with the FDA will minimize admissions or other potentially problematic material in the regulatory documents that might inadvertently undermine your future non-infringement or invalidity arguments.

Timing Considerations for 180-Day Marketing Exclusivity

If your client's goal is to obtain a 180-day marketing exclusivity, the timing of its ANDA filing is critical. Your client must be the first ANDA applicant to file a substantially complete ANDA with a Paragraph IV certification. An ANDA that is sufficiently complete to permit a substantive review qualifies as substantially complete.¹² If marketing exclusivity is the goal, you need to be aware of the factors that could cause forfeiture of the 180-day marketing exclusivity. Your client will forfeit its exclusivity if it fails to market its generic drug after the later of the following dates:

- The date that is the earlier of the following two dates:
 - 75 days after approval of its ANDA
 - 30 months after its ANDA filing date
- The date that is 75 days after the date as of which (for each patent for which it qualified for 180-day exclusivity), at least one of the following has occurred:
 - A final decision that the patent is invalid or not infringed
 - A settlement agreement entering a final judgment that the patent is invalid or not infringed
 - The patent listing is withdrawn from the Orange Book¹³

The statutory scheme for forfeiture is both complex and relatively new. An FDA publication offers some assistance with interpreting the statute.¹⁴

Given the dire consequences of forfeiture for failure to market, make sure that your client understands the timing requirements. In particular, your client should ensure that it does not forfeit due to inability to begin the marketing of its generic drug because of lack of FDA approval or other blocking patents. Your client should carefully plan the filing of its ANDA to allow sufficient time to obtain FDA approval and prepare to start marketing its product soon after approval so that it meets the statutory time frames.

Venue Analysis

Before filing an ANDA, you should investigate the venue in which the brand-name drug company is most likely to sue your client. If the most likely venue is not favorable for your client, you may be able to take steps to make it an improper venue for the litigation. A review of the specific rules and other requirements of the most likely venues will also help you prepare for the litigation.

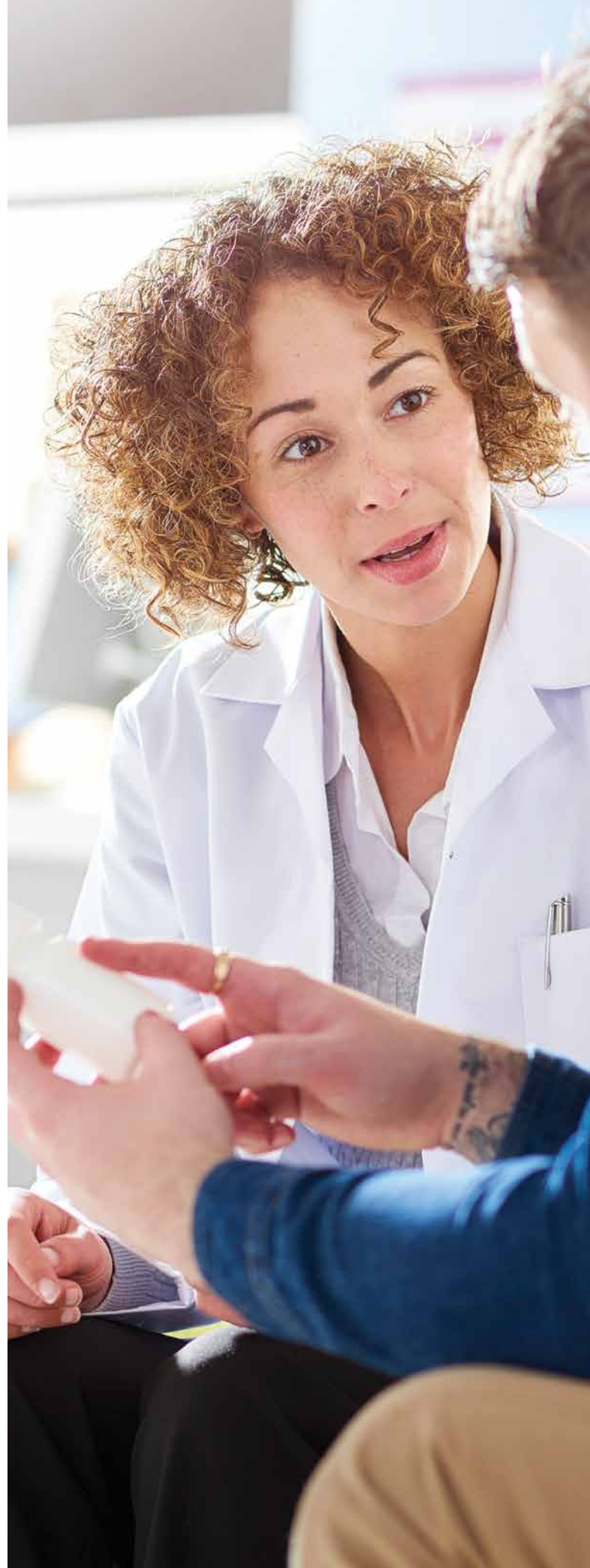
The Supreme Court's decision in *TC Heartland* clarified that, under 28 U.S.C.S. § 1400(b) (the so-called patent venue statute), a patent infringement suit must be filed either (1) where the defendant is incorporated, or (2) where the defendant has committed acts of infringement and has a regular and established place of business.

However, a venue analysis is not straightforward in a Hatch-Waxman suit because the artificial act of infringement does not fit the statutory language of Section 1400(b). Thus, the analysis of proper venue in Hatch-Waxman litigation has differed among district courts. In at least one case, the patent owner tried to argue that Section 1400(b) was never meant to govern venue in Hatch-Waxman suits and that courts should instead look to the general venue statute, 28 U.S.C.S. § 1391.¹⁵

For domestic ANDA applicants, the location under the first prong of Section 1400(b) (i.e., the state of incorporation) is clear. However, district courts are divided on how to identify the location of infringement under the second prong as the act of infringement consists of the ANDA filing rather than the sale of the accused generic drug.¹⁶

In *Bristol Myers Squibb*, the Delaware court looked to the venues in which the proposed generic drug would likely be marketed in determining that infringement was committed in Delaware. In contrast, in *Galderma*, the Texas court dismissed the suit for improper venue, holding that the act of infringement occurred where the ANDA was prepared and filed with the FDA, not where the generic drug would be marketed.

¹² See 21 U.S.C.S. § 355(j)(5)(B)(iv)(II)(bb)-(cc). ¹³ See 21 U.S.C.S. § 355(j)(5)(D). ¹⁴ See Guidance for Industry—180-Day Exclusivity Questions and Answers. ¹⁵ See *Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.*, 2018 U.S. Dist. LEXIS 179154, at *15-17 (D. Del. Oct. 18, 2018) (rejecting that argument). ¹⁶ Compare *Bristol-Myers Squibb Company v. Mylan Pharms., Inc.*, 2017 U.S. Dist. LEXIS 146372, at *20-21 (D. Del. Sept. 11, 2017) with *Galderma Labs. LP v. Teva Pharms.*, 290 F. Supp. 3d 599 (N.D. Tex. 2017).



If the proper venue in an infringement suit against your client would be undesirable, consider whether a corporate affiliate with a place of business and state of incorporation in a more desirable venue could be the ANDA applicant instead of your client. Also note that if your client is a foreign ANDA applicant, it can select a U.S. agent for filing the ANDA, making the residence of the agent a potentially proper venue.

When reviewing possible venues, investigate the following:

- Local patent rules
- Any special local rules for Hatch–Waxman litigation
- The timing of any mandated early exchange of infringement and invalidity contentions and claim construction positions (bearing in mind that you should prepare for any early deadlines even before the litigation starts)
- The court’s experience with Hatch–Waxman litigation
- The average time to trial in a Hatch–Waxman (or patent) litigation
- Potential local counsel in any proper venue where you are not admitted (considering early retention of local counsel in popular venues such as New Jersey or Delaware, where ANDA litigations often involve numerous defendants, to avoid having your preferred choice retained by another party)
- The potential for jury bias against your client, noting as follows:
 - In a Hatch–Waxman litigation, there is generally no right to a jury trial since there is usually no damages claim.
 - If your client might launch at risk (i.e., market its generic product before a ruling on infringement or validity), thereby giving rise to an amended complaint for damages and a potential jury trial, you should consider possible jury bias in any venue reputed to be biased against alleged infringers.

The Patent Certification

Other than any method of use patent for which the ANDA applicant makes a Section VIII carve-out statement, an ANDA applicant must include a patent certification in the ANDA, or an amendment or supplement to the ANDA, as to any Orange Book listed patents.

While you can challenge whether a patent is properly listed in the Orange Book, the FDA will not independently verify whether the listing is proper or accurate.¹⁷ The NDA holder need only confirm the correctness of its patent listing for the listing to remain. Even if a patent appears to be improperly listed,

your client must still make one of the four patent certifications in 21 U.S.C.S. § 355(j)(2)(vii)(I)–(IV). After a litigation is instituted, an ANDA applicant can counterclaim for an order requiring the NDA holder to correct or delete improper Orange Book patent listings.¹⁸

The wording of a patent certification is relatively succinct. For example, a Paragraph IV certification may state as follows: “Company A certifies that Patent No. [number] is invalid, unenforceable and/or not infringed by the manufacture, use or sale of [ANDA Product] under this ANDA.”

You must provide a detailed statement of the factual and legal basis for your Paragraph IV certification in the notice letter that you must serve within 20 days from the FDA’s acceptance of the ANDA filing. See Preparing the Notice Letter below.

When selecting the certification as to each Orange Book patent, you should consider the impact on the exclusivity period and stay current on the latest interpretation of the statutory intricacies. For example, in 2019 the FDA indicated that two ANDA applicants that filed a Paragraph IV certification and then withdrew their applications before providing notice to the NDA holder and patent owner, were nonetheless first filers, destroying the potential 180-day marketing exclusivity of the next ANDA applicant with a proper Paragraph IV certification.¹⁹ In another decision, the Federal Circuit held that a Paragraph IV certification as to a disclaimed patent and subsequent declaratory judgment action filed by the ANDA applicant on that patent, could result in a decision that triggers the forfeiture period and the possible forfeit by the first filer of its exclusivity rights.²⁰ These cases teach that you should consider including a paragraph IV certification to imminently expiring or disclaimed patents, and file as early as possible.

Asserting Invalidity

Before deciding how to certify for each listed patent, you should conduct a comprehensive prior art search to uncover any possible grounds for asserting that the patent is invalid for anticipation or obviousness.


As part of that search, you should carefully review the patent claims and files histories of the Orange Book patents and related patents and patent applications. Also, you need to review the record of any prior litigations and PTAB proceedings involving the patents or patent applications. Depending on your client’s budget, you should also review the prosecution history of any foreign counterpart patents and applications and the record of any foreign proceedings. Such review may uncover invalidity and unenforceability issues, such as defects

¹⁸. See 21 U.S.C.S. 355(c)(3)(D)(ii)(I). ¹⁹. See Teva Pharms. USA, Inc. v. Azar, 2019 U.S. Dist. LEXIS 30346 (D.D.C. Feb. 26, 2019). ²⁰. See Apotex Inc. v. Daiichi Sankyo, Inc., 781 F.3d 1356 (Fed. Cir. 2015).

Related Content


For a discussion of Hatch-Waxman litigation strategies, see

> [HATCH-WAXMAN PATENT LITIGATION STRATEGIES](#)

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To review pharmaceutical patent terminology, see

> [PHARMACEUTICAL PATENT LITIGATION TERMINOLOGY CHECKLIST](#)

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> Patents > Patent Litigation > Checklists


For an outline of pre-suit tasks for a brand-name drug company seeking to maximize product exclusivity, see

> [PRE-LITIGATION PREPARATION AND STRATEGY FOR PHARMACEUTICAL PRODUCT PATENTS AND EXCLUSIVITY](#)

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For an overview on 505(b)(2) applications, see

> [HATCH-WAXMAN ACT FUNDAMENTALS](#)

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For an analysis of issues arising in concurrent district court and PTAB proceedings, see

> [COORDINATING PTAB PROCEEDINGS WITH PARALLEL DISTRICT COURT PATENT LITIGATION](#)

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For an explanation about proper practice and venue post-TC Heartland, see

> [VENUE RULES AND PRACTICE FOR PATENT INFRINGEMENT LITIGATION](#)

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

For details on marketing exclusivities, see

> [MARKETING EXCLUSIVITIES FOR PRESCRIPTION DRUGS](#)

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> Patents > Patent Litigation > Practice Notes

¹⁷. See 21 C.F.R. § 314.53.

Also remember that if, as the litigation proceeds, you decide to abandon your validity challenge, you can amend your Paragraph IV certification for the challenged patent to a Paragraph III certification...

in the chain of title affecting standing, failure to cite prior art disclosed in foreign proceedings, or prosecution history estoppel preventing a claim of infringement under the doctrine of equivalents. These issues may be significant in determining what patent challenges you will assert.

As part of your patent review and certification process, you should consider the construction of key terms in the patent claims. File histories of related and foreign counterpart patents and applications, as well as the record of U.S. and foreign proceedings, may offer important information as to the meaning of the patent claims. Other patent litigations in which the NDA holder or the patent owner was a party may also be a useful source of their positions and assertions regarding the technology (e.g., formulations, polymorphs, enantiomers) and relevant patent law issues. You should also analyze any possible patentable subject matter or enablement and written description issues under 35 U.S.C.S. §§ 101 or 112.

Comprehensive studies of Hatch-Waxman patent challenge outcomes can also be a helpful resource. In *Pharmaceutical Patent Challenges: Company Strategies and Litigation Outcomes*,²¹ Henry Grabowski and his co-authors compiled Hatch-Waxman patent challenge statistics according to drug and patent type. The historical data in the study details the number of first ANDA filers according to drug type, and litigation outcomes according to patent type. For example, a review of outcomes may reveal that you are unlikely to invalidate a polymorph patent as obvious but may be able to demonstrate that the patented polymorph is anticipated by the prior art. However, while statistics reveal trends, they do not necessarily predict the outcome in any given case due to the inherent uncertainty of patent litigation. For example, to the surprise of many patent lawyers, in one case a generic drug company succeeded in an obviousness challenge to a patent on the API.²² The lesson from this result is that you should always explore potential validity challenges even to seemingly invincible patents.

Also remember that if, as the litigation proceeds, you decide to abandon your validity challenge, you can amend your Paragraph IV certification for the challenged patent to a Paragraph III certification (certifying that your client will not market its generic drug until the patent has expired).

Asserting Non-Infringement

An ANDA applicant cannot assert that it does not infringe a patent that claims the API because the proposed generic drug must have the same API as the RLD. However, you may argue that your client's proposed generic drug does not infringe other types of patents that may be listed in the Orange Book (e.g., patents directed to a formulation, composition, or polymorph), while still qualifying as bioequivalent to the RLD.

To prepare your non-infringement defense, you should retain a technical expert who can testify about the differences between your client's generic product and the patent claims (and patented product). Because the NDA holder will usually assert that its product practices the patented invention, you may be able to use differences between the generic and the brand name drug to demonstrate that your client's product does not infringe. You may also need an expert to perform tests if, for example, your non-infringement argument relates to the crystalline nature of the product or the presence of a polymorph.

Unclaimed subject matter disclosed in the patent specification, as well as the prosecution history and the record of any Patent Office post-issuance proceedings concerning the patent, may suggest possible claim constructions on which to base your non-infringement arguments.

Non-infringement arguments have an advantage over invalidity and unenforceability arguments. Unlike a successful invalidity or unenforceability argument, a successful non-infringement defense may benefit only your client and not any co-defendant ANDA filers who may, for example, use a different formulation for the drug.

Relying on a Section VIII Carve-out Statement

For each Orange Book method of use patent, the NDA holder must provide a use code to be listed in the Orange Book. Your client should carefully consider whether to seek approval for each listed use. If your client excludes (or carves out) a patented use, omitting the labeling language relating to that use, it can submit a so-called Section VIII carve-out statement (also called a skinny label) under 21 U.S.C.S. § 355(j)(2)(A)(viii). As a result, your client may avoid the need to certify as to the patent.



With a carve-out statement, your client can also avoid any marketing exclusivity period granted to the NDA holder that is predicated on the excluded use.²³ A Section VIII carve-out can thus provide significant benefits. For example, in one case, a generic drug company with a carve-out was the first to sell the generic drug, beating to market the first ANDA filer (which had 180-day marketing exclusivity).²⁴

Preparing the Notice Letter

Within 20 days from the date of the postmark on the FDA's letter of acceptance of the ANDA for filing, your client must send a notice letter for each certification that it makes as to each Orange Book patent. The letter must be sent to each patent owner and the domestic NDA holder or authorized agent (if the NDA holder has no domestic place of business). While the patent owner and the NDA holder are generally the same entity, they may be different.

Technical Requirements

Ensure that the notice letter meets all of the technical requirements of 21 C.F.R. § 314.95 and 21 U.S.C.S. § 355(j)(2)(B)(v) as to the ANDA number, name of the drug product, and the active ingredient strength and dosage. Work with your client's scientific and regulatory personnel to ensure the accuracy and completeness of this information.

Detailed Statement of Basis for Paragraph IV Certification

The notice letter must include a detailed statement of the factual and legal basis for your client's Paragraph IV certification that the patent is invalid, unenforceable, or will not be infringed.²⁵ This statement is the foundation for your defense of a Hatch-Waxman complaint. Prepare the statement with the same care that you would take in preparing an important pleading or legal opinion. Carefully investigate and state the factual and legal basis for your contentions, bearing

²¹ Henry Grabowski et al., 3 AM. J. HEALTH ECON. 33 (2017). ²² See *Eurand, Inc. v. Mylan Pharms., Inc.* (In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.), 676 F.3d 1063 (Fed. Cir. 2012).

²³ See, e.g., *Otsuka Pharm. Co., Ltd. v. Burwell*, 2015 U.S. Dist. LEXIS 68230 (D. Md. May 27, 2015). ²⁴ See *Hospira, Inc. v. Burwell*, 2014 U.S. Dist. LEXIS 123972 (D. Md. Sept. 5, 2014). ²⁵ See 21 U.S.C.S. § 355(b)(3)(D)(ii).



in mind that you risk sanctions if your contentions are later shown to be knowingly ill-founded or carelessly prepared.

Among the considerations when preparing the detailed statement are your ability to change or amplify the arguments and the possible consequences of doing so. Be aware that courts have not limited ANDA applicants to the defenses identified in the notice letter. Efforts by NDA holders to restrict the defenses in the litigation to the substance of the notice letter have been unsuccessful.²⁶ Nor have the courts required a further certification and notice letter based on the changes.²⁷

Thus, although the statement needs to be detailed, it need not be comprehensive. You should, therefore, carefully consider how much information to disclose in the statement. There may be a tactical advantage in the litigation, relative to the brand-name drug company, to initially limiting your disclosure of the full details of your arguments. For example, limiting the initial disclosure delays the brand-name drug company's ability to take countermeasures to correct an issue. In considering possible tactical advantages, be aware, however, that you may have to disclose the full scope of your non-infringement and

invalidity contentions early in the litigation. Many courts, either in the local patent rules or an initial case management or scheduling order, require early service of detailed non-infringement and invalidity contentions.

While you may expand your contentions during the litigation, you cannot abandon them without risking sanctions. Your notice letter must present a good faith, legally and scientifically vetted, statement of non-infringement, invalidity, or unenforceability. Always have more than one set of eyes review the final statement. Have your client's relevant scientific personnel and outside technical expert (if one has been retained) review the scientific statements for accuracy. Have at least two attorneys with patent experience review the statement. At least one of the attorneys should be an experienced patent litigator since the contentions will ultimately have to be litigated and presented to a judge.

A notice letter statement not made in good faith, sloppily prepared, and abandoned by the defendant and its experts at trial have been factors supporting an award of attorney's and expert fees to the plaintiff.²⁸

An Offer of Confidential Access to the ANDA

If the patent owner does not file an infringement suit against the ANDA applicant within 45 days of the Paragraph IV notice letter, the ANDA applicant may file a declaratory judgment action seeking a declaration of non-infringement, or patent invalidity or unenforceability. The declaratory judgment action is also designed to achieve a determination of patent infringement issues before the generic drug is launched and potential damages for infringing sales are incurred. If your declaratory judgment suit would be limited to invalidity for anticipation or obviousness based on prior art publications or patents, consider filing an IPR instead to obtain the same objective at a lower cost.

However, there may be a reason to file a declaratory judgment action rather than an IPR. If your client is not the first ANDA filer, bear in mind that a first ANDA filer who is not ready to launch its generic drug within 75 days after a final decision that the patent is not infringed, may forfeit its 180-day marketing exclusivity (see Preparing to File an ANDA; Timing Considerations for 180-Day Exclusivity above). As discussed, the courts might find that, under the statute, an IPR decision may not be a proper trigger of the forfeiture period.

To preserve your client's right to file a declaratory judgment action for a declaration of non-infringement (whether in a complaint or counterclaim), you must include in your notice letter an offer of confidential access to your client's ANDA for the sole purpose of allowing the patent owner to evaluate possible infringement of the patent that is the subject of the certification.²⁹ The offer must contain restrictions similar to those that would be contained in a protective order to protect confidential business information. The ANDA may be redacted to remove irrelevant information before it is reviewed.

Your offer of confidential access should only cover access to relevant information but be careful not to be overly restrictive or unreasonable. You should negotiate the terms of access in good faith. In one case, the court concluded that the NDA holder was not precluded from suing for infringement despite lacking sufficient information to evaluate infringement, because the ANDA applicant made an unreasonably restrictive offer of confidential access and refused to negotiate.³⁰

Opinion Letter

While a pre-suit opinion letter to help defend against a charge of willful patent infringement is usually advisable, it may be less useful in the context of Hatch-Waxman litigation. Courts have generally decided that the artificial act of infringement

under 35 U.S.C.S. § 271(e)(2) cannot be the basis for a finding of willful infringement. However, there may be exposure to a willfulness determination and enhanced damages under 35 U.S.C.S. § 284 if your client decides to launch at risk (i.e., offer its generic drug for sale before a ruling on infringement or validity). Therefore, as a precaution in the event of a later decision to launch at risk, outside counsel should prepare an opinion letter that tracks the conclusions and reasoning of the notice letter. Trial counsel may produce the opinion letter during the litigation to help defend against a claim of willful infringement or a claim of bad faith in asserting an invalidity counterclaim. Preferably, the attorney who prepares the opinion should not be trial counsel. Nonetheless, in practice, the opinion letter is frequently prepared by patent litigation counsel to save costs, given the overlap with the notice letter and litigation preparation.

Conclusion

This article summarizes some of the key issues and strategy considerations in preparing for a Hatch-Waxman litigation from the generic perspective. However, not only is the governing law complicated, it is continually evolving. Significant issues remain unresolved and pending legislation could change the rules once again. Effective preparation requires extensive business, technical, and legal input from regulatory counsel and patent counsel knowledgeable about the most recent developments in the FDA and the courts. **L**

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²⁶ See *Acorda Therapeutics Inc. v. Apotex Inc.*, 2011 U.S. Dist. LEXIS 102875, at *32, n.3 (D.N.J. Sept. 6, 2011) (The "volume of authority" does not require every defense to be asserted). ²⁷ See, e.g., *Abbott Labs. v. Lupin Ltd.*, 2011 U.S. Dist. LEXIS 53846, at *16 (D. Del. May 19, 2011), citing *3M v. Barr Labs.*, 289 F.3d 775, 777 (Fed. Cir. 2002) (statutory requirement regarding notice cannot be enforced by a private party in a patent infringement action); *Abbott v. Apotex, Inc.*, 725 F. Supp. 2d 724 (N.D. Ill. 2010); *SmithKline Beecham Corp. v. Apotex Corp.*, 2000 U.S. Dist. LEXIS 667 (N.D. Ill. Jan. 24, 2000). ²⁸ See *Takeda Chem. Indus. v. Mylan Labs.*, 549 F.3d 1381, 1384-85 (Fed. Cir. 2008), affirming an award of \$16.8 million in attorney's and expert fees and expenses against Alphapharm and Mylan. See also *Yamanouchi Pharm. v. Danbury Pharmacal*, 231 F.3d 1339 (Fed. Cir. 2000), granting judgment as a matter of law after trial and awarding \$1,635,440 in attorney's fees and \$400,000 in disbursements.

²⁹ See 21 U.S.C.S. § 355(j)(5)(C)(i)(III). ³⁰ See *In re Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litigation*, 693 F. Supp. 2d 409 (D. Del. 2010). See also discussion in *Pfizer v. Apotex*, 726 F. Supp. 2d 921 (N.D. Ill. 2010).



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Corporate Debt Securities in U.S. Capital Markets

The U.S. debt capital markets are an important source of capital for companies that borrow money to finance their businesses. Companies borrow money for a variety of reasons, from financing day-to-day operations and managing seasonal fluctuations in working capital, to funding acquisitions or paying dividends. Most companies obtain debt through loans from banks and other institutional lenders or by issuing debt securities in the capital markets.

THIS ARTICLE PROVIDES A HIGH-LEVEL INTRODUCTION TO debt securities commonly issued by companies in the U.S. debt capital markets and discusses the offering process and key characteristics of different types of transactions. Counsel should be aware that there are a significant number of other legal terms and issues relevant to issuers, underwriters, and investors that are outside the scope of this article. In addition, different transactions may give rise to different issues based on the facts and circumstances at hand.

What Is a Debt Security?

A debt security is a tradable instrument evidencing the obligations of one party (the issuer) to repay money to the holders of the security. U.S. corporate debt securities are often referred to as notes or bonds. Key characteristics of debt securities include the following:

- **Principal amount.** The amount the issuer must repay at maturity and on which interest is calculated is the principal amount.
- **Maturity.** The time at which any outstanding amounts still owed under a debt security must be repaid is known as the maturity. The length of the period from the date of issuance of a debt security to its maturity date is sometimes referred to as the term or tenor. Maturities vary significantly depending on the nature of the offering and the issuer.



- **Ranking.** Notes may either be senior obligations or subordinated obligations. Senior obligations rank equally in right of payment with general unsecured claims against the issuer and ahead of subordinated claims, whereas subordinated debt may not be paid until all senior claims to which the debt has been subordinated have been repaid in full.
- **Interest.** Noteholders are typically entitled to be paid interest on the outstanding principal amount of their notes. The interest rate may be a fixed rate or a floating rate based on a benchmark rate. Interest is typically paid in cash at

regular intervals during the term of the debt security. In the case of paid-in-kind or PIK notes, the issuer is permitted to pay interest in kind by adding the amount of interest owed to the outstanding principal amount in lieu of a cash payment. Zero coupon notes are notes that do not pay interest; instead, the notes are issued to investors at a discount to their face amount and then repaid at face value at maturity.

- **Redemption.** Corporate debt securities often include restrictions on the issuer's right to redeem (or repay) the securities before maturity or require the issuer to pay an additional premium to do so. Call protection is attractive to debt investors because it helps protect against the risk that the issuer will refinance the bonds at a lower interest rate as soon as business or market conditions improve, in which case investors may be unable to reinvest their capital at the same rate. This is important as most debt securities are fixed rate. The notes may also include mandatory redemption provisions requiring the issuer to redeem the notes before maturity if certain events occur (such as asset sales and change of control).
- **Credit ratings.** Many issuers of debt securities in the United States are rated by one or more credit ratings agencies, the most prominent of which are S&P, Fitch, and Moody's. The ratings reflect the agencies' assessment of an issuer's ability to repay the particular debt security. Issuers also have corporate credit ratings which speak to the issuer's credit more broadly. Often, different securities issued by the same company will have different credit ratings depending on their terms. For example, a secured note with a 5-year maturity may have a higher rating than a 10-year unsecured note. Highly rated investment grade securities typically have terms that differ significantly from non-investment grade (or high yield) securities, as discussed below.
- **Transferability.** Debt securities are usually easily transferable between investors, facilitating trading and providing liquidity to investors.
- **Guarantees.** Debt securities may be guaranteed by the issuer's parent holding company (if any) or all or certain of its operating subsidiaries. Whether guarantees are provided and the scope of the guarantees are primarily determined by the credit ratings of the debt securities, market conditions, and negotiations between the issuer and underwriters.
- **Collateral.** Debt securities may be either unsecured or secured by certain assets of the issuer and any guarantors.
- **Covenants.** The documentation governing debt securities usually includes covenants that the issuer must comply with as long as the securities remain outstanding, with the nature of the covenants varying depending on the nature

of the security, the credit worthiness of the issuer, and market conditions.

- **Registration.** Debt securities are subject to the U.S. securities laws. Accordingly, transactions in debt securities must either be registered with the Securities and Exchange Commission (SEC) or qualify for an exemption from registration.

The Offering Process

Engaging the Underwriters and Initial Purchasers

Issuers typically engage one or more banks early in the process to act as underwriters for the offering and to advise on pricing and other aspects of the offering. In an unregistered offering, the lead banks are referred to as initial purchasers in marketing documentation, rather than as underwriters. The underwriters are closely involved in most aspects of the offering, including the strategy for marketing the debt, the preparation of the disclosure documents and other marketing materials, conducting due diligence, organizing road shows, and negotiating the legal documentation. In selecting the lead bank, issuers take into account several factors including:

- Indicative terms proposed by each underwriter for the financing, including the underwriting fees
- The underwriter's experience in arranging similar debt financings for companies in the same industry
- The issuer's relationship with the underwriter and the underwriter's familiarity with its business

In cases where multiple underwriters are engaged, the underwriter with primary responsibility for the offering is often referred to as the left lead, after the customary practice in which the lead underwriter's name is listed on the left-hand side of marketing materials for the offering.

Registered vs. Unregistered Offerings

The steps involved in conducting an offering of debt securities differ depending on whether the transaction is being done on a registered basis or on an unregistered basis in reliance on an exemption from the securities laws.

In a registered offering, as is the case for equity offerings, the issuer must draft and file a registration statement and prospectus for the offering with the SEC, which must be declared effective (or be deemed effective pursuant to SEC rules) before the offering can be consummated. The registration statement includes disclosures regarding the issuer's business as well as a detailed description of the terms of the debt securities being offered.

In an unregistered offering, the issuer typically prepares an offering memorandum to be shared with potential investors.



Although unregistered offerings are not subject to many of the specific disclosure requirements contained in the Securities Act applicable to registered deals, the anti-fraud provisions set forth in Rule 10b-5 under the Securities Exchange Act apply to all offerings of securities, whether registered or unregistered. Rule 10b-5 forbids issuers and underwriters from making any untrue statement of a material fact or omitting to state a material fact necessary in order to make statements made not misleading in light of the circumstances in which they were made in connection with the purchase or sale of any security. In light of this broad requirement and to protect against potential liability arising from potential lawsuits by noteholders, offering memoranda in unregistered offerings often look to SEC disclosure requirements for registered offerings as a guide post and include disclosures similar in scope to what would be required for a registered offering. That said, the appropriate scope of disclosure in an unregistered offering requires careful legal analysis and consideration of the circumstances of the offering, including the nature of the issuer's business, the terms of the securities, and the number of the investors and their degree of financial sophistication.

In some unregistered offerings, investors receive registration rights with respect to the debt securities, pursuant to which the issuer agrees to register resales of the debt securities by the holders within a certain time period after issuance or if particular conditions are met or, alternatively, to exchange the initial securities with new securities issued in a registered offering with otherwise identical terms (referred to as an A/B exchange offer). Other offerings are marketed on a 144A-for-life basis and are never registered.

From an issuer's perspective, the decision whether to conduct an offering on a registered or unregistered basis depends on several factors, including:

- **Nature of target investors.** Unregistered offerings usually must be limited to investors that satisfy size or sophistication criteria set forth in the relevant exemption or safe harbor, such as qualified institutional buyers in Rule 144A offerings, whereas registered offerings may be marketed to all investors.
- **After-market liquidity.** Securities issued in a registered offering are generally more liquid.
- **Whether the issuer is already an SEC reporting company.** Issuing securities in a registered offering may cause the issuer to become subject to ongoing SEC reporting requirements to the extent the issuer is not already a reporting company. This makes registered offerings unattractive to most privately held companies that are not otherwise subject to SEC reporting requirements.
- **Other reporting burdens.** If the securities will be guaranteed by the issuer's subsidiaries or secured by pledge of equity interests in such subsidiaries, consideration must also be given to SEC Rule 3-10, which may require delivery of additional financial information or separate financial statements with respect to certain guarantors in a registered offering. Though, we note the SEC has recently announced proposed changes to make these rules less burdensome on issuers.

Documentation

Most notes are issued pursuant to an indenture that sets forth the key terms governing the notes, including payment terms, redemption provisions, covenants, and events of default. Individual noteholders are not parties to the indenture and can only exercise their rights with respect to the notes collectively through the trustee, a financial institution appointed to act on behalf of the noteholders. These notes themselves are generally issued in registered form (as opposed to bearer form) as global notes and are generally cleared and settled using book-entry clearing systems, most commonly the Depository Trust Company (DTC).

Offering Types

Investment Grade vs. High-Yield Securities

High-yield bonds are debt securities with non-investment grade ratings, that is, ratings below BBB-/Baa3. There are several important differences between high-yield and investment grade bonds arising from the lower risk of default by investment grade issuers, though the covenant package and terms vary as an issuer moves up and down the credit spectrum. These include:

- High-yield bonds typically have a higher interest rate since they carry a greater risk of default.
- High-yield bonds are often guaranteed by the issuer's subsidiaries and are more likely to be secured by the assets of the issuer and its subsidiaries.
- Covenants in high-yield bonds are typically more restrictive and apply to a wider scope of activities than in investment grade debt. For example, high-yield bonds typically include closely negotiated limits on the amount of secured and unsecured debt that can be incurred, investments that can be made, and dividends that can be paid, whereas investment grade bonds typically only restrict liens (i.e., secured debt).
- Investment grade bonds are often subject to more restrictive call protection provisions than high-yield debt. High-yield bonds can typically be redeemed halfway to maturity at a redemption premium equal to half of the coupon, which declines to zero over the remaining term of the notes. Investment grade bonds, in contrast, are often only callable at a make-whole premium (which is calculated based on the discounted present value of all remaining interest payments) for their entire term, making them significantly more expensive to refinance prior to maturity.
- Investment grade notes are more likely to be registered with the SEC since they are frequently issued by large creditworthy companies that are likely to be SEC reporting companies, whereas high-yield notes are often unregistered and typically marketed in a Rule 144A offering.
- Because high-yield issuers tend to be more highly leveraged and hence more vulnerable to shocks in their business or to markets more generally, the high-yield bond market tends to be more strongly impacted by market volatility.

Medium Term Notes

Medium term note programs (MTN programs) are a form of debt financing used by large companies with an ongoing need to raise additional capital in the debt capital markets.

To establish an MTN program, issuers file a shelf registration statement with the SEC to permit delayed and continuous registered offerings. They also enter into master legal

Related Content

For additional information on various types of debt transactions, see

- > [MARKET TRENDS 2017/18: INVESTMENT GRADE DEBT OFFERINGS](#)
- > [MARKET TRENDS 2017/18: HIGH YIELD DEBT OFFERINGS](#)
- > [MARKET TRENDS 2017/18: CONVERTIBLE BOND OFFERINGS](#)
- > [MARKET TRENDS 2017/18: MEDIUM-TERM NOTE PROGRAMS](#)
- > [MARKET TRENDS 2017/18: SOVEREIGN BONDS](#)

 **RESEARCH PATH:** *Capital Markets & Corporate Governance > Trends and Insights > Practice Notes*

For further information on debt securities, see

- > [DEBT FINANCE: SYNDICATED LOANS, DEBT SECURITIES, AND MEZZANINE LOANS](#)

 **RESEARCH PATH:** *Capital Markets & Corporate Governance > Debt Securities Offerings > Rule 144A/Regulation S Debt Offerings > Practice Notes*


For an overview of international debt transactions, see

- > [DEBT CAPITAL MARKETS IN INTERNATIONAL JURISDICTIONS](#)

 **RESEARCH PATH:** *Capital Markets & Corporate Governance > Debt Securities Offerings > Rule 144A/Regulation S Debt Offerings > Practice Notes*

For a discussion of medium term notes, see

- > [MEDIUM-TERM NOTE \(MTN\) PROGRAMS](#)

 **RESEARCH PATH:** *Capital Markets & Corporate Governance > Debt Securities Offerings > Medium-Term Note Programs > Practice Notes*

documents governing the program, including agreements with one or more banks to act as selling agents or dealers under the program. The master documents provide for flexibility to issue a wide variety of debt securities with different terms.

Once an MTN program has been established initially, issuers can complete offerings with minimal new documentation, usually limited to a prospectus supplement indicating the issue price, interest rate, amount, maturity, and other terms specific to the offering. This significantly reduces the amount

Most MTNs have a maturity of two to five years, though there is no legal requirement that the notes have medium terms...

of time and expense required to launch and complete a new offering and enables issuers to react more quickly to favorable market conditions.

Most MTNs have a maturity of two to five years, though there is no legal requirement that the notes have medium terms, and it is not uncommon for issuers to issue short or long-term notes under MTN programs. MTNs usually carry an investment grade rating.

Convertible Bonds

A convertible bond is a hybrid debt security that provides the holder, and sometimes the company, with the option to convert the debt security into another security of the issuer—typically common equity shares—after a fixed date or upon certain conditions being met at a specified conversion price. Until converted, a convertible bond behaves like a typical debt security.

Convertible bonds usually include anti-dilution provisions, pursuant to which the conversion price is automatically adjusted in order to preserve the value of the conversion option in the event of new equity issuances, stock splits, mergers, or other transactions affecting the equity of the issuer.

Convertible bonds can be an attractive financing tool for emerging companies or companies with high growth potential, because they allow them to obtain debt financing at a lower interest rate than would otherwise be available (due to the imbedded value of the option) while delaying the dilutive effect on the issuer's common equity. Technology and biotechnology companies are frequent convertible bond issuers.

However, the hybrid debt/equity nature of convertible bonds introduces additional legal, tax, and accounting complexity. In addition, many convertible bonds issued in recent years can only be called by the issuer if certain market price conditions are satisfied, which can create difficulties in structuring a sale or merger involving the issuer.

Commercial Paper

Commercial paper is a short-term, unsecured debt instrument used by large highly rated investment grade issuers.


Commercial paper has a maturity ranging from two days to 270 days, with most maturing between five and 45 days.

At maturity, issuers typically either pay the commercial paper from cash on hand or roll the paper by issuing new commercial paper and using the proceeds to repay the paper that has come due. Due to its short maturity, commercial paper is only a viable financing tool for highly creditworthy companies that are confident of being able to sell commercial paper at attractive rates on a continuous basis. These qualities make commercial paper an attractive and relatively low-risk investment for certain institutional investors, such as money market mutual funds, and as a result commercial paper tends to be less expensive than other forms of debt financing, such as a bank credit facility. These investors typically hold commercial paper for its entire term.

Related Content

For an explanation of the role of underwriters in and the regulations impacting registered securities offerings, see

[> UNDERWRITING REGISTERED SECURITIES OFFERINGS AND REGISTERED OFFERINGS: APPLICABLE LAWS, RULES, AND REGULATIONS](#)

 **RESEARCH PATH:** [Capital Markets & Corporate Governance > IPOs > Conducting an IPO > Practice Notes](#)

For guidance on managing a private or unregistered offering of securities, see

[> PRIVATE OFFERING MANAGEMENT](#)

 **RESEARCH PATH:** [Capital Markets & Corporate Governance > Private Offerings > Private Placements > Practice Notes](#)


For an exploration on the special considerations that are applicable to offerings involving convertible bonds, see

[> CONVERTIBLE DEBT SECURITIES](#)

 **RESEARCH PATH:** [Capital Markets & Corporate Governance > Debt Securities Offerings > Rule 144A/Regulation S Debt Offerings > Practice Notes](#)

For more information on the different types of commercial paper programs, see


[> COMMERCIAL PAPER PROGRAMS](#)

 **RESEARCH PATH:** [Capital Markets & Corporate Governance > Debt Securities Offerings > Exempt Securities > Practice Notes](#)



Commercial paper is almost always issued on an unregistered basis pursuant to an exemption from registration. The most commonly relied upon exemptions are Sections 3(a)(3) and 4(a)(2) of the Securities Act. Section 3(a)(3) of the Securities Act provides an exemption from registration for debt securities with a maturity of nine months or less, the proceeds of which are used to finance current transactions. Issuers must take steps to ensure that the proceeds from commercial paper sold under this exemption are only used to finance working capital and other current transactions, such as paying operating expenses. SEC guidance has established other requirements for commercial paper issued pursuant to this exemption, including that the paper must be of prime quality and may not be of type ordinarily purchased by the public. In addition, the commercial paper must be eligible for discounting by the Federal Reserve Banks.

Companies typically issue commercial paper through one or more banks referred to as dealers. Similar to the role of an underwriter in a registered securities transaction, dealers purchase the commercial paper from issuers and immediately resell it to investors. The issuer also typically appoints a third-party financial institution, usually a trust company or bank, to act as issuing and paying agent, which performs functions similar to those of a trustee under a bond indenture, including processing payments and coordinating clearing and settlement with DTC.

Like MTNs, commercial paper is typically issued on an ongoing basis pursuant to a pre-established program. The documentation for a commercial paper program is typically negotiated by the issuer and the lead dealer and include an offering circular, one or more dealer agreements, and an issuing and paying agent agreement. Given the high credit quality and short maturity of commercial paper, terms are relatively standardized compared to other corporate debt securities and are not heavily negotiated. 

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Jessica Millett DUVAL & STACHENFELD LLP

Economic Advantages for Existing Property Owners in Opportunity Zones

AS KNOWLEDGE OF THE OPPORTUNITY ZONE PROGRAM (the OZ Program), which was tucked away inside the 2017 Tax Reform package,¹ trickled out to the real estate community, ears began to perk up all over the country. As tax professionals parsed through the new provisions in the Internal Revenue Code (the Code) and explained the suite of tax benefits, investors and developers alike sat up a bit straighter in their chairs to make sure they had heard correctly.

No tax at all upon exit after 10 years? *That's right!*

Reinvestment of capital gains from any source, so no like-kind requirement? *Correct!*

You can self-certify, so no pool of credits to be awarded through an application process? *Yes!*

I own property in an opportunity zone and I can take advantage of these tax benefits too? *Well . . . maybe.*

An existing owner of property in an opportunity zone may have an economic advantage in the opportunity zone era to sell the property at a higher price as a result of the opportunity zone classification, but the OZ Program requires an existing owner to jump through a series of hoops in order to be eligible for the opportunity zone tax benefits (the OZ Tax Benefits).

The OZ Program is complex, and the rules are still evolving. To illustrate the structuring hurdles for existing owners of property in opportunity zones, I have included below some of the basic rules, but there are additional requirements that are not covered here that are critical to properly structure a Qualified Opportunity Fund (QOF). Specialized tax counsel familiar with the intricacies of the OZ Program is a must for properly structuring and executing such a transaction.

A Quick Primer on OZ Tax Benefits

This article does not go into depth on the OZ Tax Benefits, but in case you need a refresher, the benefits package available to investors in a QOF includes:

- Deferral until 2026 of the eligible capital gain timely invested into a QOF
- Potential reduction of the gain required to be included in income at the end of the deferral period if the QOF interest is held for at least five or seven years
- Tax-free exit upon sale of the QOF interest after 10 years

Requirements at Every Level

The OZ Program rules can be difficult to parse, in part because every level of the structure has a different set of requirements.

For a bit of context, assume the following two-tier QOF structure (for a number of reasons beyond the scope of this article, this two-tier structure is the recommended structure for QOF investments):

- Investors with eligible capital gains invest those gains into a QOF.
- The QOF contributes at least 90% of the eligible gain from investors into a lower-tier partnership, hereinafter referred to as the JV, in exchange for a partnership interest.
- The JV uses the QOF's cash contributions, as well as cash from other investors or obtained through financing, to acquire and either construct or improve property in an opportunity zone.

At the investor level, each investor must invest eligible capital gain into a QOF within a prescribed time period. The general rule is that an investor has 180 days from the date of the sale that generated the capital gain, but partners in a partnership may have a bit longer when the partnership itself sells the appreciated asset and passes the gain up to its partners on IRS Schedule K-1.

At the QOF level, the QOF has a 90% asset test to meet every six months. Qualifying assets can include property in an opportunity zone or an interest in a JV, as long as the JV meets its own set of requirements. Cash is not a good asset. The testing dates are typically June 30 and December 31, but the first testing date in the QOF's first taxable year may vary.

At the JV level, one of the key requirements is that the JV qualify as a Qualified Opportunity Zone Business (a QOZB). One of the asset tests at the QOZB level requires 70% of the tangible property owned or leased by the JV to be Qualified Opportunity Zone Business Property (a QOZBP).

How Existing Owners Can Qualify Their Property as QOZBP

The QOZBP rules are the reason that existing owners of property in opportunity zones must get creative to take advantage of the OZ Tax Benefits.

As defined in the Code and as applied to our two-tier structure, QOZBP is tangible property used in a trade or business of the QOZB if:

- The property was acquired by the QOZB by purchase after December 31, 2017 (the Acquired by Purchase Requirement).
- The original use of such property in qualified opportunity zone commences with the QOZB or the QOZB substantially improves the property.
- During substantially all of the QOZB's holding period for such property, substantially all of the use of such property was in a qualified opportunity zone.

¹ Codified at I.R.C. §§ 1400Z-1 and 1400Z-2.

Keep in mind that neither the IRS nor the U.S. Department of Treasury has explicitly blessed the concept that an existing owner can reinvest gain from the sale of opportunity zone property into a QOF that acquires that same property.

Hoop #1 – Acquired by Purchase

The first hoop that existing property owners need to jump through is the Acquired by Purchase Requirement. This requirement is the roadblock that limits existing property owners' access to the OZ Tax Benefits, since in many cases those owners acquired the property prior to December 31, 2017. Those owners need to sell their property to a new QOF/QOZB structure for the property itself to qualify as QOZBP. Contributions of property to an entity do not meet the Acquired by Purchase Requirement.

Hoop #2 – The 20% Related Party Rule

The second hoop to jump through is that the QOZB must acquire the property from an unrelated person, and the relatedness standard is set very low for this purpose. If both the QOZB and the selling entity are partnerships for tax purposes, the seller and the buyer will be considered related if the same persons own, directly or indirectly, more than 20% of the capital interests or profits interests of both entities.

Wholly apart from its application in the context of the OZ Program rules, the measurement of a partner's ownership interest in a partnership is not well defined generally in tax law, particularly with respect to partnership profits. Without exaggeration, there are tax articles well in excess of 100 pages that painstakingly run through all the various ways you could measure a partner's interest in partnership profits, without a clear winner. The main uncertainties relate to profits interests and promotes, both in respect of timing (when do you measure ownership?) and likelihood (do you have to include speculative profits or only certain ownership?).

For example, assume Geoff owns property in an opportunity zone and wants to develop it. He acquired the property well before 2018, so he needs to sell the property to a new QOF/QOZB structure and bring in other investors. Geoff has real estate expertise and will assist in the development of the property, so he strikes a deal with his other investors so that he is paid a promote of 20% after the other members get their capital back and a return on that capital. However, Geoff's investors want him to be at risk as well, so he agrees to invest 10% of the capital. What is Geoff's interest in partnership capital and profits at the time the QOZB acquires the property? Do you measure just the 10% capital interest because the 20% promote is speculative? Or do you have to assume all possible

future outcomes, including the upside, in which case he could be cumulatively over the 20% limit on partnership capital and profits?

The short answer is that no one knows. Given the risk of getting it wrong (that the property fails to be QOZBP, in which case the JV fails as a QOZB, so that the QOF flunks its asset test), most people are taking the conservative route and limiting either capital investment or promotes to any carryover investors from the seller side to keep them below 20% under any scenario.

Even in a straight percentage interest deal with no promote, existing owners are limited to no more than 20% of the QOF/QOZB ownership, so the policy behind this rule appears to weigh heavily on bringing new investors into Opportunity Zones, rather than letting existing property owners claim the OZ Tax Benefits.

Hoop #3 – The Sale Has to Occur Before the Gain

There is a third hoop to jump through for existing owners of opportunity zone property that want to sell their property to a new QOF/QOZB structure and reinvest some or all of the resulting gains from that sale into the new QOZ/QOZB structure that is acquiring their property. A taxpayer must invest eligible gain into a QOF to qualify for the OZ Program tax benefits. That gain must exist before it can be reinvested into a QOF. By definition, a taxpayer can only have gain after a taxable disposition occurs, so the sale has to happen before the seller can have gain to invest.

For example, assume Lea owns property in an opportunity zone that she acquired before 2018, and she is going to sell it to a new QOF/QOZB structure for \$10 million. Because of the related party rule, she can only invest \$2 million into the deal, and she has no other eligible gains to invest into the QOF. In this case, the other investors could invest \$8 million into the QOF, and the QOF would invest that \$8 million into the JV that will qualify as a QOZB (assume there is another minority investor in the JV so it is a partnership for tax purposes). The JV would then acquire the property from Lea for \$8 million in cash plus a note of \$2 million. Lea could then take \$2 million of the cash she received at closing and invest that amount into the QOF. The QOF would contribute the \$2 million of cash to the JV, and the JV would use the cash to pay off the note of \$2 million.



Although the Code does say that an investor's 180-day period to invest begins on the date of sale, it may be prudent to let the gain settle for at least a day before reinvesting it into a QOF that owns the same property. This would add some certainty to the characterization of the investor's QOF contribution as eligible gain, and it helps in avoiding a recharacterization risk that 20% of the property was contributed as opposed to having been acquired by purchase.

Keep in mind that neither the IRS nor the U.S. Department of Treasury has explicitly blessed the concept that an existing owner can reinvest gain from the sale of opportunity zone property into a QOF that acquires that same property. However, the related party rule appears to be the main guardrail on the QOZBP definition to address this, so as long as existing owners can jump through these hoops, they should be in compliance with the rules.

Land Contributions – A Potential Shortcut to QOZB Status, but No OZ Tax Benefits

If existing owners of property in an opportunity zone are not interested in OZ Tax Benefits themselves but want to use QOF funds to develop the property, they may be able to contribute the property to the QOZB in exchange for a JV interest. Hang on, you may be saying, what about the Acquired by Purchase Requirement? I thought contributions were not permitted?

It is true that any property contributed to a QOZB will not meet the Acquired by Purchase Requirement and therefore will not be QOZBP. However, the asset test at the QOZB level requires that only 70% of the QOZB's tangible property be QOZBP. So technically, up to 30% of a QOZB's tangible property does not need to be QOZBP and therefore does not need to meet the Acquired by Purchase Requirement.



Related Content

For an overview of proposed regulations on qualified opportunity zones, see

> [QUALIFIED OPPORTUNITY ZONES: PROPOSED REGULATIONS EXPLAINED](#)

RESEARCH PATH: [Real Estate > Commercial Purchase and Sales > Tax Considerations > Practice Notes](#)

For practical guidance on the purchase and sale of commercial properties, see

> [COMMERCIAL PURCHASE AND SALE AGREEMENTS](#)

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For a summary of the tax incentives to encourage investment in qualified opportunity zones, see

> [TAX CUTS AND JOBS ACT OF 2017: AN ANALYSIS](#)

RESEARCH PATH: [Real Estate > Commercial Purchase and Sales > Tax Considerations > Practice Notes](#)

For an analysis on the impact of the opportunity zone program, see

> [WHAT TO KNOW ABOUT BUILDING IN TAX 'OPPORTUNITY ZONES'](#)

RESEARCH PATH: [Real Estate > Commercial Purchase and Sales > Miscellaneous Ownership Issues > Articles](#)

Assume that Max owns property in an opportunity zone that he acquired before 2018. The property is raw land, but a developer approaches Max with a proposal to build a mixed-use complex on the site. Max contributes the property to a QOZB, and a QOF contributes cash to the QOZB to develop the property. Once the project is built, if the land value is less than 30% of the tangible property in the QOZB, then perhaps it does not matter that the initial land was contributed instead of acquired by purchase, as long as at least 70% of the QOZB's tangible property constitutes QOZBP.

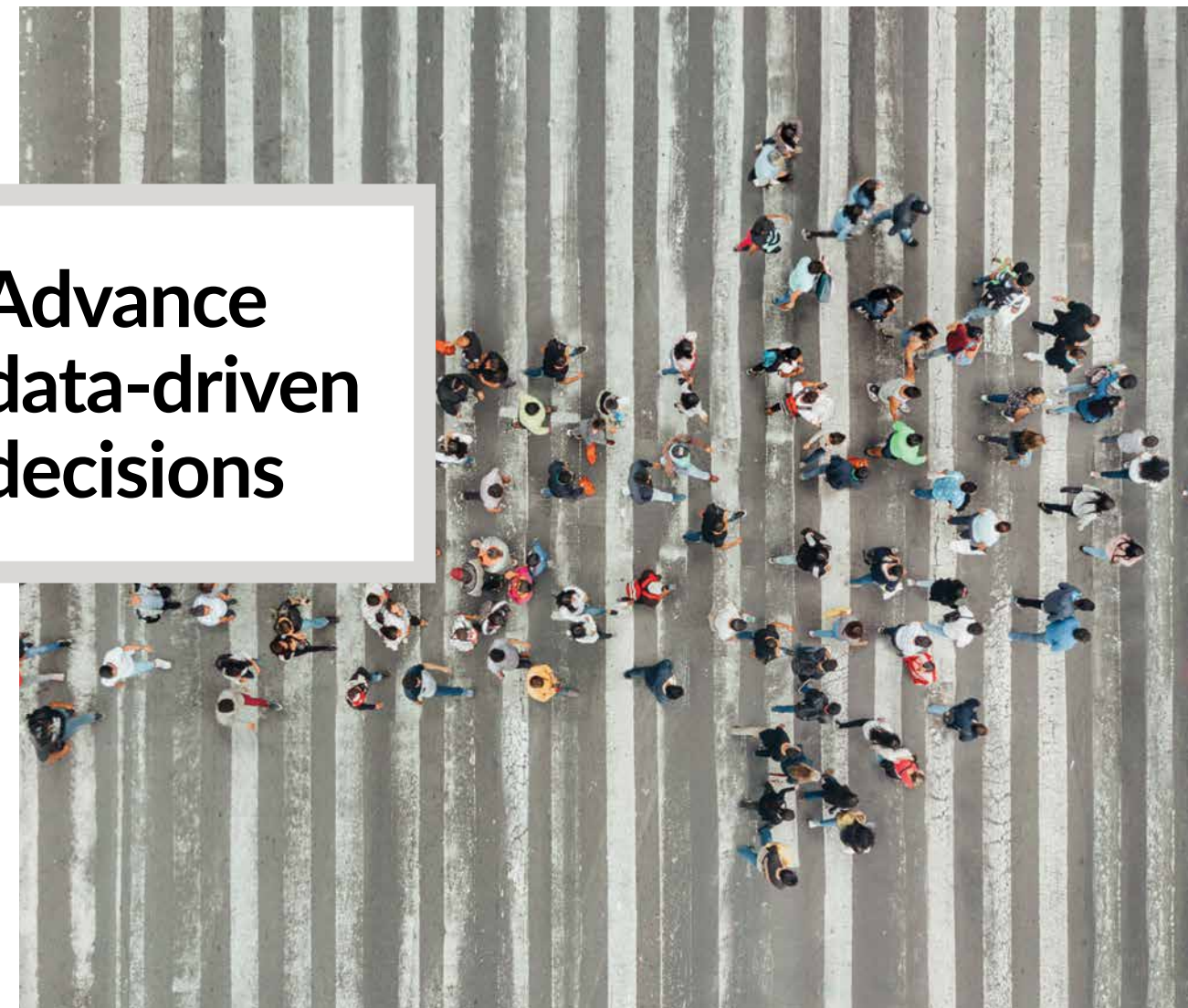
This scenario is a bit riskier at the moment given the lack of guidance on exactly when the various tests at the level of the JV need to be measured and fulfilled. If the 70% test is applied before the project is finalized and the land is still more than 30% of the value of the property, then the QOZB flunks its test. However, if we get comfort on this scenario, that will ease some of the structuring for these existing landowners in opportunity zones that want to admit QOF investors without triggering their own gains.

Until then, existing opportunity zone property owners should be prepared to jump through the hoops. **L**

Jessica Millett is co-chair of Duval & Stachenfeld's Tax Practice Group. She has particular expertise in U.S. tax issues that arise in complex real estate transactions, notably QOF structures. She regularly advises clients on tax structuring and documentation for QOF investments, real estate acquisitions, joint ventures, restructurings, and refinancing arrangements, including inbound and outbound investments, and structures involving REITs. Most recently, Ms. Millett has been at the forefront of structuring investments into Opportunity Zones.

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Cynthia Borrelli and Michael J. Morris BRESSLER AMERY & ROSS, P.C.

Special Considerations for Excess and Surplus Lines Brokers

This article addresses special considerations about surplus lines (SL) brokers like the surplus lines agent's (SLA) license status, due diligence searches by agents of admitted marketplace prior to a SL placement, and broker disclosure of status of excess and surplus (E&S) insurers as unauthorized. Audit recordkeeping reports and tax collection by SLA are also detailed.

SURPLUS AND EXCESS LINES PLACEMENTS OF INSURANCE

are subject to markedly different laws and regulations than those in the admitted marketplace. Excess and surplus lines insurers are not fully licensed and should export coverage from their states of domicile and only through a duly licensed SLA in each jurisdiction. Failure to fully comply with each state's SL rules can create substantial risk to the insurer, agency, brokerage, and even the insured. All market participants should be well-versed in the rules of SL placements and aware of the numerous potential pitfalls before becoming involved in this market sector.

Surplus Lines Insurance Overview

To those unfamiliar with commercial insurance, a brief introduction to the concept of SL insurance may be helpful. In the ordinary insurance transaction, the insurer is licensed by applicable state insurance regulators to provide the particular lines of insurance coverage sought by the insured policyholder in the states where it resides and/or operates. The insurer is subject to the jurisdiction of the applicable regulators. The regulator's rules and/or the laws of the applicable states may require the insurer to conform to any of these core regulatory requirements placed on admitted insurers:

- File and seek approval of its policy forms
- File and seek approval of premium rates



- Be subject to the state's specific capital and surplus requirements
- Be subject to market conduct examinations

SL insurance is coverage offered by an insurer that is not licensed (i.e., admitted) in the state(s) where the policyholder is located under a specific set of laws and regulations that permit such transactions under the limited circumstances where the policyholder's insurance needs cannot be met by the admitted insurance market. The policyholder's insurance needs are in surplus of what is available in the admitted market—

hence, surplus lines. Under those limited circumstances, coverage is exported into the state by an out-of-state carrier offering a solution to the insured's unique coverage needs.

SL insurance coverage has become increasingly common for many reasons, not all of which are immediately evident. There is the obvious benefit that the insurer's policy forms and rates are only subject to review by the insurer's domestic regulator, which in many instances is an alien (i.e., international) government agency. The insurer is also subject to severely limited regulatory monitoring, as it forgoes the licensing and admissions process, instead opting for an eligibility process. Because the very concept of SL insurance is predicated on the non-admitted status of the insurer—and, hence, lack of regulatory jurisdiction over the insurer—most SL regulation is directed at the producers who stand in the middle of the transaction between insureds and insurers. A non-domestic regulators' hook into the transaction is limited to jurisdiction over the producer. Thus, there are generally both extra requirements and enhanced regulatory scrutiny of SL producers.

Surplus Lines Producer Licensing

All persons who sell, solicit, or negotiate a policy of insurance must be licensed as an insurance producer in the relevant jurisdictions, and they must also be licensed to transact the applicable lines of business. This means that to sell a policy of life insurance, the producer must hold life agent and/or broker authority in the state where it is selling the policy. Property, casualty, health, and disability are additional common lines of authority that tie to certain types of products. SL is effectively treated as an additional line of authority that must be held by any producer involved in the transaction, even though SL can refer to a variety of property and casualty coverages that, if offered on an admitted basis, would be covered by the traditional lines of authority.

A licensed producer must hold SL authority to participate in an SL placement. SL authority requires more training and a separate licensure examination. Holding an SL license subjects the producers to added regulatory scrutiny as well because SL licensees are required to do the following:

- Maintain detailed records of transactions
- Submit regular reports to state regulators on the SL insurance they placed
- Be responsible for remitting premium taxes to applicable taxation authorities (described in further detail below)

In short, SL is not a business line in which producers should simply dabble. Producers with clients seeking SL coverage often contact and involve an SL licensee and specialist in the sale of insurance to the client. This expertise is essential.

It is imperative that any person who sells, solicits, or negotiates SL insurance coverage hold a producer license with that line of authority. A property/casualty licensee cannot have a third-party SL broker simply paper the transaction and share commission, while the property/casualty licensee with no SL authority exclusively communicates with the client. SL coverage is distinct from coverage in the admitted market, and it is the SL licensee's obligation to communicate these distinctions. These distinctions can include, but are not limited to, the following:

- The obligation of the SL licensee to collect and remit premium tax
- The lack of regulatory oversight of policy forms and premium rates
- The absence of the backstop of state insurance guaranty association coverage¹

For this reason, regulators will pursue enforcement action against producers who engage in sales practices that separate the SL licensee from the insured.

Non-Admitted & Reinsurance Reform Act

While SL placements can be complex from a regulatory compliance standpoint in comparison to admitted market transactions, the producers' compliance obligations were simplified by the Non-Admitted & Reinsurance Reform Act of 2010 (NRRRA), passed by Congress as part of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act). A primary effect of the NRRRA was to limit the obligation of SL producers to collect premium taxes on SL policies to a single state's premium tax regime. This was a significant undertaking because SL policyholders often are large, sophisticated, multistate (if not multinational) entities with insured business operations across numerous jurisdictions. Additionally, a primary function of SL regulation is to ensure the existence of a mechanism by which states can collect premium tax revenue on policies placed with non-admitted insurers. Following passage of the NRRRA, only the insured's home state regulator's SL laws and regulations apply to the collection of premium taxes on the transaction, despite the fact that most premiums on the policy may be allocable to risks located in different states. The NRRRA, as drafted, envisioned states' entry into one or more multistate compacts

¹ Except in New Jersey, where there is a Surplus Lines Insurance Guaranty Fund for limited lines. See N.J. Stat. § 17:22-6.70 et seq.

When contemplating engaging in a Surplus Lines transaction with an insured, producers must be able to identify the insured's home state so that the applicable set of state premium tax collection and remittance rules and procedures can be followed.

by which home states that collected 100% of the premium tax revenues on a policy with exposures across multiple states would allocate and true-up premium tax receipts such that the home state taxation authority did not collect a windfall share of premium taxes on policies written to large multistate insureds. Several years later, no significant multistate compact has taken root, and although some states have entered limited agreements with specific other states, the national compact foreseen by drafters of the NRRRA does not exist.

Notwithstanding the interesting and unforeseen tax policy consequences of the Dodd-Frank Act, one major and net positive change resulting from the NRRRA is that identifying the applicable state rules for collecting premium taxes on an SL

transaction is now much easier. The NRRRA defines home state as one of the following:

- The state in which an insured maintains its principal place of business or, in the case of an individual, the individual's principal residence.
- If 100% of the insured risk is located out of the state referred to in the clause above, the state to which the greatest percentage of the insured's taxable premium for that insurance contract is allocated.

When contemplating engaging in an SL transaction with an insured, producers must be able to identify the insured's home state so that the applicable set of state premium tax collection and remittance rules and procedures can be followed.

Obligations of the Originating Producer and Surplus Lines Producer

Assume that a licensed insurance producer has a customer with unique coverage needs. The producer believes that the SL market may be better suited for this particular customer's coverage. What must the producer do to place the customer with an SL carrier?

Good Faith Effort to Find an Admitted Carrier

As a baseline requirement, most states require the originating producer to undertake a good faith effort first to place the customer with a carrier in the admitted market. To demonstrate such good faith effort, in the ordinary course, a producer must complete an affidavit or certification attesting to efforts to place coverage in the admitted market. States can require producers to contact as many as five admitted carriers authorized to write the lines of insurance sought by the customer and obtain declinations to write the customer's requested coverage before the producer is permitted to begin placement efforts in the SL market.

An originating producer without SL authority should make diligent efforts to contact admitted insurers before handing the customer off to an SL licensee for placement in the SL market. A producer holding both the underlying lines of authority for the coverage sought by the customer as well as SL coverage may be tempted to proceed directly to shopping the SL market to meet the customer's needs. This producer must still undertake the good faith search of the admitted market required by applicable state law.

State Affidavit or Certification Forms

The affidavit and/or certification form and the good faith efforts to place in the admitted market the form represents are critical to avoiding regulatory sanctions. Each state's certification or affidavit form will include the following:


- Space to identify the names of the insurers contacted
- The representatives of the insurer with whom the producer spoke
- Identification of the reason for declination of coverage

All portions of this form must be completed accurately and truthfully—producers and insurers cannot have standing agreements or arrangements for declination of coverage. Such arrangements are likely to be exposed during regulatory audits or market conduct examinations and will result in adverse enforcement activity for producers and carriers alike. Moreover, when state regulators conduct audits of SL activity, the affidavits/certifications of good faith efforts will be at the top of the list of requested documents. Regulators will not

Related Content

For an explanation on the purpose, scope, and navigation of market conduct examinations, see

> MARKET CONDUCT EXAMINATIONS

 **RESEARCH PATH:** [Insurance > Interacting with Regulators and Responding to Investigations > Practice Notes](#)

For more information on administrative actions and sanctions of licensed insurance producers, see

> AGENT AND BROKER ADMINISTRATIVE ACTIONS AND SANCTIONS: REPORTING REQUIREMENTS

 **RESEARCH PATH:** [Insurance > Managing Insurance Representatives > Practice Notes](#)


For an analysis on minimizing agent and broker conduct risk by insurers, see

> MARKET CONDUCT: CONTROLLING AND MINIMIZING AGENT AND BROKER RISK

 **RESEARCH PATH:** [Insurance > Managing Insurance Representatives > Practice Notes](#)

For a discussion on the requirements for agent and broker licensing and compliance, see

> AGENT AND BROKER ANNUAL COMPLIANCE CHECKLIST

 **RESEARCH PATH:** [Insurance > Managing Insurance Representatives > Checklists](#)

hesitate to make inquiries of the identified contact persons if violations are suspected.

Check the Applicable State's Exportable List and White List

A notable and significant exception to the general rule that producers must engage in a diligent search of the admitted market before offering an insured SL coverage is that most states offer a list of specific lines of coverage for which the state has determined that there is no adequate admitted market, and such coverages may be exported to the SL market without a diligent search of the admitted market. This list is known as the exportable list in most states. The breadth of coverages included on such exportable lists can vary significantly from state to state. Under many states' rules, if a producer is relying on the exportable list to place an insured in the SL market, the SL policy in question must be boldly marked exportable. States with exportable lists generally have an administrative process





Related Content

For more information on the regulation of surplus lines insurers, see

> [NEW APPLEMAN ON INSURANCE LAW LIBRARY EDITION §§ 8.04, 9.09, 80.02](#)

For more information on taxation of surplus lines insurance, see

> [NEW APPLEMAN ON INSURANCE LAW LIBRARY EDITION § 12.10](#)

For more information on special treatment of designated lines and exportable lists, see

> [NEW APPLEMAN ON INSURANCE LAW LIBRARY EDITION § 10.06](#)

Ensure Delivery of Applicable Disclosures to Insured

Most states' laws require a disclosure form be provided to the customer indicating that SL policies have the following disadvantages in that they are:

- Not filed nor approved by the applicable state regulator
- May have different terms and conditions than would otherwise be allowed for an admitted carrier's policies
- Generally not afforded guaranty fund coverage in the event of insolvency of the SL insurer

The SL producer is generally required to obtain and then retain a customer-signed disclosure form. Many of these same disclosures may be included in a required stamp on the SL policy, but at minimum, the fact that the policy is surplus line (i.e., non-admitted) and not subject to guaranty fund protection will be included in the stamp.

Collection of Premium Taxes

SL producers are required by applicable state law to collect premium taxes from insureds on policies placed in the SL market. The SL producer is generally required to collect from the policyholder the effective rate of premium tax in effect in the insured's home state for the entire premium charged under the policy following NRRRA and state legislative enactments. The SL producer must diligently document funds collected from the insured and regularly remit receipts of such premium tax dollars to the applicable state taxing authority.

Abide by Higher Standard of Record-keeping

SL producers are required to maintain a higher standard of record-keeping than ordinary producers. SL producers are generally required to assign a case or file number to each prospective SL coverage purchaser, must attach this unique file number to each document produced during the placement, and must maintain records of such placement for a state-specified number of years. The SL producer's file on the placement must include all of the following documentation:

- Good faith search efforts and admitted insurer declinations
- Disclosure forms obtained from the insured
- Any commission sharing arrangement or fees charged to the originating producer or insured (if permitted by applicable state law)
- Taxes collected and remitted
- Communications with the insured

Such documentation should be kept by the SL producer in a readily accessible, and preferably easily searchable, electronic format, such that files can be produced to a regulator on demand. Failure to maintain records in an organized format

can quickly lead a regulator to expand the scope of an inquiry or audit.

Comply with Limitations on Commission Sharing and Fees

Producers and their employers should be mindful of limitations on commission sharing and fees charged by SL producers due to the referral relationships that frequently exist among producers for the placement of SL coverage. In a referral arrangement where the SL producer will earn commission on the sale of a policy to an insured referred by another producer, to share in the commission the originating producer must generally be licensed as producer in the applicable jurisdictions with authority to write the lines covered by the SL policy. Most states' laws will prohibit, for example, a licensed life and health (only) agent from sharing commission with an SL agent on exported property/casualty coverage. Additionally, many SL producers attempt to charge fees for the rather substantial efforts required of them in the placement of SL coverage. Some states permit SL producers to charge such fees subject to obtaining signed disclosures from the insured and/or strict limitations on the amount of fees that can be charged, while other states may prohibit such fees.

Additional Considerations

The compliance concerns noted thus far do not mention procedures required by a particular state's SL stamping office. At present, 15 states maintain SL stamping offices that effectively function as compliance-ensuring clearinghouses for SL transactions, including Arizona, California, Florida, Idaho, Illinois, Mississippi, Minnesota, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Utah, and Washington.

Stamping office refers to printing the disclosure to the policyholder on the face of the policy form that the policy is written by a non-admitted insurer. Many stamping offices have adopted this disclosure to ensure that each transaction has generally complied with the requirements described herein and elsewhere. For producers transacting SL business in these states, it is imperative to consult with and review the

procedures of the applicable stamping office. In the other 35 states, the compliance of each transaction with applicable SL law is primarily the responsibility of the SL producers and is self-enforced. Hence, a robust internal compliance and self-monitoring function is imperative for agencies and brokerages to avoid significant compliance pitfalls and potential adverse enforcement action.

Surplus Lines Placement Compliance Flowchart

The following Surplus Lines Placement Compliance Flowchart provides a chronological visual depiction of key events in the course of a compliant sale of a surplus/excess lines insurance policy, depicting how an insurance producer may identify a customer's need for insurance coverage that is not necessarily available in the admitted (i.e., licensed) insurance market, and may therefore turn to the market of coverage available from eligible non-admitted insurers through a licensed surplus lines producer. The flowchart highlights the diligent efforts that must be undertaken by the producer with the primary relationship with the customer and the surplus lines producer, and further delineates the point at which substantive engagement with the customer regarding sale, solicitation, and negotiation of surplus lines insurance coverage must be handled by the surplus lines-licensed producer. ■

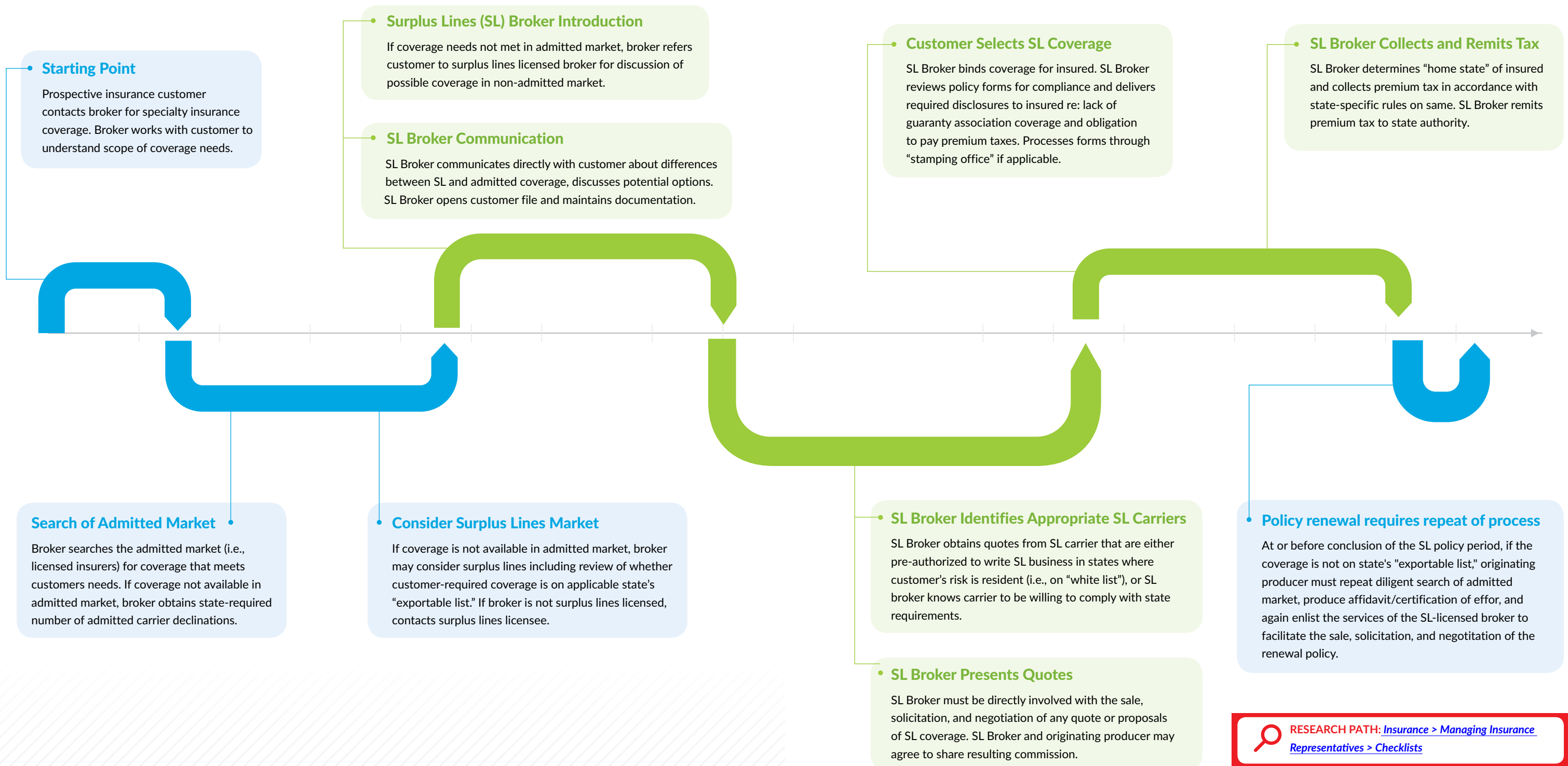
Cynthia Borrelli is the head of the Insurance Law Practice Group at Bressler, Amery & Ross, P.C. Cynthia brings three decades of knowledge and insight to the firm and her clients. She provides quality legal advice relating to property-casualty and life, annuity and health, managed care, disability insurance, and reinsurance matters, with particular emphasis on insolvency regulation. Michael J. Morris is an associate in the firm's Insurance and Business practice groups and concentrates his practice on representing and advising insurance industry clients in the handling of regulatory matters.



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Surplus Lines Placement Compliance Flowcart

Cynthia Borrelli and Michael J. Morris BRESSLER AMERY & ROSS, P.C.



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Jason Amster LEXIS PRACTICE ADVISOR

Secured Overnight Financing Rate in Loan Transactions

This article describes the Secured Overnight Financing Rate (SOFR), a broad credit-risk measure that is a frontrunner to replace the London Interbank Offered Rate (LIBOR). The article addresses how SOFR is calculated, how it compares with LIBOR, and its advantages and disadvantages in loan transactions. These are important considerations in legacy deals and in new financings, as either could soon face the prospect of losing the loan market's primary pricing mechanism.

Exit LIBOR

LIBOR (sometimes referred to as the Eurodollar Rate in credit agreements) is flexible and widely accepted, being available for maturities ranging from overnight to one year and is calculated in five currencies. It has long been the baseline pricing mechanism in loan agreements (and many other contractual arrangements for that matter). However, its future is uncertain.

As of February 1, 2014, the responsibility for overseeing and administering LIBOR passed from the British Bankers Association (BBA) to the ICE Benchmark Administration Limited (ICE) following the LIBOR manipulation scandal of 2012. ICE said that LIBOR will continue to be calculated in the same manner as it had been under the BBA to minimize the impact of this change on existing lenders and borrowers. Also following the scandal, banks themselves no longer wanted to report LIBOR, for fear of becoming embroiled in LIBOR-related trouble. The United Kingdom's Financial Conduct Authority, the regulator overseeing LIBOR, said that it would no longer require banks to provide LIBOR estimates beginning in 2021. Many market participants have concluded that, at that time, LIBOR will cease to be the predominant interest rate benchmark. The question then was what would replace LIBOR as the reference rate in the \$200 trillion in contracts



that use LIBOR as of 2016. Of that, there are about \$1.5 trillion in syndicated loans and \$800 billion in non-syndicated loans that would need to be converted to a rate other than LIBOR (the derivatives market makes up about 95% of the outstanding gross notional value of all financial products referencing LIBOR).

Related Content

For practical guidance on analyzing or amending existing credit agreements to allow for SOFR (or any alternative rate), see

> LIBOR REPLACEMENT IN CREDIT AGREEMENTS

RESEARCH PATH: Finance > The Credit Agreement > Credit Agreement Guide > Practice Notes

For sample language to use in a LIBOR successor/conversion clause, see

> LIBOR SUCCESSOR AND CONVERSION CLAUSE

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For background on interest rates in general, see

> INTEREST RATE PROVISIONS IN CREDIT AGREEMENTS

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For an overview of factors that have impacted the loan market since the 2008 financial crisis, see

> MARKET TRENDS 2017/18: FACTORS AFFECTING THE LOAN MARKET

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For a discussion of revolving credit facilities and term loans, see

> TRANCHES OF LOANS AND LOAN MECHANICS IN CREDIT AGREEMENTS

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For guidance on amending credit agreements, see

> AMENDMENTS AND LENDER VOTING RIGHT ISSUES IN CREDIT AGREEMENTS

RESEARCH PATH: Finance > The Credit Agreement > Credit Agreement Guide > Practice Notes

Existing deals would generally default to the alternate base rate (ABR) or prime rate. These rates have been provided in the credit agreement as an alternative to LIBOR in instances in which, for example, banks cannot ascertain LIBOR or LIBOR does not accurately reflect their cost of funding. However, borrowers prefer to borrow at the LIBOR rate, which is lower. In fact, borrowers in default are generally prohibited from

converting ABR loans to LIBOR. Therefore, simply switching over to these rates is not an ideal outcome for borrowers. For that reason, the loan market has begun to seek a viable alternative to LIBOR.

To address this problem and find a replacement for LIBOR, in 2014 the Board of Governors of the Federal Reserve System and the Federal Reserve Bank of New York (New York Fed) established the Alternative Reference Rate Committee (ARRC), comprising financial institutions and banks, trade associations (such as the Loan Syndication and Trading Association (LSTA)), and official sector members. ARRC noted that “the risks surrounding [LIBOR] pose a potential threat to the safety and soundness of individual financial institutions and to financial stability.” The ARRC set out to find an alternative reference rate to LIBOR, best practices for contract robustness, and plans to adopt and implement an alternative rate. It initially recommended as an alternative rate the Broad Treasuries Financing Rate, which subsequently became known as SOFR.

Enter SOFR

SOFR is based on several risk measurements for the purchase and resale of U.S. Treasury securities under repurchase agreements (as described below). As a secured rate, it cannot replace the unsecured LIBOR directly, as the SOFR rate on any day is lower than LIBOR. Borrowers and lenders would have to determine an appropriate conversion mechanism.

The New York Fed began publishing quotes of the SOFR rate in April 2018. SOFR measures the cost of borrowing cash overnight backed by U.S. Treasury securities as collateral. It is a benchmark rate that incorporates trading data from three risk-free reference overnight repurchase (repo) rates. In a repo agreement, a dealer (or borrower) sells a government security to investors and buys it back at an agreed-on higher price at a later date (in this case, the next day). The difference between the selling price and the repurchase price (i.e., the discount) is the basis of the repo rate and is the same as an interest rate. Treasuries can be traded through repos in three ways:

- Tri-party repo, which uses a clearing bank as a go-between for a specific buyer and seller
- General Collateral Financing (GCF) repos, which are like tri-party repos but are traded on exchanges, with transactions between anonymous buyers and sellers (i.e., they are blind brokered) settled on the clearing banks' platforms
- Bilateral repos, which are direct transactions between buyers and sellers. These do not use third parties such as clearing houses, but they may be cleared through the Delivery-Versus-Payment (DVP) service offered by the Fixed Income Clearing Corporation (FICC)

The relative weakness of LIBOR was exacerbated by the financial crisis and subsequent LIBOR scandal, when banks drastically limited (in fact, nearly eliminated) reporting LIBOR. SOFR is based on data from far more trades than is LIBOR, ideally making it a more accurate measure of the cost of credit.

The New York Fed has included all three of these types of repo transactions in its calculation of SOFR. SOFR is calculated as a volume-weighted median of transaction-level tri-party repo data collected from the Bank of New York Mellon as well as transaction data and data on bilateral U.S. Treasury repo transactions cleared through DVP, which are obtained from Depository Trust & Clearing Corporation (DTCC) affiliate DTCC Solutions LLC. The New York Fed also includes in SOFR data from its Broad General Collateral Rate (a tri-party GCF rate). The FICC acts as a central counterparty for GCF and bilateral repos. Removed from these calculations are transactions the New York Fed refers to as “specials,” or specific-issue collateral. These specials trade at cash-lending rates (i.e., rates lower than those for general collateral repos); cash providers accept this lower yield, so they can obtain a particular security.

The New York Fed publishes the result of this calculation, SOFR, on its website at about 8 a.m. New York time each business day.

Differences between LIBOR and SOFR

SOFR differs from LIBOR in that there is a far higher volume of SOFR-based trading and in the underlying nature of the rate itself. Higher volume generally makes SOFR safer from manipulation than LIBOR. For example, just after the New York Fed began quoting the SOFR rate, \$754 billion in daily trading volume made up SOFR, as opposed to \$500 million in three-month LIBOR, according to the ARRC. Thus, a very large number of contracts based on LIBOR (see below) are derived from a relatively small amount of underlying trades—making LIBOR susceptible to manipulation. The relative weakness of LIBOR was exacerbated by the financial crisis and subsequent LIBOR scandal, when banks drastically limited (in fact, nearly eliminated) reporting LIBOR. SOFR is based on data from far more trades than is LIBOR, ideally making it a more accurate measure of the cost of credit.

LIBOR and SOFR themselves are based on different metrics as well. The most significant difference between LIBOR and SOFR is that LIBOR is an unsecured rate and represents banks' estimates as to their cost of funds. SOFR meanwhile is a secured, risk-free rate. Thus, LIBOR arguably reflects banks'

costs of funding more accurately than SOFR. On the other hand, the calculation of LIBOR was opaque, based on polling of certain banks. The calculation of SOFR is more transparent, based on market data. In addition, because of the size of the SOFR market and the different components that go into its calculation (see above), the ARRC concluded that SOFR does reflect the economic cost of lending and borrowing relevant to a wide array of market participants.

In addition, LIBOR quotes are available for deposits with several different maturities (interest periods), from overnight to one year. At its launch in April 2018, SOFR lacked a term reference rate, being limited only to an overnight rate (the ARRC was unable to find a term rate like LIBOR that otherwise met its criteria for a replacement rate). However, in May 2018, the ARRC published an indicative three-month SOFR rate. Otherwise, issuers selling bonds tied to SOFR have been making do with the overnight rate (Fannie Mae made the first issuance of SOFR bonds, \$6 billion worth in July 2018). That is, a term interest rate is derived from extrapolating from the daily SOFR rate (i.e., an average daily rate). The disadvantage of such extrapolation is that the parties do not know the final rate at the start of the interest period, as is the case with LIBOR. However, SOFR has begun trading on futures markets, and this should allow for the calculation of true term rates. The ARRC timeline anticipates the creation of a SOFR term reference rate as the final step in its “paced transition plan,” expected to be completed by the end of 2021.

The differences between LIBOR and SOFR are most essentially represented in the underlying rates themselves. For that reason, you cannot simply amend a credit agreement to replace LIBOR with SOFR. For example, on January 3, 2018, the overnight LIBOR rate was 2.39188% and SOFR was 2.7%. At other points in the cycle, SOFR has been lower than LIBOR, and the overnight rate for LIBOR is not the most representative of LIBOR measurements. In any event, some credit adjustments to the spread must be made to account for the difference rates.

Challenges and Next Steps

Practitioners should keep abreast of these changes, as they will have an impact on many existing credit agreements and



on new deals. To avoid defaulting to costly ABR or prime rates, credit agreements should either have language allowing for a streamlined amendment to a to-be-determined benchmark (in this case, SOFR). Ideally, your credit agreement already has such a mechanism in place. Before you advise your client on this point, check to see what level of lender consent is necessary to make such a change. Most recently negotiated deals do have such language, and the parties can replace LIBOR through an amendment that can be blocked only by a required lender vote (i.e., a negative consent). Some credit agreements require no consent other than the administrative agent and the borrower, and an unfortunate few demand an affirmative required lender vote to make such a change.

New loans should have this LIBOR successor language baked into the credit agreement. Some things to consider in drafting these provisions are making the appropriate adjustments for the difference in spread between LIBOR and its replacement, what events will trigger a move to the new rate, how and who selects the new rate (e.g., the administrative agent alone,

or the agent with borrower consent), and whether required lenders will be allowed to sign off on this change. **L**

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LexisNexis Canada Donates Laptops to Innocence Canada's Exoneration Effort

LexisNexis Canada has once again collaborated with long-time rule of law partner Innocence Canada to promote its efforts in exonerating wrongly convicted individuals and educating the public on the legal system in Canada.

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“to identify, advocate for, and exonerate individuals who have been convicted of a crime they did not commit and to prevent wrongful convictions through education and reform.”

Since its founding in 1993, the organization has reviewed hundreds of cases and assisted in the exoneration of 22 individuals who had spent a combined total of more than 190 years in prison for crimes they did not commit. Currently, its team of volunteer attorneys are reviewing approximately 80 additional cases.

In the most recent cooperative effort between the two groups, more than two dozen LexisNexis employees, acting under the supervision of the company's IT team, prepared 12 decommissioned company laptops for donation by deleting all proprietary data and ensuring their fitness for use. The laptops were given to Innocence Canada for use by their staff and by clients of the organization seeking paid employment.

Previously, LexisNexis employees participated in fundraisers, such as charity walks and bake sales, on behalf of Innocence Canada. In addition, LexisNexis Canada was a major sponsor of the organization's Wrongful Conviction Day event at the Law Society of Ontario in October 2018.

LexisNexis Canada has also provided Innocence Canada with products and services in support of its legal advocacy, including textbooks and complimentary access to Lexis Advance.

In return, Innocence Canada has provided guest speakers for LexisNexis Canada's Rule of Law Speaker Series, including exonerees and experts in the wrongful conviction advocacy community, and facilitated contributions by three exonerees to Canada at 150: Building a Free and Democratic Society, a book about Canada's constitutional past and present published by LexisNexis.

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