Pre-litigation Preparation and Strategy for Pharmaceutical Product Patents and Exclusivity

A Practical Guidance® Practice Note by
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Market exclusivity from patents and drug approval authorities is essential for the existence of innovative drug companies. This practice note outlines preemptive steps that should be considered by in-house and outside counsel for an innovator drug company to maximize a product's regulatory and patent exclusivities and the company's chances of success in future patent litigation against generic drug applicants.

Overview

Monitoring Generic Competitors

The framework provided by the patent and food and drug laws enables brand name drug companies to monitor prospective generic competitors long before any drug applications are submitted to the Food and Drug Administration (FDA). (For an overview of the Hatch-Waxman Act, see Hatch-Waxman Act Fundamentals.) To effectively monitor generic competitors, you will want to:

- Know the earliest date an application for approval to market a generic product may filed or approved
- Monitor active ingredient Drug Master File submissions
- Monitor process patent disclosure requests
- Monitor product sample requests
- Monitor U.S. and international patent activity
- Monitor ex-U.S. regulatory activity
- Monitor ex-U.S. patent challenges –and–
- Monitor ClinicalTrials.gov and newly reported clinical trial data

By monitoring these activities, you can gain a sense for the progress potential competitors are making in the development of a generic drug, as well as for when patent infringement litigation may arise.

Preparing for Litigation

Once you reasonably anticipate patent infringement litigation, there are several steps you can take to prepare for litigation. You may want to:

- Review ownership to ensure standing to assert patents
- Create or review community of interest agreements
- Identify people with unique knowledge about the drug or patents and review inventorship
- Ensure relevant documents are preserved
- Identify and review key documents
- Prepare for document collection and possibly begin targeted collections
- Identify potential experts

- Develop a narrative of the invention story and create a preliminary theory of the case
- Monitor and harmonize positions being taken in ongoing patent proceedings and publications
- Consider whether to close prosecution –and–
- Evaluate venue options

In some cases, you may wish to begin this preparation as part of a product portfolio review even before any litigation is anticipated.

Other Advising Activities to Maximize Exclusivity

Early in the life of the branded drug product, in order to ensure all available exclusivities are acquired, it can be helpful to have litigation counsel:

- Review the brand name company's FDA listing of patents covering the product or its approved indications and usage codes
- Consider the best use of pending applications or post-issuance actions to ensure optimal protection of the invention
- Consider the availability and interplay of Patent Term Extensions and Adjustments
- Consider the FDA's guidance to generics regarding the drug product and potential Citizen Petitions –and–
- Monitor competing innovative products and their associated patent space

Monitoring Generic Competitors

As soon as a branded drug product receives FDA approval—or even earlier—counsel for the brand name company should consider monitoring various activities of potential generic competitors. These activities can provide some indication of whether a competitor product is in development.

Know the Earliest Date an Application for Approval to Market a Generic Product May Be Filed or Approved

The earliest date on which an application to market the generic version of a brand name product may be filed or approved varies, depending on the brand name product.

New Chemical Entity: No Generic Application for Four or Five Years

When a drug containing a New Chemical Entity (NCE) (drug products with an "active moiety"—the bioactive chemical species—not in any previously approved product) is approved, brand name drug companies are afforded a period of marketing exclusivity during which generic applicants cannot file for approval to market a generic product . This period runs until five years after approval of the Reference Listed Drug (RLD;) (the brand name product), or four years after, if their filing indicates an intention desire to market the product prior to the expiration of patents listed in the FDA's "Orange Book" based on a belief that the patents are not infringed or are invalid. See Review the Brand Name Company's FDA Listing of Patents Covering the Product or its Approved Indications and Usage Codes under Other Advising Activities, below; 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2); New Chemical Entity (NCE) Exclusivity under Marketing Exclusivities for Prescription Drugs.

Other Exclusivities: Applications May Be Submitted as Soon as Ready

Only NCE products gain the four- or five-year buffer before a generic application may first be **filed**. However, other regulatory exclusivities restrict when the FDA may **approve** a generic product, and are mentioned below. Where there is no restriction on when a generic applicant can file, they may do so as early as they are ready. Given the incentive of gaining 180 days of marketing exclusivity by being the first generic filer for a product, some commercially successful non-NCE drug products see early generic filings. Because the commercial promise of a non-NCE product is often not immediately clear, generic applicants may put off certain more demanding steps needed to complete an application. But it is not uncommon to see generic applications be filed around two years prior to the expiration of any innovator marketing exclusivity, as that has generally provided enough time for FDA review and approval prior to the expiration of the RLD's marketing exclusivity. See GDUFA: Enabling Generic Drug Program Success.

Orphan Indication: No Generic Marketing for Seven Years

Orphan drugs, drugs approved to treat conditions affecting fewer than 200,000 in the U.S., or more but with no hope of recovering costs, receive seven years of marketing exclusivity from the date of approval of the indication to which the orphan designation applies. See 21 U.S.C. § 360cc(a); 21 C.F.R. § 316.31; Clinical Research Compliance Manual § 13.02 - Orphan Drug Exclusivity (Seven-Year Exclusivity).

New Clinical Investigation: No Generic Marketing for Three Years

If a new clinical investigation is carried out (other than bioequivalence) that is essential to approval of, for example, a new dosage strength, dosage form, route of administration, condition of use of a previously approved drug, or a modification of the drug substance in an approved drug (without changing the active moiety), three years of marketing exclusivity for that form/usage runs from the resulting approval. See 21 U.S.C. § 355(c)(3)(E)(iii); 21 C.F.R. § 314.108(b)(4)-(5); Clinical Research Compliance Manual §13.02 - New Conditions of Approval Exclusivity (Three-Year Exclusivity).

Pediatric Indication: FDA Treats Any Exclusivity, Including Patent, Extended by Six Months

If the FDA provides a written request for pediatric studies and those studies are fulfilled within the allotted time frame, any existing regulatory exclusivity (NCE, Orphan, or New Clinical Investigation) for that product is extended by six months (provided the FDA completes its review and accepts the study report at least nine-months before any exclusivity is set to expire). The FDA will also treat any Orange Book-listed patent expiration that is precluding approval as if extended by six months. See 21 U.S.C. § 355a(b); Clinical Research Compliance Manual § 13.02 - Pediatric Exclusivity.

GAIN Exclusivity: Automatically Extends All Regulatory Exclusivities An Additional Five Years

In 2012, Congress enacted the Generating Antibiotic Incentives Now Act (GAIN Act). The Gain Act provides five years of additional non-patent exclusivity (added on top of NCE, Orphan, New Clinical Investigation, Pediatric, and the four- or five-year restrictions on when generic applications may be filed for NCE products) to manufacturers of Qualified Infectious Disease Products (QIDPs): antibacterial and antifungal drugs "intended to treat serious or life-threatening infections" caused by qualifying pathogens, generally novel, or drug-resistant bacteria or fungi. See 21 U.S.C. § 355F. For example, an NCE Orphan antibiotic drug qualifying for GAIN exclusivity will have twelve years of market exclusivity and generic applications may not be filed until nine- or ten-years after approval. GAIN exclusivity does not change availability of ANDA filings any time after approval for non-NCE products.

Monitor Active Ingredient Drug Master File Submissions

A Drug Master File (DMF) is a submission to the FDA that provides confidential detailed information about facilities, processes, or articles used in manufacture, processing, packaging, or storing a drug. The FDA maintains a list of DMFs that is updated quarterly, and the list will indicate if a party has submitted manufacturing information on the active ingredient in the RLD. See 21 C.F.R. § 314.420; FDA - Drug Master Files (DMFs).

This information may convey that generic manufacturers are gearing up for regulatory filings.

Monitor Process Patent Disclosure Requests

Generic drug manufacturers will sometimes send a request pursuant to 35 U.S.C. § 287 for an identification of all process patents that the patent owner reasonably believes could be asserted to be infringed under 35 U.S.C. § 271(g). The nominal purpose of such a letter is to evidence good faith to acquire notice of patent rights before any infringing action is taken. These letters may convey that generic manufacturing is contemplated or underway.

Monitor Product Sample Requests

Generic manufacturers usually must carry out in vitro and in vivo studies to demonstrate bioequivalence of the proposed generic product to the RLD. Often, generic manufacturers are able to obtain the branded samples for comparison from wholesalers. But in some circumstances, for example, if the branded drug is covered by FDA-mandated Risk Evaluation Mitigation Strategies, distribution may be restricted. See 21 U.S.C. § 355-1. Generics may then have to request samples directly from the branded manufacturer.

Monitor Patent Activity

Generic manufacturers will sometimes seek to acquire patent protection over variations of the RLD such as alternative salts, prodrugs, or solid-state forms of the active moiety in the RLD, processes of manufacturing or synthesizing the API, or alternative dosage forms. In addition to evidencing possible commercial interest in a generic product, these applications can reveal prefiling work on design-around strategies.

Monitor Ex-U.S. Regulatory Activity

Information evidencing steps being taken by generic manufacturers may also be gleaned from submissions made to foreign drug approval authorities.

Monitor Ex-U.S. Patent Challenges

Challenges to the patent portfolio covering a product can sometimes kick off in foreign jurisdictions before they do in the U.S. These also indicate which manufacturers may have invested in development of a generic product.

Monitor Newly Reported Clinical Data

Additionally, monitoring ClinicalTrials.gov and newly reported clinical data can indicate which manufacturers are preparing for regulatory submission or product approval.

Preparing for Litigation

A general pre-suit checklist for patent infringement litigation can be found here: Pre-suit Considerations Checklist for Patent Infringement Litigation. The case preparation steps set out below have been tailored to the pharmaceutical patent context where possible. The extent to which these steps are taken prior to initiating the lawsuit will vary with the circumstances, including the nature of the patent claims, the nature of the branded product, client preferences, available information on generic activities, and budget.

Review Ownership to Ensure Standing to Assert Patents and to Identify Controlling Parties

It is important to be aware of the distribution of patent and patent enforcement rights to ensure the appropriate parties are named as plaintiffs in any infringement suit. You should consider taking the following steps:

- Collect all assignments and licenses between the inventor(s), patent owner(s), and licensee(s).
- Identify which legal entity owns the relevant patents. Identify which legal entities are needed to enforce the patents.
- Confirm that all intended rights are transferred to the entities who will participate in litigation or take corrective steps to do so. Ensure that ownership and associated rights will not impair the ability to obtain injunctive or monetary relief.
- Consider whether the party with the right to control enforcement is clear. Do the same with respect to prosecution. If the parties differ, consider whether to amend the agreement to avoid disputes once litigation begins.

Create or Review Community of Interest Agreements

Community of interest agreements make explicit that discussions between, for example, patent owners and licensees, will remain confidential, helping to demonstrate a basis for asserting privilege over any shared legal advice during future litigation. To ensure these agreements effectively preserve privilege, consider taking the following steps:

- Create community of interest agreements that cover those individuals and entities who may reasonably be expected to engage in communications involving potentially privileged information, in particular communications with litigation counsel.
- Review any existing agreement protecting the confidentiality of discussions concerning legal strategy on topics in which the owners/licensees/inventors, etc., share a common legal interest.
- Collect all additional agreements (i.e., beyond assignments and licenses) between the owners/licensees, etc., that may inform when the community of interest arose (e.g., any sponsored research agreement or pre-license letter of intent to exclusively negotiate).
- Confirm all intended protections are explicit in the existing community of interest agreement and, if appropriate, update the agreement.

Identify People with Unique Knowledge about the Drug or Patent and Review Inventorship

Speaking with people knowledgeable about the product early is important to developing a narrative of the invention, issue spotting, advancing case theory (e.g., learning the benefits of the invention), evaluating potential litigation witnesses, and ensuring fact discovery proceeds efficiently. The following people will generally play a role in the upcoming litigation:

- **Inventors and key researchers.** Locate and speak with all inventors and key researchers. In connection with these meetings, explore each individual's views on inventorship (claim-by-claim if appropriate).
- **Employees.** Identify employees who may serve as corporate representatives in depositions (e.g., concerning discovery, licensing, patent prosecution, pre-clinical development, clinical development, and commercial strategy).
- **Upper management.** Speak with upper management to ensure, to the extent possible, that the company stays on good terms with employee witnesses in order to minimize that chances that they will act in a hostile manner in future litigation.
- **Prosecuting attorneys.** Interview the in-house and outside attorneys who played roles in prosecuting the patents-in-suit and related patents.
- **Third-party witnesses.** Identify any other key third-party witnesses (e.g., former employees) and determine if they are friendly or may be hostile. Where reasonable, start to create a relationship in anticipation of asking them for help during the litigation. Research any limitations on witness compensation in the likely jurisdictions for suit should a witness ask.

Ensure Relevant Documents Are Preserved

As soon as litigation is reasonably anticipated, you should take the necessary steps to ensure any potentially relevant information is preserved:

- Speak with the information technology team. Understand the client's document retention policies. Understand the technology used to store documents.
- When speaking with key witnesses, inquire into the makeup of project teams, the location of documents related to each team, and who beyond the key witnesses (e.g., other team members, third parties, predecessor company repositories) may have non-duplicative documents.
- When speaking with any key third-party witnesses, inquire whether they have any materials that might be the property of the patent owner or licensees (e.g., research documents) that may be non-duplicative with materials still with the respective company.
- Include information technology team members in interviews in which document collection is to be discussed.
- Draft or review the litigation hold instruction letter and confirm the recipient list captures those individuals likely to have discoverable material. Where appropriate, inform third parties of the anticipated action.

Identify and Review Key Documents

Reviewing key documents is important for all of the reasons noted above in connection with speaking with people knowledgeable about the patent and product. You should collect or obtain the following documents:

- Records of primary discovery research (e.g., laboratory notebooks), summary reports, and bases for examples and data within the relevant patents
- The FDA package, and review at least the summary and Chemistry, Manufacturing, and Control (CMC) sections
- Records of licensing activities
- Patent prosecution records and cited art

Prepare for Document Collection and Possibly Begin Targeted Collections

If certain categories of documents can be identified that are likely to be produced in the litigation, it can be helpful to take all of the needed steps to complete those collections before the suit is filed, or at least before the discovery effort heats up during litigation. Take the following steps:

- Understand the client's preferred collection mechanisms, vendors for document collection, review, and management. On logistics matters for which the client has no preference, be prepared to provide appropriate recommendations.
- Obtain a rough estimate of the magnitude of a likely collection, production, and, eventually, privilege log.
- Initiate discussions with possible vendors and consider possible collection, review, and production timelines.
- Carry out targeted collections ahead of full-blown document discovery.

Identify Potential Experts

Certain issues, like obviousness, are raised in nearly every patent infringement action. Lining up suitable experts in likely technical areas in advance permits early exploration of case theory and ensures key opinion leaders remain available for the expert discovery phase of the case.

You should research and engage possible technical experts (e.g., chemists, biologists, pharmacologists, clinicians, formulators, toxicologists, etc.). Such research should include investigating whether the experts have any potential conflicts of interest, and whether the experts will be unavailable during trial or other key litigation periods. After experts have been engaged, discuss key documents with them to get a sense of how their expert opinions can be most effectively utilized.

Develop a Narrative of the Invention Story and Create a Preliminary Theory of the Case

The earlier you have a grasp of the invention story and start to synthesize a theory of the case—interpretation of the claims, benefits of the invention, capture of the infringing acts, alignment with the invention story—the more targeted and efficient each subsequent case preparation and litigation step will be. The following steps can help form your narrative and theory of the case:

- Review the record of patent-related proceedings, both U.S. and elsewhere. Identify patentability issues that repeatedly arose and that could arise in connection with an invalidity defense during litigation. Consider any other potential basis for challenges to validity (e.g., challenges pursuant to 35 U.S.C. §§ 101, 112; double patenting).
- Make a collection of key prior art (e.g., by considering all art-based rejections or invalidity/unpatentability assertions globally).
- Evaluate possible interpretations of claim language.
- Identify real-world indicators of the value of the invention (e.g., unmet need and accelerated FDA review, clinical/market impact, failure of competitors in field to arrive at comparable alternative products).
- Identify strategies generics may use in an effort to avoid infringement of the patents.

- Begin to synthesize a theory of the case. That is, evaluate interpretations of the patents and claims that exemplify the unique and unexpected features of the invention, avoid key prior art and potential invalidity arguments, aligns with the contributions made by the inventors, and covers anticipated generic products.

Monitor and Harmonize Positions Being Taken in Ongoing Patent Proceedings and Publications

Patent proceedings, whether ex parte prosecution or inter partes patent challenges, anywhere in the world, can provide inspiration for patent challengers, and potentially limit future arguments by the patentee. The sooner litigation counsel can involve themselves with these proceedings, the less likely positions may be taken that could be harmful in future litigation.

As litigation counsel, take steps to ensure you have the opportunity to review planned actions for ongoing patent proceedings, such as ongoing prosecution or patent challenges in foreign patent offices. Ensure that positions are consistent across jurisdictions and align with the invention story and theory of the case. Additionally, review drafts of relevant scientific journal articles prior to submission for publication to ensure no statements are made that, for example, speculate beyond what is evident from the data, as such statements by inventors or researchers are sometimes misused by litigation opponents.

Consider Whether to Close Prosecution

Patent prosecution presents a number of risks. For example, consider the following possibilities:

- Could a newly issued patent—either of the patent owner or potentially of an exclusive licensee—present a potential double patenting reference for an earlier issued, but later expiring patent?
- If a patent examiner took action on a pending claim, or uncovered additional prior art, could it signal new strategies to opponents in the infringement action? Or to overseas patent offices or patent challengers?
- Would the disclosure obligations of 37 C.F.R. § 1.56 require constant ongoing submission of litigation materials, potentially stimulating action by the examiner?

The risk-reward calculation will differ depending on the value added by the claims being pursued. Consider whether any possible additional claim scope is worth the risk of maintaining prosecution.

Evaluate Venue Options

Selection of a suitable venue is often considered late in the pre-suit process, generally after receiving notification from generic drug applicant that it has filed for marketing approval with the FDA. 21 U.S.C. §§ 355(b)(3), 355(j)(2)(B); 21 C.F.R. §§ 314.52, 314.95. When selecting a venue, consider which venues are most likely to be unchallenged by the expected generic manufacturers. Also consider pros and cons of likely possible venues given your theory of the case, such as experience of the bench with relevant pharmaceutical patent issues or accelerated litigation timelines for patent cases.

Other Advising Activities

Review the Brand Name Company's FDA Listing of Patents Covering the Product or Its Approved Indications and Usage Codes

When issued patents cover the brand name product or an approved method of use, the drug sponsor will submit FDA Form 3542/a with (3542a) or shortly after approval (3542) of an original NDA (or amendment or supplement). This form identifies these patents, and identifies usage codes for claimed methods (these can be thought of as an articulation of any indications or uses of the product that are both described in the product label and claimed in a patent). This information is then listed in the FDA's "Orange Book." Generic applicants wishing to market a competing product before expiration of any listed patent must submit a "Paragraph IV" certification as to their opinion, and to the best of their knowledge, that the patent in question is invalid, unenforceable, or will not be infringed. 21 U.S.C. §§ 355(b)(2), 355(j)(2)(A).

Consequently, you should collect and review all submitted FDA 3542/a Forms and consider whether any updates would be appropriate.

Consider Best Use of Pending Applications, Reissue Applications, or Certificates of Correction to Ensure Optimal Protection of the Invention

Optimizing patent protection, through pending applications or reissue, over a new drug product is essential to future litigation success, and, for the reasons discussed above, is best pursued long before litigation nears. Consider the following to ensure your new drug product has optimal protection:

- Whether possible invalidity defenses warrant pursing narrower claims. For example, could you obtain a claim that more narrowly captures the commercial dosage form? The clinical treatment protocol?
- Whether possible noninfringement defenses evident from your intelligence gathering on generic activity warrant pursuing broader claims.

- Whether there may be any benefit to submitting additional art through supplemental examination. 35 U.S.C. § 257.
- Determine whether a Certificate of Correction is warranted under 35 U.S.C. § 255 and 37 C.F.R. § 1.323.

Consider the Availability and Interplay of Patent Term Extensions and Adjustments

35 U.S.C. § 156 provides an extension to one patent claiming a product, a method of using that product, or a method of manufacturing that product, for a portion of the patent life overlapping with the clinical approval process (patent term extension (PTE)). The total extension is capped at 5 years from the original patent expiration, and at 14 years from drug product approval. See Patent Term Restoration under Calculating and Modifying Patent Term — Modifying the Patent Term.

35 U.S.C. § 154 provides an adjustment of patent term for certain delays by the Patent Office in advancing prosecution of an application (patent term adjustment (PTA)). See Patent Term Adjustment (PTA) under Calculating and Modifying Patent Term — Modifying the Patent Term.

Terminal disclaimers present a mechanism to bypass double patent challenges, including during litigation. The PTA provision does not permit adjustment of a term that has been disclaimed. 35 U.S.C. § 154(b)(2)(B). The PTE provision has no comparable language and has been interpreted as permitting extension from any terminally disclaimed date. See Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc., 482 F.3d 1317, 1322 (Fed. Cir. 2007).

For a patent with extra PTE (i.e., additional term would have been possible but for the 5- or 14-year caps), consider whether any PTA term may be exchanged for any unused periods of PTE. For example, a patent with one year of additional exclusivity due to PTA and four years of additional exclusivity due to PTE to the 5-year cap, but with another year or more of unused PTE, may be less susceptible to term-shortening due to double patenting if the PTA term is exchanged for PTE.

Consider the FDA's Guidance to Generics Regarding the Drug Product

For some products, such as solution-phase oral dosage forms, immediate-release solid oral dosage forms containing highly soluble and permeable active ingredients, or oral dosage forms intended to act locally on the GI tract, waivers of in vivo bioequivalence studies may be possible. See, e.g., FDA Guidance for Industry: Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System. Consider whether waivers might enable earlier generic applications.

For other products that might present safety concerns, the RLD sponsor may be able, through petition, to get the FDA to require generic applicants to carry out studies in addition to the normal demonstration of bioequivalence. See, e.g., Draft Guidance on Rifaximin, Revised March 2017. Consider whether any product-specific considerations warrant specialized testing, and avenues for alerting the FDA to these concerns (e.g., through a Citizen Petition).

Monitor Competing Innovative Products and Their Associated Patent Space

Although the litigation focus of branded companies tends to be on the activity of generic competitors, it is worth staying abreast of the state of exclusivity protecting other competing branded products. Steps taken by other brand name drug sponsors could stimulate ideas for further protection of your product. Approval of new brand name products, or loss of exclusivity by a competitor, could impact the expected market return of your product. Often these assessments of market impact require legal assessment of the strength of implicated patents.

You should monitor pending patent activity of brand names in similar patent space. Consider whether any potential claim scope could present an issue, or serve to motivate a similar patent strategy for your product. Assist your client in assessing the potential impact that the approval or genericization of competing brand name products may have on the market return of your product.

Conclusion

The above pre-litigation tasks are crucial to maximizing a product's exclusivity and ensuring best outcomes in litigation, and should be given serious, and ideally, early, consideration.

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Michael Furrow is a former medicinal chemist who counsels pharmaceutical and biotech innovators on all aspects of patent and related regulatory strategy from the early development stages through product launch and eventual high-stakes patent disputes. He has counseled on products covering dozens of therapeutic areas and has handled actions in federal courts and before the U.S. Patent and Trademark Office. Mike's background as a chemist affords him an intimate understanding of the challenges innate to the discovery of new medicines, and clients value his resulting drive to help them explore creative ways to maximize market exclusivities.

Combining his science background with his legal prowess, Mike is known for exhaustively exploring the facts and pushing the envelope on merits strategy. He engages with the technology at a level that permits him to develop strong relationships with inventors, scientific officers, and technical experts, and typically takes the lead on critical issues of patent infringement and validity throughout a matter, including trial. Mike has protected and defended innovation in all aspects of drug discovery, including new chemical entities, salt forms, prodrugs, solid-state forms, dosage forms, combination products, therapeutic methods, methods of manufacture, REMS programs, DNA polymerization, genetically modified organisms, and laboratory techniques and tools.

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April Abele Isaacson has 25 years of experience as a trial lawyer and is a registered United States patent attorney. Her practice focuses on pharmaceutical, biotechnology, and chemical patent litigation, particularly Hatch-Waxman cases on behalf of drug innovators. April has tried cases in several federal district courts throughout the United States, as well as appeals before the Federal Circuit, representing both plaintiffs and defendants. April also provides counseling on patent and related regulatory issues faced by the biopharma industry, including patent portfolio strategy, litigation preparation and strategy, licensing, patent term extension strategy, and Orange Book patent listing and Use Code strategy, and provides opinions on issues of patentability/validity, freedom-to-operate, and loss of exclusivity.

April previously served for nearly five years as in-house counsel at a public specialty pharmaceutical company where she provided broad intellectual property and regulatory strategic counseling during all stages of product development and managed numerous Hatch-Waxman litigations. She also served as a partner at a major international law firm and at a predecessor firm to Kilpatrick Townsend.

April began her legal career as a U.S. Navy JAG Corps prosecutor where she won several high profile jury cases and earned multiple achievement medals and letters of commendation for superior service and leadership. Prior to attending law school, she was an HIV/AIDS research scientist at Boston Children's Hospital.

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