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THE LIFE SCIENCES REPORT

Biotech Client Spotlight:

Siolta Therapeutics

From Bugs to Drugs: Siolta Aims to Leverage the Microbiome to Prevent and Treat Disease

Leveraging a deep understanding of the gut microbiome's systemic modulation of immune development and overall health, San Carlos, California-based

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Induced Infringement: Employing Safety and Efficacy to Extend Drug Exclusivity Periods

By Lizzy Doctorov (Associate, Palo Alto) and Rona Lamiquiz (Senior Associate, San Francisco)

Safety and efficacy findings that would require revisions to a drug label after bringing a drug to market can be used as an effective patent lifecycle management tool to postpone entry of generic drugs into the market and retain commercial exclusivity. Exclusivity refers to a period of time when a brand-name drug is protected from generic drug competition. The results of safety and efficacy trials can be pursued in subsequent new patents and can then be used to request that the U.S. Food and Drug Administration (FDA) require patented labeling resulting from the new patents on the drug. This, in turn, requires any generic manufacturers to include those elements on their labels, which may result in potential infringement of the new patents or eventually lead to delayed market entry for a generic drug. In short, the exclusivity period of the branded drug can be extended due to safety and efficacy trials. Additionally, this can be an effective response to generic manufacturers attempting to avoid active patents using "carve-outs."

What Is Induced Infringement and How Does it Apply to Pharmaceuticals?

"Whoever actively induces infringement of a patent shall be liable as an infringer."[1] Put simply, induced infringement is inducement by the defendant that actually causes another entity to directly infringe. The defendant must possess specific intent to "encourage another's infringement."[2] This requires a plaintiff to show that the defendant's actions actually "induced infringing acts" and that he knew or should have known his actions would induce infringement.[3] Circumstantial evidence can be sufficient.[4] For example, labels, marketing materials, catalogs, press releases, and expert testimony may be used.[5] When a plaintiff relies on a drug's label accompanying the marketing of a drug to prove intent, "[t]he label must encourage, recommend, or promote infringement."[6]

This area of law, as applied to drugs, is most commonly attributed to the entrance of generic manufacturers into the market. Induced infringement is seen when a generic manufacturer induces and actually causes physicians

[1] 35 U.S.C. § 271(b).
[2] *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006).
[3] *See id.*
[4] *Glaxosmithkline LLC v. Teva Pharms. U.S.A., Inc.*, 7 F.4th 1320, 1328 (Fed. Cir. 2021).
[5] *See id.* at 1340.
[6] *Takeda Pharm. USA, Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015).

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Biotech Client Spotlight: Siolta Therapeutics *(Continued from page 1)*

Siolta Therapeutics is hard at work developing live biotherapeutic products (LBPs) that target the core drivers of disease. Siolta is advancing a robust pipeline of defined consortia LBPs for inflammatory and infectious diseases. Its lead program, STMC-103H, is currently in phase 2 clinical development to prevent atopic diseases in at-risk newborns under fast-track designation, followed by two preclinical programs for recurrent bacterial vaginosis and necrotizing enterocolitis. The company has raised over $35 million in several private financing rounds led by Khosla Ventures.

The Siolta team, led by CEO Nikole Kimes (pictured in the middle).

Live biotherapeutics are designed to work with the body's natural systems to stop diseases before they start. The human microbiome plays an essential role across a broad spectrum of critical functionalities in healthy individuals, including proper metabolism, immune modulation, inflammatory signaling, fighting infections, and even neurophysiology. This provides a natural reservoir of synergistic therapeutic agents that can work together to address the underpinnings of complex and multifactorial diseases. Siolta's scientific hypothesis and resultant drug platform use targeted live biotherapeutics that have the potential to be more efficacious with fewer side effects. These targeted consortia of LBPs are defined multi-strain combinations of live bacteria of high therapeutic value that have been isolated from the healthy human microbiome (gut and vaginal) and manufactured under strict pharmaceutical-grade GMP standards.

Siolta's approach is to develop defined consortia live biotherapeutics that target multiple mechanisms of action at the same time to repair the underlying "root" cause of disease, rather than simply addressing individual symptoms. This approach has the potential to provide more comprehensive and long-lasting treatment outcomes for patients.

There are few FDA-approved microbiome-based products, given the nascency of the science in this field. While this sector has generated much investor and clinical interest, skepticism remains due to the limited commercial success of prescription microbiome drugs to date and some clinical failures.

Siolta intends to change that. Its STMC-103H is designed to modulate the gut microbiome by down-regulating the allergic response to prevent atopic diseases in at-risk newborns. If successful, the company intends to leverage this approach to treat a range of chronic inflammatory atopic diseases that share the same underlying cause of disease, such as food allergies, asthma, and allergic rhinitis. Phase 2 data from the lead program is expected in 2026.

Dr. Nikole Kimes, Siolta's co-founder and CEO, was a researcher at the University of California, San Francisco (UCSF) before starting the company in 2016 with Dr. Susan Lynch, a UCSF professor and pioneer in the human microbiome field. Dr. Lynch's work has moved far beyond the early characterization studies and has provided a greater understanding of the gut microbiome's systemic modulation of immune development and overall health.

A first-time CEO, Dr. Kimes brings deep scientific training and an intense passion to the company's mission. "Imagine holding your newborn baby and knowing that they are at risk for developing a lifelong chronic disease. Now imagine being able to provide an effective treatment option that can be safely delivered in the first days of life that would alleviate and change that outcome," she commented.

Siolta's approach is to develop defined consortia live biotherapeutics that target multiple mechanisms of action at the same time to repair the underlying "root"

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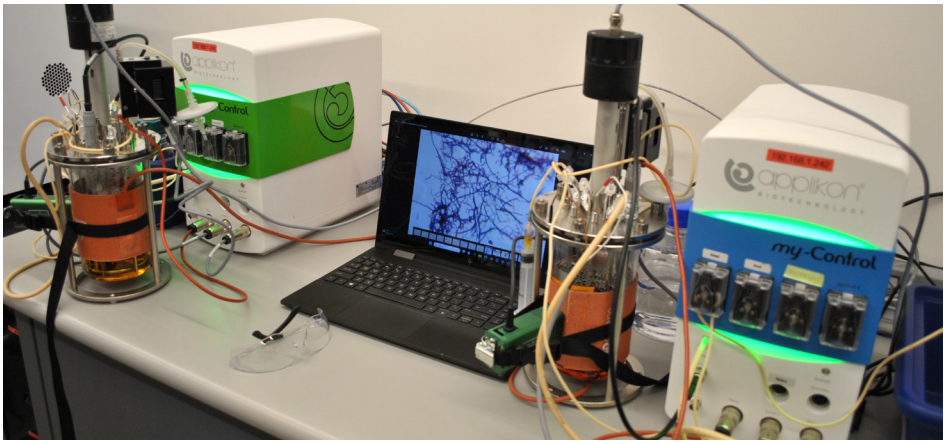
Biotech Client Spotlight: Siolta Therapeutics *(Continued from page 2)*

cause of disease, rather than simply addressing individual symptoms. This approach has the potential to provide more comprehensive and long-lasting treatment outcomes for patients. The notion of addressing disease before it causes permanent damage is a fundamentally different way of thinking about healthcare; not only would it transform health outcomes, but it would also dramatically reduce the cost burden of such diseases.

Asked about her experience building and running a biotech for the first time, Dr. Kimes said, "I learned the vast majority of what I needed to know through a welcoming community that openly and willingly shared its experiences and resources. I was willing to ask questions about all the things I never even knew I needed to know to develop therapeutics, everything from business licenses to intellectual property to accounting practices. The skills for building a team were a bit more intuitive, although they needed to be fostered through mentoring and guidance. Interestingly for me, I found all the new aspects of daily life to be just as compelling as the science, and eventually, it became clear that I was actually the perfect person to lead this company on such a unique journey."

Wilson Sonsini is advising Siolta on intellectual property and business advisory matters.



The Siolta lab, located in San Carlos, California.

About Wilson Sonsini's Business Advisory Practice

The firm's unique and innovative Business Advisory Practice (BAP) provides life sciences companies with broad business support in the areas of private financings, partnering and other strategic transactions, deal valuation and transaction comparables, and other critical business objectives. The BAP complements the firm's outstanding legal counsel with industry-experienced business and licensing advisors to support and accelerate growth through strategic business advice. For more information, please visit https://www.wsgr.com/en/life-sciences-business-advisory-practice.html.

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Induced Infringement: Employing Safety and Efficacy to Extend Drug . . . *(Continued from page 1)*

to directly infringe a patent by prescribing generic drugs for treatment.

A new small molecule drug or a new use of a previously approved small molecule drug cannot be marketed or commercialized in the United States unless the FDA has approved the new drug product or the new use via a New Drug Application (NDA).[7] The Hatch-Waxman Act allows generic manufacturers to rely on a branded drug's FDA-approved NDA by submitting an Abbreviated New Drug Application (ANDA) showing that the generic drug has the same active ingredients and is bioequivalent to the brand-name drug.[8]

Options for Generic Manufacturer Entrants

When a branded drug manufacturer receives a patent, obtains FDA approval, and markets the drug, a generic manufacturer has three options for entry: wait, proceed identically to the branded drug manufacturer, or carve out indications.

First, the generic manufacturer can wait until the branded drug manufacturer's patent expires.

Second, the generic manufacturer can ask the FDA for approval to market their generic drug while the branded patent is active by stating that they believe the branded patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." The generic manufacturer may do this by submitting a "Paragraph IV" certification, which notifies the NDA holder/patent owner.[9] The Hatch-Waxman Act provides a 30-month stay of FDA approval of the ANDA unless otherwise directed by court order, thereby giving the branded manufacturer the chance to sue the generic manufacturer.

Lastly, the generic manufacturer can propose a label to the FDA that "carves out" the patented uses and submit a "section viii" statement to that effect.[10] If the FDA approves the carved-out label, the generic manufacturer may market the drug "only for a subset of approved uses—i.e., those not covered by the brand's patents."[11] For example, the alternate uses can include different indications or use for a different population.

Case Studies: Safety and Efficacy Trials as Patent Lifecycle Management Tools

A generic drug may only carve out an indication if the label, after the carve-out, does not "render the proposed drug product less safe or effective than the listed drug for all remaining, non-protected conditions of use."[12] The FDA evaluates proposed carve-outs on a case-by-case basis to determine whether the differences would render a generic product less safe or effective than the branded product. A brand drug company can make use of this regulation by discovering and patenting relevant safety or efficacy facts that generic companies will be required to include, thereby forcing the generic company into infringing the patent or waiting until the new patent expires. Safety and efficacy findings can be useful tools both before and after generic manufacturers enter the market.

A citizen petition is a way for individuals, regulated industry representatives, or consumer groups to petition the FDA to issue, amend, or revoke a regulation, or to take other administrative action under 21 C.F.R. § 10.30.[13] As it relates to drugs, a citizen petition can be used before a generic enters the market to request that the FDA refuse ANDAs of generics unless they have a specific safety disclosure, and it can be used after a generic enters by demonstrating to the FDA that the generic is unsafe because the label does not have a specific safety disclosure. For example, Jazz Pharmaceuticals, Inc. submitted a citizen petition to the FDA to request that the FDA refuse any ANDA that did not include labeling regarding a newly discovered negative drug-drug interaction that Jazz held a patent on.[14] As the drug was a central nervous system depressant with significant side effects alone, the FDA judged that prescribing it without knowledge of the negative interaction could lead to difficulty breathing and death, and that omitting the disclosure would thus render a generic drug less safe. Jazz was able to extend its exclusivity period because any generic manufacturer that went to market would automatically be infringing the patented interaction disclosed on the drug labels.

In instances where the generic manufacturer 1) has not yet entered the market and 2) intends to use the same label as the NDA for the generic ANDA approval by the FDA, patented safety and efficacy clinical trial findings referred

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[7] *See* 21 U.S.C. § 355.
[8] *See Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404–05 (2012).
[9] *See Caraco*, 566 U.S. at 407; 21 U.S.C. § 355(j)(2)(A)(vii)(IV).
[10] *See Caraco*, 566 U.S. at 406.
[11] *Id.*
[12] 21 C.F.R. § 314.127(a)(7).
[13] Additional information on citizen petitions as they relate to drugs can be found at https://www.wsgr.com/en/insights/citizen-petitions-are-crucial-in-managing-a-drugs-life-cycle.html.
[14] *See* Food & Drug Admin, Docket No. FDA-2016-P-2672 (2017).

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to in the NDA label can be used to find induced infringement. In *Sanofi v. Watson Laboratories Inc.*, Watson submitted to the FDA an ANDA with a label that was identical to Sanofi's label, which referenced Sanofi's clinical safety studies, stating that it believed Sanofi's patent to be invalid.[15] The court did not find the patent invalid, which led to Watson's induced infringement of Sanofi's patent due to including references to the clinical trial results underlying the patent.

A drug label can be supplemented with new indications, new patient populations, new dosing regimens, and/or new companion diagnostics by citing positive or negative clinical trial results showing changed safety or efficacy. This way, clinical trials can become an effective patent lifecycle management tool for brand-name drugs.

Case Studies: Careful Carve-Outs

Generic drug manufacturers frequently use the law of carve-outs to get their drugs on the market while avoiding patented indications. However, in some cases, there may be a blurred line between a specific patented indication and the indication chosen by the generic drug manufacturer, based in part on how they market their generic drug. Even if a label does not explicitly state the patented indication, 1) marketing materials that "guided doctors to the label and to its website promoting [the] patented use," 2) a press release, 3) expert testimony, and 4) the generic drug label may suggest that the generic drug company intended to induce infringement.[16]

However, the court in the most recent induced infringement case, *H. Lundbeck A/S v. Lupin Ltd.*, explicitly contrasted *Lundbeck* to *GSK*, stating that where there are no marketing materials, press releases, or other promotional materials that encourage infringement, and the ANDA label properly carves out the patented indication, there is no induced infringement.[17] Lundbeck sued Lupin for filing an ANDA for treating major depressive disorder (MDD) in adults when Lundbeck held method patents on the same drug for treating cognitive impairment and treating MDD in patients who had previously taken certain other drugs but had ceased or reduced their use due to sexually related adverse events.[18] The court stated that "it is not an act of infringement under 35 U.S.C. § 271(e)(2)(A) to submit an ANDA for a drug if just any use of that drug were claimed in a patent" because it would then be simple for a brand company to completely control a drug, which was not intended by Congress.[19] Instead, suits for infringement of method of use patents under Section 271(e)(2)(A) are limited to patents that claim an indication of the drug for which the applicant is seeking FDA approval. The court noted that even though a doctor may end up prescribing the generic drug for an infringing use, "mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven."[20] This case narrows the power given to induced infringement suits over the past decade. Although differentiated from *GSK*, this case suggests that generics can submit ANDAs for general disease treatments without infringing specific patented uses. However, brand drug companies may still be able to use safety and efficacy forced label inclusion to drive generics into induced infringement.

A generic drug manufacturer that intends to come to market while a patent listed by the NDA holder is active can do so by carving out a use that is different than the patented use or by asserting the patent is invalid or not infringed and using the same label as the brand manufacturer

Takeaways for Practitioners

A generic drug manufacturer that intends to come to market while a patent listed by the NDA holder is active can do so by carving out a use that is different than the patented use or by asserting the patent is invalid or not infringed and using the same label as the brand manufacturer. New patent filings can provide both overlapping patent term until branded drug patent expiry and additional patent exclusivity for claims that can be translated into edits to the label. Clinical trials and studies can be an effective patent lifecycle management tool by the brand company to extend commercial exclusivity. This can include new indications, new patent populations, new dosing, new companion diagnostics, new drug interactions, and other similar types of information. Information on safety and efficacy derived from these studies can be used to demonstrate to the FDA that a drug's labels must have the information to comply with the FDA's ANDA laws. This can either be

[15] 875 F.3d 636, 642 (Fed. Cir. 2017).
[16] *See GSK*, 7 F.4th at 1338.
[17] 87 F.4th 1361, 1370 (Fed. Cir. 2023).
[18] 87 F.4th 1366-67.
[19] *See id.* at 1369.
[20] *Id.* at 1372.

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done through a citizen petition or can be included in the branded label so that generics intending to use the same label have the same patent-infringing information.

In rare cases, even though a generic manufacturer has carved out a use, the marketing materials may still induce a physician to prescribe the drug for the patented use. A brand company can potentially use the marketing materials in conjunction with the generic label as a case for inducing infringement. However, *Lundbeck* recently enforced the idea that carving out a patented indication makes it difficult to prove induced infringement, so safety and efficacy findings are likely the stronger tool in the patent lifecycle management tool belt for branded companies, as the FDA may not allow important safety considerations to be carved out.

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Wilson Sonsini Hosts LaunchBio's NextGen VC Forum in San Francisco

On May 16, 2024, Wilson Sonsini hosted LaunchBio's first NextGen VC Forum of the year in the firm's San Francisco office. The invitation-only, half-day event, which drew more than 30 attendees, included a networking breakfast, three curated education sessions featuring discussions with industry leaders, and lunch.

Following welcome remarks from Wilson Sonsini partners and program curators Dan Koeppen and Mike Hostetler, the event continued with an interactive session titled "Investment Firm/Executive Compensation: The Inside Track." Featuring Thelander Consulting CEO Jody Thelander and employee benefits and compensation partner Michelle Wallin, the session reviewed compensation data and trends for venture capital firms across all asset classes and locations. In addition, Jody shared insights into the various compensation levers, how to utilize them, what filters make a difference in customizing compensation data, and what you need to know as you move up the ranks.

In the second session, "Navigating Antitrust Regulations in Biotech Mergers: Safeguarding Innovation and Investment," antitrust partners Brendan Coffman and Michelle Yost Hale discussed the potential impact of recent challenges and antitrust agency scrutiny of life sciences M&A on biotech firms and the implications for venture capital investors. Specifically, they discussed the Federal Trade Commission and Department of Justice's approach to merger review, recent developments in merger enforcement, and how changes to merger review and enforcement could impact VC investment in the biotech industry.

Attendees then enjoyed a networking lunch, followed by a final session titled "Venture Capital Company Creation: Strong Foundations for Success" that featured Of Counsel Phil McGill and patents and innovations partner Deborah Smith. Phil and Deborah explored the essential steps of how VC firms approach company creation, including identifying promising technologies, safeguarding core assets, assembling a talented team, structuring initial funding, and enabling future syndication. They also discussed the critical role of IP in evaluating new company opportunities and developing effective strategies for maximizing company value.

Presented by LaunchBio in partnership with Wilson Sonsini, the NextGen VC Forum is the premiere event for mid-level venture capital associates to expand their skills and expertise while growing their network.

Life Sciences Venture Financings for Wilson Sonsini Clients

By Scott Murano, Partner (Palo Alto/San Francisco)

The table below includes data from life sciences transactions in which Wilson Sonsini clients participated across the first and second halves of 2023. Specifically, the table compares—by industry segment—the number of closings, the total amount raised, and the average amount raised per closing across the two six-month periods.

	1H 2023	1H 2023	1H 2023	2H 2023	2H 2023	2H 2023
Life Sciences Industry Segment	**Number of Closings**	**Total Amount Raised ($M)**	**Average Amount Raised ($M)**	**Number of Closings**	**Total Amount Raised ($M)**	**Average Amount Raised ($M)**
Biopharmaceuticals	70	$882.74	$12.61	65	$1,179.32	$18.14
Genomics	9	$128.05	$14.23	5	$82.98	$16.60
Diagnostics	14	$156.77	$11.20	10	$62.48	$6.25
Medical Devices & Equipment	69	$483.33	$7.00	36	$284.46	$7.90
Digital Health	35	$372.46	$10.64	14	$115.27	$8.23
Healthcare Services	28	$153.25	$5.47	26	$392.19	$15.08
Total	**225**	**$2,176.60**		**156**	**$2,116.70**	

The data demonstrates that overall venture financing activity decreased from the first half of 2023 to the second half of 2023 with respect to the total amount raised and number of closings. Specifically, the total amount raised across all industry segments decreased 2.8 percent, from $2,176.60 million to $2,116.70 million, while the total number of closings across all industry segments decreased 30.7 percent, from 225 to 156.

The industry segment with the largest number of closings during the second half of 2023—biopharmaceuticals—saw a slight decrease in number of closings but a significant increase in total amount raised from the first half of 2023 to the second half of 2023. Specifically, the number of biopharmaceuticals closings decreased 7.1 percent, from 70 to 65, while the total amount raised increased 33.6 percent, from $882.74 million to $1,179.32 million. Similarly, the industry segment with the third-largest number of closings during the second half of 2023—healthcare services—saw a marginal decrease in number of closings, but a significant increase in total amount raised. Specifically, the number of closings in the healthcare services segment decreased 7.1 percent, from 28 to 26, while the total amount raised increased 155.9 percent, from $153.25 million to $392.19 million.

> The total amount raised across all industry segments decreased 2.8 percent from 1H 2023 to 2H 2023, while the total number of closings decreased 30.7 percent

All remaining industry segments experienced a decrease in both the number of closings and total amount raised from the first half of 2023 to the second half of 2023. The industry segment with the second-largest number of closings during the second half of 2023—medical devices and equipment—experienced a 47.8 percent decrease in number of closings, from 69 to 36, and a 41.1 percent decrease in total amount raised, from $483.33 million to $284.46 million. The industry segment with the fourth-largest number of closings during the second half of 2023—digital health—experienced a 60.0 percent decrease in number of closings, from 35 to 14, and a 69.1 percent decrease in total amount raised, from $372.46 million to $115.27 million. The industry segment with the fifth-largest number of closings during the second half of 2023—diagnostics—experienced a 28.6 percent decrease in number of closings, from 14 to 10, and

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Life Sciences Venture Financings for Wilson Sonsini Clients *(Continued from page 7)*

a 60.1 percent decrease in total amount raised, from $156.77 million to $62.48 million. And finally, rounding out the field with the fewest number of second-half closings, genomics experienced a 44.4 percent decrease in number of closings, from nine to five, and a 35.2 percent decrease in total amount raised, from $128.05 million to $82.98 million.

In addition, our data generally suggests that Series Seed, Series A, Series B, and Series C and later-stage financing activity, as a percentage of all financing activity and measured by number of closings, increased from the first half of 2023 to the second half of 2023, while recapitalization and other non-traditional financing activity decreased over that same period. Specifically, the number of Series Seed closings as a percentage of all closings increased from 7.0 percent to 19.0 percent, the number of Series A closings increased from 16.6 percent to 28.8 percent, the number of Series B closings increased from 7.0 percent to 8.6 percent, and the number of Series C and later-stage closings increased from 7.0 percent to 12.3 percent. The number of recapitalization closings as a percentage of all closings decreased from 1.3 percent to 1.2 percent, and the number of other non-traditional financing closings decreased from 38.9 percent to 7.4 percent.

> Average pre-money valuations for life sciences companies decreased for Series B financings, but increased for Series Seed, Series A, and Series C and later-stage financings from the first half of 2023 to the second half of 2023

Average pre-money valuations for life sciences companies decreased for Series B financings, but increased for Series Seed, Series A, and Series C and later-stage financings from the first half of 2023 to the second half of 2023. Specifically, the average pre-money valuation for Series B financings decreased 71.0 percent, from $189.51 million to $55.0 million, while the average pre-money valuation for Series Seed financings increased 17.4 percent, from $13.18 million to $15.47 million; the average pre-money valuation for Series A financings increased 4.7 percent, from $33.78 million to $35.38 million; and the average pre-money valuation for Series C and later-stage financings increased 5.7 percent, from $148.70 million to $157.14 million.

Overall, the data indicates that the total dollars invested in life sciences companies during the second half of 2023 was essentially the same as the first half of 2023, but the number of closings in which those funds were deployed dropped significantly. The data aligns with the general sentiment among companies that financings are harder to come by these days. That being said, for those companies that are able to secure funding, the amount of capital deployed over the second half of 2023 was more or less constant from the prior six-month period, and for all but Series B financings, at improved pre-money valuations—data that should be encouraging to companies still looking for financing. The interest and amount of available capital is there; investors are just being more selective about which companies to invest in. We do not expect this level of private financing activity to change much until the economy settles and the public capital markets reemerge as a viable source of capital for later-stage life sciences companies.

> The interest and amount of available capital is there; investors are just being more selective about which companies to invest in

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Updated USPTO Guidance for Determining Non-obviousness Reiterates Need for Robust and Flexible Patent Applications

By Darby Chan (Of Counsel, San Francisco/Palo Alto) and Hin Au (Associate, Palo Alto)

Almost two decades ago, the U.S. Supreme Court issued a decision in the landmark *KSR Int'l Co. v. Teleflex Inc.* case. Prior to that decision, the courts and the U.S. Patent and Trademark Office (USPTO) decided whether inventions are obvious largely by applying the teaching-suggestion-motivation (TSM) test. The *KSR* decision stated that the TSM test had been applied too rigidly, which conflicted with the broader test for obviousness established by the Supreme Court in *Graham v. John Deer Co.* (1966). The *KSR* decision emphasized that a more flexible approach is required.

In February 2024, the USPTO issued updated guidance reiterating that non-obviousness should be evaluated flexibly, consistent with the *KSR* decision. This recent USPTO guidance emphasizes the need for patent applicants, including those in the life sciences, to have robust and flexible patent applications to successfully overcome obviousness rejections to issue as patents.

An Emphasis on Flexibility

The flexibility emphasized by the recent USPTO guidance has two key aspects: (1) understanding the scope of prior art and (2) reasons to modify the prior art.

(1) A Flexible Approach to Prior Art

Patent examiners need to consider what a person having ordinary skill in the art (PHOSITA) would reasonably infer from the prior art, considering this person's ordinary creativity and "common sense." A proper understanding of the prior art should extend to all that it reasonably suggests and not be limited to its explicit teachings. Examiners also need to evaluate whether the prior art is analogous or pertinent to the claimed invention.

(2) Flexible Reasons to Modify Prior Art

Patent examiners should be flexible in providing reasons to modify the prior art if their rejections are based on a modification to the prior art. Many factors can provide reasons to combine or modify prior art disclosures, such as market forces, design incentives, interrelated teachings of multiple patents, known issues in the field addressed by the claimed invention, and even so-called "common sense" of a PHOSITA. A reason to optimize prior art parameters may stem from a PHOSITA's desire to improve upon the prior art.

Flexibility, however, does not dismiss the need for sound reasoning based on evidentiary support. A proper obviousness rejection requires a clear articulation of the reasoning that a claimed invention would have been obvious.

Assessing the Complete Picture: Considering All Evidence

According to the *Graham* case, non-obviousness has to be evaluated based on the scope and content of the prior art, differences between the prior art and claims, and the level of ordinary skill. Also, "secondary considerations" or objective indicia of non-obviousness can be evidence of non-obviousness. These may include evidence of commercial success, long-felt but unsolved needs, or failure of others, which can provide insight into the circumstances surrounding the claimed invention.

The updated guidance reinforces that patent examiners should consider such objective evidence when present. Examiners must weigh such evidence against any case of obviousness from the other *Graham* inquiries and be willing to reevaluate based on any new evidence provided.

Implications for Patent Applicants

For patent applicants, this updated USPTO guidance reiterates the importance of drafting robust and flexible patent applications. Patent applicants should not view patent drafting as simple exercises in writing technical description.

Patent applicants should get ahead of possible obviousness rejections with the information drafted into their detailed descriptions. A general practice is to draft patent applications to broadly cover any possible use case for the claimed inventions. Patent applications should also provide specific and well-elaborated examples of important use cases so that patent applicants can refute assertions of certain prior art being considered analogous or pertinent. Possible advantages of the claimed inventions, including the meeting of various design constraints and providing solutions to various technical problems, should be included to be available to refute reasons to modify prior art that patent examiners may imagine. Including such inventive advantages can also serve as the basis for non-obviousness arguments based on "secondary considerations." In addition, possible advantages for key

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Updated USPTO Guidance for Determining Non-obviousness . . . *(Continued from page 9)*

parameter ranges and results should be included so that patent applicants can confidently state that such ranges are not simply "routine optimization." Prior art searching is also encouraged so that the patent applicants and drafters have a strong sense of what prior art to get ahead of.

To successfully draft and advance patent applications to grant under the latest USPTO guidance, clients are encouraged to reach out to the patent team at Wilson Sonsini early so that their patent applications can be in the best position to succeed.

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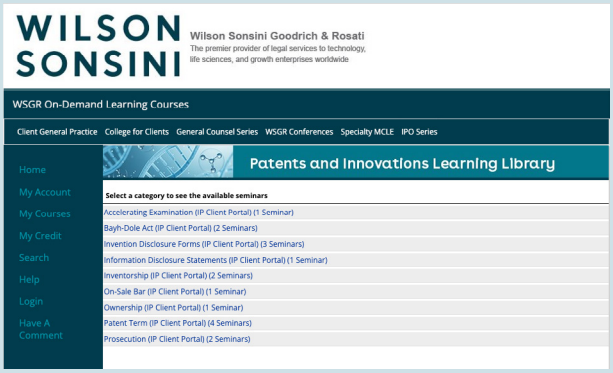
Firm Launches Patents and Innovations Learning Library for In-House IP Counsel

Earlier this year, Wilson Sonsini launched a unique offering tailored specifically to our patent clients—the Patents and Innovations Learning Library. This curated collection of educational materials is designed to empower in-house IP counsel in the life sciences and technology sectors with the knowledge and insights needed to navigate the complex world of patent law.



Available in the On-Demand Learning section of the firm's website, this comprehensive content suite covers real-world topics such as inventorship, ownership, on-sale bar, accelerating examination, the Bayh-Dole Act, disclosure statements, maximizing the patent term, prosecution, and invention disclosure forms. Current content offerings include the following:

- Inventorship in Collaborations
- Inventorship Counseling & Notebook Policies
- General Considerations on Patent Ownership
- USPTO Prosecution Petition Practice – Six Ways to Go Faster
- Do Not Get Burned by Bayh-Dole
- Information Disclosure Statement (IDS) Practice Information
- Patent Timelines – Expiration Dates, PTA, PTE, Market Exclusivity
- Patent Term Extension and Terminal Disclaimers
- Patent Term Adjustment Strategy Series – *In re Cellect* (ODP, TDS, and loss of PTA)
- Why Reply to a Final Office Action in Two Months?
- Information Disclosure Statements: Communications with the FDA and Other Government Agencies
- Invention Disclosure Forms – Digital Health Invention Disclosure Form, Antibody Biologic Invention Disclosure Form, and Biologic Invention Disclosure Form

This exclusive collection of educational materials is designed to complement—rather than replace—the firm's personalized legal advice.

To access the Patents and Innovations Learning Library, please log in to Wilson Sonsini's On-Demand Learning Portal here. (For instructions to create an account, click here.)

Now Available: New Episodes of LaunchBio and Wilson Sonsini's NextGen VC Podcast Focused on Life Sciences Investing

In late 2023, LaunchBio and Wilson Sonsini introduced the NextGen VC Podcast, the premier podcast for forward-thinking venture capitalists eager to dive in and sharpen their skills. Hosted by Wilson Sonsini partners Michael Hostetler and Jennifer Fang, the podcast unpacks the opportunities, challenges, and breakthroughs shaping life sciences investing today. Each episode features interviews with seasoned venture capitalists, successful entrepreneurs, and industry leaders. Listeners will gain an understanding of how the pros have navigated challenges, made strategic decisions, and achieved remarkable success.

Please see below for additional details on the latest podcast episodes.

Episode 4:
Amy Simmerman
Corporate Partner,
Wilson Sonsini

Amy, a corporate governance expert from Wilson Sonsini's Wilmington, Delaware office, discusses the legal nuances of serving as a biotech company board director and explores duties of care and loyalty, conflict of interest management, and the importance of confidentiality and transparency. Special attention is given to the challenges venture investors face balancing their duties to the companies they invest in with their responsibilities to their funds. Note: This episode introduces the "Venture Ed" series aimed at biotech investors.

Episode 3:
Katie Spielberg, Ph.D.
Senior Associate, 5AM Ventures

Katie, who focuses on both early-stage biotech investments and new company formation, offers insight into her career path, highlighting the significance of intellectual curiosity and networking. She also discusses the formation of MIT's first biotechnology student initiative and the potential future shifts in the biotech industry, focusing on the need for increased investment and understanding in the field of women's health.

Episode 2:
Hyung Chun, M.D.
Director, Foresite Capital Management

As a seasoned physician-scientist and cardiologist, Dr. Chun brings a unique perspective to the investment landscape, evaluating opportunities and understanding how to drive early discoveries to the clinic. He shares insights into his steps to become an investor from his tenured faculty position at Yale School of Medicine and discusses how to learn what you don't know, the similarities between being a physician-scientist and a venture capitalist, and his vision for the future of biotech.

Episode 1:
Neena Kadaba, Ph.D.
Entrepreneur in Residence,
Apple Tree Partners

Neena discusses her journey from studying chemistry at MIT to becoming a venture capitalist in the biotech industry. She addresses her initial attraction to science, her experience as a Kauffman Fellow, and her role at Apple Tree Partners, a life science venture fund that creates biotech companies to translate emerging science into new therapies. Neena also emphasizes the importance of curiosity, communication, and building a network in the world of venture capital.

To subscribe to the NextGen VC Podcast, visit https://launchbio.org/nextgen-vc-podcast/.

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Wilson Sonsini Sponsors National Inventors Hall of Fame Induction Ceremony

On May 9, 2024, the National Inventors Hall of Fame held its annual Induction Ceremony in Washington, D.C., to celebrate the latest class of inductees who have made exceptional contributions to society. Wilson Sonsini Goodrich & Rosati was a visionary sponsor of the event, which was hosted in partnership with the United States Patent and Trademark Office. Sir Shankar Balasubramanian, founder of Solexa (acquired by Illumina in 2007) and firm client Biomodal, was honored among the 2024 inductees. Numerous Wilson Sonsini patents and innovation practitioners were in attendance, including partners Vern Norviel, Lou Lieto, Ali Alemozafar, and Derrick Rowe; senior patent counselor Bruce Kisliuk; and senior counsel Jeff Seidel, as well as chief licensing advisor Kathy Ku.

Wilson Sonsini extends its congratulations to Sir Shankar Balasubramanian, who, along with co-inductee Sir David Klenerman, invented Sequencing-by-Synthesis (SBS), a next-generation DNA sequencing (NGS) method that made possible efficient, low-cost, and large-scale genome sequencing. Enhancing the understanding of life, SBS has enabled applications in genomics, medicine, and biology. Sir Shankar Balasubramanian holds 23 U.S. patents and serves as professor of medicinal chemistry at the University of Cambridge and research leader at the Cancer Research UK Cambridge Institute. He was knighted for his contributions to science and medicine in 2017, and his many awards include the 2022 Breakthrough Prize in Life Sciences.

To learn more about the National Inventors Hall of Fame, visit https://www.invent.org/inductees/induction.

Select Recent Life Sciences Client Highlights

Since the start of this year, Wilson Sonsini has provided representation in connection with the below client matters:

- Advised **Plenful** on its $17 million Series A (May 2024)
- Advised **Atropos Health** on its $33 million Series B (May 2024)
- Advised **Radar Therapeutics** on IP matters related to its $13.4 million seed financing (May 2024)
- Advised **Mirus Bio** and **Gamma Biosciences** on patent matters related to Mirus Bio's $600 million sale to Merck KGaA, Darmstadt, Germany (May 2024)
- Advised **Novo Holdings** on IP matters related to its acquisition of a majority stake in Single Use Support (May 2024)
- Advised **Venrock** on IP matters related to Lycia Therapeutics' $106 million Series C (May 2024)
- Advised **Reneo Therapeutics** on IP matters related to its merger with OnKure (May 2024)
- Advised **Karius** on IP matters related to its $100 million Series C (May 2024)
- Advised **SR One, Norwest Venture Partners,** and **Delos Capital** on Zenas BioPharma's upsized $200 million Series C (May 2024)
- Advised **Soleno Therapeutics** on its $138 million public offering (May 2024)
- Advised **Transcarent** on its $126 million Series D (May 2024)
- Advised **Novo Holdings** on Reunion Neuroscience's $103 million Series A (May 2024)
- Advised **Aledade** on its acquisition of Medical Advantage (May 2024)
- Advised **Enlaza Therapeutics** on IP matters related to its $100 million Series A (April 2024)
- Advised **Rubedo** on its $40 million Series A financing (April 2024)
- Advised **Investors** on D3 Bio's $62 million Series A+ financing (April 2024)
- Advised **Kumquat Biosciences** on its $1.2 billion strategic collaboration with Takeda (April 2024)
- Advised **ProfoundBio** on patent matters related to its acquisition by Genmab (April 2024)
- Advised **Alterome** on its $132 million Series B (April 2024)
- Advised **Boundless Bio** on IP matters related to its IPO (March 2024)
- Advised **Floreo** on its acquisition of Autism Eyes (March 2024)
- Advised **Novo Holdings** on Obsidian's oversubscribed $160.5 million Series C (March 2024)
- Advised **Aeovian Pharmaceuticals** on patent matters related to its $50 million Series A (March 2024)
- Advised **Stoke Therapeutics** on IP matters related to its upsized public offering (March 2024)
- Advised **Loyal** on patent matters related to its $45 million Series B (March 2024)
- Advised **LENZ Therapeutics** on its completed merger with Graphite Bio (March 2024)
- Advised **Tempo Therapeutics** on its $12 million Series A (March 2024)
- Advised **HealthQuest Capital** on its investment in Alcresta Therapeutics (March 2024)
- Advised **Lexeo** on its oversubscribed $95 million equity financing (March 2024)
- Advised **Milu Health** on its $4.8 million seed round (March 2024)
- Advised **C4T** on its strategic discovery research collaboration with Merck KGaA, Darmstadt, Germany (March 2024)
- Advised **Sana Biotechnology** on its upsized follow-on offering (February 2024)
- Advised **Metagenomi** on IP matters related to its $93 million IPO (February 2024)
- Advised **Freenome** on IP matters related to its $254 million funding (February 2024)
- Advised **Kinnate Biopharma** on its acquisition by XOMA (February 2024)
- Advised **Prime Medicine** on IP matters related to its upsized public offering (February 2024)
- Advised **Denali Therapeutics** on its $500 million private placement financing (February 2024)
- Advised **Janux Therapeutics** on IP matters related to its $296.5 million underwritten public offering (February 2024)
- Advised **Avidity Biosciences** on patent matters related to its $400 million private placement (February 2024)

Continued on page 14...

Select Recent Life Sciences Client Highlights *(Continued from page 13)*

- Advised **vTv Therapeutics** on patent matters related to its $51 million private placement financing (February 2024)
- Advised **Neurona Therapeutics** on its $120 million financing (February 2024)
- Advised **Tenaya Therapeutics** on its $50 million underwritten offering (February 2024)
- Advised **Fannin Partners** on Procyrion's $57.7 million Series E (February 2024)
- Advised **Fractyl Health** on patent matters related to its $110 million IPO (February 2024)
- Advised **ORIC Pharmaceuticals** on its $125 million private placement financing (January 2024)
- Advised **Halia Therapeutics** on its $30 million Series C financing (January 2024)
- Advised **Motif Neurotech** on its $18.75 million Series A financing (January 2024)
- Advised **Edgewise Therapeutics** on its $240 million underwritten offering (January 2024)
- Advised **Cleveland Diagnostics** on its $75 million growth capital financing (January 2024)
- Advised **Alector** on its $75 million underwritten offering (January 2024)
- Advised **Arena BioWorks** on patent and transactional matters related to its launch (January 2024)
- Advised **Noctrix Health** on its $40 million Series C financing round (January 2024)
- Advised **Ji Xing Pharmaceuticals (JIXING)** on its acquisition of BIIB131 from Biogen (January 2024)
- Advised **Ji Xing Pharmaceuticals (JIXING)** on its strategic collaborations with TMS Co., Ltd. (January 2024)
- Advised **Foresight Diagnostics** on its strategic partnership with Allogene Therapeutics (January 2024)
- Represented **Concord Healthcare Group Co., Ltd.** in its $72 million IPO and listing on the Main Board of the Stock Exchange of Hong Kong (January 2024)
- Advised **Ambrx Biopharma** on patent matters related to its $2 billion acquisition by Johnson & Johnson (January 2024)
- Advised **Harpoon Therapeutics** on IP matters related to its $680 million acquisition by Merck (January 2024)
- Represented **Insilico Medicine** in its exclusive license agreement with Menarini Group (January 2024)
- Advised **ImmunityBio** on its $320 million royalty financing and equity investment by Oberland Capital (January 2024)
- Advised **Radionetics Oncology** on IP matters related to its $52.5 million Series A (January 2024)
- Represented **Replace Therapeutics** in its acquisition by Tome Biosciences (January 2024)

Upcoming Life Sciences Events

Wilson Sonsini's Medical Device & Digital Health Conference
June 13-14, 2024
The Palace Hotel
San Francisco, CA
https://mdc.wsgrevents.com/

Wilson Sonsini's 31st Annual Medical Device & Digital Health Conference will address topics of critical importance to medical device and digital health companies today, including early and late-stage venture financing, partnering strategies for AI and digital health, current and future AI trends in healthcare, and developments in M&A. Join medical device and digital health entrepreneurs, CEOs of venture-backed companies, and business development executives from large Medtech companies, as well as angels, venture capitalists, and corporate investors, for two days of networking and programming that can help you craft a winning strategy.

Wilson Sonsini's Biotech Summit
October 9-10, 2024
The Newbury Boston
Boston, MA
https://biotech.wsgrevents.com/

Wilson Sonsini's inaugural Biotech Summit will bring together leaders from across the biotech industry, including esteemed researchers, policymakers, prominent investors, and CEOs. Held over the course of two impactful days, the summit will feature an intimate CEO dinner, as well as expert panel discussions covering key topics such as antitrust issues, FDA insights, and venture capital trends. Attendees will participate in enriching conversations about strategic collaborations designed to foster innovation in treatments, advancements for patients, and value for companies within the biotech sector.

Phoenix 2024: The Medical Device and Diagnostic Conference for CEOs
October 23-25, 2024
Ritz-Carlton, Half Moon Bay
Half Moon Bay, CA
https://phoenix.wsgrevents.com/

The 2024 Phoenix Conference will bring together top-level executives from large healthcare companies and CEOs of small, venture-backed firms for an opportunity to discuss critical issues of interest to the medical device industry today, as well as to network and gain valuable insights from both industry leaders and peers. This year's exclusive event will provide an unrivaled experience that will help inform and shape company strategy for the years ahead.

Elton Satusky, Scott Murano, and Kimberly Stopak have editorial oversight of *The Life Sciences Report*. They would like to take this opportunity to thank all of the contributors to the report, which is published on a semi-annual basis.

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