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THE LIFE SCIENCES REPORT

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An IP Legal Legend: Wilson Sonsini's Vern Norviel Reflects on a Diverse and High-Impact Career Fostering Innovation in Life Sciences

Since joining Wilson Sonsini more than two decades ago, Vern Norviel has led the firm's patents and innovations practice and shaped it into the life sciences industry's leading resource for intellectual property matters.

Our Chief Business Advisor, Matthew Meyer, and Chief Licensing Advisor, Kathy Ku, recently sat down with Vern to discuss his remarkable career and plans following his retirement from the firm in February 2025. The interview has been edited for length and clarity.

Q: Did you always want to be an attorney?

A: Actually, I studied chemical engineering as an undergrad at Boulder and had planned to go to medical school ever since I was young. But volunteering

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MedTech Trends and Issues for 2025

By Jonathan Trinh (Associate, Washington, D.C.) and Eva F. Yin (Partner, Seattle)

The regulatory landscape for medical devices continues to be shaped in part by innovation from industry. Over the past year, the U.S. Food and Drug Administration (FDA) has authorized a growing number of artificial intelligence/machine learning (AI/ML)-enabled devices and released new regulations and guidance—including a controversial final rule for laboratory developed tests—that can meaningfully inform the regulatory strategies and total product lifecycle management for medical device companies. Some of the top trends and issues going into 2025 include the following:

(1) Regulation of Generative AI-Enabled Devices. The FDA has authorized over 1,000 AI/ML-enabled medical devices since 1995,[1] but has not yet authorized any generative AI (GenAI)-enabled devices.

GenAI is an adaptive system with open-ended inputs and outputs. Over the last 10 years, GenAI has been deployed for a range of health care uses, from helping medical professionals interpret radiological

[1] *See* U.S. Food and Drug Administration, "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices (updated Dec. 20, 2024).

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at the University of Colorado Medical Center opened my eyes to the more emotionally challenging aspects of practicing medicine. After hearing a presentation by a lawyer, my perspective changed. From that point on, I decided I wanted to go to law school.

Q: How did that play out?

A: It turns out I was also interviewing for engineering positions during my senior year in college, and the Chevron Corporation offered to send me to law school if I took a job at Chevron as an engineer. Since I was on a *very* tight budget at the time, I joined Chevron and studied law at night. At Chevron, you were rotated into a different job about every six months, because they were trying to train you to be in upper management someday. And so yes, I started my career as an engineer. I worked on offshore oil platforms in Santa Barbara and oil fields in Bakersfield.

Q: How was the Chevron experience?

A: I would very frequently be in Santa Barbara working on oil rigs or Bakersfield in the oil fields during the day, and then I would be back in San Francisco in the evening for law school. My first patent is actually a chemical engineering patent covering a method of more efficiently processing wastewater on the rigs that operate off the coast of Santa Barbara. I believe the technology is still in use today.

Q: What came next?

A: So, I got a little bit of biotech experience, oddly, at Chevron. Oil companies wanted to get into other areas, and Chevron invested in a biotech called Cetus. Among other things, Cetus would come up with bugs to do things in oil wells or bugs to eat oil spills. I got experience filing engineered organism patents at Chevron! But, as a theme of my life, I don't really love being in giant companies, and so I very quickly left after completing my law degree and joined the law firm of Townsend and Townsend, where I worked on all kinds of IP matters.

Q: Let's jump to your in-house experience.

A: It's good to be good, but it's better to be lucky and I've been very lucky. While at Townsend, I was introduced to the team that started Affymetrix, which pioneered the DNA microarrays called "gene chips." And I started working on the patents at Affymetrix. I'm actually trying to start writing a book about the predecessor of Affymetrix (called Affymax) because I think it is very interesting. I was too young and too stupid and didn't know better, so I left my partnership at Townsend to help start Affymetrix around 1992. That worked out. We eventually went public. We had all kinds of lawsuits that, mercifully, I won, or I wouldn't be sitting here right now.

Q: Tell us about your transition to Wilson Sonsini in 2002.

A: I came here because of [Wilson Sonsini partner] Ken Clark. I'm just lucky Ken knew of me and had the vision of creating a destination IP practice, which would blossom into lots of other things for the firm. Somehow, he suckered me into coming here [laughing]. Actually, I wanted to join Wilson and was delighted to come on board. It was really the only firm I would want to be associated with.

Q: What did the patent practice look like when you started?

A: There were two people then, [current Wilson Sonsini partner] Peter Eng and Shirley Chen. Shirley is the CEO of a biotech company now. Partly because of the way I am, and also because I thought it was good business, I thought that the IP lawyers in life sciences should be the first touch at a law firm because scientists do not love lawyers at all. The only lawyers they don't mind too much are the patent lawyers who they can talk science with. So, I thought that the IP lawyers needed to be here and needed to be the best, so the scientists would start their companies here. And it turns out there's a lot of geeky scientist CEOs out there who want to talk to IP lawyers. So, it has worked out well. We clearly have the best life

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An IP Legal Legend: Wilson Sonsini's Vern Norviel Reflects . . . *(Continued from page 2)*

sciences IP group in the world, and it's also the largest. I think it does serve as a destination to draw in lots of other work for the firm.

Q: When you started here, did you have any sense for what the practice would become two decades later?

A: I don't want to sound arrogant, but I had to put together a little business plan and it is exactly pretty much what I imagined. I did not imagine it being *this* large, probably. We have lots of bright people here, and scientists call them first to start a company. We are bringing in a lot of business for the rest of the firm. Our litigation group has several lawsuits going on, and we have corporate lawyers staying busy, as well as the deal lawyers. And we get work from them, of course. So, it all works out perfectly—almost exactly like I'd imagined.

Q: Can you highlight a couple of interesting clients?

A: Some of the ones I'm most proud of are in the diagnostics area. Two companies come to mind, but it's really the same technology in a sense. Both are from Professor Steve Quake from Stanford. One is called Verinata, which is now owned by Illumina. The idea there was that women had this foot-long needle stuck in their stomach when they were having a baby to test for Down Syndrome. That wasn't comfortable for the woman and about 1 percent of the time the baby died. So, Steve and his group, including a brilliant young woman named Christina Fan, came up with the idea of just taking DNA out of the blood from the pregnant woman and sequencing it, and separating the baby's DNA from the mom's DNA. They could then figure out if there's a genetic abnormality. Turns out it worked, and now there are a lot of companies that do this test. Any pregnant woman can get it and many (maybe most) do. So, I'm pretty proud of that. Companies like Guardant and GRAIL are now also using DNA from blood to develop diagnostic tests, and these tests are helping many cancer patients.

On the therapeutic side, probably the one I'm most proud of is Semma Therapeutics, which is now part of Vertex. A brilliant young woman at Harvard came up with a way of taking skin cells (known as fibroblasts), dedifferentiating them to stem cells, and then redifferentiating them to pancreatic

beta cells. These are then injected into the pancreas of a person who is a type 1 diabetic. This led to the first type 1 diabetic (ever) being cured.

Q: Switching gears, let's talk about innovation among leading law firms. About five years ago, you had the idea to build non-legal areas within the firm, with a focus on business advisory and university licensing support. What drove your thinking there?

A: I was thinking about other ways we could grow the business. And at least in the life sciences, two of the biggest issues are dealing with universities and raising money. The big banks aren't willing to provide this service, but we could, and accelerate our clients in the process. Both initiatives are working out great.

Q: What are your plans after Wilson Sonsini?

A: I'll continue to work for companies where I like the people—and where I think the technology is cool. I will be trying to build my legacy. I've picked out a few of those companies and probably will pick out more over time. I'll also continue to serve on some nonprofit boards, including the Morris Animal Foundation and as trustee of the University of Colorado.

Q: Any hobbies?

A: My two biggest hobbies are bike riding and car racing. With biking, I'm on this bucket-list quest to do long rides in all 50 states. I just did a ride in Wisconsin. I have 44 states in the bag, and I just made a reservation for a ride in Louisiana. I'm getting close to the 50-state goal. I also received my professional car racing license last year, so I race cars. I have a nice race car that is a thrill and a half!

Thank you, Vern, and best wishes in your next life chapter.

Matt Meyer
(415) 947-2097
mjmeyer@wsgr.com

Kathy Ku
(650) 868-3694
kathy.ku@wsgr.com

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Matthew Meyer leads Wilson Sonsini's life sciences business advisory practice—an innovative practice aimed at providing start-up and emerging growth life sciences companies with business insights, capabilities, transactional support, and strategies to help them thrive and address some of their most challenging issues. Matt is an experienced executive and attorney who has held diverse roles of increasing responsibility across a wide range of private and public biopharma, medtech, and precision medicine companies from start-ups to Fortune 50 in the U.S. and Europe, including Pfizer, Novartis, and CareDx. His leadership capabilities include delivery of strong commercial results, structuring and executing partnering transactions across the product life cycle, raising debt and equity capital in the private and public markets, and working with founders, management teams, and boards to address complex business issues to support rapid growth. Click here to learn more about the firm's life sciences business advisory practice.

Katharine (Kathy) Ku is Wilson Sonsini's chief licensing advisor. She is also a member of the technology transactions and the patents and innovations practice groups. Kathy is an internationally recognized leader in the field of technology transfer. She served as the Executive Director of Stanford University's Office of Technology Licensing (OTL) for 27 years. During that period, OTL licensed hundreds of new technologies, bringing in $1.8 billion, most of which went back to support research and education at Stanford. Kathy also spearheaded the development and implementation of nine principles related to university technology licensing. The principles are set forth in a document entitled "In the Public Interest: Nine Points to Consider in Licensing University Technology." More than 120 institutions have adopted the principles since they were published in 2007.

Firm Hosts LaunchBio NextGen VC Forums

Held last year at our San Francisco office on May 16, our Boston office on October 8, and the Paramount Club in New York on November 14, Wilson Sonsini's invitation-only, half-day forums co-produced with LaunchBio included networking and educational panel sessions curated by partners Michael Hostetler and Dan Koeppen. Discussion topics included negotiating term sheets, leveraging IP diligence, and understanding board governance.

LaunchBio's NextGen VC Forum is the premiere event for venture capital associates to expand their skills and expertise while growing their network.

To learn more about these curated education sessions or request an invitation, please visit https://launchbio.org/nextgen-forum-interest-form/.

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images, diagnose and create treatment plans for patients, generate clinical documents, and summarize research papers, to helping patients assess symptoms, predict health risks, and analyze lab results and wearables' data.

However, its use in medical devices poses unique and complex regulatory considerations. The regulatory science challenges for GenAI-enabled devices include, for example:

- difficulty with defining the product's intended use;
- identification of hallucinations (which presents concerns about reliability and risk);
- adequacy and diversity of the training dataset;
- evaluation of and monitoring for performance in the real world, including bias; and
- providing transparency to users.

The FDA is grappling with how to ensure the safe and effective use of GenAI-enabled devices while promoting innovation. In November 2024, the agency convened the Digital Health Advisory Committee to discuss total product lifecycle considerations for GenAI-enabled devices, including premarket performance evaluation, risk management, and post-market performance monitoring. A common theme was the use of the existing risk-based framework for regulating devices, such as special controls. The FDA also expressed an openness toward authorizing pre-determined change control plans (PCCPs), discussed further below, for GenAI-enabled devices. It remains to be seen how any agency regulations or guidance solves for the use of GenAI in the future, as well as the current uses of GenAI today.

(2) Pre-determined Change Control Plans. Device manufacturers have received additional clarity from the FDA for authorizing a PCCP in a device marketing submission.

A PCCP describes specific device modifications that a manufacturer plans to make over time that would generally require a new marketing submission or FDA authorization. If a manufacturer obtains FDA authorization for a PCCP, it can make predetermined, specific modifications to the marketed device without having to submit a supplemental or new marketing application to the FDA.

In 2024, the FDA issued draft guidance describing its proposed approach for reviewing and authorizing a PCCP for medical devices in general, and final guidance for reviewing and authorizing a PCCP for a device with one or more AI-enabled device software functions. Even though the agency has not put out guidance on authorizing a PCCP for adaptive algorithms specifically, the FDA did preview some likely considerations during the Digital Health Advisory Committee meeting, such as:

- How specific can the modifications be?
- What are the guardrails to limit the range of automatic updates?
- How will post-market performance be monitored over time and across multiple sites?
- How will labeling be updated when modifications are automatically implemented so that users are informed?
- What notice should be made if the device does not function as intended?

Obtaining an authorized PCCP could potentially save a manufacturer substantial cost, time, and resources across a device's lifecycle. Conversely, seeking a PCCP could increase the complexity of a submission, delay marketing authorization and commercial launch, and trigger implications surrounding disclosure of information in the FDA's medical device databases.

(3) Laboratory Developed Tests. The regulation of laboratory developed tests (LDTs) as medical devices faces an uncertain future as key dates approach. In May 2024, the FDA issued a final rule that would treat LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and subject them to medical device regulations. Unless exempt, LDTs would need to meet requirements related to:

- establishment registration and product listing;
- reporting of adverse events;
- current good manufacturing practices or the quality system regulation; and
- premarket review.

The implementation of the medical device regulations for LDTs will be staggered over a four-year period and five stages, beginning on May 6, 2025.

Several events raise doubt as to whether the final rule will take effect or survive under the incoming Trump administration. The final rule is currently being challenged in federal court by the American Clinical Laboratory Association and Association for Molecular Pathology, who argue that the rule violates the Administrative Procedure Act. The Trump administration may also revive its position that questions the FDA's

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Schedule for LDT Compliance with Medical Device Regulations

STAGE 1: Starting May 6, 2025

- Medical Device Reporting (i.e., reporting of adverse events)
- Correction and removal reporting
- Quality System requirements related to complaint files

STAGE 2: Starting May 6, 2026

- Requirements not covered in the other stages, including:
  - Establishment registration and product listing
  - Labeling
  - Investigational use

STAGE 3: Starting May 6, 2027

- Quality Management System requirements other than requirements related to complaint files, including:
  - Design controls
  - Purchasing controls
  - Acceptance activities
  - CAPA
  - Records

STAGE 4: Starting November 6, 2027

- For "high-risk IVDs offered as LDTs":
  - Premarket review

STAGE 5: May 6, 2028

- For "moderate-risk" and "low-risk" IVDs offered as LDTs:
  - Premarket review

authority to regulate LDTs as medical devices, and may ultimately repeal the final rule or soften its requirements.

(4) Medicare Coverage for Breakthrough Devices. A legislative solution is in the works to confer timely Medicare coverage for FDA-designated Breakthrough Devices. Such devices are not eligible for Medicare coverage if they do not meet the reasonable and necessary standard under Section 1862(a)(1)(A) of the Social Security Act (even though they may separately meet the FDA's standards for safety and effectiveness). Without Medicare coverage, access to the latest advances in medical technology could be limited for Medicare beneficiaries.

In August 2024, the Centers for Medicare and Medicaid Services (CMS) introduced the Transitional Coverage for Emerging Technologies (TCET) pathway as a remedy, but with conditions. The TCET pathway provides expedited Medicare coverage for certain Breakthrough Devices that are provided in a CMS-approved clinical study designed to generate additional clinical evidence generalizable to the Medicare population (referred to as the National Coverage Determination and Coverage with Evidence Development processes). The TCET pathway would also accept only up to five candidates annually—a sliver compared to the number of devices that receive Breakthrough Device designations each year, including many digital health, AI, and software technologies—and not prioritize in vitro diagnostic products like LDTs.

Congress may replace CMS's limited solution with a broader one. Each chamber is considering its own bipartisan bill that, if enacted, would afford temporary Medicare coverage for Breakthrough Devices for a four-year period shortly after FDA authorization.

(5) The FDA in a Post-*Chevron* World. Eyes are on the FDA to see how the agency adapts to a legal landscape without *Chevron* deference. In June 2024, the U.S. Supreme Court dismantled the *Chevron* doctrine that required federal courts to defer to a federal agency's reasonable interpretation of an ambiguous statute that it administers. The Court also altered the statute of limitations under the Administrative Procedure Act (starting the clock when a plaintiff is injured, not when an agency action becomes final). Now, a court that reviews action by the FDA, such as the issuance of new or amended regulations, can exercise its independent judgment and decide questions of law. A court can also hear challenges that are brought many years after such regulations are finalized.

The industry may see more litigation against the FDA. Without agency deference, these challenges will likely consume additional time and resources for all parties. Facing this possibility, the FDA is likely to carefully think about how it can defend its decisions in court before issuing new or amended regulations (and take more time to do so). In view of judicial challenges, the agency may use other approaches to regulate the industry, including through enforcement actions, or may exert more pressure on Congress to act and to pass clearer laws.

Jonathan Trinh
(202) 920-8736
jtrinh@wsgr.com

Eva F. Yin
(206) 883-2572
eyin@wsgr.com

Three Pharma Trends to Watch in 2025

By Dan Orr (Senior Counsel)

GLP-1 Controversies Keep Gaining Weight

Americans can't seem to get enough GLP-1 drugs like Wegovy (semaglutide) and Mounjaro (tirzepatide). The U.S. Food and Drug Administration (FDA) first approved the drugs to treat diabetes, but within two years expanded their indications to prevent heart problems and then to facilitate weight loss. The weight loss indication transformed them into diet drugs and demand exploded. So have the controversies surrounding them.

GLP-1 drugs went into shortage when Novo Nordisk and Eli Lilly could not meet consumer demand. The resulting shortage authorized compounding pharmacies and outsourcing facilities to begin selling their own copies of the drugs. Pharmacists have practiced compounding for hundreds of years, but not on a scale or complexity as that needed for GLP-1s.[1]

Then, the litigation began. The FDA removed Mounjaro from its shortage list, citing increased production capacity.[2] But ending the shortage would mean that the drugs could no longer be compounded legally, so the compounding industry sued the agency to prevent it.[3] The FDA quickly reversed itself, only to reinstate its decision a few weeks later.[4] The suit is still pending as a result. Novo Nordisk and Eli Lilly have filed suits to prevent compounders from making copies of their drugs.[5] They have also asked the FDA to list their GLP-1s as too difficult to compound safely, which would effectively ban the compounded versions.[6]

Don't expect these controversies to end anytime soon. Physicians who try to order GLP-1s from their manufacturers report that supplies are still limited. The FDA's too-difficult-to-compound list doesn't exist yet and the agency has paused enforcement actions against compounders. The Biden administration recently added even more fuel to the fire by proposing to expand Medicare and Medicaid coverage for GLP-1s to an additional 7 million Americans.[7]

A "Legal Earthquake" Shakes Federal Agencies

In June 2024, the U.S. Supreme Court decided *Loper Bright Enterprises v. Raimondo*[8] and overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*[9] Media reports described *Chevron's* reversal as a "legal earthquake" that affects as many as 19,000 prior court decisions.[10]

Chevron had required federal courts to defer to a federal agency's reasonable interpretation of an ambiguous statute that the agency administers. But *Loper Bright* held that courts must exercise their "independent judgment" instead.[11] Dissenters argued that courts should continue to defer to agency scientific experts, citing examples such as the FDA's recent regulation that defined the term "protein."[12]

A few weeks later, the Supreme Court issued an aftershock decision in *Corner Post, Inc. v. Federal Reserve Board. of Governors.*[13] The decision held that the statute of limitations to challenge a federal agency's decision runs not

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[1] *Wellness Pharmacy, Inc. v. Becerra*, No. 20-CV-3082 (CRC), 2021 WL 4284567, at *1 (D.D.C. Sept. 21, 2021) (reviewing the history and regulation of compounding).
[2] FDA, "FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize" (Dec. 19, 2024), https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize.
[3] *Outsourcing Facilities Assoc., et al. v. U.S. Food & Drug Administration, et al.*, Complaint, 24-cv-00953-P (N.D. Tex. Oct. 7, 2024), available at: https://www.503bs.org/_files/ugd/90544a_956a40069f7c4b768199e187953cd15f.pdf.
[4] FDA, note 2 above, at *id*.
[5] *See, e.g., Nordisk v. Flawless Image Med. Aesthetics, LLC*, No. 5:23-CV-00739-GTS-ML, 2023 WL 5200435, at *1 (N.D.N.Y. Aug. 14, 2023); *Novo Nordisk, Inc. v. Brooksville Pharms. Inc.*, No. 8:23-CV-1503-WFJ-TGW, 2023 WL 7385819, at *1 (M.D. Fla. Nov. 8, 2023); *Eli Lilly & Co. v. Wells Pharmacy Network, LLC*, No. 5:23-CV-576-JSM-PRL, 2024 WL 1641673, at *1 (M.D. Fla. Feb. 5, 2024); *Eli Lilly & Co. v. RXCompoundStore.com, LLC*, No. 23-CV-23586, 2024 WL 1554339, at *1 (S.D. Fla. Apr. 9, 2024).
[6] Eli Lilly, Nomination of Tirzepatide, FDA-2017-N-2562-0028 (Aug. 28, 2024) and Novo Nordisk, Nomination of Semaglutide, FDA-2017-N-2562-0029 (Oct. 22, 2024). Both are available at https://www.regulations.gov.
[7] Alejandra O'Connell-Domenech, "Biden proposes Medicare, Medicaid coverage of obesity drugs," *The Hill* (Nov. 26, 2024), https://thehill.com/policy/healthcare/5010254-biden-administration-proposes-obesity-drug-coverage-medicare-medicaid.
[8] —U.S.—, 144 S. Ct. 2244 (2024).
[9] 467 U.S. 837 (1984).
[10] *See, e.g.*, Josephine Rozzelle, "With Chevron reversal, Supreme Court paves way for a 'legal earthquake,'" CNBC (Jul. 10, 2024), https://www.cnbc.com/2024/07/10/supreme-court-post-chevron-legal-chaos.html; Cary Coglianese, "The Supreme Court's Judicial Earthquake Will Shake the Administrative State," *Barron's* (Jul. 2, 2024), https://www.barrons.com/articles/supreme-court-decision-chevron-administrative-state-a3f-cb801.
[11] *Id*. at 2247, 2261.
[12] *Id*. at 2298 (internal citations omitted).
[13] —U.S.—, 144 S. Ct. 2440 (2024).

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Three Pharma Trends to Watch in 2025 *(Continued from page 7)*

from the date of the final decision, but from the date of the plaintiff's injury.[14] Dissenters summarized the decision as "there is effectively no longer any limitations period for lawsuits that challenge agency regulations on their face."[15]

With no deference and no time limit on when challenges can be brought, *Loper Bright* and *Corner Post* mean nearly any decision by any federal agency can be challenged at any time. Litigation against agencies, including the FDA, is likely to increase in 2025 and beyond. For example, new challenges to the FDA's approval of mifepristone and other abortion drugs are likely, even though these drugs were approved decades ago.[16] Litigation against the FDA concerning regulatory exclusivity—already a hot topic—is also likely to increase.[17]

Who Will Make America Healthy Again and How?

President-elect Donald Trump shocked the political establishment when he nominated Robert F. Kennedy to be Secretary of Health and Human Services (HHS). Kennedy, a longtime vaccine skeptic, wasted no time in accusing the FDA of waging a "war on public health" and promised to purge the agency.[18] Dr. Martin Makary, the President-elect's nominee for FDA Commissioner, is a more moderate choice. But if confirmed, both Kennedy and Makary will take policy direction from Russell Vought, Trump's nominee to lead the Office of Management and Budget (OMB) and a co-author of the Project 2025 policy playbook.

Vought's Project 2025 playbook proposes to lower prescription drug prices by bringing more generic drugs to market faster and increasing competition. Nearly 90 percent of Americans support this idea.[19] The playbook recommends significant expansions to other FDA programs as well, such as creation of a new graded inspection system for drug facilities, transferring vaccine oversight from the Centers for Disease Control and Prevention (CDC) to the FDA, and new regulation of prescription drug advertising.[20]

The FDA has struggled for years to find enough qualified doctors, engineers, and scientists to staff its programs, especially those for generic drugs.[21] According to a recent report to Congress, positions in the Center for Drug Evaluation and Research have an over 10 percent vacancy rate.[22] Approximately a third of senior FDA employees are eligible for retirement.[23] Although Makary's nomination was reassuring, many FDA employees would see little reason to remain under an HHS Secretary like Kennedy who is openly hostile to them. There's little chance OMB will be able to accomplish its health policy goals without them.

Litigation against agencies, including the FDA, is likely to increase in 2025 and beyond. For example, new challenges to the FDA's approval of mifepristone and other abortion drugs are likely, even though these drugs were approved decades ago.

Something has to give here. The new Trump administration will need to decide how to balance competing interests and its policy goals.

Dan Orr
(302) 304-7648
dorr@wsgr.com

[14] *Id*. at 2460.
[15] *Id*. at 2470.
[16] *See Food & Drug Admin. v. All. for Hippocratic Med*., 602 U.S. 367 (2024).
[17] *See, e.g.*, *Depomed v. HHS*, 66 F. Supp. 3d 217, 220 (D.D.C. 2014); *Eagle Pharmaceuticals, Inc. v. Azar*, 952 F.3d 323 (D.C. Cir. 2020); *Catalyst Pharmaceuticals v. Becerra*, 14 F.4th 1299, 1312 (11th Cir. 2021); *Jazz Pharmaceuticals, Inc. v. Becerra*, 23-CV-01819 (D.D.C. filed Jun. 22, 2023).
[18] Christina Jewett, "Kennedy's FDA Wish List: Raw Milk, Stem Cells, Heavy Metals," *New York Times* (Nov. 14, 2024), https://www.nytimes.com/2024/11/12/health/robert-kennedy-jr-fda.html.
[19] Kaiser Family Foundation, "Public Opinion on Prescription Drugs and Their Prices," https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices (Oct. 4, 2024).
[20] Project 2025, 456-462 Mandate for Leadership: 180 Day Playbook, The Heritage Foundation (2023), https://www.project2025.org/playbook.
[21] Matthew Perrone and Nicky Forster, "Nearly 2,000 drug plants are overdue for FDA checks after COVID delays, AP finds," Associated Press (Sep. 6, 2024), https://www.ap.org/news-highlights/spotlights/2024/nearly-2000-drug-plants-are-overdue-for-fda-checks-after-covid-delays-ap-finds.
[22] FDA, Report to Congress: Strategic Workforce Plan FYs 2023 to 2027 (2023), at 35. https://www.fda.gov/media/176025/download.
[23] *Id.* at 40.

Eligibility of Life Sciences Companies for Qualified Small Business Stock

By Rob Sherrill (Associate, Palo Alto) and Myra Sutanto Shen (Partner, Palo Alto)

The "qualified small business stock" (QSBS) tax exemption under Section 1202 of the Internal Revenue Code[1] allows non-corporate founders and investors in certain emerging growth companies organized as corporations to potentially exclude up to 100 percent of the U.S. federal capital gains tax incurred when selling its stake in the business.[2] QSBS is a useful tool for founders and investors in life sciences companies, but care must be taken to ensure that such companies continue to meet the eligibility requirements of a qualified small business. This article focuses on the requirement that the company must use at least 80 percent of its assets towards the active conduct of one or more "qualified trades or businesses," and specifically, the meaning of qualified trade or business in the context of a life sciences company. The article further explores the potential implications of utilizing a friendly PC/MSO-PC structure on QSBS eligibility.

For purposes of QSBS, a "qualified trade or business" is generally defined to exclude certain businesses, including (of particular relevance to life sciences companies) any trade or business involving the performance of services in certain fields, such as health … or any other trade or business where the principal asset is the reputation or skill of one or more of its employees. Neither Section 1202 nor the Treasury Regulations promulgated thereunder further explains what activities are regarded as health services. While it is generally accepted that a company that provides medical care or treatment to patients, such as a doctor's office, would be excluded from QSBS eligibility, the extent to which this rule applies to emerging growth life sciences companies is unclear.

Defining Health Services: IRS Guidance

Over the past 10 years, the Internal Revenue Service (IRS) has issued a number of private letter rulings[3] (PLRs) that helpfully clarify that the exclusion for health services is meant to be limited, not expansive. In PLR 2014-36-001 (Sept. 5, 2014), the company helped its clients commercialize experimental drugs by researching drug efficacy, conducting other pre-commercialization testing procedures, and manufacturing drugs. The IRS ruled that the company was akin to a manufacturing company that offered value by deploying physical and intellectual property assets rather than individual expertise and so was engaged in a qualified trade or business for purposes of the QSBS rules. Similarly, in PLR 2021-12-5004 (June 25, 2021), the company evaluated, measured, designed, fabricated, manufactured, adjusted, fit, and serviced prescriptions for referred patients. The IRS concluded that the company's business is more analogous to custom manufacturing than health services.

In PLR 2017-17-010 (Apr. 28, 2017), the company had developed proprietary technology to detect a specific condition. The company conducted the tests ordered by health care providers and provided a lab report to the provider, which included a summary of whether a given condition was detected. The IRS concluded that the diagnostic testing services of the company were a qualified trade or business for purposes of Section 1202 because the company did not itself diagnose patients, recommend medical treatment, or otherwise provide medical care to patients, and, aside from a licensed lab director, none of its employees were subject to state licensing requirements or developed transferable skills during employment.

The lack of employees subject to state licensing requirements was also important in PLR 2022-21-006 (May 27, 2022), in which the company filled and distributed prescription orders for a limited number of drugs. The IRS ruled that the principal asset of the company was its exclusive right to distribute pharmaceuticals, and the sale of the drug generated all revenues. The IRS emphasized that the company did not diagnose, treat, or manage any aspect of care for the patients, any interaction with patients was primarily conducted by non-pharmacist employees who were not regulated under state or federal law, and such interaction was merely incidental to the services provided (e.g., ensuring receipts and answering questions).

In PLR 2021-44-026 (Nov. 5, 2021), the company developed and commercialized software to be used by medical providers to individualize patient treatment. The IRS ruled that the company created tools to be utilized by customers in the health services industry but did not

[1] All "Section" or "Treasury Regulations Section" references are to sections of the Internal Revenue Code, 1986, as amended (the Code), and the Income Tax Treasury Regulations, respectively, as of [December 10, 2024].

[2] For more information on QSBS eligibility requirements and benefits, see "Understanding Section 1202: The Qualified Small Business Stock Exemption."

[3] While private letter rulings generally apply only to the taxpayer to whom they are written, they often are viewed as an indication of the IRS's current position on issues.

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Eligibility of Life Sciences Companies for Qualified Small Business Stock *(Continued from page 9)*

provide health services itself. Similarly, in PLR 2024-18-001 (May 3, 2024), the company conducted medical testing using specialized equipment and software and delivered reports to medical service providers. The IRS ruled that the company's medical testing service was a qualified trade or business for purposes of Section 1202 because the company did not diagnose or provide medical advice, and its licensed physicians only developed policy and procedure and did not interact with customers.

The PLRs issued by the IRS generally focused on one or more of the following factors:

1. the QSBS-eligible company does not diagnose, treat, or manage any aspect of care for patients—any interaction with the patients is incidental;

2. the source of revenue for the QSBS-eligible company is either from the sales of a product or from a medical provider or third party, not the patient directly;

3. the employees of the QSBS-eligible company often are not required to be specially licensed, meet specific education requirements, or have prior experience; and

4. the employees of the QSBS-eligible company often develop skills unique to the company's business that cannot be easily transferred.

Notably, not all factors need to be met, but two guiding themes stand out: either the company has developed proprietary IP to sell and manufacture assets, or the company provides a service that is not highly specialized or technical and does not involve the diagnosis or treatment of patients.

What About Friendly PC/MSO-PC Structures?

While the PLRs and guidance issued by the IRS are helpful for a number of life sciences companies, one difficult fact pattern is where a company engages medical providers, either directly (or through wholly owned subsidiaries) or through a "friendly PC" or "MSO-PC" structure.

First, as evidenced by PLR 2024-18-001, engaging medical care providers who do not provide services to patients (e.g., a chief medical officer at a medical device company) is not sufficient to disqualify a company from QSBS. Second, the relevant question is whether the company uses 80 percent of its assets towards the active conduct of one or more qualified trades or businesses. Accordingly, a company can use up to 20 percent of its assets towards the conduct of non-qualified trades or businesses, including health services. For example, a company that sells diagnostic equipment directly to medical providers as its primary business could engage medical providers to provide a limited amount of diagnostic services if the 20 percent threshold is not crossed. In light of such guidance, the difficulty is ensuring that the assets used towards the non-qualified activities stay well below that 20 percent threshold.

In a typical "friendly PC" structure, the medical providers are generally employed by a separately owned professional corporation (PC), usually to accommodate the corporate practice of medicine rules. The company (usually called the "management company") and the professional corporation enter into a number of agreements to transfer economic benefits and voting control (to varying degrees) to the management company. The question of whether the management company is an eligible qualified small business may turn on whether it is considered to own the PC for U.S. tax purposes. The IRS has issued private letter rulings addressing when PCs were regarded as members of a consolidated group (e.g., PLR 2014-51-009 (Dec. 19, 2014)) such that they could join in the filing of a consolidated tax return.

While there is no guidance on the application of QSBS to the friendly PC structure, one school of thought is that if the PC is included in the consolidated tax return of the management company, stock issued by the management company is unlikely to be QSBS eligible (unless the less-than-20-percent threshold described above is met). However, if the PC is not included (or not eligible to be included) in the consolidated tax return of the management company, arguably, the activity of the PC does not taint the trades or businesses in which the management company is engaged. Accordingly, companies that are considering engaging medical providers or forming a friendly PC or MSO/PC structure should consult with counsel regarding the impact of doing so on QSBS.

Rob Sherrill
(650) 849-3052
rsherrill@wsgr.com

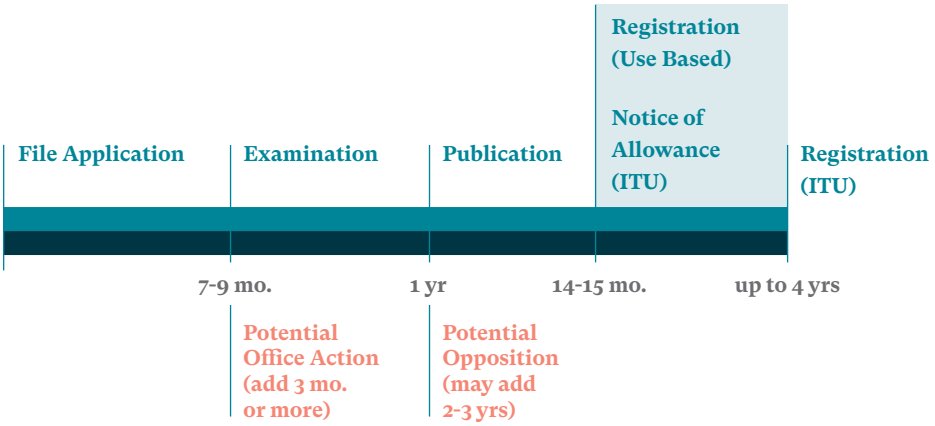
Myra Sutanto Shen
(650) 565-3815
msutantoshen@wsgr.com

Trademarks 101: What Life Sciences Companies Need to Know About Brands

By Aaron Hendelman (Partner, Seattle and Palo Alto) and Alyssa Worsham (Partner, Seattle)

Brands can be strategically useful, high-value assets in a life sciences company's IP strategy. With the growing marketing emphasis on life sciences brands—from proprietary platform names to branded clinical trials to drug names—early attention to brand strategy has become increasingly important, particularly given the need in the U.S. to navigate both U.S. Food and Drug Administration (FDA) and potential United States Patent and Trademark Office (USPTO) approval.

Typical U.S. Trademark Application Timeline for Life Sciences Companies



Failure to adequately address brand strategy early can result in an inability to use a desired name or, worse, potential liability.

Some Initial Things to Know:

- *FDA and Trademark Naming Approvals Are Different.* When reviewing potential names, the FDA and the USPTO both consider whether the new name is likely to cause confusion with respect to pre-existing third-party names. However, the FDA proprietary name review process is independent of the USPTO review process. It is possible that a party could obtain FDA approval without being able to secure trademark rights, or vice versa. Formulating a strategic back-up plan can be especially important for life sciences companies.
- *Brand Clearance Saves Big Headaches.* Best practice is to conduct clearance searches on names and logos to help assess availability and risk level before selecting a new brand. Legal clearance is often done in parallel with the creative work done by branding agencies. Clearing clinical trial names can also be key, as many companies grow attached through early use but later find there is a bar to registration or expanded use.
- *Trademark Filings Are Particularly Important Tools for Life Sciences Companies.* Trademark applications can be critical to locking in trademark rights for life sciences companies given their years-long path to commercialization. For example, company name use, domain name use, use of a name merely with investors, name use merely for marketing, or use in connection with internal R&D generally does not establish trademark rights. Trademark filings also put third parties on notice of a company's rights and help safeguard the name from unauthorized and infringing use.
- *Early Focus Is Critical.* Brand rights are "first come, first served." Waiting until later-phase studies to secure brand rights, for example, may be too late.
- *Trademark Protection Provides Flexibility.* Trademark applications can be filed broadly initially to encompass a range of potential indications, and can later be tailored specifically to reflect actual offerings when the full range of drugs or targets becomes clear.
- *Trademark Rights Are Jurisdictional.* Foreign trademark filings can be an important IP bulwark. Life sciences companies can strategically benefit from targeted foreign filings. For example, a single EU filing covering all EU countries is often a cost-effective "no brainer."

Aaron Hendelman
(206) 883-2514
ahendelman@wsgr.com

Alyssa Worsham
(206) 883-2592
aworsham@wsgr.com

Double-Patenting Jeopardy

By Richard Torczon (Senior Counsel, Washington, D.C.)

The past year has been a busy one for obviousness-type double-patenting (ODP), a doctrine intended to prevent an inventor from obtaining two patents for the same invention. Both the U.S. Court of Appeals for the Federal Circuit (the principal patent reviewing court) and the U.S. Patent and Trademark Office (USPTO) seemed on the cusp of radically changing how ODP works—to the detriment of patentees. By the end of the year, the threat seemed to have receded, but many questions remain.

Statutes bar claiming the exact same invention twice,[1] however it arises, but what about claiming an obvious variant? If the earlier invention is in a prior-art disclosure, then the obviousness statute[2] bars the new claim. However, no statute bars claiming an obvious variant of one's own invention (provided the first variant is not in a prior-art disclosure). Courts have stepped in, however, to impose an equitable bar[3] against patent owners double-dipping on the same invention unless the patentee has (1) disclaimed any patent term that would extend the term of the obvious variant beyond the first patent and (2) agreed to ensure common ownership of both patents.[4] Failure to meet either of these requirements makes the ODP claim invalid.

An inventor might reasonably need to claim an obvious variant of an earlier-claimed invention to cover the evolution of its own products more closely. More controversially, an inventor might use claims to obvious variants to better cover a competitor's products. Consequently, both patent owners and potential defendants (often the same entities in an ultra-competitive industry) follow ODP developments closely. In particular, ODP can feature prominently in pharmaceutical cases, where the end of a patent term can be its most lucrative period, making the stakes for a terminal disclaimer that much higher.

In late 2023, the Federal Circuit caused a stir with its *In re Cellect*[5] decision, in which it affirmed a USPTO decision to reject patent claims in a reexamination proceeding. The issue was whether the requirement for a terminal disclaimer to overcome an ODP rejection could abrogate a patent term adjustment (PTA), which Congress authorizes to overcome delays during the original patent examination. The Federal Circuit had recently held that ODP-forced terminal disclaimers do *not* abrogate patent term extensions (PTE), a different statutory program to address regulatory delays at the U.S. Food and Drug Administration (FDA).[6] Nevertheless, in *Cellect*, the Federal Circuit held that, as a matter of plain statutory language, these different statutory programs had different language, and the language in the PTE statute that compelled it to uphold patent term extension was absent from the PTA statute. This distinction surprised many patent owners and caused great concern for those patent owners with portfolios that had been carefully expanded over the years on the assumption that PTA was also an exception.

In May 2024, the USPTO created even greater consternation with a notice of proposed rulemaking[7] that would have vastly expanded the scope of the ODP terminal-disclaimer requirement to add a third commitment from the inventor that its terminally disclaimed patents would be invalid if any claim linked by a terminal disclaimer were held invalid. This proposal appeared to arise from congressional and other federal agency perceptions that the USPTO and FDA were not doing enough to police perceived abuses of pharmaceutical patents.[8] The proposal was not limited to pharmaceutical patents, however.

Superficially, the proposal made sense—after all, if one claim is obvious, its obvious variants should also be obvious. On closer inspection, however, the logic falls apart. First, ODP works claim-by-claim, while terminal disclaimers operate at a patent level. Thus, patents could be linked by a terminal disclaimer to cure an ODP rejection between claims unrelated to the claim that is held invalid. Second, as case law had already held,[9] inventors sometimes agree to a terminal disclaimer just to move examination along, meaning that the basis for the ODP rejection had never been contested. Thus, the proposal would greatly increase the incentive of inventors to fight ODP rejections rather

[1] 35 U.S.C. 101 (in which "whoever invents … may obtain a patent" is read to mean a single patent); 102 (anticipation by prior-art disclosure).
[2] 35 U.S.C. 103.
[3] The Federal Circuit has consistently stated that ODP is "judicially created," but also that it is "based" in §101. Only equity could judicially create a doctrine inspired by, but not present in, a statute.
[4] So no hapless defendant finds itself sued by two different patent owners for allegedly infringing the same invention.
[5] 81 F.4th 1216 (Fed. Cir. 2023).
[6] *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018).
[7] *Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting*, 89 Fed. Reg. 40439 (May 10, 2024).
[8] Specifically, that a branded drugmaker could serially hop from one patent to another obvious variant to keep generic competitors perpetually barred from entering an established market.
[9] *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376, 1385 (Fed. Cir. 2007).

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Double-Patenting Jeopardy *(Continued from page 12)*

than terminally disclaim. In the face of considerable negative comments, the USPTO withdrew the proposal in December.[10]

In the meantime, the same panel of judges at the Federal Circuit decided another case that many patent owners saw as limiting its previous *Cellect* decision. In *Allergan USA v. MSN Laboratories*,[11] the panel reversed a district court's ODP invalidity determination. The court held (narrowly, in its view) that the first-filed, first-issued patent in a family[12] of patents "sets the maximum period of exclusivity for the claimed subject matter and any patentably indistinct variants."[13] In short, the first-issued patent determines when the public expects claims to the invention will expire, so later patents might be required to terminally disclaim over the earlier patent, but the first-issued patent cannot be invalid for failing to disclaim over a later-issuing patent. Sun[14] petitioned for rehearing, and the court ordered Allergan to respond, but Sun subsequently withdrew its rehearing request.

Strictly speaking, the court was addressing different questions in the two cases; hence, *Allergan* does not directly limit *Cellect*. Nevertheless, patent owners reacted with relief. First, it was good news for patent owners in what had thus far been a bad year for them regarding ODP. Second, and more importantly, it provided useful and limiting guidance on how ODP works during examinations, and thus indirectly limited some of *Cellect*'s fallout. Inventors could return to expanding their portfolios with greater guidance on what to avoid.

While the story seems to have ended happily for patent owners (less so for accused infringers), several issues remain. First, *Allergan* addresses what happens to obvious variants within the *same* family,[15] not what happens when the ODP rejection bridges different families. Presumably the occurrence of obvious variants between ostensibly different patent families will receive less sympathy, which may limit the complexity of patent portfolios and create a trap for inventors who fail to keep their patent families distinct. Second, *Allergan*'s exception is for the *first-filed*, first-issued patent. "First-issued" is clear enough, but if the patents are all from the same family, then by definition they should share an effective filing date, so what does first-issued mean and how does it contribute to the analysis? *Allergan* offers no direct answer, but the first-filed requirement does not seem to fit into the rationale of setting public expectations the way the first issuance does. Moreover, if "first-filed" only applies to the application that issues as a patent, what happens when the second-filed application issues first?

The complex edifice of ODP invalidity arises solely from case law equities.[16] As such, it has grown piecemeal and without legislative guidance. All the more remarkably, the USPTO rejects claims—a substantive result—solely on courts' acquiescence to the USPTO exercising equitable powers on a question of substantive law. Without congressional guidance, ODP law continues to evolve, possibly in more surprising ways.

Richard Torczon
(202) 973-8811
rtorczon@wsgr.com

[10] 89 Fed. Reg. 96152 (Dec. 4, 2024).
[11] 111 F.4th 1358 (Fed. Cir. 2024).
[12] A group of applications and patents claiming the benefit of a common original application. Because applications can claim the benefit of more than one earlier patent, families can overlap.
[13] 111 F.4th at 1369.
[14] Sun was a co-defendant with MSN.
[15] 11 F.4th at 1369 ("As the first-filed, first-issued patent in its family….").
[16] Congress has obliquely recognized ODP practice in 35 U.S.C. 121, but has yet to legislate directly on how it thinks invalidity should arise (if at all) for obvious variants.

Life Sciences Venture Financings for Wilson Sonsini Clients

By Scott Murano (Partner, Palo Alto)

The table below includes data from life sciences transactions in which Wilson Sonsini clients participated across the second half of 2023 and the first half of 2024. 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.

	2H 2023	2H 2023	2H 2023	1H 2024	1H 2024	1H 2024
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	65	$1,179.32	$18.14	67	$1,891.48	$28.23
Genomics	5	$82.98	$16.60	6	$134.36	$22.39
Diagnostics	10	$62.48	$6.25	19	$142.80	$7.52
Medical Devices & Equipment	36	$284.46	$7.90	46	$716.61	$15.58
Digital Health	14	$115.27	$8.23	28	$576.63	$20.59
Healthcare Services	26	$392.19	$15.08	19	$290.08	$15.27
Total	**156**	**$2,116.70**		**185**	**$3,751.96**	

The data demonstrates that venture financing activity increased significantly from the second half of 2023 to the first half of 2024 with respect to the total amount raised and number of closings. Specifically, the total amount raised across all industry segments increased 77.3 percent, from $2,116.70 million to $3,751.96 million, while the total number of closings across all industry segments increased 18.6 percent, from 156 to 185.

The industry segment with the largest number of closings during the first half of 2024—biopharmaceuticals—increased in number of closings and total amount raised from the second half of 2023 to the first half of 2024. Specifically, the number of closings in biopharmaceuticals increased 3.1 percent, from 65 to 67, while the total amount raised increased 60.4 percent, from $1,179.32 million to $1,891.48 million. Similarly, the industry segment with the second-largest number of closings during the first half of 2024—medical devices and equipment—saw a substantial increase in number of closings and in total amount raised. Specifically, the number of closings in the medical devices and equipment segment increased 27.8 percent, from 36 to 46, while the total amount raised increased 151.9 percent, from $284.46 million to $716.61 million.

> From 2H 2023 to 1H 2024, the total amount raised across all industry segments increased 77.3 percent, while the total number of closings across all industry segments increased 18.6 percent

Digital health, the industry segment with the third-largest number of closings during the first half of 2024, also experienced an increase in number of closings and total amount raised across these same periods, as the number of closings increased 100 percent, from 14 to 28, and the total amount raised increased a massive 400.2 percent, from $115.27 million to $576.63 million. One of the industry segments tied for the fourth-largest number of closings during the first half of 2024—diagnostics—also experienced an increase in both number of closings and total amount raised. Specifically, the number of closings increased 90 percent, from 10 to 19, while the total amount raised increased 128.6 percent, from $62.48 million to $142.80 million. Rounding out the field of industry segments experiencing growth over the two six-month periods was genomics, which experienced a modest 20 percent gain in number of closings,

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Life Sciences Venture Financings for Wilson Sonsini Clients *(Continued from page 14)*

from five to six, and a more meaningful 61.9 percent gain in total amount raised, from $82.98 million to $134.36 million.

The only industry segment to buck this upward trend and experience a decline in activity between the second half of 2023 and the first half of 2024 was healthcare services. Specifically, the number of healthcare services closings decreased 26.9 percent, from 26 to 19, while the total amount raised decreased 26 percent, from $392.19 million to $290.08 million.

In addition, our data generally indicates that Series Seed, Series A, Series C and later-stage, and recapitalization financing activity, as a percentage of all financing activity and measured by number of closings, decreased from the second half of 2023 to the first half of 2024, while Series B and non-traditional financing activity increased over that same period. Specifically, the number of Series Seed closings as a percentage of all closings experienced a slight decrease, from 19.0 percent to 17.9 percent; the number of Series A closings decreased from 28.8 percent to 20 percent; the number of Series C and later-stage closings decreased from 12.3 percent to 10 percent; and the number of recapitalization closings decreased from 1.2 percent to 0.5 percent. The number of Series B closings as a percentage of all closings increased significantly, from 8.6 percent to 14.2 percent, and the number of other non-traditional financing closings also experienced a meaningful increase, moving from 7.4 percent to 13.7 percent.

> Average pre-money valuations for life sciences companies increased across the board from the second half of 2023 to the first half of 2024 for all stages of financings

Average pre-money valuations for life sciences companies increased across the board from the second half of 2023 to the first half of 2024 for all stages of financings. In particular, the average pre-money valuation for Series Seed financings increased 14.6 percent, from $15.47 million to $17.72 million; for Series A financings, it increased 4.2 percent, from $35.38 million to $36.86 million; for Series B financings, it increased 256.6 percent, from $55 million to $196.15 million; and for Series C and later-stage financings, it increased 331.3 percent, from $157.14 million to $677.82 million.

Overall, the data indicates that financing activity improved dramatically between the second half of 2023 and the first half of 2024—and moreover, this increase was substantial in terms of total amounts raised and number of closings. It is also worth highlighting that this increase in financing activity occurred most significantly at the Series B stage, with dramatically improved valuations over the prior period, suggesting an increased, robust demand among investors to take companies at that stage forward, which will come as much relief to the glut of companies unable to raise Series B funding over the past few years because of the weak financing environment. Whether this improved financing activity will last is anyone's guess, given the effect a new administration will have on short-term macroeconomic factors that will influence venture financing investment, but at least the activity is now trending in the right direction.

> The data indicates that financing activity improved dramatically between 2H 2023 and 1H 2024—and moreover, this increase was substantial in terms of total amounts raised and number of closings

Scott Murano
(650) 849-3316
smurano@wsgr.com

An Offering for Wilson Sonsini Life Sciences Clients: Technical Writing and IPO Documentation

Wilson Sonsini is pleased to offer a suite of services for life sciences clients navigating the complexities of initial public offerings (IPOs). Leveraging the scientific expertise of the firm's patents and innovations and corporate practices, our team provides specialized business and technical writing services, including drafting the business section of the registration statement, preparing investor presentations, and handling other technical writing needed during the IPO process.

Uniquely, our life sciences-focused patent team consists of more than 170 legal professionals with Ph.D. degrees and other advanced degrees in biology, chemistry, biomedical sciences, or engineering. Our technical writing expertise encompasses biopharmaceuticals, small molecule therapeutics, research tools, medical devices, genomics, bioinformatics, artificial intelligence, and materials. Because our professionals are credentialed scientists who are intimately familiar with the science at the core of the client's business, as scientific writers, they are well positioned to draft a Form S-1 or Form F-1 business section that meets the SEC's exacting standards for registration statements, dovetails with the client's patent strategy, and tells a compelling and exciting story about the client's technology, business, and value proposition to educate potential investors.

The firm has a 60-plus-year history of representing trailblazers in the life sciences industry, from the earliest innovators to those shaping the future of healthcare today. Our attorneys work closely with entrepreneurs, scientists, and investors who trust Wilson Sonsini's strategic advice to establish and realize their companies' business objectives. We represent life sciences companies through the entire business life cycle, from formation through IPO and strategic partnerships, and we are often the company's only counsel and provide broad strategic advice with support from our cross-functional, global life sciences team. This breadth of experience informs our IPO-related scientific writing and allows us to produce optimal capitalization results for our clients.

Wilson Sonsini's IPO scientific writers are professionals in global patent portfolio development and management. They include former senior technology licensing executives at top-tier research universities and former in-house legal counsel for major life sciences companies.

The unparalleled combination of our scientific backgrounds and industry experience enables us to accelerate and streamline the IPO process by producing a business description in advance of an IPO organizational meeting, thereby allowing management to maintain its focus on operating the business.

For more information on the firm's technical writing and IPO documentation services, please contact:

Marty Waters
Partner, Corporate
(858) 350-2308
mwaters@wsgr.com

Lou Lieto
Partner, Patents and Innovations
(617) 598-7802
llieto@wsgr.com

Michael Hostetler
Partner, Patents and Innovations
(858) 350-2306
mhostetler@wsgr.com

Jennifer Fang
Partner, Corporate
(617) 598-7800
jfang@wsgr.com

Wilson Sonsini Hosts Inaugural Biotech Summit in Boston

On October 9-10, 2024, the firm held its inaugural Biotech Summit, which addressed topics of critical importance to biotech and biopharmaceutical companies. The unique event, which took place at The Newbury Boston, brought together 280 leaders from across the biotech industry, including CEOs, prominent investors, policymakers, and esteemed researchers.

Following a welcome reception and dinner the evening of October 9, the Summit continued with a full day of panel discussions and networking on October 10. The panels covered topics including venture capital financing trends, navigating antitrust issues and Federal Trade Commission scrutiny in the life sciences sector, leveraging AI in therapeutics, patent issues for biotech entrepreneurs, life sciences capital markets and IPO trends, M&A strategies and trends, engaging with the U.S. Food and Drug Administration, successful biotech collaborations with pharma, and biological mapping. The Summit also featured a fireside chat with Chris Gibson, co-founder and CEO of Recursion Pharmaceuticals, moderated by Wilson Sonsini partner Farah Gerdes.

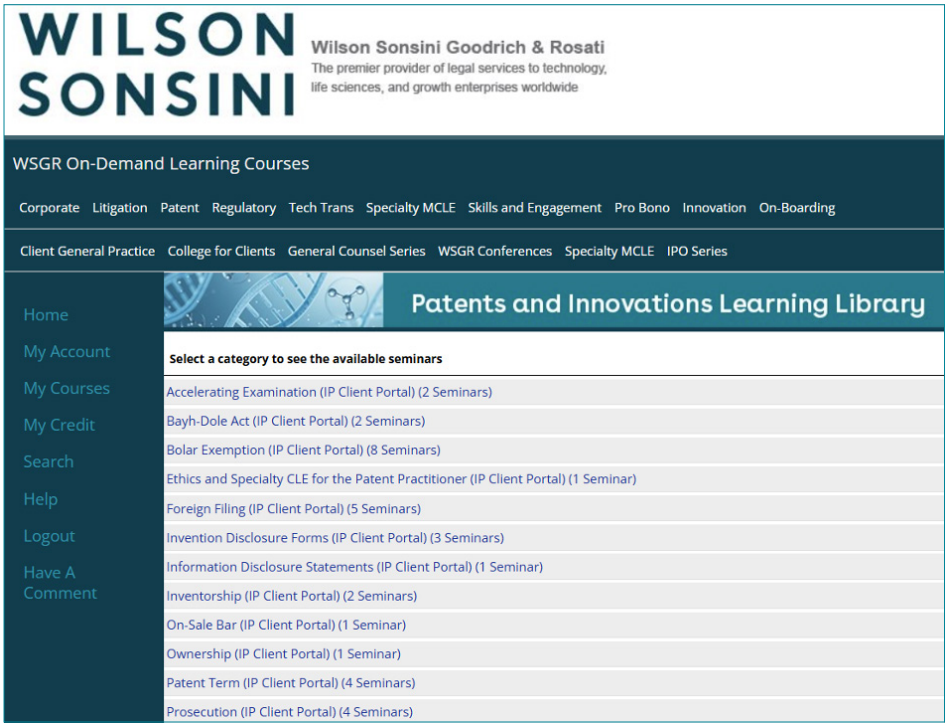
In addition, throughout the day, a Partnering Hall provided personalized opportunities for attending investors and large pharma companies to meet with start-ups searching for and pursuing potential investment, partnering, and acquisition opportunities.

The Summit concluded with a lively wine tasting reception featuring venture capitalists serving as sommeliers.

Click here to view a brief video of highlights from the event. For more information on the 2024 Biotech Summit, please visit https://biotech.wsgrevents.com/.

New Course Offerings: Life Sciences Patents and Innovations Learning Library for In-House IP Counsel

Wilson Sonsini's Patents and Innovations Learning Library has recently been updated to include new topics and educational courses. Available in the On-Demand Learning section of our firm's website, this curated collection of legal learning by our patent attorneys is designed to empower in-house IP counsel in the life sciences sectors with the knowledge and insights needed to navigate the complex world of patent law.



Our latest additions include a Foreign Filing mini-series to help clients understand foreign filing licenses and global filing strategies, as well as a 2024 summer associate-curated mini-series covering Infringement Safe Harbors and Research Exemptions. In addition, we have added a specialized CLE on AI and Patent Practice, offering guidelines on key considerations when using AI during the inventive process.

Current content offerings include the following:

- **Foreign Filing mini-series:**
  - Where Should I File?
  - What Do I Do If I Don't Get a FFL?
  - Secrecy Orders
  - Recommendations and Special Considerations
- **Bolar Exemption – Safe Harbors and Research Exemptions:**
  - An Introduction to Infringement Safe Harbors and Exemptions
  - What About Research Tools for Infringement Safe Harbors and Exemptions?
  - Infringement Safe Harbors and Exemptions: Part 3, Research Tools - Methods of Producing
  - Safe Harbors and Exemptions: Part 4, Importing Samples
  - *Amgen v. Hospira* Case
  - *Classen Immunotherapies v. Elan* Case
  - Non-Exempt Post-Approval Activities
- **Specialty CLE:**
  - AI and the Patent Practice

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Firm Holds 29th Annual Phoenix Conference

On October 23-25, 2024, Wilson Sonsini hosted its 29th annual Phoenix Conference at The Ritz-Carlton in Half Moon Bay, California. More than 130 top-level executives from large healthcare companies and CEOs of small, venture-backed firms attended the exclusive event, which provided an opportunity to explore critical issues of interest to the medical device industry today. Attendees also networked and gained valuable insights from industry leaders and peers.

The conference kicked off on October 23 with a women's networking lunch, followed by an open discussion on how unconscious bias in the boardroom can influence decision-making, board dynamics, and corporate governance. The event continued with a fireside chat featuring Haemonetics President and CEO Chris Simon; a presentation by HSBC Managing Director Jon Norris on the current climate for medtech investment; an investor panel providing insights on what they look for in new opportunities; and a panel addressing pricing and reimbursement strategies. The first day concluded with David Cassak of Medtech Strategist interviewing Coridea co-founders Mark Gelfand and Dr. Howard Levin, winners of the Phoenix Hall of Fame 2024 Innovator Award. Mark is Managing Partner and Chief Technical Officer and Dr. Levin is Managing Partner, President, and Chief Medical Officer of Coridea, a global medical device incubator that specializes in cardiac, pulmonary, and renal innovation. The interview was followed by a welcome reception and dinner.

The second day of the conference began with panel discussions addressing successful execution in high-growth organizations and the steps and multiple layers of an M&A transaction. It continued with David Cassak interviewing Phoenix Hall of Fame 2024 Lifetime Achievement Award winner Dr. Stephen Oesterle, a former faculty member at Stanford and Harvard Medical Schools who was previously Medtronic's SVP for Medicine and Technology and a member of the company's Executive Committee, and currently serves as a healthcare industry consultant and independent director on public and private boards in the U.S., Switzerland, Germany, and China. Then, Congresswoman Anna G. Eshoo and Stanford Byers Center for Biodesign Director Josh Makower provided an update on current legislative initiatives with the potential to impact the healthtech sector. In addition, Congresswoman Eshoo was honored with the Phoenix Lifetime Leadership Award for her dedication to innovation in the industry. The formal program concluded with an open Town Hall session where attendees were invited to raise top-of-mind issues.

During the evening of October 24, the event featured the 2024 Phoenix Hall of Fame Reception and Dinner, which celebrated this year's award winners.

For more information about the 2024 Phoenix Conference, please visit https://phoenix.wsgrevents.com/.

MedTech Innovator and BioTools Innovator Applications for 2025 Now Open – Apply by January 15!

As a longtime partner of MedTech Innovator, the world's largest accelerator for medical device, digital health, and diagnostic companies, Wilson Sonsini is pleased to share that the 2025 application cycle for MedTech Innovator and BioTools Innovator is now open. Applications are due by January 15, 2025; please see below for more information:

MedTech Innovator (MTI) is the largest and highest-performing accelerator of medical technology in the world and the medtech industry's premiere showcase and global competition for innovative medical device, digital health, and diagnostic companies. Its mission is to accelerate the growth of start-ups that are revolutionizing patient care and outcomes. **BioTools Innovator** (BTI), powered by MTI, focuses on advancing life science tools and enabling technologies, nurturing entrepreneurs addressing challenges, and creating new opportunities to transform drug discovery and diagnostic accuracy.

Both programs offer unparalleled access to top-tier mentoring, coaching, and education in a tailored four-month curriculum designed to help innovators overcome obstacles and bring their products to market quickly and effectively. The accelerators connect start-ups with leading investors, strategic partners, suppliers, and peer networks, providing ongoing coaching and mentorship. A robust schedule of in-person events and virtual webinars delivers timely, relevant insights from industry experts who have "been there and done that."

Finalists can win up to $1 million in non-dilutive cash prizes to fuel ongoing innovation. To date, MTI and BTI have collectively reviewed nearly 12,000 applicants, supported the growth of 717 companies, helped them raise over $8.7 billion in funding, and introduced more than 350 products to the market. These accelerators are dedicated to driving health innovation and improving patient outcomes by fostering the next generation of healthcare solutions.

Don't miss your chance! Submit your application by January 15:

MedTech Innovator
www.medtechinnovator.org/apply

BioTools Innovator
www.biotoolsinnovator.org/apply

New Episodes of NextGen VC Podcast Focused on Life Sciences Investing Now Available

LaunchBio and Wilson Sonsini's NextGen VC Podcast is 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 details on the latest podcast episodes.

Episode 9:
Danjuma Quarless
Associate Director, AbbVie Ventures

Danjuma shares insights on how corporate VCs like AbbVie differ from traditional VCs, particularly in the biotech and pharmaceutical industries. He discusses the strategic focus of AbbVie Ventures, the importance of scientific and competitive differentiation in securing investment, and the fluid communication within AbbVie's ecosystem. In addition, Danjuma talks about his personal journey from a research scientist to a venture capitalist, offering valuable advice for those looking to break into the VC space. The podcast also touches on current trends in biotech, the challenges and opportunities in various regional ecosystems, and the importance of promoting diversity within the venture capital industry.

Episode 8:
Jeff Chu
Founder and Managing Partner, Features Capital

In Part 2 of a two-part series, Jeff discusses his journey from owning a consulting firm to co-founding a venture fund, the unique approach that Features Capital takes toward investing in medtech start-ups, and the importance of diversity and first-generation wealth creators in the venture capital space. He also shares the personal philosophies and strategies that have shaped his career and the culture of Features Capital.

Episode 7:
Jenny Barba, MBA
Founder and Managing Partner, Features Capital

In Part 1 of a two-part series, Jenny discusses her journey from neuroscience and finance to founding her own VC firm, her passion for supporting diverse and first-time founders in medtech, and the unique challenges and opportunities in venture capital investment. Jenny also offers a behind-the-scenes look at building a portfolio and shares personal anecdotes, including the touching story behind the name "Features Capital," driven by a conversation with her son.

Episode 6:
Jody and Morgan Thelander
J. Thelander Consulting

With a deep background in executive compensation and a unique understanding of the biotech industry, Jody shares how Thelander Consulting's real-time compensation survey has become an essential resource for over 5,000 investment firms. Jody and Morgan also discuss crucial aspects of VC compensation, including base pay, bonuses, and carried interest, and share insights for both established VCs and those new to the industry. In addition, they provide practical advice on leveraging data to make informed decisions that drive growth and success for careers in venture capital.

Episode 5:
Jeni Lee
Partner, Pivotal bioVenture Partners

Jeni discusses a range of topics, from the announcement of Pivotal's second fund to specific investment strategies and the unique aspects of investing in life sciences. She also shares insights into her Ph.D. journey, her strategy in transitioning to the investment world, the importance of embracing risk, and what has shaped her career trajectory thus far. In addition, the conversation explores the crucial role of network building for aspiring venture capitalists and the dynamics between investors and companies within the venture ecosystem.

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New Episodes of NextGen VC Podcast . . . *(Continued from page 21)*

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 at 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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Select Recent Life Sciences Client Highlights

Over the past six months, Wilson Sonsini has provided representation in connection with the below client matters:

- Advised **Novo Holdings** on its investment in SiteOne Therapeutics' $100 million Series C (December 2024)
- Advised **OrbiMed** on patent matters related to its investment in Ottimo Pharma's $140 million Series A (December 2024)
- Advised **USANA Health Sciences** on its acquisition of a controlling ownership stake in Hiya Health Products (December 2024)
- Advised **Aadi Bioscience** on its $100 million sale of FYARRO®, $100 million PIPE financing, and license agreement for ADC portfolio (December 2024)
- Advised **TigaRx** on its receipt of up to $35.5 million in ARPA-H and NIH funding for engineered IgA platform for cancer and infectious disease (December 2024)
- Advised **BioSapien** on its $5.5 million pre-Series A funding (December 2024)
- Advised **Lumos Pharma** on tender offer and $38 million merger with Double Point Ventures (December 2024)
- Advised **Cimeio Therapeutics** on its research collaboration with Kyowa Kirin to develop novel cell therapies (December 2024)
- Advised **Nvelop Therapeutics** on IP matters related to its merger with Chroma Medicine (December 2024)
- Advised **Dewpoint Therapeutics** on its strategic research collaboration with Mitsubishi Tanabe Pharma Corporation to advance Dewpoint's novel TDP-43 small molecule condensate modulator for ALS (December 2024)
- Advised **Janux Therapeutics** on patent matters related to its $350 million underwritten public offering (December 2024)
- Advised **6 Dimensions Capital** and its portfolio company **VFLO Medical** on joint venture with medical device company Inari Medical in Greater China to provide access to Inari's technology for patients with significant unmet needs (December 2024)
- Advised **Saniona** on its partnership with Acadia Pharmaceuticals for the development and commercialization of SAN711 in neurological diseases (November 2024)
- Advised **Doron Therapeutics** on its $11 million Series A (November 2024)
- Advised **GI Windows Surgical** on its $37 million Series B (November 2024)
- Advised **Kura Oncology** on its global strategic collaboration with Kyowa Kirin to develop and commercialize ziftomenib (November 2024)
- Advised **OneSkin** on IP matters related to its Series A financing (November 2024)
- Advised **Forte Biosciences** on its oversubscribed $53 million equity financing (November 2024)
- Advised **Invus Opportunities, F-Prime Capital, and Medical Technology Venture Partners** on their investments in Zenflow's $24 million Series C (November 2024)
- Advised **LaNova Medicines** on its exclusive global license with Merck to develop, manufacture, and commercialize LM-299 (November 2024)
- Advised **Pacific Biosciences of California, Inc.** on its $459 million convertible note exchange (November 2024)
- Advised **PrognomiQ** on patent matters related to its $34 million Series D (November 2024)
- Secured a total victory for **Inhibrix Biosciences** and **Dr. Brendan Eckelman** in a trade secrets misappropriation trial (November 2024)
- Advised **General Atlantic** on patent matters related to Seaport Therapeutics' $225 million Series B (October 2024)
- Advised **Novo Holdings** and **F-Prime Capital** on AvenCell's $112 million Series B (October 2024)
- Advised **Opus Genetics** on IP matters related to its acquisition by Ocuphire Pharma (October 2024)
- Advised **Terray Therapeutics** on its $120 million Series B (October 2024)
- Advised **Goldman Sachs Alternatives** on patent matters related to its Series B investment in Triveni Bio (October 2024)
- Advised **Crinetics Pharmaceuticals** on patent matters related to its upsized $500 million common stock offering (October 2024)

Continued on page 24...

Select Recent Life Sciences Client Highlights *(Continued from page 23)*

- Advised **Evercore** on Longboard Pharmaceuticals' $2.6 billion acquisition by Lundbeck (October 2024)
- Advised **MARAbio Systems** on IP matters related to its $19 million Series A financing (October 2024)
- Advised **Cytovale** on IP matters related to its $100 million Series D financing (October 2024)
- Advised **Circle Pharma** on its research collaboration with Boehringer Ingelheim (October 2024)
- Advised **Ahren, OMX Ventures, +ND Capital, and Fine Structures Ventures** on Constructive Bio's $58 million Series A financing (September 2024)
- Advised **858 Therapeutics** on IP matters related to its $50 million Series B financing (September 2024)
- Defeated $341 million arbitration claim against **Aadi Bioscience, Inc.** (September 2024)
- Advised **GC Therapeutics** on its $65 million Series A financing (September 2024)
- Advised **Ripple Therapeutics** on its collaboration and option-to-license agreement with AbbVie (September 2024)
- Advised **Neurode** on its $3.5 million pre-Seed financing (September 2024)
- Advised **Neo Medical SA** on its $68 million equity investment (September 2024)
- Advised **MBX Biosciences** on patent matters related to its $188 million IPO (September 2024)
- Advised **Candid Therapeutics** on patent matters related to three-way merger and $370 million capital raise (September 2024)
- Advised **ONL Therapeutics** on patent matters related to its $65 million Series D financing (September 2024)
- Advised **Cellino Biotech** regarding its award from the Advanced Research Projects Agency for Health (ARPA-H) for up to $25 million in funding (September 2024)
- Advised **eGenesis** on patent matters related to its $191 million Series D financing (September 2024)
- Advised **HAYA Therapeutics** on patent matters related to its multi-year collaboration with Eli Lilly (September 2024)
- Advised **Circle Pharma** on its $90 million Series D financing (September 2024)
- Represented **Vertos Medical Inc.** in its acquisition by Stryker (August 2024)
- Advised **JP Morgan Life Sciences Private Capital** on Pathalys Pharma's $105 million Series B financing (August 2024)
- Advised **Borealis Biosciences** on its $150 million Series A and strategic research collaboration funding (August 2024)
- Advised **Avidity Biosciences** on IP matters related to its public offering (August 2024)
- Advised **Neptune Medical** on its $97 million Series D financing (August 2024)
- Represented **Recursion** in its definitive agreement to combine with Exscientia (August 2024)
- Advised **MBX Biosciences** on patent matters related to its $63.5 million Series C financing (August 2024)
- Advised **Novo Holdings** on IP matters related to its £50 million investment in Oxford Nanopore Technologies (August 2024)
- Advised **Autobahn Therapeutics** on IP matters related to its $100 million Series C financing (July 2024)
- Advised **Dren Bio** on its strategic collaboration with Novartis Pharma AG (July 2024)
- Advised **Novo Holdings** on Magenta Medical's $105 million financing (July 2024)
- Advised **Vida Ventures** on IP matters related to Third Arc Bio's $165 million Series A financing (July 2024)
- Advised **Digestiva** on its $18.4 million Series A financing (July 2024)
- Advised **LENZ Therapeutics** on its $30 million private investment in public equity common stock financing (July 2024)
- Advised **Adona Medical** on its $33.5 million Series C financing (July 2024)
- Represented **Fluent BioSciences** in its acquisition by Illumina (July 2024)
- Advised **Radionetics Oncology** on patent matters related to its strategic agreement with Eli Lilly (July 2024)

Upcoming Life Sciences Events

Wilson Sonsini's Medical Device & Digital Health Conference
June 5-6, 2025
InterContinental San Francisco
San Francisco, CA
https://mdc.wsgrevents.com/

Wilson Sonsini's 32nd Annual Medical Device & Digital Health Conference will address topics of critical importance to medical device and digital health companies today. 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.

Phoenix 2025: The Medical Device and Diagnostic Conference for CEOs and Medtech Executives
October 8-10, 2025
Hyatt Regency Scottsdale at Gainey Ranch
Scottsdale, AZ
https://phoenix.wsgrevents.com/

The 2025 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 exclusive, two-day event will provide an unrivaled experience that will help inform and shape company strategy for the years ahead.

Wilson Sonsini's Biotech Summit
October 22-23, 2025
The Newbury Boston
Boston, MA
https://biotech.wsgrevents.com/

Wilson Sonsini's Second Annual Biotech Summit will address topics of critical importance to biotech and biopharmaceutical companies. This unique event will bring together leaders from across the biotech industry, including CEOs, prominent investors, esteemed researchers, and policymakers.

Elton Satusky, Scott Murano, T.O. Kong, 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.

Elton Satusky
(650) 565-3588
esatusky@wsgr.com

Scott Murano
(650) 849-3316
smurano@wsgr.com

T.O. Kong
(415) 947-2016
tkong@wsgr.com

Kimberly Stopak
(415) 947-2024
kstopak@wsgr.com

WILSON SONSINI

650 Page Mill Road, Palo Alto, California 94304-1050 | Phone 650-493-9300 | Fax 650-493-6811 | www.wsgr.com

Wilson Sonsini has 18 offices in technology and business hubs worldwide. For more information, visit wsgr.com/offices.