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WILSON SONSINI

THE LIFE SCIENCES REPORT

Firm Launches Salt Lake City Office to Better Serve Local Clients, Emerging Companies

In November 2021, Wilson Sonsini announced the launch of a new office in Salt Lake City, Utah, to enhance the

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In This Issue

Spotlight on Foresight Diagnostics and Its Co-founder and CEO, Jake Chabon

Wilson Sonsini's legal and business advisory teams helped Foresight Diagnostics progress from a concept at a Stanford University lab to a VC-funded operating company that recently relocated to the Fitzsimons Innovation Center in Denver, Colorado. Foresight is developing the most accurate non-invasive cancer detection technologies available to improve the lives of patients worldwide.

Matthew Meyer, the firm's Chief Business Advisor for Life Sciences, recently sat down with Foresight co-founder and CEO Jake Chabon to discuss the evolution of his venture and learn about the experience of starting a diagnostics business and raising capital in the midst of the COVID-19 pandemic.

Matt: You've had a busy couple of years since you founded Foresight in early 2020, at the beginning of the pandemic. What was the catalyst to do this at such a challenging time?

Jake: My three co-founders and I had been focused on developing a more accurate non-invasive cancer detection platform for some time. When we generated breakthrough data in 2019 that showed the potential to achieve a ~10 to 100-fold increase in analytical sensitivity for cancer detection compared to existing methods based on published literature, we knew it was time to launch the company.

Starting a business is challenging even in the best of times. You started Foresight just as the pandemic was getting going and the world was in

lockdown. How did that play out for you and what did you learn along the way?

Initially, we weren't sure how it was going to affect our efforts. Fortunately, within a few months of the pandemic's beginning, it became clear that business would be able to continue, thanks to technologies that enable remote work. My co-founders were able to focus on performing experiments while incorporating the company and obtaining a license to the technology and IP from Stanford. During this period, the broader investment climate actually improved for companies like ours in the diagnostics sector, given the increased focus on identifying diseases.

Foresight retained Wilson Sonsini to help Foresight get off the ground and operating. What were the factors that led to this decision?

This is my first start-up. I knew that I needed advisors who could help the

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Spotlight on Foresight Diagnostics and Its Co-founder and CEO, Jake Chabon *(Continued from page 1)*

company across a range of domains, from incorporation to protecting our intellectual property to financing the business. When I learned that Wilson Sonsini also had a business advisory practice, I was particularly interested in taking advantage of that offering because Foresight ideally wanted a one-stop shop for all legal and advisory services. It just made sense to have one firm provide all of this. That's what ultimately led to our decision to engage Wilson Sonsini. The ability of the firm to provide us with a seamless range of legal and business support proved helpful and efficient in establishing the company and successfully executing on the fundraising process.

> "Wilson Sonsini's business advisory practice helped us develop a strong business plan and supported us throughout the process of engaging with VCs, honing our pitch over time, and going through the technical due diligence process"

Can you elaborate on the fundraising piece?

We felt that to successfully raise our first round of financing, we needed a team that understood our business, as well as the process of discovering, developing, and ultimately commercializing our diagnostic products. We also needed a team that could help us connect with the more thoughtful institutional investors active in this segment. Wilson Sonsini's business advisory practice helped us develop a strong business plan and supported us throughout the process of engaging with VCs, honing our pitch over time, and going through the technical due diligence process. During this time, we were also actively building out our team, and the business advisory practice helped by making introductions to people with relevant domain expertise. In addition, I worked with the firm's corporate and IP practices to engage the venture capital community and support our path to a successful $12 million Series A financing.

Tell us more about Foresight's products.

There are 1.2 million new cancers each year in the U.S. that are amenable to the Foresight approach, corresponding to a $25 billion market opportunity. We are prioritizing cancers where detection by our assay could lead to curative-intent treatments, including lung, breast, colon, skin, bladder, and blood cancers, which can lead to direct clinical utility. To establish an initial market, we are focusing on diffuse large B-cell lymphoma (DLBCL). With ~18,000 new cases per year, DLBCL is the most common blood cancer.

You decided to move Foresight to Colorado in late 2020. Why make that move?

We wanted to base the company in a locale that had a lower cost of living while also offering access to world-class talent. The Denver/Boulder market offered a rich mix of research universities, life sciences talent, and more cost-effective access to lab and office space.

As you grow Foresight and look to the future, what advice would you share with fellow life sciences entrepreneurs about starting and scaling a knowledge-based life sciences business like yours?

I would start by being clear about what you know and don't know. Engaging with advisors was very important and helpful to Foresight, and allowed us to move faster and avoid some mistakes. Of course, all companies are on a learning pathway and missteps do occur. Surround yourself with a supportive and hard-working team, from your co-founders and board members to the legal and business counsel you retain. Ultimately, your extended team is what will help lead your venture to success, so everyone is a critical part of the effort.

Thank you, Jake.

Jake Chabon, Ph.D., is the CEO and CSO of Foresight Diagnostics, which he co-founded with academic partners in 2020. He is a molecular biologist and bioinformatic scientist with more than 20 peer-reviewed publications and 2,700+ citations to date (including a Nature *paper related to Foresight's liquid biopsy platform). Prior to founding Foresight, Jake's research focused on using cancer genomics to inform more personalized treatment strategies for cancer patients. He has extensive experience with NGS assay development with an emphasis on developing non-invasive cancer detection methods and applying these methods to better understand mechanisms of response and resistance to cancer therapies. Jake completed his Ph.D. and his postdoctoral training at Stanford University under the co-mentorship of Dr. Max Diehn and Dr. Ash Alizadeh, with whom he co-founded Foresight Diagnostics. For more information, please visit https://foresight-dx.com/.*

Recent Pharmaceutical Antitrust Developments and Expectations for 2022

By Jeff Bank (Partner, D.C.), Paige Hammond (Law Clerk, D.C.), Nathan Mendelsohn (Associate, D.C.), Seth Silber (Partner, D.C.), and Brendan Coffman (Senior Counsel, D.C.)

Life sciences companies, and particularly pharmaceutical manufacturers, have long been in the antitrust spotlight, and we expect this trend to continue in 2022 and beyond. Increased attention from federal and state legislators, media, and health care experts has generated pressure on antitrust enforcers to address perceived issues relating to pricing, mergers and acquisitions, and access to care. As part of this energized focus on antitrust in the health care industry, President Biden signed a historic Executive Order calling on federal agencies to curb perceived antitrust abuses,[1] including asking the Federal Trade Commission (FTC) to curb "unfair anticompetitive conduct or agreements in the prescription drug industries" and calling for a "whole-of-government approach" to antitrust enforcement.[2] But antitrust law is not a panacea, and courts continue to look carefully at claims brought in this space to properly balance innovation against any alleged harms.

This article provides a high-level overview of some recent developments in antitrust litigation relating to pharmaceutical manufacturers, which typically arises in two contexts: 1) alleged anticompetitive patent litigation settlement agreements between brand manufacturers and generic manufacturers, and 2) manufacturers' allegedly exclusionary conduct, often relating to regulatory processes, commercial strategies, and product development.[3]

Patent Litigation Settlements

In typical patent litigation settlements, the defendant may pay the plaintiff for a license or to compensate for infringement. However, in so-called "reverse payment" pharmaceutical patent settlements (also called "pay-for-delay" settlements), the plaintiff brand patentholder compensates the generic defendant, who in exchange agrees on a future licensed entry date. In *FTC v. Actavis*, the Supreme Court found that this practice may violate the antitrust laws if the payment is "large and unjustified" and delays generic entry.[4] Under this precedent, brands and generics can settle patent litigation by negotiating an entry date that presumably reflects both sides' views of the underlying merits; however, any additional provision that constitutes a "large and unjustified" payment from the brand to the generic may be an unlawful payment if it results in a later entry date than would have occurred but for that payment. However, courts have struggled to consistently interpret the law in the wake of *Actavis*, with new scenarios and questions constantly testing the contours of the decision.

Courts have struggled to consistently interpret the law in the wake of *Actavis*, with new scenarios and questions constantly testing the contours of the decision

Types of Payment

Although courts agree that cash payments in exchange for delayed entry (beyond certain litigation savings payments)[5] are unlawful, courts have also analyzed various other types of provisions to evaluate whether the settlement is anticompetitive, including 1) side deals, 2) agreements by the brand not to launch an authorized generic ("no-AG" deals), and 3) acceleration clauses coupled with other conduct.

Side Deals

Side deals are alleged agreements between a brand and generic to engage in business transactions unrelated to merits of the underlying patent litigation. If the side deal is found to be a pretextual vehicle to convey payment from the brand to the generic in exchange for a later entry date on the product at issue in that litigation, it may constitute an anticompetitive reverse payment.[6] For example, the settling manufacturers

[1] 3 CFR Executive Order 14036.
[2] As one example, the Food and Drug Administration (FDA) recently requested the FTC investigate whether a manufacturer filed a Citizen Petition with the FDA "with the primary purpose of delaying approval" of a generic's ANDA as an anticompetitive business practice.
[3] These are just some of the many legal issues facing life sciences companies, and future articles can address other hot issues, such as close scrutiny of transactions particularly relating to hospitals and biotech, regulator pressure on pharmacy benefit managers and insurers, and alleged price-fixing and labor market conspiracies.
[4] *FTC v. Actavis, Inc.*, 570 U.S. 136, 156 (2013).
[5] Litigation savings payments of $7 million or less are generally considered lawful.
[6] *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 334 (D.R.I. 2017).

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Recent Pharmaceutical Antitrust Developments and Expectations for 2022 *(Continued from page 3)*

may enter into licensing arrangements, joint ventures, or marketing deals related or unrelated to the product at issue. If those agreements are for greater than reasonable fair market value, a court may find them to be pretext and unlawful. Sometimes, the parties might also settle other claims as part of the primary settlement.[7]

No-AG Agreements

In a no-AG agreement, the brand agrees not to launch an "authorized generic" for some period of time after the settling generic enters the market. Such an agreement may be considered an unlawful payment if a court finds it has an adverse effect on competition.[8] For example, a court recently held that a brand manufacturer's agreement not to launch its own AG until a year after generic entry is actionable.[9] Courts may also find that an implicit no-AG agreement is actionable, if, for example, a brand retains the right to launch an AG but is otherwise disincentivized or unlikely to do so.[10]

Acceleration Clauses

Acceleration clauses, also known as Most Favored Nation (MFN) or Most Favored Entry (MFE) clauses, allow the settling generic manufacturer to enter the market if some condition is met, typically if another generic enters the market. No court has found an acceleration clause in a settlement to be an anticompetitive payment on its own,[11] but such a clause may be anticompetitive when combined with other settlement clauses that delay generic entry. This includes MFEs in which the brand agrees not to grant a license to other generics for some period of time, effectively granting exclusivity to a particular settling generic ("MFE-Plus"). For example, a district court found that an MFE-Plus clause could be anticompetitive where it conveyed exclusivity to a generic that was not otherwise entitled to statutory exclusivity because such an arrangement may have deterred other generics from continuing to litigate or trying to enter the market.[12]

> Recently, plaintiffs and enforcers are pursuing holistic theories of exclusion that combine multiple strategies by a pharmaceutical company, including sometimes combining allegations of unlawful patent litigation settlements with allegations of exclusionary conduct

Alleged Exclusionary Conduct

Under U.S. antitrust laws, obtaining or maintaining a monopoly by offering a new or superior product is generally considered lawful. However, certain conduct to extend or maintain a monopoly may be unlawful, particularly when the purpose or result is to delay, foreclose, or blunt the impact of generic competition.[13] Recently, plaintiffs and enforcers are pursuing holistic theories of exclusion that combine multiple strategies by a pharmaceutical company, including sometimes combining allegations of unlawful patent litigation settlements with allegations of exclusionary conduct.

Market Foreclosure

Enforcers and courts look carefully at conduct designed to foreclose competitors' access to essential supplies ("input foreclosure") or customers. Since there may be procompetitive reasons for such conduct, courts evaluate the benefits versus the harm.

Input Foreclosure

One example of input foreclosure is where a pharmaceutical manufacturer enters into an exclusivity agreement with a supplier (e.g., for an active pharmaceutical ingredient (API) or an essential ingredient). Such an agreement may be lawful depending on the circumstances, but if a potential competitor is unable to enter a market (or is delayed from entering) due to the exclusivity agreement, then there may be liability.[14] Another example is where a generic is unable to obtain sufficient samples of a brand product to perform the requisite testing necessary

[7] *In re Nexium Antitrust Litig.*, 968 F. Supp. 2d 367, 381 (D. Mass. 2013).
[8] *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F. 3d 388 (3d Cir. 2015).
[9] *In re Glumetza Antitrust Litig.*, No. 19-08155-WHA, Dkt. 537 (N.D. Cal. May 6, 2021).
[10] *In re Xyrem Antitrust Litig.*, No. 20-MD-02966-LHK, 2021 U.S. Dist. LEXIS 153343 (N.D. Cal. Aug. 13, 2021).
[11] *See, e.g.*, *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244 (RA), 2015 U.S. Dist. LEXIS 127748, at *47-50 (S.D.N.Y. Sept. 22, 2015).
[12] *Staley v. Gilead Scis., Inc.*, 466 F. Supp. 3d 578, 612 (N.D. Cal. 2020).
[13] This is consistent with the Hatch-Waxman Act, which was designed to balance innovation against encouraging cheaper generic entry.
[14] Press Release, New York State Office of the Attorney General, "AG James Facilitates Access to Life-Saving Opioid Overdose Drug" (Jan. 2, 2020) https://ag.ny.gov/press-release/2020/ag-james-facilitates-access-life-saving-opioid-overdose-drug.

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Recent Pharmaceutical Antitrust Developments and Expectations for 2022 *(Continued from page 4)*

to apply for an Abbreviated New Drug Application.[15] In one case, a court found plausible allegations that the brand manufacturer cut off generic access to both samples of its brand drug (which were needed for bioequivalence testing) and the API in the drug.[16]

Customer Foreclosure

Competing on the merits by offering a better product is generally lawful, even if it limits a competitor's ability to compete, but some conduct may cross the line where it substantially forecloses competition through other means. One example is "product hopping," which has been a recent area of focus for the courts, the FTC, and Congress.[17] Some courts have found that a brand manufacturer engages in unlawful product hopping when, just prior to facing generic entry, it takes steps to switch patients to a reformulated product that has no material benefit over the old product. In such cases, the brand manufacturer discontinues the old product, essentially locking in patients to the new version of the branded drug, because, under most states' laws, the generic version may only be automatically substituted by pharmacists for prescriptions of the older brand version that is no longer marketed.

Abuse of Regulatory Process

Some courts have found that abuse of certain government processes designed to ensure drug safety and encourage innovation may be anticompetitive.[18] For example, some manufacturers may file Citizen Petitions to persuade the FDA to take or not take a formal action. These petitions often serve legitimate purposes to impact health policy. However, in some circumstances, courts have found that a manufacturer abused the process by filing sham or serial petitions designed to divert FDA resources from approving competitors' applications and thus delaying generic entry.[19]

Other examples include instances where courts have found that manufacturers filed sham patent litigations[20] or purposefully misled standard-setting organizations to capitalize on confidential patent rights.[21]

Conclusion

We expect that life sciences companies, and particularly pharmaceutical manufacturers, will continue to be in the spotlight when it comes to antitrust enforcement. This extends beyond small molecules, as Congress and courts have begun examining potentially anticompetitive practices in the biosimilar industry as well.[22] As the law continues to the develop, pharmaceutical manufacturers should carefully consider their competitive strategies to avoid liability.

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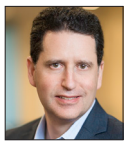

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[15] Congress passed the CREATES Act in 2019 in part to curb this conduct.
[16] *FTC v. Vyera Pharms., LLC*, 479 F. Supp. 3d 31, 39 (S.D.N.Y. 2020).
[17] There are many other types of conduct that may foreclose competition, and manufacturers should carefully consider such practices, including but not limited to agreements with PBMs and other downstream entities, rebating and discounting practices, and marketing strategies.
[18] Because petitioning the government is generally protected under the First Amendment, a plaintiff must show that such conduct does not qualify for this protection by proving that it was 1) objectively baseless and 2) used as an attempt to interfere with a competitor by way of a governmental *process* as opposed to the *outcome* of that process. *E.g.*, *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997 (KSH) (CLW), 2015 U.S. Dist. LEXIS 177541, at *30-31 (D.N.J. Oct. 29, 2015).
[19] *1199SEIU Nat'l Ben. Fund v. Allergan, Inc. (In re Restasis Antitrust Litig.),* 333 F. Supp. 3d 135, 158 (E.D.N.Y. 2018); *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665, 691 (E.D. Pa. 2014).
[20] *FTC v. AbbVie Inc.*, 976 F.3d 327, 368 (3d Cir. 2020).
[21] *Amphastar Pharm. Inc. v. Momenta Pharm., Inc.*, 850 F.3d 52, 54 (1st Cir. 2017).
[22] Congress has generally imposed similar antitrust regimes on biosimilars. *E.g.*, 115 Pub. L. No. 263, 132 Stat. 3672 (2018). *See also In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811 (N.D. Ill. 2020).

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 2020 and the first half of 2021. 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 2020	2H 2020	2H 2020	1H 2021	1H 2021	1H 2021
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	51	$1,456.13	$28.55	48	$2,326.07	$48.46
Genomics	7	$339.98	$48.57	4	$11.15	$2.79
Diagnostics	12	$104.40	$8.70	10	$156.17	$15.62
Medical Devices & Equipment	38	$492.50	$12.96	33	$788.16	$23.88
Health IT	17	$388.58	$22.86	14	$225.95	$16.14
Healthcare Services	17	$641.90	$37.76	25	$890.23	$35.61
Total	**142**	**$3,423.49**		**134**	**$4,397.74**	

The data demonstrates that venture financing activity decreased from the second half of 2020 to the first half of 2021 with respect to the total number of closings, but increased with respect to the total amount raised. Specifically, the total number of closings across all industry segments decreased 5.6 percent, from 142 to 134, while the total amount raised across all industry segments increased 28.5 percent, from $3,423.49 million to $4,397.74 million.

Notably, the industry segment with the largest number of closings during the first half of 2021—biopharmaceuticals—experienced a slight decrease in number of closings, but a significant increase in total amount raised from the second half of 2020 to the first half of 2021. Specifically, the number of closings in the biopharmaceuticals segment decreased 5.9 percent, from 51 to 48, while the total amount raised increased 59.7 percent, from $1,456.13 million to $2,326.07 million. Similarly, the industry segment with the second-largest number of closings during the first half of 2021—medical devices and equipment—decreased in number of closings, but increased in total amount raised from the second half of 2020 to the first half of 2021. Specifically, the number of closings in medical devices and equipment decreased 13.2 percent, from 38 to 33, while the total amount raised increased 60 percent, from $492.50 million to $788.16 million. Finally, the industry segment with the fifth-largest number of closings—diagnostics—similarly experienced a decrease in number of closings but an increase in total amount raised from the second half of 2020 to the first half of 2021. Specifically, the number of closings in diagnostics decreased 16.7 percent, from 12 to 10, while the total amount raised increased 49.6 percent, from $104.40 million to $156.17 million.

> The total number of closings across all industry segments decreased 5.6 percent, from 142 to 134, while the total amount raised across all industry segments increased 28.5 percent, from $3,423.49 million to $4,397.74 million

Meanwhile, the industry segment with the third-largest number of closings during the first half of 2021—healthcare services—experienced an increase in both total amount raised and number of closings from the second half of 2020 to the first half of 2021. Specifically,

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Life Sciences Venture Financings for Wilson Sonsini Clients *(Continued from page 6)*

the total amount raised for healthcare services increased 38.7 percent, from $641.90 million to $890.23 million, and the number of closings increased 47.1 percent, from 17 to 25.

Rounding out the field, health IT and genomics—the fourth- and sixth-largest industry segments during the first half of 2021, respectively—experienced a decrease in both number of closings and total amount raised. Specifically, the total number of closings for health IT decreased 17.6 percent, from 17 to 14, while the total amount raised decreased 41.9 percent, from $388.58 million to $225.95 million. The total number of closings for genomics decreased 42.9 percent, from seven to four, and the total amount raised decreased 96.7 percent, from $339.98 million to $11.15 million.

In addition, our data suggests that Series Seed and Series A financing activity, in each case as a percentage of all financing activity and measured by number of closings, increased from the second half of 2020 to the first half of 2021, while Series B, Series C and later, and bridge financing activity all decreased across the same period. Specifically, the number of Series Seed closings as a percentage of all closings increased from 7.5 percent to 9.8 percent, and the number of Series A closings as a percentage of all closings increased from 19.2 percent to 24.5 percent. Series B closings as a percentage of all closings decreased from 16.4 percent to 10.5 percent, Series C and later closings as a percentage of all closings decreased from 17.8 percent to 14 percent, and bridge financing closings as a percentage of all closings decreased from 17.8 percent to 16.1 percent.

Average pre-money valuations for life sciences companies increased across the board for all stages of equity financings, including Series Seed, Series, Series B, and Series C and later-stage financings, from the second half of 2020 to the first half of 2021. The average pre-money valuation for Series Seed financings increased 16.6 percent, from $10.92 million to $12.73 million; Series A financings increased 13.9 percent, from $31.76 million to $36.17 million; Series B financings increased 130.9 percent, from $97.74 million to $225.67 million, and Series C and later-stage financings increased 25.9 percent, from $375.13 million to $472.14 million. Notably, this is the third consecutive six-month period during which average pre-money valuations for life sciences companies increased across the board for all stages of equity financing.

Notably, this is the third consecutive six-month period during which average pre-money valuations for life sciences companies increased across the board for all stages of equity financing

Other data taken from transactions in which all firm clients participated in the first half of 2021 suggests that life sciences is still the second-most active industry for investment among our clients, as was the case at the time of the last report, but it is losing ground to other historically less popular industries. For the first half of 2021, life sciences represented 18 percent of total funds raised by our clients, while the software industry represented 49 percent of total funds raised. During the second half of 2020, life sciences represented 35 percent of total funds raised by our clients, while software represented 44 percent of total funds raised.

Overall, the data indicates that there was less financing activity during the first half of 2021 compared to the second half of 2020 in terms of number of closings, but the total aggregate amount raised by our life sciences company clients increased significantly over the same period. Moreover, the closings that did occur were conducted at higher valuations for all stages of equity financing. It was the third consecutive six-month period during which average pre-money valuations increased across the board for all stages of equity financing, suggesting that investors are doing fewer deals, but committing more money at higher valuations to the deals that are getting done. We expect this trend to persist as companies continue to struggle to connect with potential investors during the ongoing pandemic.

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Genus v. FDA Decision Clarifies Products That Meet Both "Drug" and "Device" Definitions Must Be Regulated as Devices

By Eva Yin (Associate, Seattle)

In August 2021, the U.S. Food and Drug Administration (FDA) announced that it will not appeal the decision from the U.S. Court of Appeals for the District of Columbia Circuit in *Genus Med. Techs., LLC v. FDA*, 994 F.3d 631, which held that the FDA does not have discretion to regulate products that meet both "device" and "drug" definitions as a drug product, asserting that "[e]xcepting combination products … devices must be regulated as devices and drugs—if they do not also satisfy the device definition—must be regulated as drugs."[1] Going forward, in implementing the *Genus* decision, the FDA will further examine product classifications, especially products previously approved as drugs that may have met the definition of a "device."

Background

Under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq*., devices and drugs, among other products, are subject to different regulatory regimes and review pathways before the products can be legally marketed in the U.S. Obtaining FDA approval for a drug product and maintaining regulatory compliance as a drug product are generally much more expensive and onerous than for medical devices. Unlike drug products, the FDA takes a risk-based approach in regulating medical devices, many of which are cleared by the FDA based on substantial equivalence to a predicate device. As such, the *Genus* case has significant financial and regulatory implications for manufacturers of affected products.

The statutory definitions of a "drug" and a "device" include the following language:[2]

> "drug" means … articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and … articles (other than food) intended to affect the structure or any function of the body of man or other animals…
>
> "device" … means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is … intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or … intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Notably, because both statutory definitions include the intended-use clause (i.e., intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease) and because the definition of a drug has fewer limitations than the device definition, any product that meets the narrower definition of a device could also satisfy the definition of a drug. The converse is not true.

Historically, the FDA has interpreted this overlap in the definitions to mean that it has regulatory discretion to regulate medical products as either a drug or a medical device as long as the product meets both statutory definitions. The court in *Genus* rejected this position and expressly requires the FDA to regulate products that meet the device definition as medical devices.

Imaging Contrast Agents

In *Genus*, the FDA asserted that the oral solution contrast agents, Vanilla SilQ, produced by Genus Medical Technologies (Genus), were regulated as drug products and issued a warning letter. Genus argued that its contrast agents, comprising barium sulfate, an inert metal salt, were devices and that the FDA could not regulate them as drugs because their primary intended purposes were not achieved through chemical action within or on the body or through metabolization. When swallowed, barium sulfate coats the inside of the gastrointestinal tract and provides contrast in X-ray imaging by facilitating the absorption of X-rays, causing tissue coated with the contrast agent to appear lighter than the surrounding uncoated tissue.[3]

Genus also submitted a Request for Designation (RFD) to the Office of Combination Products, which is responsible for designating the agency component with primary jurisdiction for the premarket review and regulation of any product where the regulatory jurisdiction and identity of a product as a drug, device, biologic, or combination product are unclear or in dispute. Here, even though the official Designation

[1] FDA, Notice, 86 Fed. Reg. 43553 (August 9, 2021), *available at* https://www.govinfo.gov/content/pkg/FR-2021-08-09/pdf/2021-16944.pdf; *Genus Med. Techs. LLC v. United States FDA*, 994 F.3d 631, 644 (April 16, 2021).
[2] 21 U.S.C. §§ 321(g)(1)(B) and (h)(1).
[3] *Genus*, 994 F.3d at 635.

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Genus v. FDA Decision Clarifies Products That Meet . . . *(Continued from page 8)*

Letter recognized that the diagnostic contrast agents "appeared" to meet both the device and drug definitions, the FDA concluded that it was appropriate to regulate all contrast agents uniformly as drugs.[4]

Transitioning Applicable Drugs to Devices

According to the August 2021 Notice, going forward, the FDA "intends to regulate products that meet both the device and drug definition as devices, except where the statute indicates that Congress intended a different classification…."[5] In applying the *Genus* decision, the FDA will examine product classifications of previously approved products, especially products that may have met the definition of a device. Key determining factors for such classification include whether the product achieves its primary intended purposes through chemical action within or on the body or is dependent upon metabolization. The FDA also noted that it will examine other statutory provisions beyond the definitions to determine whether Congress intended a product to be regulated under either the drug or device authorities.

Implementation of the *Genus* decision will require the FDA to transition some approved products from drug status to device status. The FDA plans to publish a list of approved drug products that will be subject to transition to device status. While imaging contrast agents similar to the Genus contrast agents are expected to undergo this transition, the FDA also noted that it plans to reexamine other product categories, as appropriate. Once the list of products subject to this transition is published, stakeholders will have an opportunity to comment on the agency's tentative determinations before classification determinations are made.

Given the significant financial and business impact of this transition, manufacturers of imaging contrast agents or other drug products that meet the definition of a device should work closely with their regulatory counsel to seek further guidance from the FDA sooner than later and plan for bringing the affected products into compliance with applicable device regulatory requirements, including changes to labeling, marketing materials, and quality controls and procedures pursuant to the quality system regulations. For entities with product candidates in preclinical or clinical stages, this transition may mean a significantly shorter and less costly pathway to market.

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[4] *Id.* at 636.
[5] 86 Fed. Reg. at 43554.

Firm Launches Salt Lake City Office to Better Serve Local Clients . . . *(Continued from page 1)*

firm's longstanding client relationships and better serve the emerging companies in the market—including numerous fast-growing life sciences innovators.

The Salt Lake City office will include corporate partners Marc Porter and Alison Johnson, who recently joined the firm from Holland & Hart, and Matt Squires, who was previously based in the firm's Seattle office. Utah Supreme Court Justice Deno Himonas will also join the office upon his retirement from the bench in March 2022.

"Our new Salt Lake City office will provide on-the-ground support to life sciences companies and build upon the firm's already active engagement with the life sciences community," said Marc. "Not only will it be a place for clients and community leaders to meet and collaborate, but it will underscore Wilson Sonsini's commitment to Utah."

Wilson Sonsini has advised more venture capital firms on Utah-related deals and more Utah-based issuers on IPOs than any other firm since 2016, ranking first in each category by a substantial margin. The firm ranks fourth among law firms in advising on Utah-related mergers and acquisitions in the same period. "We have been actively advising on capital markets, venture financing, M&A, and other transactions in the Utah business community for many years," said Allison Spinner, the leader of Wilson Sonsini's corporate department.

Since 2019, Wilson Sonsini has had a physical presence in Utah through SixFifty, a software subsidiary that develops automated tools that make legal processes—such as drafting employee handbooks—efficient and affordable. "The firm has recognized Utah as a site of innovation, and the opening of a firm office here just confirms that," said Kimball Dean Parker, the CEO of SixFifty and the director of LawX, a legal design lab at Brigham Young University Law School.

For more information, please see the firm's press release.

FDA Regulatory Framework for Innovator Drug Products and Public Disclosures – Implications for Patent Strategies

By Yael Webb (Associate, New York), Hee Min Noh (Law Clerk, San Diego), Eva Yin (Associate, Seattle), and Ingo Hardt (Partner-Elect, San Diego)

In general, while regulatory submissions to the U.S. Food and Drug Administration (FDA) are highly confidential up to FDA approval of a drug product, certain information is subject to public disclosure. Regulatory submissions can create prior art that adversely affects a company's patent estate, including at the BLA/NDA approval stages, drug regulatory designations, expedited approval requests, and clinical trial registration. Companies should share their regulatory submissions with their patent counsel before submitting to the FDA to ensure that they have been considered from a patent perspective.

1. Unpublished Information in INDs Is Generally Confidential

An Investigational New Drug Application (IND) contains confidential unpublished information regarding an investigational drug, including the clinical protocol, chemistry, manufacturing and controls (CMC), and non-clinical information (e.g., pharmacology and toxicology). This information is important for the sponsor's patent estate. The FDA generally does not disclose INDs, or any information provided as part of the IND, unless released as part of the FDA's approval package or other reports by the FDA, or as required by law,[1] such as disclosure under a FOIA request, unless exempt.[2]

It is important to strategically plan what IND content will be incorporated into patent applications. Some of the considerations include balancing the need to seek broad patent coverage while not prematurely disclosing confidential unpublished information in the IND (e.g., the lead candidate and trade secrets that may give competitors an advantage). In some cases, a request for non-publication of a U.S. patent application or other patent strategies can be used to protect confidential IND information in patent applications.

It is also important to note that FDA regulatory review is an iterative process. Companies should keep patent counsel apprised of material changes to clinical development plans, to ensure adequate patent coverage.

2. Registration of Clinical Trials

While INDs are generally confidential, certain clinical trials are required to be publicly registered on https://clinicaltrials.gov/. For investigational drug products, this requirement generally applies to interventional clinical trials other than Phase 1 studies involving FDA-regulated drug products, where one of the following conditions applies: (i) the trial is subject to an IND; (ii) the investigational drug product is manufactured in and exported from the U.S. or U.S. territory for study in another country; or (iii) at least one clinical site is within the U.S. or U.S. territory.[3] Clinical trial registration can include information such as study design, study phase, intervention description, and outcome measures. In general, clinical trial results information must be submitted for applicable clinical trials no later than one year after the primary completion date, with certain exceptions.[4] Once posted, the information becomes public disclosure, which may affect future patent filings.

3. FDA Approval

Once an investigational product has been approved by the FDA through either a New Drug Application (NDA)[5] or a Biologics License Application (BLA),[6] the approval package is posted on the FDA website at https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases. The package includes approval letter(s), label(s), and certain review files, including medical, chemistry, and pharmacology review(s). Thus, certain information that was deemed confidential during the regulatory review period is subject to public disclosure by the FDA after approval, unless exempt from public disclosure, such as confidential commercial, trade secret, personal privacy, etc.[7]

[1] 21 C.F.R. § 312.130 (a).
[2] Generally, all applications and information submitted to the FDA are subject to the Freedom of Information Act (FOIA). However, drug manufacturer-sponsors or applicants can request redaction for certain information that is exempt from public disclosure, including trade secrets and commercial or financial information under exemption 4 of the FOIA. After a FOIA request is submitted seeking disclosure, the FDA typically sends the sponsor a pre-disclosure notification and allows the sponsor to request redaction of information under applicable exemptions from FOIA disclosure.
[3] 42 C.F.R. § 11.22 (b)(2).
[4] 42 C.F.R § 11.44.
[5] 21 C.F.R. § 314.
[6] 21 C.F.R. § 601.2.
[7] Similarly, once a Marketing Authorization Application (MAA) is approved in Europe, the approval package is published in the Union Register at

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FDA Regulatory Framework for Innovator Drug Products . . . *(Continued from page 10)*

Moreover, during NDA/BLA review, the FDA may seek advice from its Advisory Committees (ACs) to provide recommendations on issues pertaining to its review and evaluation of the investigational drug product. AC meetings are typically open to the public, and briefing materials submitted by sponsors, unless exempt, are subject to public disclosure by the Agency, notably prior to approval and publication of the NDA/BLA package.

4. FDA Regulatory Designations and Accelerated Pathways

Certain regulatory milestones lead to public disclosure, whether by law or via company press releases that accompany them.

For example, Orphan Drug Designation (ODD)[8] provides incentives to drug companies to develop drugs to treat rare diseases. Approved ODD requests are published on the FDA website https://www.accessdata.fda.gov/scripts/opdlisting/oopd/.[9] In many cases, companies keep the structural/chemical identity of their clinical lead confidential by using generic or code names. FDA publication of ODD approval can lead to the inadvertent disclosure of the structure of a company's clinical lead before the company had planned to identify the structure as the clinical lead. This is because the application for ODD requires the company to include a "meaningful description" of the drug, and companies sometimes submit the chemical name or structure as the meaningful description. Once the ODD is approved, the approval—together with the meaningful description—is published on the FDA website. While the FDA announcement does not necessarily connect the structure with the clinical lead, the accompanying press release by the sponsor may refer to the internal code name of the lead, thus connecting the structure with the internal code. Regulatory and patent departments should collaborate to mitigate this risk. For example, it may be possible in the U.S. to submit a more general meaningful description (based, for example, on mechanism of action), although this may not be available in foreign jurisdictions.

Additionally, companies that successfully obtain the FDA's Orphan Products Grants Program awards are required to post their study on https://clinicaltrials.gov/. These awards are also mentioned in FDA press releases at https://www.fda.gov/news-events/press-announcements/fda-awards-11-grants-clinical-trials-develop-new-medical-products-rare-disease-treatments.

Finally, the FDA has implemented other incentive-based designations and expedited approval pathways, including rare pediatric disease (RPD) designation,[10] Fast Track,[11] Priority Review,[12] Breakthrough Therapy,[13] and Accelerated Approval.[14] Information included in applications for these designations and pathways is generally confidential, but companies should review announcements of these milestones to prevent inadvertent disclosures of confidential unpublished information. The FDA also publishes basic information in expedited approval reports at https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/nda-and-bla-approvals, as well as issuance of RPD vouchers in the Federal Register.

Therefore, until drug approval, unpublished information in regulatory submissions should be kept confidential, and companies should be mindful of information subject to public disclosure. All regulatory submissions and companies' press releases should be shared with patent counsel before submission/publication to ensure the integrity and robustness of the company's patent estate.

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https://ec.europa.eu/health/documents/community-register_en, and a European Public Assessment Report (EPAR), including authorization details, product information, and assessment history, is published on the EMA website at https://www.ema.europa.eu/en/medicines/ema_group_types/ema_medicine.

[8] 21 C.F.R. § 316.

[9] In Europe, approved ODD requests are published on the EMA website at https://ec.europa.eu/health/documents/community-register/html/reg_od_act.htm?sort=a.

[10] Federal Food, Drug, and Cosmetic Act § 529.

[11] *Id*. § 506(b).

[12] Prescription Drug User Fee Act of 1992, 106 Stat. 4491.

[13] Federal Food, Drug, and Cosmetic Act § 506(a).

[14] *Id*. § 506(c).

Select Recent Life Sciences Client Highlights

Verana Health Announces $150 Million Series E Funding

On January 14, 2022, Verana Health, a digital health company that delivers quality drug lifecycle and medical practice insights from an exclusive real-world data network, announced a $150 million Series E funding round led by Johnson & Johnson Innovation and Novo Growth, the growth-stage investment arm of Novo Holdings. Existing Verana Health investors GV (formerly Google Ventures), Casdin Capital, and Brook Byers also joined the round, as well as notable new investors, including the Merck Global Health Innovation Fund, THVC, and Breyer Capital. Wilson Sonsini advised Verana Health on the financing.

ABL Bio Announces Global Collaboration, License Agreement with SANOFI

On January 11, 2022, ABL Bio, Inc., a clinical-stage biotech developing bispecific antibody technology for immuno-oncology and neurodegenerative diseases, announced an exclusive collaboration and worldwide license agreement with SANOFI to develop and commercialize ABL301, a pre-clinical stage bispecific antibody targeting alpha-synuclein and IGF1R to treat Parkinson's disease and other potential indications with enhanced blood-brain barrier (BBB) penetration. ABL will receive $75 million in upfront payments and is eligible to receive up to $985 million based on the achievement of predefined development, regulatory, and commercialization milestones, including $45 million in near-term milestones. Wilson Sonsini advised ABL on the transaction.

Insilico Medicine Announces Drug Discovery Collaboration with Fosun Pharma

On January 11, 2022, Shanghai Fosun Pharmaceutical (Group) Co., Ltd., a leading innovation-driven international healthcare group in China, and Insilico Medicine, an end-to-end artificial intelligence (AI)-driven drug discovery and development company, announced they have entered into a collaboration agreement to advance the discovery and development of drugs targeting a number of different targets globally through the use of AI technology. The agreement includes an AI-driven drug discovery R&D collaboration on four biological targets, as well as the co-development of Insilico's QPCTL program. Insilico will receive a total upfront payment of $13 million for the R&D collaboration projects and the co-development of the QPCTL program, potential milestone-based payments, and share commercialization profits from the QPCTL program. In addition, Fosun Pharma will make an equity investment in Insilico. Wilson Sonsini advised Insilico on the transaction.

Regeneron and Ultragenyx Collaborate to Commercialize Eykeeza Outside the U.S.

On January 7, 2022, Regeneron Pharmaceuticals, Inc. and Ultragenyx Pharmaceutical Inc. announced a license and collaboration agreement for Ultragenyx to clinically develop, commercialize, and distribute Evkeeza® (evinacumab) in countries outside of the United States. Regeneron discovered and developed Evkeeza and launched the medicine in the U.S. in February 2021 when it was approved by the FDA. Under the terms of the agreement, Regeneron will receive a $30 million upfront payment and is eligible to receive up to $63 million in additional potential regulatory and sales milestones. Ultragenyx will receive the rights to develop, commercialize, and distribute the medicine in countries outside of the U.S. and make payments to Regeneron based on net sales. Wilson Sonsini advised Ultragenyx on the transaction.

Ambagon Announces $85 Million Series A Financing

On January 6, 2022, Ambagon Therapeutics, a biotechnology company unlocking intrinsically disordered proteins and other difficult-to-target protein classes, announced an $85 million Series A to augment its drug discovery platform and advance its pipeline of molecular glues. Ambagon's initial focus is on oncology, with five programs in discovery. The financing was led by Nextech Invest. Wilson Sonsini advised Ambagon on IP matters related to the Series A transaction.

Mylan Beats Sanofi Appeal in Patent Fight

On December 29, 2021, Wilson Sonsini secured another win for Mylan as the U.S. Court of Appeals for the Federal Circuit affirmed eight decisions from the Patent Trial and Appeal Board (PTAB) holding patent claims for five Sanofi device patents unpatentable. Sanofi had asserted the patents against Mylan in the U.S. District Court for the District of New Jersey. Both the district court and the PTAB held the claims unpatentable, leading to 11 appeals consolidated into four groups. The Federal Circuit heard argument on December 6, 2021, and issued short but strong opinions on December 29 categorically rejecting Sanofi's arguments in eight PTAB appeals and dismissing the remaining appeals as moot in view of the affirmances. Wilson Sonsini represented Mylan in patent matters, including those related to the litigation.

Adanate Raises $30 Million in Series A Financing

Adanate, a biotech company focusing on therapies in oncology and immunology, recently raised $30 million in a Series A financing led by Westlake Village BioPartners with participation from Avalon Ventures. Adanate's lead program (ADA-011) is a monoclonal antibody

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Select Recent Life Sciences Client Highlights *(Continued from page 12)*

targeting a novel family of immune checkpoint receptors called leukocyte immunoglobulin-like receptors B (LILRB). The company is preparing to initiate clinical development of ADA-011 in 2022. Wilson Sonsini advised Adanate on patent matters related to the transaction.

Sorriso Pharmaceuticals Announces Closing of $31 Million Series A
On December 22, 2021, Sorriso Pharmaceuticals, a biotechnology company advancing a pipeline of disease-modifying antibodies for the treatment of inflammatory disease, announced that it has closed on a $31 million Series A financing. The round was co-led by New Enterprise Associates (NEA) and Arix Bioscience plc. The new funding will be used to advance the company's pipeline of novel oral antibodies to address unmet needs in immune-mediated diseases. Wilson Sonsini advised Sorisso on patent matters related to the transaction.

Aramis Biosciences Launches with $10.5 Million in Series A Financing
On December 15, 2021, Aramis Biosciences, a clinical-stage immuno-ophthalmology biopharmaceutical company, announced its launch and the completion of a $10.5 million Series A financing led by Safar Partners with a strategic investment from a global leader in ophthalmic pharmaceuticals. Proceeds from the financing will be used to advance the company's pipeline, including its lead product candidate, A197, a novel, first-in-class, topical immunomodulatory agent licensed from Dompé farmaceutici, through Phase II clinical proof of concept for the treatment of dry eye disease. Wilson Sonsini represented Aramis Biosciences in the launch and Series A financing.

Regor Therapeutics Enters Research Collaboration and Licensing Agreement with Eli Lilly
On December 10, 2021, Eli Lilly and Company and Regor Therapeutics Group entered into a multi-year research collaboration and licensing agreement to discover, develop, and commercialize novel therapies for metabolic disorders. Under the terms of the agreement, Lilly will have a license to select Regor intellectual property with an option to extend the license. Lilly will be responsible for clinical development, manufacturing, and commercialization worldwide, except for People's Republic of China, Macau, Hong Kong, and Taiwan, where Regor will maintain these rights and responsibilities. The agreement will allow each company the opportunity to fully leverage both parties' existing compounds and technologies globally to maximize patient treatment choice. Regor will receive an upfront payment of up to $50 million, which partially includes an equity investment by Lilly in Regor, subject to the parties entering into standard equity agreements. The company is also eligible to receive up to $1.5 billion in potential payments based on the achievement of prespecified preclinical, clinical development, and commercial milestones, as well as tiered royalties from low-single to low-double digits on sales resulting from the agreement. Wilson Sonsini represented Regor Therapeutics Group in the transaction.

Cerebral Closes $300 Million Series C Financing
On December 8, 2021, Cerebral Inc. announced the close of its $300 million Series C round led by the SoftBank Vision Fund 2. The round also included participation from new and existing investors, including Prysm Capital, Access Industries, WestCap Group, and ARTIS Ventures. Cerebral is investing in new service offerings, strategic partnerships, international expansion, and M&A opportunities to further solidify its position as the one-stop shop for behavioral care and to provide top-quality treatment options through data science and precision medicine. Wilson Sonsini advised Cerebral on the financing.

The EVERY Company Closes $175 Million in Series C Financing
On December 7, 2021, The EVERY Company, the leading precision fermentation platform accelerating a global transition to animal-free protein, announced it has closed $175 million in Series C financing. The round was co-led by new investor McWin and existing investor Rage Capital. Other new and existing investors joined the round, including Temasek, Grosvenor's Wheatsheaf Group, and TO Ventures. Prosus Ventures also contributed to the funding. The company will use the capital to scale production, commercialize a pipeline of animal-free protein products nationwide, and expand into a broad array of new food applications. Wilson Sonsini advised EVERY on corporate and IP matters related to the transaction.

Recursion Announces Collaboration with Roche and Genentech
On December 7, 2021, Recursion, a clinical-stage biotechnology company decoding biology to radically improve lives by industrializing drug discovery, development, and beyond, announced a transformational collaboration with Roche and Genentech, a member of the Roche Group. Recursion will work with both Roche and Genentech's R&D units to leverage technology-enabled drug discovery through the Recursion

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

Operating System (OS) to more rapidly identify novel targets and advance medicines in key areas of neuroscience as well in an oncology indication. Under the terms of the agreement, Recursion will receive an upfront payment of $150 million and is eligible for additional performance-based research milestones. Wilson Sonsini represented Recursion in the transaction.

Arbutus Biopharma Wins Patent Dispute Against Moderna

On December 1, 2021, the Federal Circuit affirmed the Patent Trial and Appeal Board's earlier rulings that ModernaTX, Inc. (formerly Moderna Therapeutics Inc.) failed to invalidate claims in two Arbutus Biopharma Corp. patents, known as the '069 and '435 patents, and left the '069 patent fully intact. Arbutus's U.S. Patent Nos. 8,058,069 and 9,364,435 relate to a composition based on lipid nanoparticle (LNP) technology that delivers nucleic acid payloads to allow the human body to make its own therapeutic proteins. Wilson Sonsini represented Arbutus in the matter.

Blueprint Medicines Corporation Acquires Lengo Therapeutics

On November 29, 2021, Blueprint Medicines Corporation announced that it has entered into a definitive agreement under which it will acquire Lengo Therapeutics, a privately held precision oncology company, for $250 million in cash plus up to $215 million in additional potential payments based on the achievement of certain regulatory approval and sales-based milestones. The acquisition includes Lengo Therapeutics' lead compound LNG-451, a potential best-in-class oral precision therapy in development for the treatment of non-small cell lung cancer (NSCLC) in patients with EGFR exon 20 insertion mutations. Wilson Sonsini advised Lengo Therapeutics on patent matters related to the acquisition.

Chroma Medicine Launches with $125 Million in Series A Financing

On November 17, 2021, Chroma Medicine, a new genomic medicine company pioneering epigenetic editing, launched with $125 million in financing. Atlas Venture and Newpath Partners seeded the company with participation from Sofinnova Partners. The Series A was led by Cormorant Asset Management, with participation by Casdin Capital, Janus Henderson Investors, Omega Funds, funds and accounts advised by T. Rowe Price Associates, Inc., and Wellington Management, in addition to all seed investors. The financing will support continued development of the company's epigenetic editing platform and advancement of its pipeline of targeted therapeutics. Wilson Sonsini advised Chroma on patent and technology matters related to the transaction.

Ignis Therapeutics Announces $180 Million Series A Financing

On November 11, 2021, Ignis Therapeutics, a biopharmaceutical company focusing on the central nervous system that was incubated by 6 Dimensions Capital (6D), a Shanghai-based global investment firm, announced its $180 million Series A financing led by 6D. The proceeds will be used for the development and commercialization of SK Biopharmaceuticals clinical compounds. The financing includes co-investor participation by Ruentex Group, KB Investment, WTT investment, Mubadala Investment Company, HBM Healthcare Investments, and Goldman Sachs. Wilson Sonsini represented 6D and Ignis Therapeutics in the transaction.

Moderna Announces Collaboration with Metagenomi

On November 2, 2021, Moderna Inc., a biotechnology company pioneering messenger RNA therapeutics and vaccines, and Metagenomi, Inc., a genetic medicines company known for next-generation gene editing tools, announced that they have entered into a strategic research and development collaboration focused on advancing new gene editing systems for in vivo human therapeutic applications. The collaboration will utilize Metagenomi's novel gene editing tools and leverage Moderna's mRNA platform, as well as lipid nanoparticle (LNP) delivery technologies, with the goal of developing curative therapies for patients with serious genetic diseases. Wilson Sonsini advised Metagenomi on patent matters related to the transaction.

Dunad Therapeutics Collaborates with Novartis

On November 2, 2021, Dunad Therapeutics, a biopharmaceutical company focusing on the development of next-generation targeted protein degradation therapies, announced that it has entered a collaboration and license agreement with Novartis to generate orally bioavailable covalent and protein degrading small molecule drugs. Dunad will receive $24 million in an upfront payment and equity investment, as well as significant research funding; the company will also be eligible to receive up to $1.3 billion in discovery, regulatory, and sales-based milestones, in addition to royalty payments. Wilson Sonsini advised Dunad on patent matters related to the transaction.

Cambridge Epigenetix Announces $88 Million in Series D Financing

On November 2, 2021, Cambridge Epigenetix, a life sciences tools and technology company, announced the signing of an $88 million Series D financing, bringing its total funds raised to date to $146 million. Proceeds from the financing will be used to commercialize the company's proprietary genetic and epigenetic sequencing technology, which easily integrates into existing sequencing platforms to enable more information

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Select Recent Life Sciences Client Highlights *(Continued from page 14)*

to be read from DNA. Temasek led the Series D round, with participation from new investors including Third Point and existing investors such as GV, New Science Ventures, Ahren Innovation Capital, and Sequoia. Wilson Sonsini advised Cambridge Epigenetix on IP matters related to the transaction.

Synthekine Collaborates with Merck to Develop Therapeutic Candidates
On November 1, 2021, Synthekine Inc., an engineered cytokine therapeutics company, announced a collaboration and license agreement with Merck, known as MSD outside the United States and Canada. The collaboration will leverage Synthekine's proprietary surrogate cytokine agonist platform to discover, develop, and commercialize novel cytokine therapeutics. The initial focus of the collaboration is on a target that has the potential to treat autoimmune diseases. Wilson Sonsini advised Synthekine on the transaction.

Arcaea Announces $78 Million in Series A Financing
On October 27, 2021, Arcaea, a company launched on the Ginkgo Bioworks platform, announced a $78 million Series A financing to build a new, regenerative future for the beauty industry through expressive biology—where biology is used as a creative tool for self-expression. Arcaea will grow new ingredients and product experiences for beauty by leveraging technology such as DNA sequencing, biological engineering, and fermentation to activate unique storytelling. Funding comes from financial investors including Cascade Investment L.L.C., Viking Global, CHANEL, Givaudan, and Wittington Ventures. Wilson Sonsini advised Arcaea on IP, patent, licensing, and contracts related to the matter.

Quanta Therapeutics Completes $60 Million Series C Financing
On October 26, 2021, biopharmaceutical company Quanta Therapeutics, Inc., which is pioneering complex-directed therapies to treat RAS-driven cancer types, announced that it closed a $60 million Series C financing round led by Surveyor Capital (a Citadel company) and Vida Ventures. New investors Longitude Capital and BVF Partners joined existing investors Sofinnova Investments, Logos Capital, AbbVie Ventures, and Vida Ventures in the financing. Wilson Sonsini provided IP counsel to Quanta Therapeutics in the transaction.

Ventyx Biosciences Closes $174 Million Upsized IPO
On October 25, 2021, Ventyx Biosciences, a clinical-stage biopharmaceutical company focused on advancing new therapies for millions of patients living with inflammatory diseases and autoimmune disorders, announced the closing of its upsized initial public offering of 10,893,554 shares of its common stock at an initial public offering price of $16.00 per share. The aggregate gross proceeds from the offering were approximately $174.3 million, before deducting underwriting discounts and commissions and offering expenses payable by Ventyx. Wilson Sonsini advised Ventyx on the offering.

ReCode Therapeutics Closes $80 Million in Series B Financing
On October 21, 2021, ReCode Therapeutics, a biopharmaceutical company pioneering disease-modifying genetic medicines, announced the closing of an $80 million Series B financing round co-led by Pfizer Ventures and EcoR1 Capital. New investors include Sanofi Ventures, funds managed by Tekla Capital Management LLC, Superstring Capital, and NS Investment. Existing investors who participated included OrbiMed, Vida Ventures, MPM Capital, Colt Ventures, Hunt Technology Ventures, L.P., and Osage University Partners. The proceeds will be used to drive programs in primary ciliary dyskinesia and cystic fibrosis into human clinical studies, expand the pipeline of treatments for patients with life-limiting genetic respiratory diseases, advance its LNP platform for organ-specific delivery of RNA and gene correction therapies, and increase internal manufacturing capabilities. Wilson Sonsini represented ReCode Therapeutics in the transaction.

BIOMILQ, Inc. Closes $21 Million in Series A Financing
On October 20, 2021, mammary biotechnology company BIOMILQ, Inc., announced the close of $21 million in Series A financing, which will accelerate its plans to bring cell-cultured human milk to market. Leading the fundraise are Danish life science investor Novo Holdings and clean tech leader Breakthrough Energy Ventures. Additional support comes from Blue Horizon, Spero Ventures, Digitalis Ventures, Green Generation Fund, Alexandria, and Gaingels. Wilson Sonsini represented Novo Holdings in the transaction.

Crinetics Pharmaceuticals Launches Radionetics Oncology
On October 18, 2021, Crinetics Pharmaceuticals, a clinical-stage pharmaceutical company focused on nonpeptide therapeutics for rare endocrine diseases and endocrine-related tumors, together with 5AM Ventures and Frazier Healthcare Partners, announced the formation of an independently operated new company, Radionetics Oncology. Radionetics aims to develop a deep pipeline of novel, targeted, nonpeptide radiopharmaceuticals for the treatment of a broad range of oncology indications. Wilson Sonsini advised Crinetics on both transactional and patent matters related to the transaction.

For additional life sciences client highlights, please click here.

Upcoming Life Sciences Events

rEVOLUTION 2022: The Symposium for Chief Scientific Officers Focused on R&D Issues
May 4-6, 2022
The Line Hotel
Washington, D.C.
https://revolution.wsgrevents.com/

Founded in 2002 and now in its 12th gathering, the rEVOLUTION Symposium has become the place to discuss the most important strategic problems facing pharma and biotech CSOs. We will examine the organization and management of R&D to uncover new disruptive discovery and development models and assess the continued impact of pricing, reimbursement, regulation, and globalization on our industry.

Wilson Sonsini's Medical Device Conference
June 17, 2022
https://mdc.wsgrevents.com/

Wilson Sonsini's 2022 Medical Device Conference will address issues of critical importance to today's medical device companies. In a series of topical panels, attendees will hear from industry CEOs, venture capitalists, industry strategists, investment bankers, and market analysts. In addition, a Partnering Hall will offer personalized opportunities for investors and large medtech companies to meet with start-ups that are searching for and pursuing potential investment, partnering, and acquisition opportunities.

Phoenix 2022: The Medical Device and Diagnostic Conference for CEOs
October 19-21, 2022
https://phoenix.wsgrevents.com/

The 2022 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, two-day event will provide an unrivaled experience that will help inform and shape company strategy for the years ahead, as well as celebrate the industry's incredible, life-saving work throughout the pandemic.

Casey McGlynn, a leader of the firm's life sciences practice, has editorial oversight of *The Life Sciences Report* and was assisted by Elton Satusky, Scott Murano, Brian Appel, and Jesse Schumaker. 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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