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Ten Considerations for Companies Evaluating a Pre-Negotiated Acquisition

By James Huie (Associate, Palo Alto) and Andrew Ellis (Associate, Palo Alto)

In recent years, there has been a shift in the research and development strategy of large pharmaceutical and medical device companies from internal development of new technology to external investment in promising young companies. As opposed to a large company facing scrutiny over the failure of an internal project, funding external development allows these large companies to abandon projects that do not meet expectations at a lesser cost. From their perspective, they want access to technology and a "finger on the pulse" of its development without a wholesale commitment to its costs. One common way to achieve this goal is through an option structure, where a cash payment is made up front to an early-stage company to fund the development of its project(s) in exchange for the right—but typically not the obligation—to acquire the technology or the company in the future. Consideration under these so-called "pre-negotiated acquisitions" often takes the form of a smaller upfront payment upon the acquisition, with more significant contingent payments occurring in the future based on milestones or a certain date.

From the perspective of the target company, funds are needed to pursue its research and development strategy in what is still a difficult market for fundraising. Although the public markets have been strong for the last two years, many companies still encounter difficulty raising early-stage funds, and the market volatility seen thus far in 2016 may prove to be an additional headwind. As such, companies may need to increasingly rely on strategic investors for early-stage funds. Pre-negotiated acquisitions have the effect of front-loading the negotiation and related diligence for an acquisition at the financing stage and present unique issues for target companies. The following is a list of 10 key considerations unique to this deal structure that warrant focus when structuring these transactions.

1. **Option Payment Amount**. It is appropriate to begin with the most basic consideration, which is the

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WSGR to Open Boston Office

Wilson Sonsini Goodrich & Rosati has announced that it will open a Boston office in February 2016, allowing it to better serve the growing life sciences community as well as the expanding technology, energy, and other growth companies resident in the market. The office address will be 28 State Street, 37th Floor, Boston, MA, 02109.

For more information, please visit www.wsgr.com.

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amount paid to obtain the option to acquire. How much cash will the strategic investor be contributing, and will that be enough to achieve any trigger events for the acquisition option? It is important for the company to ensure that it has enough funds to reach key trigger events and, if not, that it retains enough flexibility to seek funding from other sources during the option term. Additionally, it is important for the company to have sufficient financial resources for any unforeseen obstacles or delays.

2. **Option Timelines.** An option to acquire may start on day one or be triggered by the passage of time, by the achievement of a specific milestone such as regulatory approval, or by some other target metric. In some cases, there is also a deadline by which any trigger events must have occurred; otherwise, the option expires. And any option to acquire will restrict a company from being sold to a third party during the option period. The company must weigh the benefit of the capital infusion against having its hands tied during the negotiated option period. In addition, some options are early exercisable, which may provide comfort to a target company knowing that an acquisition could occur at any time, but companies should consider the effect that a "premature" acquisition may have on future milestone or earnout payments, if any, given they will cede control to the acquirer at the time of the acquisition. As previously mentioned, rarely is it the case that an acquirer is obligated to purchase a company or, stated differently, that a company has a right to force the acquirer to purchase it. In that case, many query the true value of the option feature itself to a company and view it simply as capping the company's upside potential.

3. **Acquired Assets.** Depending on an option's trigger events, it may be years after the option payment and negotiation before the strategic investor is able to exercise its option to acquire. By that time, the company may have developed another product, an improved product, or additional intellectual property that was not contemplated when the original agreement was negotiated. In order to protect the company against the strategic investor receiving the benefit of assets for which it did not negotiate, the company should work with its legal and business advisors at the option negotiation stage to segregate the assets that are to be purchased under the option, or to otherwise provide some flexibility at the acquisition stage to allow for the company's security holders to receive value in respect of these developments or allow the developments to be spun out. Moreover, if assets are to be segregated, the company should ensure that appropriate protections are put in place to protect segregated intellectual property and related confidential information from its strategic investors.

4. **Securities Purchases.** Sometimes option payments are simple cash payments, but other times they take the form of an investment, such as stock, debt, or another security. In these cases, the company should negotiate against attempts by the strategic investor to obtain approval or veto rights over the company's actions. Even in the absence of any special rights given to the strategic investors in the purchase documents and charter, the company should avoid a situation where merely holding the security results in a voting block that could prevent the sale of the company or its assets, a recapitalization of the company, or future fundraising. In any case, it is always advisable to implement a drag-along agreement that requires the strategic investor to approve such transactions, subject to customary exceptions, as a third-party acquirer may be reluctant to close over a non-consenting competitor.

5. **Acquisition Structure.** There are several basic ways in which the acquisition resulting from the option could be structured, the most common of which would be a stock purchase, an asset purchase, or a merger. Each has its pros and cons. For example, in order to affect the stock purchase structure, every current stockholder and every future investor or equity recipient would have to sign the pre-negotiated purchase agreement, which may be logistically difficult, especially for companies with many individual investors. An asset purchase structure eliminates that problem, but introduces others, such as difficulty with the assignment of existing contracts, the inability to take advantage of certain tax benefits, and the difficulty of separating acquired and excluded assets when the assets that will eventually be sold are still under development and the future liabilities unknown. The merger structure is what we often recommend to our start-up clients because it may be logistically easier to accomplish and leads to a smoother transition of existing contracts. The company should consult with its legal, business, and tax advisors to determine the best structure at the initial stages of the process.

6. **Mandated Disclosures.** In addition to more customary information rights, some strategic investors will require the company to disclose certain information, such as clinical trial results, without the strategic investor incurring an obligation to exercise its option to acquire. It is always important to remember that while a strategic investor may be interested in your company as an acquisition candidate, it may also simply be interested in monitoring your development for its own strategic purposes, so this type of mandatory disclosure should be limited or avoided if possible. However, since it is often not avoidable, the company must create contingency plans for this situation if a strategic investor decides to (i) back out entirely, having received the strategic information it wanted, or (ii) attempt to renegotiate better terms based on the information.

7. **Allocation of Risk.** Pre-negotiated acquisitions are inherently riskier than a typical acquisition scenario for both parties because the negotiation is taking place months or even years before the terms of the acquisition come into effect, if ever. As such, there tend to be more unknowns that must be addressed by the company's legal advisors through representations and warranties, indemnification provisions, covenants, termination rights, and other provisions that protect the company at each stage of the process. Counsel for the strategic investor may attempt to add onerous restrictive covenants that prevent the company from raising funds, operating effectively, or implementing backup plans during the option term. Overly restrictive terms should be avoided or minimized in order to give the company sufficient flexibility to raise funds and pursue opportunities that may serve as contingency plans if the strategic investor relationship is not fruitful. In addition, as with any acquisition, the division between upfront and milestone payments represents an allocation of risk between the company and the strategic investor and should be thoughtfully negotiated.

8. **Antitrust Concerns.** Under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, target companies must determine within 60 days prior to the expected closing whether filings must be made with the Federal Trade Commission. The acquisition will not be able to close until after the required waiting period or, if the Federal Trade Commission rules against the transaction, the acquisition may never occur. Depending on the timeline for a particular transaction, this may not be a rate-limiting factor, but it is nonetheless something to keep in mind.

9. **Publicity and Confidentiality.** If a pre-negotiated acquisition is disclosed to the public, strategic investors may wish to control how the transaction and relationship are described by the company. Depending on the situation, the strategic investor may request that the company keep the strategic investor or the entire transaction confidential or, more commonly, may require that the approval of the strategic investor be obtained prior to any public statement regarding the transaction. Since a pre-negotiated acquisition inspires confidence in the company's technology, the company may want to resist total confidentiality and work with the strategic investor to come to an agreement regarding public disclosure.

10. **Tax Concerns.** Tax and legal advisors to both the company and the strategic investor should be involved beginning at the option negotiation in order to ensure that the tax treatment of each payment under the transaction is fully considered. Option payments, especially if distributed to stockholders, can be a complicated tax matter, as can milestone payments after the acquisition.

While pre-negotiated acquisitions can be beneficial to both sides of the transaction, there are important issues to resolve beginning at the earliest stages of the process in order to avoid potential pitfalls. If you would like to discuss any of the above issues further, please feel free to contact James Huie, Andrew Ellis, or another member of Wilson Sonsini Goodrich & Rosati's life sciences practice.

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Q&A with Multiple Myeloma Research Foundation Founder and Chairman Kathy Giusti

Wilson Sonsini Goodrich & Rosati attorneys Vern Norviel, David Hoffmeister, and Charles Andres recently sat down with Kathy Giusti, founder and executive chairman of the Multiple Myeloma Research Foundation (MMRF). Since its inception, the MMRF—a client of WSGR—has opened more than 60 clinical trials of 30 compounds and combination approaches and helped win FDA approval of seven new drugs. Most impressively, these treatment innovations have helped to more than double the average life expectancy of multiple myeloma patients.

Q: Please tell us about your background and why you founded the MMRF.

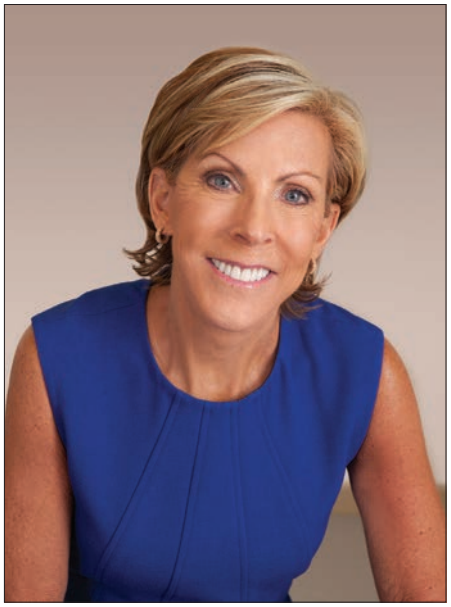
A: When I was diagnosed in 1996 with multiple myeloma, a rare and incurable cancer, the landscape was bleak. The same drugs had been used to treat the disease—and not very effectively—for the past several decades. There was very little research into the disease and few drugs on the horizon. I was given a life expectancy of about three years, but I was determined to beat those odds. My hope was that the business acumen I first developed at Harvard Business School and then honed as a pharmaceutical executive could be used to build a new kind of cancer research foundation—one that was optimized to run like a Fortune 500 company. In 1998, I founded the MMRF along with my identical twin sister, Karen, a corporate lawyer. By taking a business approach to science, the MMRF removed barriers that have impeded progress in other research efforts and, in their place, built collaborative research models that have accelerated the development of life-extending treatments.

Q: You recently testified before the U.S. Senate Committee on Health, Education, Labor and Pensions on the need to standardize the platforms for electronic health records (EHRs). How important are EHRs to the MMRF's end-to-end system in precision medicine and what can start-up companies developing new medicines learn from the MMRF's experience with EHRs?

A: A lack of easily accessible health data remains a major barrier to progress in precision medicine. This is changing thanks in part to the Meaningful Use Program, which began in 2009 to encourage the 491,000 physicians who serve Medicaid and Medicare patients and almost 4,500 hospitals to begin to adopt and use EHR systems. At the same time, patients are increasingly able to access their digital health records through patient portals. This allows patients to follow their cancer journey through data—monitoring blood work and other lab results, for example, over time. It also allows them to share their data for research, where it can be aggregated and analyzed alongside the data of many other patients.

Unfortunately, when we look at the numbers, we see that the number of patients taking advantage of these technologies is too low. According to a recent survey, only 36 percent of Americans are using patient portals and 35 percent of Americans did not even know they had a patient portal. In contrast, when we looked at MMRF data, we found that 85 percent of our newly diagnosed patients know they have a portal, and over 95 percent use their portal. This shows just how important trusted third parties—like the MMRF and other disease-based foundations—can be in raising awareness and education among our patients.

Q: The MMRF has been aggregating cancer patient molecular data and



pushing the data, in de-identified form, out to the public. Why is the MMRF doing this and how can interested start-ups developing new medicines and researchers access the data?

A: Realizing the full promise of precision medicine requires access to data and information available at multiple levels. This data, of course, must first be shared by patients, without whose tissue and personal and health data the science would not be possible. Data must also be shared by and among the global research community, from a single academic scientist to pharmaceutical giants; together we can then take a collective approach to making sense of massive quantities of data—so big that no one person or research lab could do it on its own—and generate new hypotheses, targets, and therapeutic approaches.

We recognized this early on at the MMRF and, most recently, with the launch of our CoMMpass trial, a long-term study to identify specific molecular alterations that are driving

myeloma. One thousand patients agreed to have their cancer genome sequenced at diagnosis; some will also be sequenced again when they relapse. Along the way, we've opened up and shared this data—the most robust look at myeloma to date—with qualified researchers through our Researcher Gateway, allowing scientists from around the world to be part of the cure. Our genomic studies have already yielded important discoveries, such as a mutation in the BRAF gene that had previously never been linked to myeloma. Treatments that target this same BRAF mutation have already been approved for other cancers and will be under study next year in our clinical network for myeloma patients who harbor the cancer-causing mutation.

Q: The MMRF has a long history of providing research grants to non-profits, universities, and senior researchers. Your efforts have already made a large impact on patient care for multiple myeloma. Where do you think the biggest impacts will be made in the next 10 years to improve the situation even more?

A: There are three innovations that I believe will dramatically change the way we treat myeloma in the near future. The first is genomically informed treatments; that is, those that target specific alterations in an individual—a mutated gene or errant protein, for example—that give rise to cancer or promote its spread. The second is immunotherapies, like checkpoint inhibitors and immunostimulatory antibodies, which are drugs that make use of a patient's own immune system to fight cancer. And the third is novel and rational combinations of both, which will allow us to attack cancer in multiple myeloma and disrupt its growth.

Q: The MMRF and its partners have helped gain FDA approval of seven drugs, with three more approvals expected in the coming year. What are some key factors contributing to this high success rate with the FDA?

A: Because myeloma is a rare disease with an unmet medical need, certain regulatory opportunities exist—such as orphan drug designation and priority review—that can lead to faster FDA review and approval times. Still, the drugs that have been approved in myeloma were based on strong data showing robust efficacy, even among those with advanced, hard-to-treat disease. From the beginning, we have been focused and prepared to work with the FDA as needed. We have also leveraged the FDA's willingness to meet face-to-face and have often invited representatives to our scientific strategy meetings.

Q: **What are the three most important lessons you have learned in implementing your precision medicine initiative?**

A: Precisely selecting the best treatment based on a person's sub-type rather than a one-size-fits-all-approach has the power to dramatically transform the way we treat cancer. We've already seen that in some sub-types of cancers, like HER+ breast cancer or ALK+ lung cancer. Bringing these same advances to myeloma has required that we develop an end-to-end model in precision medicine. By aggregating patients' clinical and genomic data, and making this data publicly available to researchers worldwide, we will uncover important mutations associated with the disease. We then rapidly advance the most promising discoveries into clinical trials through our clinical network, where patients can immediately benefit. This can only be done by engaging patients from the beginning and at every step of the research process. It has also proven critical to look to partners as both advisors and funders. And, lastly, staying on top of technology is an absolute must because it is constantly changing.

Q: What are some ways interested individuals and companies can help the MMRF advance its mission?

A: There are so many ways to join us in our mission—by bringing innovative new ideas to the table, by offering up technical expertise, by providing funding and other support. Curing cancer cannot be done alone. It takes a team.

In addition to serving as the founder and executive chairman of the Multiple Myeloma Research Foundation, Kathy Giusti has more than two decades of experience in the pharmaceutical industry, previously holding senior positions at G.D. Searle and Merck. Since founding the MMRF in 1998, Kathy has led the foundation in establishing innovative, collaborative research models in the areas of tissue banking, genomics, and clinical trials. She is widely recognized as a champion of open-access data sharing and a strong advocate for patient engagement, not only in their cancer care, but as part of the research and drug development process.

Kathy's leadership has earned her several prestigious awards and recognitions. Most recently, she was ranked No. 19 on Fortune Magazine's *World's 50 Greatest Leaders list. In 2011, she was named to the TIME 100 List of the world's most influential people. She has been named an Open Science Champion of Change by the White House and has also received the American Association for Cancer Research Centennial Medal for Distinguished Public Service, the Harvard Business School Alumni Achievement Award, and the Healthcare Businesswomen's Association's Woman of the Year Award. She currently sits on the White House Precision Medicine Initiative Working Group.*

To learn more about the MMRF, please visit http://www.themmrf.org/.

Preventing the Preventable: How to Protect Your Life Sciences Company from Self-Insuring Large-Dollar Patent Infringement and Patent Enforcement Litigation

By Matthew L. Cohn, Senior Vice President, Alliant Insurance Services

According to the PwC 2015 Patent Litigation Study, biotech/pharma and medical devices were two of the five most active industries in patent litigation and two of the top three industries for the largest median damage awards. IP litigation in the life sciences industry is not a question of if, but rather of when, how often, and how bad. The real question is whether you are going to continue to self-insure the exposure because the insurance brokerage community is unaware of and/or intimidated by IP infringement and IP enforcement insurance coverage.

Generally speaking, risk management experts do not recommend self-insuring risks that are both frequent and severe. So why is it that the vast majority of life sciences companies are completely uninsured for IP litigation? Let's face it, the world of IP is intimidating even to the most experienced sales professionals. Unfortunately, the insurance brokerage community does an inadequate job of educating its clients on IP coverage, which results in the vast majority of life sciences executives self-insuring their IP risk by default rather than relying upon careful decision-making and due diligence.

Since IP is not covered in traditional product liability policies and patent infringement claims are excluded in most if not all other liability policies, there is a need to secure stand-alone, specialty coverage for IP exposures.

The Stakes Are High

According to the American Intellectual Property Law Association's (AIPLA's) 2015 Survey, the average cost of patent infringement litigation—excluding amounts paid to settle or satisfy judgment—is $3,500,000 when the amount in controversy is extremely small ($10-25 million). Add another approximately $4 million if you lose the fight. And, of course, the greater the amount of dollars in controversy, the greater the cost of litigation.

Some "Small" Numbers

Patent trolls/non-practicing entities (NPEs) cost U.S companies more than $10 billion a year. This number increases substantially when factoring in indirect costs such as diversion of resources, delay in new products, and loss of market share.

One common misperception is "I'm just a small company—it's not going to happen to me." In actuality, however, the number of lawsuits filed by patent trolls increased to 2,026 in the first half of 2015—and companies with less than $100 million in revenue were hit the hardest. Specifically, 1,410 new patent troll lawsuits (or approximately 70 percent of such lawsuits) targeted these companies in the first half of this year.

It is often said that success creates conflict. All too often, smaller companies are targeted because their bigger alleged infringers believe they don't have the financial capacity to fight. Thus, litigation sometimes is won *not* based on the merits of the case, but by the party with the deeper pockets.

It's Time to Even the Playing Field

On the following page is a brief discussion of various types of IP infringement and IP enforcement insurance coverage.

IP Enforcement Insurance (Abatement Insurance)

With IP enforcement insurance, also known as abatement insurance, a legal fund is provided by the insurance company to help finance the enforcement of your IP against the alleged infringer. The insurance company can send out an early intervention letter to quickly alert the alleged bad actor of your financial ability to fight (paid for by the insurance carrier). This insurance coverage basically allows you to go pick a fight with the alleged infringer utilizing insurance company money.

Coverage can include a legal fund/enforcement fund, expenses associated with invalidity counterclaims made by an alleged infringer, and costs associated with post-grant and reexamination proceedings.

IP Infringement (Defense Cost Reimbursement Insurance)

Many believe it is the patent troll's sole objective in life to target companies (often smaller companies) that are unable to pay patent litigation defense costs, forcing them into signing licensing agreements and paying royalties. IP infringement

defense cost insurance will at times deter frivolous litigation brought by patent trolls and/or competitors. Coverage can include reimbursement of your litigation expenses incurred when defending against allegations of IP infringement, costs to assert patent invalidity as a defense, costs associated with post-grant and reexamination proceedings, and optional coverage for the reimbursement of settlements or damages awarded against you.

Business Interruption Coverage for IP

This optional coverage can provide first-party coverage directly to the insured client for non-compensated loss of value or loss of business income that is the consequence of legal actions. Coverage can respond after the final adjudication of a civil proceeding that directly caused or gave rise to the loss of value. Perils insured can include business interruption, loss of commercial advantage, cost of redesign, remediation, and reparation.

Cost-Benefit Analysis: Does IP Insurance Pencil Out?

Generally speaking, the purchase of IP coverage pencils out when considering how frequent IP litigation is in the life sciences space and the average costs involved. Premiums are typically calculated based on a number of factors, including but not limited to the number and types of IP insured, how strong the IP portfolio is perceived by the IP attorneys underwriting the risk, how litigious your niche is viewed to be, and the limit of coverage desired.

Additional Potential Advantages of Insuring Your IP

Many insiders suggest that insuring your IP makes it more valuable when considering a transaction or exit. In addition, it may facilitate quicker and easier access to financing for smaller, early-stage companies.

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Overcoming Restriction Requirements on Pharma Patents

By Vern Norviel (Partner, San Diego and San Francisco), David Hoffmeister (Partner, Palo Alto), Mike Hostetler (Partner, San Diego), Prashant Girinath (IP Specialist, Washington, D.C.), David Van Goor (Patent Agent, Washington, D.C.), and Charles Andres (Associate, Washington, D.C.)

Patent prosecutors strive to optimize protection afforded by pharmaceutical patents for branded pharmaceutical clients. For reasons discussed below, one underappreciated way to optimize pharmaceutical patent protection is to successfully address a restriction requirement (or lack of unity of invention counterpart) raised by a U.S. Patent and Trademark Office (USPTO) examiner during a patent examination.

Restriction occurs when, in the opinion of the USPTO, there are at least two inventions in a single patent application and (i) the inventions are independent or distinct and (ii) there would be a serious burden on the examiner if restriction is not required.[1] The effect of a restriction requirement, if made final and not withdrawn, is that at least one invention will not be examined. The non-examined invention can be separately pursued in a divisional application.[2]

Overcoming a USPTO restriction is not trivial. Attempts to overcome a restriction can produce more prosecution history estoppel than simply not traversing. Additionally, because restricted claims can be separately pursued in follow-on applications, accepted thinking is often that one patent that includes claims to both a drug product and methods of making the drug is essentially equivalent to two patents—the first containing claims to a drug and the second containing claims to methods of making the drug. For some or all of these reasons, patent practitioners may choose not to contest a restriction requirement.

[1] *See*, e.g., M.P.E.P. § 803.
[2] *See*, e.g., 35 U.S.C. § 121.

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The thinking that one patent containing two types of claims (e.g., drug product and methods of making the drug) is "about equal" to two patents each containing one claim (e.g., a drug patent and a method of making the drug) is upset by Orange Book listing rules. From Orange Book and subsequent pharmaceutical patent litigation lenses, the single patent containing two claim types can provide significantly more value.

The Orange Book

The Orange Book[3] contains a listing of drugs approved by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act. Among other things, the Orange Book:

- lists periods of market exclusivity associated with drug approvals;
- lists U.S. patent numbers associated with drugs and their expiration dates; and
- provides use codes for patents having method of treatment claims.

Orange Book Listing Rules

Patents eligible for Orange Book listing must be timely filed.[4] And, only patents containing at least one claim to the approved:

(i) drug substance (active ingredient), including some polymorphs;
(ii) drug product (formulation and composition); and
(iii) method(s) of use

qualify for Orange Book listing.[5] In contrast, "[p]rocess patents, patents claiming packaging, patents claiming metabolites and patents claiming intermediates are not covered . . . and information on these patents must not be submitted to the FDA." Thus, the only way to get issued claims to methods of making a drug, intermediates used therein, and drug metabolites into the Orange Book is to have those "unlistable" claims issue in a patent also containing at least one Orange Book-listable claim.

Contesting a Restriction Requirement – An Alternative Strategy

It is not unusual for a restriction requirement to be issued by a USPTO examiner, which forces a patentee to choose between:

- a drug;
- a key intermediate for making the drug;
- methods of making the drug;
- a drug metabolite; and
- methods of treating patients using the drug.[6]

Because drug patent claims are generally perceived to be valuable, these are often selected when responding to a restriction requirement. If restriction is maintained, the resulting patent will issue containing only drug claims and this drug patent will end up being Orange Book listed. Claims to the remaining inventions, excluding methods of treating patients with the drug, are pursued in separate divisional patents that are not Orange Book listable. But where a restriction requirement is successfully traversed or rejoinder[7] is requested and affected, the Orange Book-listed patent will contain additional diverse claims drawn to potentially include key intermediates for making the drug, methods of making the drug, and a drug metabolite.

Implications of Diverse Orange Book-Listed Claims

The process of commercializing a generic drug begins by reviewing Orange Book-listed patents for the branded drug. If the intent is to file an abbreviated new drug application, or ANDA, before Orange Book-listed patents expire, the would-be ANDA filer then usually obtains opinions from patent counsel as to why the patents are not infringed, invalid, or unenforceable.[8] Positions taken in the opinions form the basis for the notification letter that is legally required to be sent to the branded patent holder after the ANDA is filed by the FDA. Filing of an ANDA is an infringing act[9] and the branded patent holder, after receiving notice, is provided the opportunity to sue the ANDA filer in a federal district court, thereby triggering an automatic 30-month stay in ANDA approval.

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[3] Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, last accessed July 27, 2015.

[4] To be timely listed, U.S. patents in force at the point of new drug application (NDA) approval must be Orange Book listed within 30 days of approval. *See*, e.g., 21 C.F.R. § 314.53(c)(2)(R)(ii). "Within 30 days after the date of approval of its application or supplement, the applicant shall submit FDA Form 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition) or approved method of use . . . "

For U.S. patents issuing after NDA approval, ". . . the applicant shall submit to FDA the required patent information within 30 days of the date of issuance of the patent." 21 C.F.R. § 214.53(d)(2).

[5] *See*, e.g., 21 C.F.R. § 314.53(b)(1).

[6] A restriction requirement between a drug, a method of treating a disease using that drug, and a pharmaceutical formulation of that drug could be useful, as it allows the separation of different Orange Book categories into putatively patentably distinct patents. It may make sense to not contest that type of restriction requirement. Restriction requirements should be evaluated on a case-by-case basis as part of a general patent strategy.

[7] *See*, e.g., M.P.E.P. § 821.04.

[8] *See*, e.g., D. Hoffmeister, V. Norviel, J. Guise, P. Munson, S. Williams, D. Carsten, R. Torczon, and P. Girinath, "Takeaways for Generics After *Octane* and *Highmark*," *Law360*, September 15, 2014.

[9] *See* 35 U.S.C. § 271(e)(2).

Having a diversity of claims in Orange Book-listed patents creates significant added barriers to would-be generic manufacturers. For example, because the diverse claims are Orange Book listed, a 30-month stay of FDA approval can be based upon these claims. In the absence of having these diverse claims Orange Book listed, a patentee would need to take additional action, for example attempting to get a preliminary injunction based on diverse claims not found in the Orange Book listed patent(s).
Also, the inclusion of diverse claims can force the generic manufacturer to take invalidity or noninfringement positions earlier in time than they may otherwise would. Opinions for non-Orange Book-listed claims can be finalized later in time—because of the notification and lawsuit timelines—than those for Orange Book-listed claims. Formulating invalidity positions that can survive challenge takes time and rigorous thinking. Given time pressures associated with opinions and related ANDA filings, some of these positions may end up being rushed, may be suboptimal, and therefore may be more open to successful rebuttal by the branded drug patent holder. The ANDA filer may then feel pressure to move away from these initial positions to new legal theories during litigation. Doing so can be more likely to result in sanctions and fee shifting—which can easily run into millions of dollars.[10, 11, 12]

Dealing with Restriction Requirements

Successfully addressing restriction requirements can improve the protection afforded by pharmaceutical patents. While each restriction requirement is unique and must be treated as such, potential ways to increase the odds of having more diverse Orange Book-listed claims include:

- Attack mere assertions that the claims are distinct. In some instances, patent examiners will merely assert that claims to two or more inventions are distinct without providing a reasonable basis for this conclusion. In these instances, arguing that the patent examiner has not met the legal burden for showing restriction is necessary may overcome the requirement.
- Argue no serious burden. In cases containing small numbers of claims of relatively consistent claim scope, it may be possible to persuade a patent examiner through reasoned argument that examining all claims would not represent a serious burden.
- Call out misconstruing of special technical features and mischaracterization of applied references. Doing so can overcome some unity of invention rejections.
- Ask for rejoinder where appropriate.
- Make judicious use of product-by-process claims. If a requirement is sustained and a follow-on application is filed with claims drawn to methods of making a drug, patent examiners may allow inclusion of dependent product-by-process claim(s). Because product-by-process claims that cover the drug are Orange Book listable, inclusion of one of these claims can allow method-of-making claims to be Orange Book listed.[13]

Conclusion

Restriction requirements (and lack of unity of invention equivalents), if not challenged and overcome, can decrease the claim diversity of Orange Book-listed patents and smooth the allowance pathway for generic manufacturers. At multiple levels, overcoming restriction requirements provides advantages for protecting pharmaceuticals. Addressing restriction requirements (and lack of unity of invention equivalents) should therefore be given appropriate attention.

The authors dedicate this article to Peter Munson—friend, colleague, mentor, lawyer, scholar, Renaissance man. You are and will be missed.

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[10] *See*, e.g., *Yamanouchi Pharmaceutical Co. Ltd. v. Danbury Pharmacal Inc.*, 231 F.3d 1339 (Fed. Cir. 2000).
[11] For an example of method-of-making claims keeping generics off the market, *see*, e.g., *Albany Molecular Research Inc. v. Dr. Reddy's Laboratories Ltd. et al.*, case number 09-cv-4638; and *Albany Molecular Research Inc. v. Sandoz Inc. et al.*, case number 09-cv-4639; both in the U.S. District Court for the District of New Jersey.
[12] Examples of drugs that that have Orange Book-listed patents containing diverse claims include rivaroxaban and sofosbuvir.
[13] When deciding to include product-by-process claims, consider the possibility that doing so may result in loss of divisional application safe harbor status and the implications thereof.

Life Sciences Venture Financings for WSGR Clients

By Scott Murano (Partner, Palo Alto)

The table below includes data from life sciences transactions in which Wilson Sonsini Goodrich & Rosati clients participated across the second half of 2014 and the first half of 2015. Specifically, the table compares—by industry segment—the number of closings, the total amount raised, and the average amount raised per closing across the second half of 2014 and the first half of 2015.

Life Sciences Industry Segment	2H 2014 Number of Closings	2H 2014 Total Amount Raised ($M)	2H 2014 Average Amount Raised ($M)	1H 2015 Number of Closings	1H 2015 Total Amount Raised ($M)	1H 2015 Average Amount Raised ($M)
Biopharmaceuticals	13	261.99*	11.66**	19	139.93	7.36
Genomics	2	5.10	2.55	4	12.84	3.21
Diagnostics	5	88.38	17.68	4	9.50	2.37
Medical Devices & Equipment	47	254.15	5.41	41	306.32	7.47
Digital Health	4	9.75	2.44	6	20.07	3.34
Healthcare Services	7	106.15	15.16	2	88.00	44.00
Total	**78**	**725.52**		**76**	**576.66**	

**Includes one megadeal ($100 million and over).*

***This is a truncated average that excludes the highest and lowest amounts raised in the calculation of the average.*

The data generally demonstrates that venture financing activity decreased during the first half of 2015 compared to the second half of 2014 with respect to total amount raised and number of closings. Specifically, the total amount raised across all industry segments during the first half of 2015 decreased by 20.5 percent compared to the second half of 2014, from $725.52 million to $576.66 million, and the total number of closings across all industry segments decreased by 2.6 percent, from 78 closings to 76 closings.

The industry segment with the largest number of closings—medical devices and equipment—experienced a decrease in number of closings during the first half of 2015 compared to the second half of 2014, but saw an increase in total amount raised. Specifically, medical devices and equipment decreased 12.8 percent in number of closings, from 47 closings to 41 closings, but increased by 20.5 percent in total amount raised, from $254.15 million to $306.32 million.

> The industry segment with the largest number of closings—medical devices and equipment—saw a decrease in number of closings during 1H 2015 compared to 2H 2014, but saw an increase in total amount raised

Conversely, the industry segment with the second-largest number of closings—biopharmaceuticals—experienced an increase in number of closings during the first half of 2015 compared to the second half of

Pre-money valuations for life sciences companies decreased at all stages of financing during the first half of 2015 compared to the second half of 2014

2014, but saw a decrease in total amount raised. Specifically, the number of closings in the biopharmaceuticals industry segment increased 46.2 percent, from 13 closings to 19 closings, while the total amount raised decreased by 46.6 percent, from $261.99 million to $139.93 million. Meanwhile, the digital health and genomics industry segments experienced an increase in number of closings and in total amount raised during the first half of 2015. Specifically, digital health experienced a 50 percent increase in number of closings, from four closings to six closings, and a 105.9 percent increase in total amount raised, from $9.75 million to $20.07 million, while genomics experienced a 100 percent increase in number of closings, from two closings to four closings, and a 151.8 percent increase in total amount raised, from $5.10 million to $12.84 million. All remaining industry segments were either flat or down during the first half of 2015 compared to the second half of 2014 on both measures.

In addition, our data suggests that Series A financing and bridge financing activity compared to Series B and later-stage equity financings and recapitalization financings increased during the first half of 2015 compared to the second half of 2014. Specifically, the number of Series A closings as a percentage of all closings increased from 26.9 percent to 38.2 percent, while the number of bridge financing closings as a percentage of all closings increased from 26.9 percent to 31.6 percent. Offsetting those gains, Series B financing, Series C and later-stage financing, and recapitalization financing activity compared to all other financings decreased during the first half of 2015 compared to the second half of 2014. Specifically, the number of Series B closings as a percentage of all closings decreased from 19.2 percent to 15.8 percent, the number of Series C and later-stage financing closings as a percentage of all closings decreased from 16.7 percent to 10.5 percent, and the number of recapitalization financing closings as a percentage of all closings decreased from 7.7 percent to 2.6 percent.

Pre-money valuations for life sciences companies decreased at all stages of financing during the first half of 2015 compared to the second half of 2014. The average pre-money valuation for Series A financings decreased by 41.3 percent, from $14.6 million to $8.57 million; the average pre-money valuation for Series B financings decreased by 41.3 percent, from $81.62 million to $47.91 million; and the average pre-money valuation for Series C and later-stage financings decreased by 5.2 percent, from $114.75 million to $108.75 million.

Other data taken from transactions in which all firm clients participated in the first half of 2015 suggests that life sciences is now the third-most attractive industry for investment, down from second during the second half of 2014. For the first half of 2015, life sciences represented 14 percent of total funds raised, while the software industry—historically the most popular industry for investment—represented 34 percent of total funds raised and retail represented 23 percent of total funds raised.

Overall, the data suggests that access to venture capital for the life sciences industry has decreased during the first half of 2015 compared to the second half of 2014. Deal activity has declined and pre-money valuations are down. It is also worth noting that financing activity during the second half of 2014 had decreased from the first half of 2014, so the lackluster activity during the first half of 2015 represents the second-straight six-month period of declining financing activity in life sciences.

Life sciences is still the third-most-popular industry for investment among all sectors in which our clients participate

Looking closer at the data, Series A financings now represent a greater percentage of all deals, suggesting that whatever investor appetite remains is moving to earlier-stage deals—and the success of those deals may translate into improved activity at the later stages. Whatever the case may be, life sciences is still the third-most-popular industry for investment among all sectors in which our clients participate, and while it may be down, it's definitely not out.

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WSGR Hosts Successful 22nd Annual Phoenix Conference

On October 21-23, 2015, Wilson Sonsini Goodrich & Rosati hosted the 22nd annual Phoenix Conference at The Ritz-Carlton in Half Moon Bay, California. The exclusive event brought together more than 160 high-level executives from large healthcare companies and CEOs of 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 insight from industry leaders and peers.

The two-day conference featured presentations on a variety of topics, including the opportunities and challenges of medical device investment, the role of analytics in driving more precise patient engagements, the shifts taking place in consumer healthcare, and medtech company exit strategies. The event also included a lunch with speaker Paul Yock, M.D., the founder of Stanford's BioDesign program, who discussed the market conditions faced by medical device innovators and the criteria for future healthcare technology development. In addition, interviews were conducted with Gary Pruden, the head of Johnson & Johnson's medical device business, and John Capek, executive vice president of venturing at Abbott Laboratories, as part of the event's Corporate Spotlight series.

In connection with the event, the Phoenix Hall of Fame for Medical Device & Diagnostic Leadership recognized the accomplishments of companies and individuals at a reception, dinner, and awards ceremony on the evening of October 22. The NeuroPace RNS System, the world's first closed-loop responsive neurostimulation system, was honored with the "Most Promising New Product" award and Nevro, a leading innovator in the field of spinal cord stimulation technology, was presented with the "Emerging Growth Company" award. Mark Deem and Hanson Gifford of The Foundry received the "Phoenix Innovator Award," while Mike Mussallem of Edwards Lifesciences was named the "Lifetime Achievement Award" recipient. As such, Mike participated in a discussion the following morning with David Cassak of the *Medtech Strategist,* during which he discussed his career path that led up to the honor.

Recent Life Sciences Client Highlights

Benvenue Medical Secures $60 Million in Financing

On January 6, 2016, Benvenue Medical, a developer of minimally invasive solutions for spine repair, announced that it has completed a $60 million round of financing, which is a combination of $23 million in equity supplemented with $37 million in debt. The equity financing was provided by DeNovo Ventures, Domain Associates, Esquilime Partners, InterWest Partners, Technology Partners, and Versant Ventures. CRG is the sole debt provider and also participated in the equity financing. WSGR represented Benvenue Medical in the transaction. For more information, please see http://benvenuemedical.com/press-release/benvenue-medical-secures-60-million-financing/#sthash.bs8AD1Uc.dpuf.

Quartzy Raises $17 Million in Series B Round

On January 4, 2016, Quartzy, a creator of lab management software for life scientists, announced that it has closed a $17 million Series B round of financing, which will help it build up the supply of lab equipment offered to customers. The new round brings the company's total funding to nearly $25 million. Led by Eminence Capital, the round included Khosla Ventures, the YC Continuity fund, A Capital, Yelp CEO Jeremy Stoppelman, Binary Capital's Justin Caldbeck, Scribd and Parse founder Tikhon Bernstram, and Factual's Gil Elbaz. WSGR represented Quartzy in the transaction. For additional details, please see http://techcrunch.com/2016/01/04/life-sciences-marketplace-quartzy-raises-17-million-to-build-up-the-supply-side/.

CryoLife to Acquire On-X Life Technologies Holdings

CryoLife, a leading medical device and tissue processing company focused on cardiac and vascular surgery, announced on December 22 that it has entered into a definitive agreement to acquire privately held mechanical heart valve company On-X Life Technologies Holdings. Under the terms of the agreement, CryoLife will acquire On-X for an upfront payment of $130 million on a cash and debt-free basis, consisting of approximately 70 percent in cash and 30 percent in CryoLife common stock. The merger agreement has been approved by both companies' boards of directors and On-X's stockholders, and the transaction is expected to close in January 2016. WSGR is advising CryoLife in the transaction. Please refer to http://phx.corporate-ir.net/phoenix.zhtml?c=80253&p=irol-newsArticle&ID=2124815 for further details.

CareDx Announces Purchase of Allenex AB and Plans to Launch Tender

On December 16, molecular diagnostics company CareDx announced that it has agreed to acquire approximately 78 percent of the outstanding shares of transplant diagnostics company Allenex AB from its three principal shareholders, and plans to launch a tender offer for the remaining 22 percent of the shares of Allenex in the first quarter of 2016. Allenex's board of directors has unanimously recommended that Allenex shareholders accept the tender offer. Completion of the tender offer is expected by the end of March 2016. The total purchase price of Allenex will be approximately $35 million, consisting of a combination of cash and stock in CareDx. WSGR is advising CareDx in the transaction. Please see http://investors.caredxinc.com/releasedetail.cfm?ReleaseID=947185 for more information.

WuXi PharmaTech Announces Completion of Going-Private Transaction

WuXi PharmaTech, a leading open-access R&D capability and technology platform company serving the pharmaceutical, biotechnology, and medical device industries with operations in China and the United States, announced on December 10 that it has completed its merger with WuXi Merger Limited, a wholly owned subsidiary of New WuXi Life Science Limited. As a result, New WuXi Life Science Limited has acquired WuXi PharmaTech in a cash transaction valued at approximately $3.3 billion. WSGR acted as U.S. and Hong Kong counsel to the founders, and was lead counsel to the buyer group in the transaction. For further details, see http://www.prnewswire.com/news-releases/wuxi-pharmatech-cayman-inc-announces-completion-of-going-private-transaction-300191201.html.

Eargo Raises $25 Million in Series B Funding

On December 9, Eargo, a consumer medical device company focused on innovative hearing solutions, announced that it has raised $25 million in Series B funding from New Enterprise Associates. Eargo will use the funds to expand business operations and accelerate production of its discreet in-ear hearing device, which is designed to help people live with and feel better about hearing loss. WSGR represented Eargo in the financing. Additional information is available at http://www.eargo.com/assets/news/eargo-b27ea73b18f3bda2df94bf51df908fa2.pdf.

Bristol-Myers Squibb Completes Acquisition of Cardioxyl Pharmaceuticals

Global pharmaceutical company Bristol-Myers Squibb announced on December 8 that it has completed its acquisition of Cardioxyl Pharmaceuticals, a private biotechnology company focused on the development of novel therapeutic agents for the treatment of cardiovascular disease. Bristol-Myers Squibb had previously agreed to upfront and

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near-term milestone payments of up to $300 million and potential additional consideration of up to $1.775 billion upon the achievement of certain development, regulatory, and sales milestones. WSGR represented the principal selling stockholder funds in the transaction. Please see http://investor.bms.com/investors/news-and-events/press-releases/press-release-details/2015/Bristol-Myers-Squibb-Completes-Previously-Announced-Acquisition-of-Cardioxyl-Pharmaceuticals-Inc/default.aspx for additional details.

MD Revolution Raises $23 Million

Digital chronic care management leader MD Revolution announced on December 7 that it has completed a $23 million round of financing, which was co-led by Chicago-based Jump Capital and a leading global healthcare technology company. The new round brings the company's total funding to more than $30 million. M D Revolution currently serves more than 100 practices and plans to add hundreds of additional practices representing several hundred thousand patient users next year. WSGR advised MD Revolution in the transaction. For further details, please see http://www.businesswire.com/news/home/20151207005454/en/MD-Revolution-Raises-23-Million-Furthers-Market.

Human Longevity Acquires Cypher Genomics

On November 30, genomics-based, informatics-driven company Human Longevity (HLI) announced that it has acquired Cypher Genomics, a leading genome informatics company offering highly accurate, rapid, and robust human genomic interpretation software solutions. The financial terms of the deal were not disclosed. HLI has created the world's largest and most comprehensive database of whole genome, phenotype, and clinical data. WSGR represented Cypher Genomics in the transaction. For more information, please refer to http://cyphergenomics.com/news/human-longevity-inc-hli-acquires-cypher-genomics-inc/.

Quality Systems to Acquire HealthFusion Holdings

On October 30, Quality Systems announced an agreement to acquire HealthFusion Holdings, a privately held developer of web-based, cloud computing software for physicians, hospitals, and medical billing services, for $165 million plus potential additional contingent consideration of up to $25 million. The transaction is expected to close in March 2016. WSGR advised HealthFusion in the transaction. More information is available at http://www.businesswire.com/news/home/20151030006051/en/Quality-Systems-Announces-Agreement-Acquire-HealthFusion-Holdings.

Silk Road Medical Raises $57 Million

Medical device developer Silk Road Medical announced on October 20 that it has received up to $57 million in equity and debt funding from new and existing investors. CRG, a premier healthcare investment firm and a new investor in Silk Road Medical, led the debt financing and also participated as an equity investor alongside returning investors Warburg Pincus and The Vertical Group. WSGR advised Silk Road Medical in the transaction. For further details, visit http://www.silkroadmedical.com/news-5/.

Medtronic Completes Acquisition of Twelve

On October 2, global medical technology leader Medtronic announced that it has completed its acquisition of Twelve, Inc., a privately held medical device company focused on the development of a transcatheter mitral valve replacement device. Medtronic had previously agreed to pay up to $458 million for Twelve, including $408 million at closing and $50 million upon the achievement of CE marking. WSGR advised Twelve in the transaction. For more information, visit http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2092736.

District Court Dismisses Consumer Class Action Against Align Technology

On September 29, the U.S. District Court for the Northern District of California dismissed, with prejudice, all claims against Align Technology, maker of the Invisalign teeth aligning system, in a consumer class action alleging that the Invisalign aligners prescribed to the plaintiff did not cure a dental condition caused by her worn-down teeth, and asserting claims for false advertising, breach of warranty, and violations of California consumer protection laws. WSGR represented Align Technology in the matter. More information is available at https://www.wsgr.com/WSGR/Display.aspx?SectionName=clients/1015-align-technology.htm.

Medtronic Acquires Lazarus Effect

Global medical technology leader Medtronic on September 28 announced that it has acquired Lazarus Effect, a privately held medical device company focused on acute ischemic stroke products that facilitate the capture and removal of clots. The acquisition was an all-cash transaction worth $100 million at closing. Lazarus Effect's "mesh cover" technology complements Medtronic's ischemic stroke portfolio and further enhances the ability of Medtronic's neurovascular business to deliver next-generation technologies. WSGR represented Lazarus Effect in the acquisition. For additional details, please see http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2090887.

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Avinger Secures Up to $55 Million in Financing from CRG

Avinger, a developer and manufacturer of image-guided, catheter-based systems for the treatment of peripheral arterial disease and pioneer of the lumivascular approach to treating vascular disease, announced on September 23 that it has entered into a term loan agreement and a securities purchase agreement with CRG. The agreements provide Avinger with new financing of up to $55 million. WSGR advised Avinger in connection with the financing. More information is available at http://investors.avinger.com/phoenix.zhtml?c=253894&p=irol-newsArticle&ID=2089746.

Incyte and Jiangsu Hengrui Medicine Announce Global License Agreement

On September 2, Delaware-based biopharmaceutical company Incyte Corporation announced a global license and collaboration agreement with China-based pharmaceutical company Jiangsu Hengrui Medicine Co., Ltd. (Hengrui) for the worldwide development and commercialization of SHR-1210, an investigational anti-PD-1 monoclonal antibody for the treatment of cancer. Under the agreement, Incyte will acquire the exclusive development and commercialization rights to SHR-1210 worldwide—with the exception of Mainland China, Hong Kong, Macau, and Taiwan—in exchange for an upfront payment of $25 million and milestone payments of up to $770 million to Hengrui. WSGR represented Hengrui in the transaction. Please refer to http://investor.incyte.com/mobile.view?c=69764&v=203&d=1&id=2084330 for further details.

Abbott Completes Acquisition of Tendyne Holdings

Also on September 2, global healthcare company Abbott announced that it has completed its acquisition of Tendyne Holdings, a private medical device company focused on developing minimally invasive mitral valve replacement therapies. Abbott acquired the equity of Tendyne that it did not already own for $225 million upfront, resulting in a total transaction value of $250 million, plus potential future payments tied to regulatory milestones. WSGR advised Tendyne in the transaction. For more information, please see http://www.prnewswire.com/news-releases/abbott-completes-acquisition-of-tendyne-holdings-inc-300136563.html.

Firm's Life Sciences Practice Earns Top Honors

Wilson Sonsini Goodrich & Rosati's life sciences practice was recently named a 2015 "Practice Group of the Year" by *Law360* and was ranked No. 1 in the inaugural Life Sciences Law Firm Index published by litigation finance firm Lake Whillans based on research conducted by Breaking Media that looked at law firm corporate, intellectual property, and regulatory practices; experience working with start-up companies; and thought leadership to identify which law firms are the most active and relevant for life sciences companies.

WSGR Achieves Top Venture Financing Rankings from Dow Jones VentureSource

Dow Jones VentureSource recently ranked Wilson Sonsini Goodrich & Rosati as the leading law firm for U.S. venture financings for the first three quarters of 2015. Specifically, Dow Jones VentureSource's legal rankings for Q1-Q3 2015 issuer-side venture financing deals placed Wilson Sonsini Goodrich & Rosati ahead of all other firms by the total number of rounds of equity financing raised on behalf of clients. WSGR is credited as legal advisor in 172 rounds of financing, while its nearest competitor advised on 150 rounds of financing. Of particular interest to *The Life Sciences Report*, WSGR ranked No. 1 for Q1-Q3 2015 issuer-side U.S. deals in the healthcare and medical devices and equipment industries.

Upcoming Life Sciences Events

Biotech Board of Directors and Senior Executives Reception
January 13, 2016
Clift Hotel
San Francisco, California

Wilson Sonsini Goodrich & Rosati's Biotech Board of Directors and Senior Executives Reception is an exclusive networking event geared toward executives and directors of biotechnology companies.

rEVOLUTION Symposium 2016
April 6-8, 2016
St. Regis Hotel, Washington, D.C.
https://www.wsgr.com/news/revolution

Now in its 12th year, the rEVOLUTION Symposium has become the place to discuss the most important strategic problems facing pharma and biotech CSOs. The invitation-only event 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 the industry.

24th Annual Medical Device Conference
June 23-24, 2016
The Palace Hotel
San Francisco, California
https://www.wsgr.com/news/medicaldevice/

Wilson Sonsini Goodrich & Rosati's 24th Annual Medical Device Conference, aimed at professionals in the medical device industry, will feature a series of panels and discussions addressing the critical business issues facing the sector today.

Phoenix 2016: The Medical Device and Diagnostic Conference for CEOs
October 5-7, 2016
Montage Laguna Beach
Laguna Beach, California
https://www.wsgr.com/news/phoenix

Phoenix 2016 will be the 23rd annual conference for chief scientific officers and the senior leadership of medical device and diagnostic companies. The event will bring together executives from large healthcare companies and small, venture-backed firms to discuss issues of interest to the medical device industry, as well as to network and gain valuable insights from industry leaders and peers.

Casey McGlynn, a leader of the firm's life sciences practice, has editorial oversight of *The Life Sciences Report* and was assisted by Philip Oettinger, Elton Satusky, Scott Murano, and James Huie. 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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