Wilson Sonsini Goodrich & Rosati
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The Life Sciences Report

A New Accelerator Takes Digital Health Start-Ups to the Next Level

When co-founders Fred Toney and Ted Ridgway decided to create a new accelerator focused on digital healthcare, they started by analyzing what was working well—and more important, what wasn't—at current business incubators and accelerators focused on the space. After months of research and numerous caffeine-fueled discussions with CEOs who had gone through the accelerator process, they were able to identify three basic problems: too little time, too little capital, and too little attention. "In general, the accelerators lasted only about three to four months, the companies were funded to the tune of $20,000 to $50,000, and participants didn't get the kind of intense, hands-on advice they needed from the programs on a continual basis," Fred explains. "We set out to change all that."

Which is exactly what they did when they formed Launchpad Digital Health, which the founders like to call a "next-generation accelerator" but could also be described as an accelerator program on steroids. Each of their chosen early-stage companies typically gets $200,000 to $400,000; the companies are required to co-locate with Launchpad at Hatch Today (formerly The Hatchery) in San Francisco for the duration of the year-long program; and participants receive frequent, ongoing attention and counsel from Launchpad's team of advisors on all aspects of their businesses.

The generous and comprehensive nature of the program attracted a good deal of attention in the digital healthcare world when Fred and Ted announced their company last year, with a large number of start-ups vying to be one of the participants in the first cohort. They started accepting business plans and submissions last November, and then winnowed the pool down to 10 highly promising contenders. In late February, Launchpad held a Finalists Day, during which

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In This Issue

The Return of the MedTech IPO Market

By Jed G. Cohen, Managing Director, Leerink Partners

As we approach the middle of 2014, the medical technology IPO market is showing signs of life following a six-year period of inactivity. This long-anticipated development has started to breathe a new energy into a venture-backed medical technology community that had settled into the new realities of an IPO-less world.

Historical Perspective on MedTech IPO Markets

To understand the significance of a healthy IPO market on the path to liquidity for venture-backed medical technology, let's start with a little historical perspective on the medical technology IPO markets. For the last two decades, the existence of a public market source of funding for medical technology companies has been more or less assured. Occasionally, there was a temporary pause in market activity for 18 to 24 months, such as in the late '90s or from mid-2002 to early 2004, but in each case, the medical technology IPO market quickly snapped back to its regular pace.

This "regular" pace had been approximately 15 IPOs per year from 2004-2008. In contrast, from the financial crisis in March 2008 through Fall 2013, there had only been approximately one IPO per year. The majority of these post-2008 IPOs were for more mature companies like AGA Medical ($200 million

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the fledgling companies presented their ideas and were peppered with questions by Launchpad's advisors and partners, including Casey McGlynn and Scott Murano from Wilson Sonsini Goodrich & Rosati's life sciences practice, as well as experienced hands from the venture capital, accounting, insurance, technology, social media, and healthcare sectors. "It wasn't easy—so many of the companies had great ideas and a lot of heart—but we finally were able to select five companies for the first cohort, who will join us at Hatch in May." Moving forward, the founders plan to launch a new set of five or more companies every six months, with the newbies overlapping with the more-seasoned group at Hatch to promote partnership, mentorship, and synergy.

The companies selected for the first cohort were a diverse group, all focused on some aspect of digital healthcare, which Fred notes is a new term for what people used to call healthcare technology and incorporates fresh aspects such as the mobile Internet, cloud, and personal applications. "It's a pretty wide net that includes products and services that use the Internet, mobile technology, and information technology to promote better patient care and wellness," he says. That includes everything from makers of wearable fitness sensors to providers of secure transmissions between healthcare institutions. For example, although the successful contenders won't be announced until early May, Fred says that one of their companies is focused on disease management, leveraging information gleaned from call centers charged with monitoring patients' health so they can intervene when someone is experiencing serious health issues before that person ends up in the emergency room or incurs a mountain of avoidable healthcare costs. "All of the companies we selected had some common characteristics," he says. "They weren't ready for venture money or a Series A preferred round yet, but they were well beyond the business-plan stage and were already working on a product or ready to begin marketing it. In fact, all of the companies we selected will be launching products during our year with them." In addition, Fred and Ted were looking for companies with a solid management team in place that was ready to steer them through funding rounds and product development. "A team with strong technology experience and some background in medicine or healthcare is the ideal combination," Fred says. "We are looking for folks who are driven, dynamic, and grounded, and who truly understand how much work it takes to make a company successful."

Fred Toney **Ted Ridgway**

LAUNCHPAD DIGITAL HEALTH

For the two founders, Launchpad is a reunion of sorts, and the result of a natural trajectory. In the early 1990s, both worked at what became Volpe Brown Whelan, an investment bank later purchased by Prudential, with Ted on the investment banking side and Fred serving as a research analyst focused on the healthcare industry. They did many deals together, and then left to work in a number of capacities at different healthcare companies and investment firms, where they gained substantial operational experience throughout the technology and healthcare sectors as chief executive officers, chief financial officers, and business development executives. The two remained close over the course of their careers, and started seriously talking about joining forces a couple of years ago. "Launchpad is where everything came together for us," Fred says. "Our company-side and operational experience really helps us guide the entrepreneurs in our accelerator because we have seen so many good and bad decisions that companies have made, and we have fought a lot of those battles ourselves. That experience, along with a deep knowledge of the unique healthcare ecosystem, gives our companies a huge advantage.

"There's a lot of change and innovation in the digital health field, and that makes it exciting and ripe for finding great new companies," he continues. "And at the end of the day, you're really helping people be healthier and live longer, more productive lives. That's the reason we have stayed in the healthcare space for all these years, and why we're so passionate about Launchpad."

To learn more about Launchpad Digital Health and founders Fred Toney and Ted Ridgway, please visit http://www.launchpdh.com/.

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revenue run-rate at October 2009 IPO), Globus Medical ($380 million revenue run-rate at August 2012 IPO), and Tornier Holdings ($275 million revenue run-rate at February 2011 IPO). These mature companies represented a different flavor than those involved in traditional venture-backed medical technology IPOs, which typically ranged from entities that had obtained FDA approval but generated no revenue to companies with $60 million run-rate revenue.

Without an active IPO market, backers of early-stage private medical technology companies have had to adjust to a new reality characterized by a reliance on private financing markets and an emphasis on mergers and acquisitions as the preferred path to shareholder liquidity. Given a dwindling universe of venture investors interested in or capable of leading new private rounds, private financings have increasingly leaned on the insider support of existing investors. The market pace of mergers and acquisitions has not been sufficiently robust in picking up the slack, forcing many companies to continue independently with constrained capital.

Reasons for Optimism

With that backdrop, it is easy to see why a revitalized medical technology IPO market has captured the imagination of many in venture-backed medtech. Reasons for optimism center on the fact that there were as many completed medtech IPOs in the last six months as in the prior five-and-a-half years combined. Since October 2013, there have been five traditional medical technology IPOs, with LDR Holdings (October 2013), Tandem Diabetes Care (November 2013), Inogen (February 2014), Lumenis (February 2014), and TriVascular (April 2014) making it out the door. The Tandem Diabetes Care IPO is probably the one that provided the most intrigue, given the company's revenue run-rate of approximately $40 million, which brought back memories of the earlier-stage development bar of years prior. TriVascular, the most recent medtech IPO, which priced on April 15, shared a similarly early stage of development.

The newfound medtech IPO market has benefited from the fact that the overall healthcare IPO market of 2010 to 2014 has been so heavily weighted toward biopharma. In the last six years, biopharma IPOs have outnumbered medtech IPOs by a factor of 10 to 1. Institutional investors have expressed an interest in rebalancing their portfolios with new medtech names. Without the replenishment from new IPOs, the existing public universe of medtech has largely remained unchanged for years, with many of the high-growth names having enjoyed meaningful stock price appreciation. As often is the case as IPO markets reopen, public investors are driven by their perceptions of tradeoff in risk and return. More specifically, less seasoned IPO issuers typically have relatively higher risk of execution relative to existing public companies. But, with many existing public companies coming off of spikes in their stock price and looking richly valued at higher-than-normal trading multiples, investors are intrigued by the return potential of this new batch of IPOs. So far, the return potential has not disappointed, with LDR Holdings and Tandem each doubling their stock prices since their IPOs before more recently giving back some of the gains.

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The irony is that the return of the medtech IPO market arguably could have been fast forwarded by one or two years. Many believe that the public markets were ready and willing to invest in medtech IPOs for quite a while. The constraint has been more on the supply than on the demand. Many top-notch, emerging-growth IPO candidates have overemphasized M&A as "Plan A," believing that the acquisition valuations and back-end earnout structures would be far more attractive than the corresponding public values. Besides, it takes a certain conviction to be the guinea pig who lines up first to go public. However, as often is the case, it is difficult for private companies to control their M&A destiny and a subset of these companies are now embarking on "Plan B," the IPO.

Now, with the initial wave of IPOs behind us, there is no shortage of medical technology companies contemplating entering the public markets. Some are appropriately positioned to follow in the footsteps of the recent new issuers, while others may be misinterpreting the recent successes and underappreciating the corporate characteristics required for a successful IPO. Even if there are some bumps on the road to recovery, the venture-backed medtech community is excited to see what lies ahead, as an extra possibility on the financing and liquidity options menu is poised to create interesting boardroom discussions.

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Is There a Deal in Your Future? A Guide to Navigating Antitrust Waters

By Andrea Agathoklis Murino, Partner, and Kellie Kemp, Associate (Washington, D.C.)

Companies in the life sciences arena are affected by a range of federal, state, and local laws, often in ways that are not always self-evident. For those companies considering an acquisition or seeking to be acquired, it is crucially important to understand that these events may be subject to federal antitrust scrutiny. In fact, even patent acquisitions, pharmaceutical patent licenses, and certain marketing and distribution arrangements can raise antitrust issues. Unknowingly entering into a transaction that violates the antitrust laws can lead to federal and state government investigations, cumbersome litigation, and substantial fines. In order to ensure that your time is spent focusing on your core business objectives rather than responding to antitrust investigations, understanding the basic scope of transaction-related antitrust reporting requirements is essential.

Premerger Notification Requirements

Some mergers, acquisitions, and transfers of securities or assets—including patent acquisitions and pharmaceutical patent licenses—are subject to federal antitrust review and may not close until after approval is granted. The most important fact for you to remember is that under certain circumstances, the Hart-Scott-Rodino Antitrust Improvements Act (also known as the HSR Act) requires that both parties to a transaction file a premerger notification form with both the U.S. Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ) if certain dollar thresholds are exceeded (these thresholds are adjusted annually).

Generally speaking, a transaction must be reported to the antitrust agencies if it is valued at more than $303.4 million. Valuation takes into account the total amount of consideration paid by the buyer to the seller, including cash paid at closing, cash paid at any other time, the face amount of any note, the value of any securities or non-corporate interests (i.e., interests in any unincorporated entity giving the right to any profits, or the right to any assets in the event of dissolution), the fair market value of other assets transferred, the face value of accrued liabilities assumed, and any other consideration paid.

Failing to file an HSR form can result in the imposition of stiff financial penalties (the statutory maximum is $16,000 for every day there was a violation) and place the validity of the entire transaction in jeopardy

A transaction may be reportable if it is valued between $75.9 million and $303.4 million, depending on the size of the buyer's ultimate parent entity (UPE) and the seller's UPE. If one party's UPE recognized at least $151.7 million in sales or total assets in the last fiscal year, and the other party's UPE recognized at least $15.2 million in sales or total assets, then the transaction must be reported to the antitrust agencies.

Failing to file an HSR form can result in the imposition of stiff financial penalties (the statutory maximum is $16,000 for every day there was a violation) and place the validity of the entire transaction in jeopardy. Importantly, there are also a number of exemptions to the requirements to file an HSR form. These exemptions range from the acquisition of foreign assets or voting securities, to acquisitions of certain kinds of real property, to acquisitions based on the characteristics of the buyer, and beyond. Because the HSR rules can be quite cumbersome and finicky, it is advisable to seek out advice in the early stages of a proposed transaction to determine whether it meets the requirements to file.

Pharmaceutical Patent Licenses

New HSR rules that took effect in December 2013 expanded the reportability of pharmaceutical patent licenses. In general, the FTC takes the position that transfers of "exclusive" patent rights are subject to premerger notification requirements. Under the previous rule, the FTC considered a license to be exclusive only if the patent owner transferred all "make, use and sell" rights on an exclusive basis to the licensee. The recently established rule considers a license to be exclusive if the patent owner transfers "all commercially significant rights" to use a patent for any therapeutic area, or specific indication within a therapeutic area.

Under this new standard, a patent license may be reportable even if the patent holder retains limited manufacturing rights and/or co-rights within a therapeutic area. For example, a license would be reportable in the following scenario: a larger pharmaceutical company grants a small innovator an exclusive license to use one particular compound in order to manufacture and sell a finished product within a certain therapeutic area, while the pharmaceutical company retains the right to manufacture the same or similar products in separate and distinct therapeutic areas.

Where a patent license satisfies the FTC's standard for exclusivity, the licensee and the licensor must evaluate whether the license meets the HSR thresholds. For purposes of HSR rules, the licensee corresponds to the buyer, and the licensor corresponds to the seller in an acquisition. If the HSR thresholds are met, both the licensee and licensor have HSR filing obligations.

Transaction Approval by the Agencies

Parties proposing a deal file with both the FTC and DOJ, though only one antitrust agency actually reviews the proposed transaction.[1] Staff from the FTC and DOJ confer and the matter "clears" to one of the two agencies for review. There is an initial waiting period of 30 days, during which the investigating agency reviews documents submitted by the parties as part of their premerger filing under Sections 4(c) and 4(d) of the HSR form. These documents include reports and analyses prepared by each party to evaluate the transaction with respect to market shares, competition, markets, synergies, and the potential for sales growth or expansion into new product or geographic markets, and often provide an easy window into the deal rationale that the agency could not otherwise obtain.

At the end of the 30-day waiting period, the agency must determine whether to permit the transaction to close or to issue a Request for Additional Documents and Information, colloquially known as a "Second Request." During a Second Request, the agency will seek millions of ordinary course business documents and testimony from the parties, customers, competitors, and other market participants. The agency's goal is to amass information in such a way that it may understand the true motivations behind and competitive effects of the proposed transaction.

When the agencies review documents, they look for indications that the transaction will lead to increased prices or reduced innovation. The agencies are also interested in understanding how easy (or hard) it might be for new competitors to enter the space. Sometimes, statements that are par for the course in a competitive industry may raise considerable obstacles to government approval of the transaction. The agencies pay particularly close attention to statements that the parties have significant combined market share or are major competitors in the market, or that the market has high barriers to entry, including start-up costs, economies of scale, proprietary technology, and government clearance or patents. Whether or not the parties to a deal anticipate antitrust issues, careful supervision of document creation can help facilitate the antitrust approval process. Documents evaluating a transaction should avoid antitrust buzzwords and phrases such as "market leader," "duopoly," "high market share," "achieve pricing power," "stem price erosion," and "high barriers to entry."

Most Second Requests take between five and eight months in total to complete. Once the reviewing agency has concluded its review, it must make one of three decisions: allow the transaction to close outright; allow the transaction to close with the imposition of remedies, such as the divestiture of key products or technology to another competitor; or go to court to seek an injunction to block the transaction entirely. More than 95 percent of transactions are cleared even before the issuance of a Second Request, and in fiscal year 2012, the last year for which there is public information, just 3.5 percent of proposed transactions were issued a Second Request. Nevertheless, emboldened by recent court victories, both the FTC and DOJ are increasingly finding their way into courtrooms in attempts to block transactions outright.

Conclusion

Life sciences companies will benefit from being mindful of antitrust issues, even at the earliest stages of planning a merger, acquisition, or transfer of securities or assets. Foresight and caution with respect to antitrust issues will minimize expense and delay, and help to ensure a smooth approval process for your company's contemplated transaction.

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[1] It's worth noting that even transactions that do **not** meet the HSR filing requirements can still be reviewed by the FTC or DOJ using very similar investigative techniques. The federal antitrust rules do provide the FTC and DOJ with the authority to go to court and seek to "unwind" consummated transactions.

SBIR Funding and Venture-Backed Biotechnology Companies: Current Developments

By Jennifer Knapp, Of Counsel, and Maya Skubatch, Partner (Palo Alto)

Change in Rules

Effective January 28, 2013, the Small Business Administration (SBA) significantly expanded the eligibility rules for Small Business Innovation Research (SBIR) grants to allow small businesses that are majority owned by multiple investment companies to receive SBIR funding. Under new SBA regulations, SBIR grants are not limited to small business concerns that are at least 51 percent owned and controlled by (1) individuals who are citizens or permanent resident aliens of the United States, or (2) another business concern that is itself at least 51 percent owned and controlled by individuals who are citizens or permanent resident aliens of the United States. Provided they meet certain qualifying criteria, businesses that are majority owned by multiple Venture Capital Operating Companies (VCOCs, as defined in 13 C.F.R. 121.103(b)(5)), private equity firms (as defined in Section 13(h)(2) of the Bank Holding Company Act of 1956 (12 U.S.C. § 1851(h)(2))), or hedge funds (as defined in Section 13(h)(2) of the Bank Holding Company Act of 1956 (12 U.S.C. § 1851(h)(2))) may participate in the SBIR program, so long as the agency to whom the grant application is being submitted has elected to adopt such new ownership rules. The new regulations have separate eligibility criteria for the SBIR and the Small Business Technology Transfer (STTR) programs.[1] The investment company aspects of the new rules apply only to SBIR programs.

Expanded Eligibility Provisions

Under the new regulations, a small business may be eligible to compete for SBIR funding if (1) it is more than 50 percent directly owned and controlled by (a) one or more individuals who are citizens or permanent resident aliens of the United States, (b) other for-profit small business concerns, each of which is more than 50 percent directly owned and controlled by U.S. citizens or permanent resident aliens, or (c) a combination of (a) and (b) above; or (2) it is applying for awards from agencies that are using the authority provided in §5107 of the SBIR/STTR Reauthorization Act ("majority-VC-owned authority"), 15 U.S.C. § 638(dd)(1), and it is more than 50 percent owned by multiple VCOCs, hedge funds, private equity firms, or any combination thereof, so long as no one such VCOC, hedge fund, or private equity firm owns more than 50 percent of the small business.

> A small business that is applying for an award from an agency that has adopted §5107 of the SBIR/STTR Reauthorization Act may be eligible to participate in SBIR programs if it is majority owned by multiple VCOCs, hedge funds, or private equity firms

Under this new framework, a small business that is applying for an award from an agency that has adopted §5107 of the SBIR/STTR Reauthorization Act may be eligible to participate in SBIR programs if it is majority owned by multiple VCOCs, hedge funds, or private equity firms. For example, a small business that is 31 percent owned by a VCOC, 20 percent owned by a private equity firm, and 49 percent owned by a U.S. citizen would be eligible for SBIR funding, provided that it meets all other qualifying criteria. Under the new regulations, an SBIR business can even be 100 percent owned by investment companies. For example, a small business that is 49 percent owned by a VCOC, 49 percent owned by a hedge fund, and 2 percent owned by a private equity firm is eligible to participate in the SBIR program, provided it meets other qualifying criteria. However, if any single VCOC, hedge fund, or private equity firm owns more than 50 percent of a small business, it is not eligible for SBIR funding. For example, a small business that is 60 percent owned by a VCOC, 30 percent owned by a hedge fund, and 10 percent owned by a U.S. citizen would not be eligible for SBIR funding.

Even though the intent of the new regulations is to encourage small business to seek investment company backing and capital, the encouragement only goes this far. The expanded eligibility does not apply to small businesses that are neither majority owned by multiple investment companies nor majority owned by citizens or permanent resident aliens of the United States or other small businesses owned by such individuals. To illustrate, a small business that is 50 percent owned by a U.S. citizen, 20 percent owned by a VCOC, 20 percent owned by a private equity firm, and 10 percent owned by a non-profit organization would not be eligible for SBIR funding. Companies that have previously obtained large funding from universities, non-profit organizations, and large corporations would be disadvantaged under the new rules.

Under the new rules, VCOCs, private equity firms, and hedge funds are not required to be majority owned by U.S. citizens or permanent resident aliens. However, the new regulations require the investment companies to have a

[1] 13 C.F.R § 121.702(a) & (b).

place of business located in the United States and be created or organized in the United States or under the laws of the United States or of any state.

The Size Requirement

Under the new regulations, a small business may be eligible to compete for SBIR funding if it, together with its "affiliates," has no more than 500 employees. When determining how many employees a business has, the SBA counts not only full-time employees, but also individuals employed on a part-time, temporary, or other basis.

Affiliation

The rules regarding the determination of "affiliate" status for purposes of SBIR programs are set forth in 13 C.F.R § 121.702(c), and general principles of affiliation used by the SBA are set forth in 13 C.F.R. § 121.103. Under the new rules, affiliation exists between two businesses when one business controls or has the power to control another, or when a third party controls or has the power to control both businesses. Specifically, affiliation exists when an individual or entity (i) owns or has the power to control more than 50 percent of the SBIR applicant's voting equity, or (ii) owns and has the power to control more than 40 percent of the applicant's voting equity if there are other circumstances that demonstrate the minority shareholder has the power to control the applicant. In determining size, the SBA considers stock options, convertible securities, and agreements to merge (including agreements in principle) to have a present effect on the power to control a business concern, and treats such options, convertible securities, and agreements as though the rights granted have been exercised. The SBIR applicant can also be found to be affiliated with individuals and entities based on common management, identity of interest, the newly organized concern rule, joint ventures, the ostensible subcontractor rule, license agreements, and the totality of the circumstances. Certain exceptions apply as set forth in 13 C.F.R. § 121.103 and 13 C.F.R § 121.702.

Effect of Stock Options and Convertible Equity

When determining a concern's ownership, control, and affiliation for the purposes of the SBIR programs, the SBA will review the small business' equity ownership on a fully diluted basis, meaning that the SBA will consider the total number of shares or equity that would be outstanding if all possible sources of conversion were exercised, including, but not limited to: outstanding common stock or equity, outstanding preferred stock (on a converted-to-common basis) or equity, outstanding warrants (on an as-exercised and converted-to-common basis), outstanding options and options reserved for future grants, and any other convertible securities on an as-converted-to-common basis.[2]

Agencies Currently Using the Majority VC Ownership Authority

Eleven federal agencies currently participate in SBIR and STTR programs, including the Department of Agriculture; the Department of Commerce (National Institute of Standards and Technology; National Oceanic and Atmospheric Administration); the Department of Defense; the Department of Education; the Department of Energy; the Department of Health and Human Services (including the National Institutes of Health, Centers for Disease Control and Prevention, and Food and Drug Administration); the Department of Homeland Security; the Department of Transportation; the Environmental Protection Agency; the National Aeronautics and Space Administration; and the National Science Foundation.

Under 15 U.S.C. § 638(dd)(1) and §5107 of the SBIR/STTR Reauthorization Act, SBIR agencies have the option to use a portion of their SBIR funds to make awards to small businesses that are majority owned by multiple VCOCs, hedge funds, or private equity firms. If an agency elects to use this authority, it will secure the authority through the SBA and note this in its solicitations. Therefore, only agencies that have elected to implement §5107 of the SBIR/STTR Reauthorization Act are bound to follow the new rules regarding majority ownership by VCOCs, hedge funds, and private equity firms. As of now, it appears that only the National Institutes of Health has implemented §5107.[3]

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[2] 13 C.F.R. § 121.702(d).

[3] http://www.sbir.gov/vc-ownership-authority.

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 in 2013. Specifically, the table compares—by industry segment—the number of closings, the total amount raised, and the average amount raised per closing across the first half of 2013 and the second half of 2013.

Life Sciences Industry Segment	1H 2013 Number of Closings	1H 2013 Total Amount Raised ($M)	1H 2013 Average Amount Raised ($M)	2H 2013 Number of Closings	2H 2013 Total Amount Raised ($M)	2H 2013 Average Amount Raised ($M)
Biopharmaceuticals	12	65.31	5.44	9	102.43	11.38
Diagnostics	3	3.18	1.06	4	5.78	1.44
Genomics	2	1.10	0.55	4	11.53	2.88
Healthcare Services	4	37.37	9.34	4	107.66*	3.33**
Medical Devices & Equipment	46	205.45	4.47	38	181.42	4.77
Medical Information Systems	9	23.36	2.60	3	77.96	25.99
Total	**76**	**335.77**		**62**	**486.77**	

**Includes one mega-deal ($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 increased during the second half of 2013 compared to the first half of 2013 with respect to total amount raised, but declined during the second half of 2013 compared to the first half of 2013 with respect to number of closings. Specifically, the total amount raised across all industry segments during the second half of 2013 increased by approximately 45 percent compared to the first half of 2013, from $335.77 million to $486.77 million, while the total number of closings across all industry segments decreased by more than 18.4 percent, from 76 closings to 62 closings.

The industry segment with the largest number of closings—medical devices and equipment—experienced a decline both in total amount raised and number of closings during the second half of 2013 compared to the first half of 2013. Specifically, medical devices and equipment declined 11.7 percent in total amount raised, from $205.45 million to $181.42 million, and declined 17.4 percent in total number of closings, from 46 closings to 38 closings. The industry segment with the second-largest number of closings—biopharmaceuticals—experienced an increase in total amount raised and a decline in number of closings during the second half of 2013 compared to the first half of 2013. Specifically, biopharmaceuticals increased 56.8 percent in total amount raised, from $65.31 million to $102.43 million, and declined 25 percent in total number of closings, from 12 closings to 9 closings.

Bucking the downward trend in total number of closings were the genomics and diagnostics industry segments. The total number of closings in genomics increased 100 percent, from two closings in the first half of 2013 to four closings in the second half of 2013, while the total number of closings in diagnostics increased 33.3 percent, from three closings to four closings.

Further, in addition to biopharmaceuticals, other industry segments enjoying an increase in total amount raised from the first half of 2013 to the second half of 2013 were genomics, diagnostics, medical information systems, and healthcare services. The total amount raised in genomics increased 948.2 percent, from $1.1 million to $11.53 million; the total amount raised in diagnostics increased 81.8 percent, from $3.18 million to $5.78 million; the total amount raised in medical information systems increased 233.7 percent, from $23.36 million to $77.96 million; and the total amount raised in healthcare services increased 188.1 percent, from $37.37 million to $107.66 million.

In addition, our data suggests that Series A financing activity compared to Series B and later-stage equity financings, bridge financings, and recapitalization financings did

not change during the second half of 2013 compared to the first half of 2013. Specifically, the number of Series A closings as a percentage of all closings posted a modest increase, from 30.3 percent to 30.7 percent. On the other hand, our data shows that Series B financing activity increased significantly during the second half of 2013 compared to the first half of 2013, with Series C and later-stage financings and bridge financing activity suffering the largest declines over the same period. Specifically, the number of Series B closings as a percentage of all closings increased from 15.8 percent to 25.8 percent, the number of Series C and later-stage financings decreased from 14.5 percent to 11.3 percent, and the number of bridge financings decreased from 34.2 percent to 29 percent.

Pre-money valuations for life sciences companies increased significantly during the second half of 2013 compared to the first half of 2013. The average pre-money valuation for Series A financings increased by 54.2 percent, from $8.41 million to $12.97 million; the average pre-money valuation for Series B financings increased by 72.5 percent, from $18.34 million to $31.64 million, and the average pre-money valuation for Series C and later-stage financings increased by 73.9 percent, from $72.59 million to $126.23 million.

Other data taken from transactions in which all firm clients participated in the first half of 2013 and the second half of 2013 did not change with respect to life sciences. Specifically, life sciences continues to be the second-most attractive industry for investment among our clients, representing 19 percent of total funds raised—second to the software industry, which represents 25 percent of total funds raised. It is interesting to note that software investment itself was down during the second half of 2013, having been at 29 percent during the first half of 2013. Similarly, clean technology, historically the third-most attractive industry for investment among our clients, remained in third place during the second half of 2013, but decreased from 12 percent during the first half of 2013 to 10 percent during the second half of 2013. Industries experiencing modest upticks in activity during the second half of 2013 compared to the first half included electronics and computer hardware, media, retail, and semiconductors.

Overall, the data suggests that access to venture capital for life sciences companies may be improving for the "right" companies. The total number of closings is down across all industry segments, but total dollars raised and pre-money valuations at which those dollars are being raised increased significantly during the second half of 2013 compared to the first half. Moreover, access to capital is gaining ground at the earliest stages, which should prove to be a welcome trend for many early-stage entrepreneurs struggling to raise money, particularly as dedicated life sciences venture capital investment trends toward later or growth-stage financings. The recent strength of merger and acquisition activity and the reopening of the capital markets for life sciences initial public offerings are likely significant factors in this renewed activity. Of course, it is too early to tell what all of it means, but the early signs are positive.

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Patent Term Adjustment and Patent Term Extension: Valuable Tools to Prolong Patent Protection Through Careful Vigilance

By Charles Andres and Tommy Noh, Associates (Washington, D.C.); David Van Goor, Patent Agent (Washington, D.C.); and Vern Norviel (San Francisco), Maya Skubatch (Palo Alto), and David Hoffmeister (Palo Alto), Partners

Introduction

Branded drug companies, medical device manufacturers, and other innovators rely on utility patents to protect their products and product-associated revenue streams. U.S. utility patents provide patent holders with the ability to prevent non-licensed parties from making, using, offering for sale, selling, or importing patented inventions.[1, 2, 3]

The term of U.S. utility patents, however, begins at issue and is limited to 20 years from the filing date of the earliest non-provisional application upon which the patent is based.[4, 5] The expiration of patents protecting a key

[1] *See* 35 U.S.C. § 271.
[2] An exception exists for uses "reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." *See* 35 U.S.C. § 271(e)(1).
[3] Other forms of intellectual property protection, such as design patents and trademarks, may be available but are outside the scope of this article.
[4] For U.S. utility applications filed on or after June 8, 1995, and excluding the effects of, e.g., terminal disclaimer(s), patent term adjustment, and patent term extension. *See* 35 U.S.C. § 154(c).
[5] *See* 35 U.S.C. §§ 154(a)(2)-(a)(3).

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product can have devastating financial consequences[6] that can cause ripple effects throughout even the biggest companies, including mass layoffs[7] and business-model changes.[8]

Smaller companies (including those that are not yet selling a product) are often valued by potential acquirers in large part on the estimated value (both present and future) of their patents. Although there is no universally accepted model for valuation,[9] one factor that is almost always considered is a patent's remaining term.[10] Thus, tools to extend a patent's term can be of significant value to both small start-ups and large multinational corporations.

Patent Term Adjustment

One tool that may be available to partially extend the term of a U.S. utility patent is patent term adjustment (PTA).[11] PTA compensates a patent holder for unreasonable United States Patent and Trademark Office (USPTO) delays in examining patent applications.[12, 13] PTA is potentially available to any U.S. utility patent issuing from an application filed on or after May 29, 2000.[14] For example, PTA can potentially increase the terms of patents covering new drugs, formulations, medical devices, and methods of making and using these.

Although the availability of PTA is determined on a case-by-case basis—for instance, based on the prosecution history of the application giving rise to a patent—PTA can be significant. For instance, a 2011 survey indicated that approximately 80 percent of patents issued in 2010 and the first half of 2011 were given an average PTA of about 600 days (over a year and a half).[15]

PTA's monetary worth depends at least in part on the value of the underlying patent whose term is increased. For example, as of 2011, there were 116 "billion-dollar drugs"[16] accounting for 36 percent of the global pharmaceutical market's value.[17] In one scenario, a 600-day PTA for a patent protecting a $1 billion drug could be worth $1.64 billion.[18]

How PTA Is Calculated

PTA is calculated by adding together unreasonable USPTO delays (e.g., "A," "B," and "C" delays)[19] and subtracting any delays attributable to the patent applicant and any overlapping "A" and "B" delays.[20, 21] "A" delays most typically arise from the USPTO's failure to timely: issue first Office Actions or Restriction Requirements, respond to Office Action responses, and issue a patent after payment of the issue fee.[22] "B" delays arise from the USPTO's failure to issue a patent within three years from application filing.[23] "C" delays result from factors associated with appeals, interferences, or secrecy orders.[24]

PTA Is Increasing over Time

For every eligible issued utility patent, the USPTO automatically calculates and grants PTA. PTA has been steadily climbing over the last 10 years, both in terms of the number of patents granted PTA and the number of PTA days granted.[25] In early 2010, a break point in PTA emerged. Average PTA increased instantaneously by about 200 days because of

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[6] For example, a year after losing patent protection, sales of Merck's asthma-controlling drug Singulair declined by 75 percent, from approximately $1.35 billion to $337 million. *See* "Merck net falls on loss of Singulair patent," *The Wall Street Journal's* MarketWatch (May 1, 2013), *available at* http://www.marketwatch.com/story/merck-net-falls-on-loss-of-singulair-patent-2013-05-01 (last accessed Apr. 16, 2014).

[7] Merck announced layoffs of approximately 8,500 employees in the wake of the loss of patent protection for Singulair. *See* Daniel R. Hoffman, Ph.D., "Merck layoffs reveal fundamental problems," philly.com (Oct. 3, 2013), *available at* http://www.philly.com/philly/blogs/healthcare/Merck-layoffs-reveal-fundamental-problems.html (last accessed Apr. 16, 2014).

[8] E.g., The "externalization" of research and development. *Id.*

[9] An article for the general reader that conveys factors relevant to valuing patents and patent portfolios is: J. G. Hadzima, Jr., "How to Tell What Patents Are Worth," *Forbes* (June 25, 2013), *available at* http://www.forbes.com/sites/forbesleadershipforum/2013/06/25/how-to-tell-what-patents-are-worth/ (last accessed Apr. 16, 2014).

[10] *See* M.T. Meeks and C.A. Eldering, "Patent Valuation: Aren't We Forgetting Something? Making the Case for Claims Analysis in Patent Valuation by Proposing a Patent Valuation Method and a Patent-Specific Discount Rate Using the CAPM," 9 *Northwestern Journal of Technology and Intellectual Property* 194 (2010), *available at* http://scholarlycommons.law.northwestern.edu/njtip/vol9/iss3/5 (last accessed Apr. 16, 2014).

[11] *See* 35 U.S.C. § 154(b).

[12] *Id.*

[13] The amount of PTA can be decreased because of patent applicant delays. *See* 35 U.S.C. § 154(b)(2)(C).

[14] *See* 37 C.F.R. § 1.702.

[15] *See* "Patent Term Adjustment Statistics," *available at* http://www.patentlyo.com/patent/2011/07/pta.html (last accessed Apr. 16, 2014).

[16] A billion-dollar drug is a drug whose annual sales are at least US$1 billion.

[17] *See* S. Rickwood, "Redefining the Blockbuster Model: Why the $1 billion entry point is no longer sufficient – part 2," pharmaphorum (Sept. 18, 2012), *available at* http://www.pharmaphorum.com/articles/redefining-the-blockbuster-model-why-the-1-billion-entry-point-is-no-longer-sufficient-part-2 (last accessed Apr. 16, 2014).

[18] 600 days/365 days/year=1.64 years*$1 billion/year=$1.64 billion.

[19] "A,", "B," and "C" delays are named for the subsection of 35 U.S.C. § 154(b)(1) that codifies the delay (e.g., an "A" delay arises under 35 U.S.C. § 154(b)(1)(A)).

[20] A patent owner is entitled to the addition of "A" and "B" delay to the extent that they do not occur on the same calendar day(s). *See Wyeth v. Kappos* 591 F.3d 1364 (Fed. Cir. 2009).

[21] Readers are encouraged to contact any member of WSGR's patents and innovations practice to discuss PTA-related questions. A detailed review of PTA calculation is beyond this article's scope.

[22] *See* 35 U.S.C. § 154(b)(1)(A).

[23] *See* 35 U.S.C. § 154(b)(1)(B).

[24] *See* 35 U.S.C. § 154(b)(1)(C).

[25] *See* "Patent Term Adjustment Statistics," *available at* http://www.patentlyo.com/patent/2011/07/pta.html (last accessed Apr. 16, 2014).

an appellate court ruling that changed the way the USPTO calculated PTA.[26] A comparison of PTA for some pre- and post-*Wyeth* pharmaceutical patents starkly illustrates these differences:

Drug	U.S. Patent No.	PTA (days)	Pre- *or* Post-*Wyeth*
Mircera	6,583,272	60	Pre
Tykerb	6,713,485	49	Pre
Abilify (IM)	8,030,313	1,001	Post
Crestor	7,964,614	1,201	Post
Valchlor	7,872,050	1,219	Post

The Amount of PTA Awarded May Increase (Again)

A recent Federal Circuit court case that changes how a "B" delay is calculated has potentially opened the door for a further increase in PTA.[27] By law and with provisos, a patent's term must be extended on a day-per-day basis for every day beyond three years after a patent application's actual filing date until the patent issues.[28] The USPTO has historically taken the position that requesting continued examination—a common event—after three years from a patent application's filing date tolls the day-per-day increase in patent lifetime.

In *Exelixis*, the Federal Circuit determined that the USPTO had been incorrectly applying the law. *Exelixis* held that the time between provision of a notice of allowance and issuance of a patent should be used in calculating PTA, even where continued examination was requested. In the wake of *Exelixis*, the USPTO's PTA grants are likely too short for many patents.

In the experience of the authors, PTA is frequently miscalculated by the USPTO. Each issued patent should be checked for the proper calculation. And, for patents that were recently issued, or that will issue in the near term, patent owners should seriously evaluate and, where appropriate, request reconsideration of the PTA calculated by the USPTO to appropriately extend patent term in view of recent case law.[29, 30]

Patent Term Extension

Another way to partially extend the term of a patent is patent term extension (PTE).[31, 32] As discussed above, most U.S. patents have a 20-year term from the filing date of the earliest non-provisional application upon which the patent is based.[33, 34] On average, the patent application process for most patents is about three years from the date of filing to issuance. So, absent factors such as PTA or prioritized examination,[35] a patent's effective life is usually about 17 years from issuance.

However, for patents covering products requiring regulatory approval (e.g., new drugs, Class III medical devices, food additives, and coloring additives), there is a time-intensive approval process that typically consumes significant patent term. Thus, patent owners do not enjoy the full financial benefit of a patent until the United States Food and Drug Administration (FDA) approves the drug, medical device, or additive, and sales commence.[36] To partially remedy this situation, the Hatch-Waxman Act[37] provides for PTE.

PTE Is Distinct from PTA

PTE differs from PTA in several important ways. First, while PTA can be granted to any U.S. utility patent, PTE is limited to only U.S. utility patents claiming certain types of inventions that are required to go through a regulatory approval process.[38, 39] Second, while

[26] *See Wyeth v. Kappos* 591 F.3d 1364 (Fed. Cir. 2009).
[27] *See Exelixis, Inc. v. Lee*, No. 2013-1175 (Fed. Cir. Jan. 15, 2014). *See also Novartis AG v. Lee*, Nos. 2013-1160 and 2013-1179 (Fed. Cir. Jan. 15, 2014).
[28] *See* 35 U.S.C. § 154(b)(1)(B).
[29] Readers with PTA questions are encouraged to speak with any member of WSGR's patents and innovations practice.
[30] Prompt action is required when the patent owner is dissatisfied with initial USPTO PTA determinations. A request for reconsideration must first be made to the director of the USPTO. *See* 35 U.S.C. § 154(b)(3)(B)(ii). If the patent owner is dissatisfied with the director's decision, the patent owner has 180 days from the director's decision to file a lawsuit in the U.S. District Court for the Eastern District of Virginia. *See* 35 U.S.C. § 154(b)(4)(A).
[31] Although outside the scope of this article, a Supplementary Protection Certificate (SPC) may be available in Europe on a country-by-country basis. *See,* e.g., Regulation (EC) No 469/2009 of the European Parliament and of the Council (Medicinal Products) (SPC Regulation). Unlike PTE, an SPC does not extend a patent. SPCs only protect (uses of) specific products.
[32] The duration of an SPC may extend up to a maximum of five years. However, the duration of an SPC may be extended by a further six months when the SPC is for a human medicinal product for which data from clinical trials conducted in accordance with an agreed Paediatric Investigation Plan (PIP) has been submitted. *See,* e.g., Article 36 of Regulation (EC) No 1901/2006.
[33] For U.S. utility applications filed after June 8, 1995. This calculation excludes the effects of, e.g., terminal disclaimers, patent term adjustment, and patent term extension.
[34] *See* 35 U.S.C. §§ 154(a)(2)-(a)(3).
[35] Examination of patent applications can be prioritized through, e.g., filing a Track One request, accelerated examination, petitioning to make the application special, or the patent prosecution highway.
[36] Patent owners may enjoy partial financial benefit in that ownership of the patent may enable them to raise funds through various mechanisms: e.g., as collateral for a loan, from angel investors, from venture capitalists, through an initial public offering, through a sale or merger of the company, or, more recently, through crowdsourcing.
[37] The Drug Price Competition and Patent Term Restoration Act of 1984, P.L. 98-417.
[38] 35 U.S.C. § 156(a) recites in part:
The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if—
[39] 35 U.S.C. § 156(f)(1) recites the meaning of the term "product." Products are: "a drug product" and "any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act." Drug products are defined in 35 U.S.C. § 156(f)(2).

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the amount of PTA theoretically has no upper limit, PTE is limited by statute to a maximum of five years, and the total term of an extended patent is limited to 14 years following regulatory approval.[40] Third, only one patent covering a new product may be extended.[41] Fourth, the criteria for PTE differ from those for PTA.[42] Fifth, unlike PTA, PTE is not shortened by the filing of a terminal disclaimer.[43] Finally, unlike PTA, which the USPTO calculates and grants automatically, a patent owner must submit a PTE application in a timely fashion. Failure to submit a request for PTE within the statutory timeframe will automatically result in a denial of PTE.[44]

PTE Requirements

To apply for PTE, a patent owner must submit an application within 60 days of FDA approval (e.g., in the case of a new drug, within 60 days of FDA approval of the new drug application).[45] The patent's claims must cover the approved drug or a composition containing it, the approved method of using the drug, or a method of making the approved drug. Additionally, (1) the patent must not have expired before a PTE application is submitted; (2) the patent must not have been previously extended by PTE; (3) the PTE application must be submitted by the owner of record or the owner's agent; (4) the product (e.g., drug) must have been subjected to FDA review before its commercial marketing or use; and (5) the FDA-approved product (e.g., drug) must be the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.[46, 47]

Active Ingredient, Prior Approval, and Eligibility

By statute, the active ingredient, including any salt or ester of the active ingredient, must not have been previously approved by the regulatory body.[48] A superficial reading of the statute leads many patent owners to conclude that their active ingredient is not PTE eligible because a different form of the active ingredient may have been previously approved. This conclusion can be incorrect and costly.

For example, in one case, a court held that even though a salt of an active ingredient was previously approved, a patent covering an ester of the salt was still eligible for extension.[49] Also, an individual enantiomer of a previously approved racemate has been held to be PTE eligible.[50]

Other decisions have not been as favorable. For example, PTE has been denied for an ibuprofen and hydrocodone combination product.[51] Although the ibuprofen and hydrocodone combination was never previously marketed in a single product, both ibuprofen and hydrocodone were previously marketed alone or in combination with another drug. Thus, the court denied PTE.[52]

Failure to apply for PTE based on an incorrect assumption can be costly. Because PTE is always associated with an approved product, PTE is usually extremely valuable. Thus, the default position should be to apply for PTE in a timely manner.[53, 54]

PTE Calculation

While a complete explanation of PTE calculation is beyond the scope of this article, factors that are considered include:[55]

- the number of days between when the Initial New Drug (IND) application became effective and the date a New Drug Application (NDA) was filed (e.g., the "testing phase");
- the number of days between when the NDA was filed and the date the NDA was approved (e.g., the "approval phase");
- the issue date of the patent;
- time the PTE applicant did not act with due diligence in the testing and approval phases;

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[40] *See* 37 C.F.R. § 1.775 (for calculation of PTE for a human drug, antibiotic drug, or human biological product), as measured from the approval date.

[41] *See* 35 U.S.C. § 156(c)(4). Only one patent covering an FDA-approved product can be extended. However, if multiple patents cover the product, the patent owner can apply for PTE for each one of the patents. Because PTE approval is unpredictable, patent owners should generally consider filing a PTE application for each patent covering the recently FDA-approved product. If more than one PTE application is approved, the USPTO will ask the patent owner to choose a single patent to extend. If the patent owner does not respond, the first patent to expire is automatically extended.

[42] *See* 35 U.S.C. § 156(a).

[43] *See Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 482 F.3d 1317 (Fed. Cir. 2007).

[44] *See* 35 U.S.C. § 156(d)(1).

[45] *Id.*

[46] This list is derived from 35 U.S.C. § 156(a).

[47] Most PTE eligibility litigation focuses on the interpretation of requirement (5).

[48] *See* 35 U.S.C. § 156(f)(2).

[49] *See Glaxo v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990).

[50] *See Ortho McNeil v. Lupin*, 603 F.3d 1377 (Fed. Cir. 2010).

[51] *See Arnold Partnership v. Dudas*, 362 F.3d 1338 (Fed. Cir. 2004).

[52] *Id.*

[53] There are no extensions for late PTE applications. Once the 60-day window expires, an applicant is precluded from applying for PTE.

[54] We believe there are novel, pro-PTE arguments that can be made and are ripe for testing in the courts. We anticipate that the courts will weigh at least one of these arguments in the near future.

[55] *See* 37 C.F.R. § 1.775 entitled "Calculation of a patent term extension for a human drug, antibiotic drug or human biological product."

- a five-year PTE maximum cutoff; and

- an upper limit of 14 years of total patent term, as measured from the date of regulatory approval.

Choosing a Patent to Extend

While only one patent may have PTE per product, it is not the case that only one PTE application should be filed for each product. To the contrary, a better practice would be to apply for PTE and subsequently make a selection. For example, assuming PTE is provisionally granted for two or more patents covering an FDA-approved product, the patent owner must elect a single patent to extend.[56] While the determination of which patent to extend is fact specific, several factors should invariably be considered when making a selection. These factors include: (1) the patented subject matter (e.g., drug versus method of treatment), (2) the likelihood that the patent will ensnare an infringer, (3) the likelihood that the patent will survive a challenge (in the courts and at the USPTO), (4) the amount of PTE that would be granted, and (5) whether the patent is listable in the Orange Book.[57, 58]

PTE Is Variable but Can Be Significant

The amount of PTE is variable, but can be large. PTE days granted for some patents are shown in the table at the upper right.

PTA and PTE Can Be Inversely Related

It is worth noting that PTA and PTE can be inversely proportional. In part, this arises because of the relationship of PTA to PTE. PTA compensates a patent owner for unreasonable delays in USPTO examination. Delayed examination results in delayed patent issuance. PTE is designed to compensate patent owners for regulatory agency delay. A patent whose issuance has been significantly delayed may suffer reduced or no loss from regulatory delay (e.g., if regulatory delay occurs mostly or fully before the patent issues, then harm from and compensation for regulatory agency delay is minimized). Thus, depending on the specific facts, a long PTA can mean a short PTE or vice versa.

Drug or Device	U.S. Patent No.	PTE (days or years)
Abilify (IM)	5,006,528	5 years
Crestor	7,964,614	1,305 days
Selzentry	6,667,314	73 days
Lunesta	6,444,673	760 days
Macroplastique Implants	5,571,182	1,664 days
CEE-ON Edge Intraocular Lens	5,444,106	956 days

PTA and PTE Are Additive

PTA and PTE can work in combination to extend the "standard" term of a patent. For example, for a patent granted both PTA and PTE, the formula for determining the patent's term is:

Total Patent Term = Standard Patent Term + PTA + PTE

Conclusion

PTA and PTE, whether separately or in combination, can provide valuable extension of patent life and therefore dramatically increase company value. However, application of the rules for PTA and PTE is not entirely straightforward. PTE can be applied to many products that would not be immediately apparent, and applying for PTE should still be the default position[59] for products that have been FDA approved. In addition, the USPTO's PTA calculations should be verified for all newly issued and soon-to-issue patents since these calculations are often incorrect. If the USPTO's PTA calculations are found to be incorrect, a petition to correct PTA should be filed promptly. For questions relating to PTA, PTE, or any related intellectual property matter, please contact any member of WSGR's patents and innovations practice.

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[56] MPEP 2761 recites in part: "[w]hen plural patents are found to be eligible for patent term extension based on the same regulatory review of a product, the final determination under 37 CFR 1.750 will provide a period of time (usually one month) for the patent owner to elect the patent for which extension is desired."

[57] The Orange Book, also called the Approved Drug Products with Therapeutic Equivalence Determinations, is available online at http://www.accessdata.fda.gov/Scripts/cder/ob/default.cfm (last accessed Apr. 16, 2014).

[58] There may be additional factors to consider. Every situation is unique. Readers are encouraged to contact any member of WSGR's patents and innovations practice to discuss PTE-related questions.

[59] If there is any legally colorable basis for applying for PTE.

Recent Life Sciences Client Highlights

The Medicines Company Announces Agreement to Acquire Tenaxis Medical
On April 23, 2014, The Medicines Company, a global pharmaceutical company, and Tenaxis Medical, a medical device company focused on the development of functionally designed surgical sealants, announced an agreement for The Medicines Company to acquire Tenaxis. Tenaxis's sole product, which mechanically seals both human tissue and artificial grafts, is approved but has not been launched in the United States. Under the terms of the agreement, The Medicines Company will pay $58 million upfront upon the closing of the deal, as well as milestone payments of up to $112 million contingent upon achieving certain commercial and regulatory approval milestones. WSGR represented Tenaxis in the transaction. Additional details are available at http://ir.themedicinescompany.com/phoenix.zhtml?c=122204&p=irol-newsArticle_Print&ID=1921042&highlight.

Tendyne Raises $25 Million in Series C Funding
On April 9, 2014, Tendyne Holdings, a privately held clinical-stage medical device company developing technologies for transcatheter mitral valve replacement, announced that it has secured $25 million in an oversubscribed Series C financing led by Apple Tree Partners, along with Boulle Group members and other existing investors. Proceeds from the funding will be used for validation of Tendyne's novel transcatheter mitral valve implant to treat mitral regurgitation, including forthcoming clinical trials. WSGR advised Tendyne in the transaction. For more information, please see http://www.tendyne.com/assets/tendyneseriesc.pdf.

Ulthera Acquires Cabochon Aesthteics
On March 21, 2014, Ulthera, a global medical device company focused on developing and commercializing technologies for aesthetic and medical applications, announced that it has acquired Cabochon Aesthetics. The FDA-cleared system by Cabochon, which is used in a procedure to improve the appearance of cellulite, will allow Ulthera to expand its technology offerings for physician practices worldwide. WSGR represented Cabochon Aesthetics in the transaction. Further details are available at http://www.marketwired.com/press-release/ulthera-inc-plans-enter-cellulite-market-with-acquisition-cabochon-aesthetics-inc-1891253.htm.

Oculeve Raises $16.6 Million in Series B Funding
Oculeve, a Stanford University medical device spinout aimed at treating dry-eye condition, recently raised more than $16.6 million in Series B funding, according to a Securities and Exchange Commission filing. The company received financing from eight investors and has raised a total of over $24 million so far in support of its flagship implantable technology that stimulates the lacrimal glands in the eyes to spur natural tear production. Wilson Sonsini Goodrich & Rosati represented Oculeve in the financing. Please see http://www.bizjournals.com/sanfrancisco/blog/biotech/2014/03/stanford-oculeve-16-million-dry-eye-treatment.html for more information.

Alder Biopharmaceuticals Files for $115 Million IPO
On March 19, 2014, Alder Biopharmaceuticals filed for an IPO of up to $115 million in common stock. The company seeks to commercialize therapeutic antibodies, and its pipeline includes two internally discovered antibodies—one wholly owned and one shared in partnership with Bristol-Myers Squibb—as well as preclinical programs. Alder said it intends to use the proceeds of the IPO to fund its continuing clinical program for its wholly owned ALD403 treatment, preclinical development, and general corporate purposes. WSGR is advising the underwriting syndicate in the offering, for which Credit Suisse Securities and Leerink Partners are representatives. Additional information can be found at http://www.nasdaq.com/article/alder-biopharmaceuticals-files-for-ipo-of-up-to-115-million-20140319-00146.

Vital Therapies Revives IPO Filing
Vital Therapies, a clinical-stage biotech developing treatments for acute liver failure, revived its initial public offering by filing an amended S-1 with the Securities and Exchange Commission on March 7, 2014. The company had previously launched a deal to raise $75 million by selling 4.4 million shares at $16 to $18 per share but postponed on November 21, 2013. The company's updated filing removed the original IPO terms. Vital Therapies plans to list on the NASDAQ under the symbol "VTL." Wilson Sonsini Goodrich & Rosati is advising Vital Therapies in connection with the proposed IPO. Additional information is available at http://www.nasdaq.com/article/liver-disease-biotech-vital-therapies-revives-ipo-filing-removes-original-terms-cm334078.

Invuity Raises $36 Million in Series E Financing
On March 4, 2014, Invuity, a developer of advanced medical devices to improve access and visualization in minimally invasive and minimal access surgeries, announced that it has secured $36 million in a Series E financing led by HealthCare Royalty Partners, along with existing investors Valence Life Sciences, InterWest Partners, Kleiner Perkins Caufield and Byers, and a number of other qualified investors. The financing is a combination of $21 million in equity and up to $15 million in debt. Wilson Sonsini Goodrich & Rosati advised Invuity in the transaction. Please see http://www.invuity.com/invuity-raises-36-million-in-series-e-financing/ for more information.

Inogen Announces Closing of Initial Public Offering
On February 20, 2014, oxygen therapy innovator Inogen announced that it has closed

its previously announced initial public offering of 4,411,763 shares of its common stock at a price to the public of $16.00 per share. The shares of common stock are traded on the NASDAQ Global Select Market under the symbol "INGN." Wilson Sonsini Goodrich & Rosati advised Inogen in the offering. For further details, please visit http://investor.inogen.com/releasedetail.cfm?ReleaseID=827283.

Fluidigm Completes Acquisition of DVS Sciences

On February 13, 2014, Fluidigm, a developer and manufacturer of microfluidic systems, announced that it has completed its acquisition of DVS Sciences. With the closing of the acquisition, Fluidigm adds a high-parameter, single-cell protein analysis platform to its industry-leading, single-cell genomics platforms to create a comprehensive portfolio of advanced technologies serving the rapidly growing single-cell genomics and proteomics markets. WSGR advised Fluidigm in the transaction. To learn more, please see http://www.fluidigm.com/february-13-2014.html.

Zephyr Health Raises $15 Million in Funding

On January 8, 2014, Zephyr Health, a fast-growing big data analytics platform for companies in the life sciences industry, announced a $15 million funding round co-led by Kleiner Perkins Caufield & Byers and Jafco Ventures. The funds will help Zephyr add to its engineering capabilities and build sales and marketing operations, according to the company. Wilson Sonsini Goodrich & Rosati advised Zephyr Health in the funding. Additional information is available at https://zephyrhealthinc.com/about-zephyr/press/2014-01-08-press-release/.

PW Medtech Completes $155 Million IPO and Listing on HKSE

On November 8, 2013, PW Medtech, a leading medical device company in China, completed its HK$1.2 billion (approximately US$155 million) global offering and listing on the Main Board of the Stock Exchange of Hong Kong. A total of 400 million shares were on offer, priced at HK$3.18 each, and the offering was 19.33 times oversubscribed. WSGR and its associated Hong Kong solicitors firm Chen & Associates acted as the U.S. and Hong Kong counsel to PW Medtech in its Hong Kong IPO. Further information is available at http://www.wsgr.com/WSGR/Display.aspx?SectionName=clients/1113-PW-medtech.htm.

Biodesy Completes $15 Million Series A Financing

On October 17, 2013, Biodesy, a privately held developer of novel systems to analyze real-time protein function for research and clinical applications, announced that it has closed a $15 million Series A venture financing round from 5AM Ventures, Pfizer Venture Investments, and Roche Venture Fund. Proceeds from the financing will be used to further develop and commercialize the first platform technology to enable real-time measurement of protein conformational change. WSGR advised Biodesy on the financing. For more information, please visit http://www.biodesy.com/news/.

St. Jude Medical Completes Acquisition of Nanostim

On October 14, 2013, global medical device company St. Jude Medical announced the completion of its acquisition of Nanostim, a privately owned developer of miniaturized, leadless pacemakers. The acquisition adds the world's first and only leadless pacemaker to the St. Jude Medical product portfolio and culminates a two-year partnership between the two companies during which St. Jude Medical invested in and collaborated with Nanostim throughout its product development and commercialization initiatives. WSGR represented Nanostim in the transaction. For additional details, please see http://www.sjm.com/~/media/SJM/corporate/Media%20Kits/nanostim/NanostimAquisition_CEMarkApproval_FINAL_WEB.ashx.

Mesoblast Acquires Osiris' Culture-Expanded Stem Cell Therapeutic Business

On October 10, 2013, regenerative medicine company Mesoblast announced the Mesoblast Group's acquisition of the entire culture-expanded mesenchymal stem cell business of Osiris Therapeutics. According to Mesoblast's press release, the benefits tied to the acquisition include near-term market launch of a mesenchymal lineage product in major jurisdictions, broadened late-phase clinical programs in strategic areas of focus, and leveraged rollout of infrastructure, skills, and expertise needed to commercialize mesenchymal precursor cell products. WSGR represented Mesoblast in the transaction. Please see http://globenewswire.com/news-release/2013/10/11/579764/10052253/en/MESOBLAST-ACQUIRES-OSIRIS-CULTURE-EXPANDED-STEM-CELL-THERAPEUTIC-BUSINESS.html for more information.

Dow Jones VentureSource Ranks WSGR No. 1 for 2013 Venture Financings

Dow Jones VentureSource recently ranked Wilson Sonsini Goodrich & Rosati as the leading law firm for U.S. venture financings in 2013. Specifically, Dow Jones VentureSource's legal rankings for 2013 issuer-side venture financing deals placed WSGR ahead of all other firms by the total number of rounds of equity financing raised on behalf of clients. The firm is credited as legal advisor in 204 rounds of financing, while its nearest competitor advised on 140 rounds of equity financing. Of particular interest to *The Life Sciences Report*, Dow Jones VentureSource ranked WSGR No. 1 for issuer-side U.S. deals in the healthcare and medical devices and equipment industries.

Upcoming Life Sciences Events

rEVOLUTION Symposium
May 7-9, 2014
Mandarin Oriental
Boston, Massachusetts
http://www.wsgr.com/news/revolution

The rEVOLUTION Symposium will discuss the most important strategic challenges facing pharmaceutical and biotech chief scientific officers. The 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 our industry.

Wilson Sonsini Goodrich & Rosati's Medical Device Conference
June 11-12, 2014
The InterContinental Hotel
San Francisco, California
http://www.wsgr.com/news/medicaldevice/

Wilson Sonsini Goodrich & Rosati's 22nd 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 2014: The Medical Device and Diagnostic Conference for CEOs
September 10-12, 2014
Montage Deer Valley
Park City, Utah
http://www.wsgr.com/news/phoenix/

Phoenix 2014 will serve as the 21st annual conference for chief scientific officers and senior leadership of medical device and diagnostic companies. The event will provide an opportunity for top-level executives from large healthcare and small venture-backed companies to discuss financing, strategic alliances, and other industry issues.

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 and Scott Murano. 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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