Wilson Sonsini Goodrich & Rosati
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The Life Sciences Report

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How to Expedite Examination of a Patent Application

By Doug Portnow, Associate, and Darby Chan, Associate (Palo Alto)

Does this sound familiar? Your company is developing an innovative medical product and you have several patent applications filed with the United States Patent and Trademark Office (USPTO). The patent applications have been sitting in the queue for many months, or even years, waiting for examination. You're also in the process of fundraising or forming an alliance with a corporate strategic partner. Wouldn't it be great if you could speed up the patent examination process and show that you have granted patents? The good news is that there are several USPTO programs that may help you procure a patent more quickly.

Track One

Under the newly enacted America Invents Act, the Track One Prioritized Examination program is now being offered. Track One allows a patent applicant to get final disposition in about 12 months. The program is similar to the normal patent prosecution process, except that a complete application must be filed with all documents submitted at the time of filing and a fee is paid to bump the application to the front of the examination queue. The prioritized examination fee recently was reduced and now is $4,000 for large entities and $2,000 for small entities. At the time the Track One patent application is filed, any other fees (e.g., excess page fees) also must be paid, and the application and all related forms must be complete. Additionally, the application can have no more than four independent claims and a total of thirty claims. Applicants then can expect to see a first Office Action in a few months. Responses to Office Actions must be filed promptly within the three-month shortened statutory period, and no extensions of time are permitted. Otherwise, the application will be removed from the Track One program and placed back into the regular examination docket. Final disposition is approximately in 12 months, which means that an applicant either will have an allowance or his or her case will be on Final Rejection in about a year.

Track One permits patent applicants to get claims allowed quickly as long as they have

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In This Issue

The FDA Releases Final Guidance for Mobile Medical Applications

By David Hoffmeister, Partner, and Andrew Ellis, Associate (Palo Alto)

On September 23, 2013, the U.S. Food & Drug Administration (FDA) released its final guidance concerning mobile medical applications,[1] which had been highly anticipated since the FDA first released its proposed guidance in July 2011. In its final guidance, the FDA sets its focus on those mobile medical apps that qualify as medical devices *and* carry the highest risk to patient safety, leaving the remainder of mobile medical apps still within FDA jurisdiction, but outside the purview of active FDA regulation.

Introduction

The landscape of mobile medical apps has burgeoned in recent years, with currently available apps numbering between 30,000 and 40,000.[2] Although the FDA only released its proposed guidance in July 2011, it has had the

[1] The original PDF of the final guidance can be found at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf. In addition, the FDA has set up a mobile medical apps website at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/MobileMedicalApplications/default.htm

[2] http://mhealthwatch.com/mobile-health-care-apps-growing-fast-in-number-20052/; http://www.kaiserhealthnews.org/stories/2012/june/27/fda-medical-app-market.aspx

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reasonable expectations for the claims they are pursuing and the applicant is familiar with the prior art and has filed appropriately drafted claims that take that prior art into account. The program also may be used with continuation applications or, one time only, with a Request for Continued Examination (RCE). The total number of applications that may be filed under Track One is limited to 10,000 per year. As of July 2013, approximately 5,000 Track One applications have been filed in fiscal year 2013.

Accelerated Examination

Accelerated Examination is another program that allows faster examination. It is very similar to Track One, and also has the goal of final disposition in about twelve months. Unlike Track One, which requires entry into the program at the time the patent application or an RCE is filed, a patent application can be placed into Accelerated Examination at almost any time with the filing of a low-cost petition. At the time this petition is filed, the application and related forms must be complete.

> Accelerated Examination is another program that allows faster examination. Under Accelerated Examination, Office Actions have a much shorter period for reply . . .

While the additional fees required for Accelerated Examination are minimal, the program requires much more work and diligence upfront than normal examination or even Track One. A significant difference is a requirement that the patent applicant conduct his or her own patentability search, characterize the closest prior art, and explain why the claimed invention is distinguished from that prior art in an Accelerated Examination Support Document (AESD). An interview with the Patent Examiner also must be performed before a first Office Action is mailed out. Under Accelerated Examination, Office Actions have a much shorter period for reply—one month with no extensions of time versus three months with up to three months of extensions for normal prosecution. Not responding to the Office Action will result in the patent application being considered abandoned. Moreover, any claim amendments and additions will require an update of the AESD.

Since patent applicants are required proactively to make statements on the record about the prior art and the claimed invention, many practitioners do not like to use Accelerated Examination. Making such statements could present problems down the road, especially during litigation. Thus, Track One usually is preferable since it has fewer requirements and does not require any pre-examination search.

Petitions to Make Special

Patent applications also may be advanced for examination by submitting a Petition to Make Special. The cost of such a petition is low to none, but applications only qualify for such advancement if they fall within certain situational categories.

A number of such categories relate to the life sciences. Applications for inventions relating to the safety of research in the field of recombinant DNA can be made special. Applications also can qualify if the invention contributes to the diagnosis, treatment, or prevention of HIV/AIDS or cancer. Small biotechnology companies can make an application special if they show that the application is a significant corporate asset and that development of the technology would be significantly impaired if examination were delayed.

The health and age of applicants also can be cause for advancement. The applicant must show evidence that he or she might not be available to assist in the prosecution of the application if it were to run its normal course (usually two to five years from filing) due to his or her state of health. Advancement also may be granted if an applicant demonstrates that he or she is 65 years of age or older. In both these cases, no petition fee is required.

> Patent applications also may be advanced for examination by submitting a Petition to Make Special . . . applications only qualify for such advancement if they fall within certain situational categories.

Other categories include the prospective domestic manufacture of the patented product, infringement of the prospective patent, and inventions related to energy, superconductivity, counterterrorism, or protecting or conserving the environment.

Patent Prosecution Highway

In some cases, patent applications filed in multiple international jurisdictions can take advantage of the Patent Prosecution Highway (PPH). If a patent applicant receives a favorable ruling from an Office of First Filing indicating that at least one claim in his or her application is patentable, the PPH allows that applicant to request fast-track examination of the corresponding claims in an application filed in an Office of Second Filing. There is no

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fee for making this request, and the PPH speeds up the examination of patent applications filed in participating countries by allowing examiners to rely on search and examination results from another country. A patent application fast-tracked under this program may be examined in two or three months after the request is granted. Currently, about 15 countries participate in the PPH program.

A pilot program also has expanded the PPH eligibility for national- and regional-phase patent applications filed under the Patent Cooperation Treaty (PCT) using positive patentability results obtained during the international PCT phase. Thus, a favorable PCT Written Opinion or International Preliminary Report on Patentability from a participating office allows the applicant to request that a corresponding national-phase entry or national application filed at the USPTO be placed in the fast-track examination queue. Participating offices include the USPTO, the Japan Patent Office, the European Patent Office, the Korean Intellectual Property Office, and the Austrian, Russian, and Spanish Patent Offices.

Summary

A number of programs are available that allow expedited examination and allowance of a patent application under certain circumstances. Each program has its own special requirements, and it is important for applicants to review the requirements carefully, make sure that they qualify, and comply with the rules. These accelerated programs, especially Track One, have been well received by patent practitioners and can be great tools for expedited procurement of granted patents. The table below summarizes some of the key features of the individual programs.

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Key Features of Expedited Patent Prosecution Programs

Program	Additional Fees	Key Additional Requirements	Key Benefits	Key Drawbacks
Track One (Prioritized Examination)	- Prioritized Examination Fee: $4,000 (Large Entity), $2,000 (Small Entity), $1,000 (Micro-Entity)	- Filing of Track One Request & Complete Application at Time of Filing Patent Application	- Placement of Patent Application at Front of Examination Queue - Disposition Within 12 Months	- High Additional USPTO Fees
Accelerated Examination	- Petition Fee to Request Accelerated Examination: $130	- Complete Application at Time of Filing Petition to Request Accelerated Examination	- Examination of Patent Application upon Petition Grant - Disposition Within 12 Months	- Higher Upfront Legal Costs - Greater Diligence Required - May Need to Characterize Prior Art
Special Case	- Petition Fee to Make Special: $130 (or none if related to health or age)	- Patent Application Must Fall Within Special Situational Category	- Advancement of Application Out of Turn	- Not Available in Many Cases
Patent Prosecution Highway (PPH)	- No Fee	- Filing of Corresponding Application in Foreign Patent Office - Favorable Ruling in Foreign Patent Office	- Faster Examination with Use of Foreign Patent Office Search and Examination Results	- Corresponding Application Must Be Filed in Foreign Patent Office Before U.S.

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authority to regulate mobile medical apps for decades. Section 201(h) of the Food, Drug & Cosmetic Act (FDCA) defines a medical device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals."[3] Under this definition, some mobile medical applications have already been regulated as medical devices or accessories to medical devices; however, there has been considerable uncertainty as to whether the "intended use" of many other medical apps would qualify them for regulation as devices. While the new guidance does not clearly answer every conceivable question, it does carve out those apps that will not be regulated by the FDA, which many commentators hope and expect to stimulate further development and investment due to reduced uncertainty.

Mobile Medical Apps Under Active FDA Regulation

The final FDA guidance focuses on those mobile medical apps that meet the statutory definition of "device" under the FDCA and (1) are intended to be used as an accessory to a regulated medical device, or (2) transform a mobile platform into a regulated medical device. This wording is identical to that of the draft guidance, but the final guidance is far more detailed, providing numerous useful examples and explanations of the FDA's process for mobile medical app regulation.

The FDA divides mobile medical apps that it intends to actively regulate into three categories:

1. *Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or displaying, storing, analyzing, or transmitting patient-specific medical device data.* Examples within this category include apps that display medical device data (e.g., an app that enables remote display of bedside monitors), apps that control medical devices (e.g., an app that inflates and deflates a blood pressure cuff), and apps that display medical data in its original format.

The final FDA guidance focuses on those mobile medical apps that meet the statutory definition of "device" under the FDCA and (1) are intended to be used as an accessory to a regulated medical device, or (2) transform a mobile platform into a regulated medical device.

2. *Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.* Examples include an app that allows attachment to an ECG machine or an app that connects to a glucose monitor.

3. *Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations.* Examples include apps that perform sophisticated analysis or interpret data (electronically collected or manually entered) from another medical device, such as image processing or radiation treatment planning software.

Mobile Medical Apps Under FDA "Enforcement Discretion"

The FDA lists six categories of low-risk devices to which it intends to apply "enforcement discretion"; in other words, the FDA has jurisdiction to regulate, but does not intend to actively regulate the following categories:

1. *Mobile apps that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment.* Examples include an app that coaches obese patients on weight-loss strategies.

2. *Mobile apps that provide patients with simple tools to organize and track their health information.* Examples include an app that provides a means of logging daily blood pressure measurements.

3. *Mobile apps that provide easy access to information related to patients' health conditions or treatments (beyond providing an electronic "copy" of a medical reference).* Examples include a lookup tool for drug interactions.

4. *Mobile apps that are specifically marketed to help patients document, show, or communicate to providers potential medical conditions.* Examples include an app that allows secure videoconferencing between patients and providers.

5. *Mobile apps that perform simple calculations routinely used in clinical practice.* Examples include an app that measure Body Mass Index (BMI).

[3] http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChaptersIandIIShortTitleandDefinitions/ucm086297.htm

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6. *Mobile apps that enable individuals to interact with PHR systems or EHR systems.* Examples include an app that allows patients to download electronic health record data**.**

Mobile Medical Apps Not Under FDA Regulation

Finally, the FDA delineates five categories of mobile medical apps that it will not regulate and fall outside the definition of medical device under the statute:

1. *Mobile apps that are intended to provide access to electronic "copies" (e.g., e-books, audio books) of medical textbooks or other reference materials with generic text search capabilities.* Examples include apps for medical dictionaries and electronic copies of medical textbooks.

2. *Mobile apps that are intended for healthcare providers to use as educational tools for medical training or to reinforce training previously received.* Examples include apps for medical flashcards and surgical training videos.

3. *Mobile apps that are intended for general patient education and facilitate patient access to commonly used reference information.* Examples include patient help guides and CPR training resources.

4. *Mobile apps that automate general office operations in a healthcare setting and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.* Examples include apps that enable insurance claim data collection and those that generate reminders for medical appointments.

5. *Mobile apps that are generic aids or general purpose products. These apps are not considered devices because they are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.* Examples include apps that provide turn-by-turn directions to medical facilities and those that enable patient-provider communication via email.

Implications for Digital Health Entrepreneurs

Industry observers and participants alike have criticized the notice-and-comment system utilized by administrative agencies such as the FDA for its inability to keep up with rapidly changing technology. The FDA's final guidance on mobile medical apps applies a thoughtful risk-based balance that protects patient safety through regulation of the highest-risk apps, while innovation is cultivated by eliminating regulatory uncertainty with respect to categories of medical apps that pose little to no patient risk. Although the deregulatory nature of this guidance encourages the development of new and unforeseen technology, that same open-endedness also leaves some remaining uncertainties.

For example, clinical decision support system (CDSS) software, which aids physicians in translating patient data into diagnosis and treatment decisions, can be interpreted to overlap with the third category of regulated mobile medical applications, which is defined by the FDA as apps that "perform[] patient-specific analysis and provid[e] patient-specific diagnosis, or treatment recommendation." In a recent guidance-related announcement, Jeffrey Shuren, Director of the FDA Center for Devices and Radiological Health, specifically stated that regulatory guidance pertaining to CDSS software would be released in January 2014, which means mobile medical apps that straddle the line between a medical device and CDSS software will have to wait for more regulatory clarity.

One area in which the FDA produced absolute clarity is in its exemption of certain entities from regulation. For example, platform makers (i.e., mobile device manufacturers) and software distributors (i.e., app stores) are not regulated entities, and their mobile platforms (e.g., iPhones) are not medical devices, under the final guidance. In addition, unlike in the proposed guidance, the FDA will not regulate calculators such as Apgar scores and the NIH Stroke Scale.

> The FDA's final guidance on mobile medical apps applies a thoughtful risk-based balance that protects patient safety through regulation of the highest-risk apps . . .

In summary, the final guidance should have a favorable effect on digital health entrepreneurs, allowing innovation with reduced uncertainty, while the FDA focuses its limited resources on those apps that pose the greatest threat to patient safety.

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Creating Value in the Medtech Industry Using a Gender Lens[1]

By Nancy M. Lynch, M.D., Founder and Principal, Advisorthopædics Incorporated

In July, the FDA's Center for Devices and Radiological Health (CDRH) launched an ambitious and important initiative focused on improving women's access to and outcomes from treatments using medical devices. This follows the publication of its 2011 draft guidance on the subject. The Health of Women Program commenced with an impressive two-day public workshop and included participants from all stakeholder groups.

To say the least, the discussion was eye opening and sobering. Let me share three specific points:

- Women are less frequently asked to participate in clinical trials than men. Furthermore, when asked, women opt out of participation in those same trials at higher rates than men. As such, trial results (among other things) may not accurately reflect treatment effects or safety issues in women. That's left up to the real world to discover after the product is on the market.

- Although women undergo far more knee replacements than men, women who otherwise qualify for a knee replacement are not being offered that procedure at three times the rate of men who aren't being offered the same surgery! In other words, for an equivalent disease burden, women are underserved relative to their male counterparts. To be clear, this pattern is not unique to the orthopedic industry.

- As if being underserved weren't enough, a woman's outcome after a knee replacement is not as good as a man's. Don't get me wrong—women get better from knee replacements. They definitely do. However, on average, women start with a worse preoperative level of function and never achieve the functional outcome men do.

So, in sum, women are understudied and underserved. And when they are finally studied and served, they underrespond.

See what I mean about the discussion being eye opening and sobering?

While absorbing this information, I couldn't help but think of Joy Anderson's incredibly mind-bending MedtechWomen Fireside Chat subject, "A Gender Lens in Investing," and ponder the MedtechVision 2013 topic, "Value in Healthcare." Both relate directly to the FDA workshop. The differences and disparities mentioned above represent a multitude of unmet needs. (Hint: "unmet needs" is code for "opportunities.") By using the optics of a gender lens, the medtech industry can focus on innovation that creates value in the healthcare system where it is currently not visible.

Unfortunately, in the present reform environment, our industry is allowing value to be defined for us. In my opinion, "value" in healthcare has become synonymous with "cost containment." Sure, improving health is mentioned in passing, but the core of health (insurance) reform is about squeezing cost out of the system. To me, value is present only if an individual's outcome is optimized and the collective health of a population improves as a result. (I'm a physician and that's my bias. But I'm also influenced by Clay Christensen's teachings on innovation and concerned that efforts aimed solely at cost containment are simply "efficiency innovations" in disguise.)

Fortunately, opportunities exist to create this optimization-type of value in our industry by keenly and agnostically recognizing differences in the following:

- Sex-specific incidence and prevalence of disease

- Sex-specific expression of disease

- Sex-specific progression of disease

- Sex- and gender-specific experience of disease

- Sex- and gender-specific response to treatment

It's when these sex- and gender-specific variations are identified, acknowledged, and understood that smart, patient-centric approaches (involving the use of algorithms, diagnostics, services, and therapeutics) can be developed and implemented to improve the health of people, not just of women.

Fundamentally, the FDA's program is the foundation upon which personalized medicine will be built. We have leaps and bounds to go before we get there, and it starts not with individual differences but with pattern recognition within and between groups. (As the saying goes, even though you're one in a million, there are eight more of you in New York.) Every part of the healthcare ecosystem simply must participate in the process for personalized medicine to be realized in our time. As it relates to gender, stakeholders can employ a lot of complementary strategies. Specifically,

- For those studying the basic science of disease, it's time to highlight the translational relevance of your findings on geno- and phenotypical sex differences.

- For those designing new products and services, it's time to innovate taking into account the probability that men and women will respond differently.

- For those running clinical trials, it's time to focus on how to explore and report on sex and gender differences in what you are studying.

[1] *Please note that this article originally appeared on the MedtechWomen website (www.medtechwomen.org).*

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- For those regulating trials, it's time to encourage gender stratification and subgroup analyses in a manner that catalyzes progress.
- For those teaching the next generation, it's time to incorporate intentional and frequent didactic instruction on sex and gender differences throughout the care cycle.
- For those providing care, it's time to observe the differences, communicate them to your patients, and incorporate them into your algorithms of care.
- For those receiving care (or advocating on behalf of someone receiving care), it's time to start asking your physicians, "What differences do you see in how women respond to this treatment compared to men?"

The FDA is committed to an ongoing, interactive, multidisciplinary dialogue on this serious and complex topic. You can contribute by broadening your awareness of these issues (Gendered Innovations is an intriguing place to start), putting a gender lens in front of your gaze to see the opportunities, and then interjecting this subject as a recurring theme in your personal and professional conversations. Create a ripple effect by frequently engaging others. That's the source of change. And who better to bring about that change than the 51 percent?

Nancy M. Lynch, M.D., founder and principal of Advisorthopædics, has more than 25 years of experience in the clinical and business elements of orthopedics. She is a board-certified orthopedic surgeon and a Fellow of the American Academy of Orthopaedic Surgeons. Nancy's firm, Advisorthopædics Incorporated, which is focused exclusively on innovation in orthopedics, provides consultation services to a range of entities developing products for musculoskeletal care. http://www.advisortho.com.

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 the second half of 2012 and the first half of 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 second half of 2012 and the first half of 2013.

The data generally demonstrates that venture financing activity declined during the first half of 2013 compared to the second half of 2012. Specifically, the total number of closings completed across all industry segments during the first half of 2013 decreased by approximately 24.8 percent compared to the second half of 2012, from 101 closings to 76 closings. More significantly, the total amount

Life Sciences Industry Segment	2H 2012 Number of Closings	2H 2012 Total Amount Raised ($M)	2H 2012 Average Amount Raised ($M)	1H 2013 Number of Closings	1H 2013 Total Amount Raised ($M)	1H 2013 Average Amount Raised ($M)
Biopharmaceuticals	13	83.89	6.45	12	65.31	5.44
Diagnostics	6	19.98	3.33	3	3.18	1.06
Genomics	5	26.04	5.21	2	1.1	0.55
Healthcare Services	3	7.93	2.64	4	37.37	9.34
Medical Devices & Equipment	66	343.76	5.21	46	205.45	4.47
Medical Information Systems	6	11.04	1.84	9	23.36	2.6
Other	2	1.85	0.93	0	N/A	N/A
Total	**101**	**494.49**		**76**	**335.77**	

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of money raised across all industry segments during the first half of 2013 decreased by more than 32.1 percent compared to the second half of 2012, from $494.49 million to $335.77 million.

The two industry segments with the largest number of closings—medical devices and equipment and biopharmaceuticals—both experienced a decline in number of closings during the first half of 2013 compared to the second half of 2012. Specifically, the largest industry segment, medical devices and equipment, declined 30.3 percent, from 66 closings in the second half of 2012 to 46 closings in the first half of 2013; and the second-largest industry segment, biopharmaceuticals, declined 7.7 percent, from 13 closings to 12 closings. Similarly, in terms of total amounts raised, the two industry segments with the largest total amounts raised—medical devices and equipment and biopharmaceuticals—both experienced a decline in amounts raised during the first half of 2013 compared to the second half of 2012. Specifically, the largest industry segment, medical devices and equipment, declined 40.2 percent, from $343.76 million raised in the second half of 2012 to $204.45 million raised in the first half of 2013; and the second-largest industry segment, biopharmaceuticals, declined 22.1 percent, from $83.89 million raised in the second half of 2012 to $65.31 million raised during in the first half of 2013. Bucking the downward trend on both measures were healthcare services and medical information systems. The total number of closings in healthcare services increased 33.3% from three closings in the second half of 2012 to four closings in the first half of 2013; and the total number of closings in medical information systems increased 50% from six closings in the second half of 2012 to nine closings in the first half of 2013. Similarly, the total amount raised in healthcare services increased 371.2% from $7.93 million in the second half of 2012 to $37.37 million in the first half of 2013; and the total amount raised in medical information systems increased 111.6% from $11.04 million in the second half of 2012 to $23.36 million in the first half of 2013.

In addition, our data suggests that Series A financing activity is up compared to Series B and later-stage equity financings and bridge financings. Specifically, the number of Series A closings as a percentage of all closings during the first half of 2013 compared to the second half of 2012 increased from 28.7 percent to 30.3 percent, whereas the number of Series B closings during the same periods remained constant at 15.8 percent, the number of Series C and later closings decreased from 15.8 percent to 14.5 percent, and the number of bridge financings decreased from 35.6 percent to 34.2 percent. Moreover, the data demonstrates that the average pre-money valuations for Series A and Series B closings increased, while the average pre-money valuations for Series C and later closings decreased. Specifically, the average pre-money valuation for Series A financings increased 17.3 percent, from $7.17 million during the second half of 2012 to $8.41 million during the first half of 2013; Series B financings increased 5.2 percent, from $17.4 million to $18.3 million; and Series C financings decreased by 46.8 percent, from $136.4 million to $72.6 million.

Other data taken from transactions in which all Wilson Sonsini Goodrich & Rosati clients participated in the second half of 2012 and the first half of 2013 suggests a continued shift in investment money away from life sciences to other industries. In the second half of 2012, life sciences was the second-most attractive industry for investment among our clients, representing 19.2 percent of total funds raised, and was edged out of the number one spot by the software industry, which represented 24.9 percent of total funds raised. In the first half of 2013, life sciences retained the number two spot at 18.6 percent of total funds raised, with software gaining more ground on life sciences as the top industry for investment at 29.5 percent.

Overall, the data confirms that access to venture capital for life sciences companies continued to decline during the first half of 2013 compared to the second half of 2012. The upshot may be the uptick in Series A closings and improved Series A pre-money valuations, both suggesting that demand for those deals is on the rise. Moreover, while the traditional industry segment giants—medical devices and equipment and biopharmaceuticals—continued to decline in terms of closings and total amounts raised during the first half of 2013 compared to the second half of 2012, lesser-known and historically less-popular industry segments of healthcare services and medical information systems are experiencing double-digit growth, both in terms of closings and total amounts raised, suggesting that there is a growing appetite for investments focused on services and software-based healthcare innovations.

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Recent Life Sciences Highlights

Practice Fusion Raises $70 Million in Series D Funding
On September 24, 2013, Practice Fusion, the largest and fastest-growing healthcare platform in the U.S., announced that it had completed a $70 million Series D financing round. This investment will allow Practice Fusion to expand its offerings to patients and accelerate the company's continued leadership in the electronic medical record market, as well as fund new clinical data research and development. WSGR advised Practice Fusion in the financing. To learn more, please see the company's press release at http://www.practicefusion.com/pages/pr/pf-announces-series-d-funding.html.

Pacific Biosciences of California Signs $75 Million Deal with Roche Diagnostics
On September 25, 2013, Pacific Biosciences of California announced that it has entered into an agreement with Roche Diagnostics to develop diagnostic products, including sequencing systems and consumables. Pacific Biosciences will develop and manufacture certain products intended for clinical use, which it will sell exclusively to Roche, which has obtained worldwide rights to exclusively distribute these products in the field of human *in vitro* diagnostics. WSGR advised Pacific Biosciences in the transaction. For more details, please see Pacific Bioscience's press release at http://www.globenewswire.com/news-release/2013/09/25/575764/10049796/en/Pacific-Biosciences-Announces-Agreement-With-Roche-Diagnostics-to-Develop-and-Supply-DNA-Sequencing-Based-Products-for-Clinical-Diagnostics.html.

Transcept Pharmaceuticals and Shin Nippon Biomedical Laboratories Sign Global Licensing Agreement
On September 25, 2013, Trancept Pharmaceuticals and Shin Nippon Biomedical Laboratories (SNBL) announced in a joint press release that the companies have entered into an exclusive worldwide licensing agreement for a novel, rapidly absorbed treatment for acute migraines that incorporates dihydroergotamine as the active drug. WSGR represented Shin Nippon Biomedical Laboratories in this transaction. For more information, please see the companies' joint press release at http://www.prnewswire.com/news-releases/transcept-and-shin-nippon-biomedical-laboratories-announce-global-licensing-agreement-for-advanced-acute-migraine-treatment-225245472.html.

SafeStitch Medical Completes Merger with TransEnterix
On September 4, 2013, development-stage medical device companies SafeStitch Medical and TransEnterix announced that they have closed SafeStitch's acquisition of TransEnterix. Headquartered in North Carolina's Research Triangle, the combined company is expected to be renamed TransEnterix and is dedicated to bringing flexible minimally invasive surgical technologies to market, including SurgiBot, a novel patient-side surgical robotic system. WSGR represented TransEnterix in the transaction. For more information, please see http://www.transenterix.com/news/2013/09/safestitch-medical-completes-merger-with-transenterix/.

Otsuka Pharmaceutical to Acquire Astex Pharmaceuticals
On September 5, 2013, Otsuka Pharmaceutical and Astex Pharmaceuticals announced that their respective boards of directors unanimously approved a transaction under which Otsuka will acquire all of the outstanding shares of Astex for $8.50 per share in cash, representing a 48 percent premium to the average closing stock price for the prior 30-day period. The purchase price represents a fully diluted equity value of approximately $886 million. The transaction is expected to allow the companies to combine Astex's fragment-based drug discovery technology with Otsuka's own R&S strengths in areas such as central nervous system diseases and strengthen Otsuka's oncology offerings. WSGR is representing Astex in the acquisition. More details are available at https://www.otsuka.co.jp/en/company/release/2013/0905_01.html.

Rani Therapeutics Secures Series B Funding
On August 28, 2013, Rani Therapeutics, a company that has developed a novel approach for the oral delivery of large drug molecules, announced it has closed its Series B round of funding, led by Google Ventures. InCube Ventures and VentureHealth also joined the round. The funding will support the further development of Rani Therapeutics' novel approach for the oral delivery of large drug molecules including peptides, proteins, antibodies, RNAi therapies, and select vaccines. WSGR represented Rani Therapeutics in the financing. Further information is available at http://www.cnbc.com/id/100994267.

Johnson & Johnson Completes Acquisition of Aragon Pharmaceuticals
On August 19, 2013, Johnson & Johnson announced that it has successfully completed its acquisition of Aragon Pharmaceuticals, a privately held pharmaceutical discovery and development company focused on drugs to treat hormonally driven cancers. Development of compounds from Aragon's androgen receptor antagonist program will be managed by Janssen Research & Development. WSGR advised Aragon Pharmaceuticals in the transaction. For additional details, please see http://www.investor.jnj.com/releasedetail.cfm?ReleaseID=786092.

Actelion Enters Agreement to Acquire Ceptaris Therapeutics
On July 31, 2013, Actelion US Holdings Company and privately held Ceptaris Therapeutics announced they have entered into an agreement for Actelion to acquire Ceptaris. Under the terms of the agreement, Actelion paid Ceptaris $25 million upon signing and will pay $225 million to Ceptaris shareholders upon the close of the transaction. The merger is contingent upon certain closing conditions, including FDA of Ceptaris' product Valchlor, a topical formulation of mechlorethamine for the treatment of early-stage mycosis fungoides. WSGR represented Ceptaris in the

transaction. To learn more, please refer to http://cws.huginonline.com/A/131801/PR/201307/1719734_5.html.

Sequenta Completes $20 Million Series C Financing

On July 3, 2013, Sequenta, a biotechnology company dedicated to improving patient care in diseases mediated by immune cells through the discovery and development of novel clinical diagnostics, announced the completion of a $20 million Series C financing. The round was led by Foresite Capital Management, with participation from all inside investors, including MDV and Index Ventures. Sequenta will use the proceeds for commercial scale-up and clinical validation of the ClonoSIGHT test. WSGR advised the company in the financing. Further details may be found at http://sequentainc.com/sequenta-completes-20-million-series-c-financing/.

Avanir Pharmaceuticals and OptiNose Announce Development and Commercialization Agreement

On July 2, 2013, Avanir Pharmaceuticals and drug delivery company OptiNose AS announced they have entered into an exclusive North American license agreement for the development and commercialization of OptiNose's novel intranasal delivery system containing low-dose sumatriptan powder to treat acute migraine. OptiNose received an upfront cash payment of $20 million and is eligible to receive certain shared development costs and up to an additional $90 million linked to the achievement of future clinical, regulatory, and commercial milestones. WSGR represented Avanir in the matter. Additional information is available at http://ir.avanir.com/phoenix.zhtml?c=61699&p=irol-newsArticle&ID=1834946&highlight.

NuMedii Receives $3.5 Million in Series A Financing

On June 26, 2013, NuMedii, a company that discovers and de-risks effective new drugs by translating its predictive Big Data technology into therapies with a higher probability of therapeutic success, announced that it has received $3.5 million in a Series A funding led by Claremont Creek Ventures and Lightspeed Venture Partners, with participation by Life Science Angels and others. NuMedii raised this initial funding to further develop its proprietary technology and prepare its first three internal drug development programs for clinical testing. Wilson Sonsini Goodrich & Rosati advised the company in the financing. For more information, visit http://numedii.com/numedii-announces-series-a/.

NanoString Technologies Prices Initial Public Offering

On June 25, 2013, NanoString Technologies, a provider of life science tools for translational research and molecular diagnostic products, announced the pricing of its initial public offering of 5.4 million shares of common stock at a price to the public of $10.00 per share. The bookrunning managers of the offering were J.P. Morgan and Morgan Stanley, and the co-managers were Leerink Swann and Robert W. Baird & Co. NanoString Technologies common stock trades on the NASDAQ Global Market under the symbol "NSTG." WSGR represented NanoString in connection with the offering. Further details can be found at http://www.nanostring.com/company/corp_press_release?id=87.

U.S. Supreme Court Adopts Firm's Arguments in *Myriad* Decision

On June 13, 2013, the United States Supreme Court issued its long-awaited decision in *Association for Molecular Pathology v. Myriad Genetics*, concluding that isolated fragments of genomic DNA are naturally occurring and thus are not patent eligible, while complementary DNA (cDNA) is not a product of nature and thus is patent eligible. The arguments adopted by the court mirror those put forth in an amicus brief previously filed by WSGR on behalf of Dr. Eric Lander, of the world's leading genomics researchers, in the case. At the oral argument, three of the justices referred repeatedly to WSGR's brief in questioning Myriad's counsel. Please see the U.S. Supreme Court's decision at http://www.wsgr.com/PDFs/myriad-0613.pdf for more information.

St. Jude Medical Signs Equity Investment and Option to Purchase Agreement with Spinal Modulation

On June 7, 2013, St. Jude Medical, a global device company, and privately held Spinal Modulation announced that they have entered into a series of agreements under which St. Jude Medical made a $40 million equity investment in Spinal Modulation, which has developed an innovative neuromodulation therapy that provides a new pain management option for patients with chronic pain. The agreement provides St. Jude Medical with an exclusive option to distribute the Axium Neurostimulator System, developed and manufactured by Spinal Modulation, in international markets where it is approved for sale. WSGR advised Spinal Modulation in the transaction. To learn more, please visit http://investors.sjm.com/phoenix.zhtml?c=73836&p=irol-newsArticle&ID=1828124&highlight.

Life Sciences Events: Wilson Sonsini Goodrich & Rosati Hosts 21st Annual Medical Device Conference

On June 19, 2013, the firm hosted its 21st Annual Medical Device Conference, at which a variety of industry experts addressed topics of critical importance to medical device companies. More than 650 executives, entrepreneurs, investors, and in-house counsel from medical device companies attended the event, which took place in San Francisco, California.

In a series of panels, industry CEOs, venture capitalists and other investors, industry strategists, investment bankers, and market analysts addressed such topics as funding strategies, med-tech investment models, the Sunshine Act and physician payments, crowdfunding, patent strategies, digital health, university licensing, and recent regulatory developments.

The event's lunch session featured an interview with representatives from The Fogarty Institute for Innovation, an educational, nonprofit organization that promotes medical innovation by providing support to entrepreneurial innovators working on promising new medical therapies. The discussion, which was moderated by David Cassak, VP of content and managing director of medical devices for Elsevier Business Intelligence, included institute founder and director Thomas Fogarty, M.D.; president and CEO Ann Fyfe; and director Frederick St Goar, M.D. They discussed the state of innovation in medical devices today and how programs like The Fogarty Institute offer a novel approach to a challenging environment.

In addition, the conference included the first annual MedTech Idol Competition, through which four medical device start-ups were selected to present pitches to a panel of investor judges. The judges evaluated the presenters and the audience members voted for the winner. This year, LIM Innovations, a developer of prosthetic socket technology, took first place, earning them a presenting slot at an upcoming IN3 Medical Device conference and a profile in an upcoming issue of Elsevier's monthly magazine, *START-UP: The Review of Emerging Medical Ventures*. The competition was produced by RCT Ventures, an investment program of Research Corporation Technologies that is focused on early-stage biomedical companies.

Please visit http://www.wsgr.com/news/medicaldevice/agenda.htm to view the 2013 Medical Device Conference agenda, which includes links to videos of the various presentations.

WSGR Receives Top Rankings from Dow Jones Venture Source, *LMG Life Sciences*, and BioPharm Insight

Wilson Sonsini Goodrich & Rosati recently received third-party recognition from Dow Jones VentureSource, *LMG Life Sciences*, and *BioPharm Insight* for its achievements on behalf of clients.

Dow Jones VentureSource's legal rankings for issuer-side venture financing deals in the first half of 2013 placed Wilson Sonsini Goodrich & Rosati 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 98 rounds of financing, while its nearest competitor advised on 64 rounds of equity financing. Of particular interest to *The Life Sciences Report*, Dow Jones VentureSource ranked WSGR No. 1 nationally for issuer-side deals in the healthcare and medical devices and equipment industries.

Further, a number of the firm's life-sciences-related practices received recognition in the 2013 edition of *LMG Life Sciences*, a guide published by the UK-based Euromoney Legal Media Group. Wilson Sonsini Goodrich & Rosati was "highly recommended" in the areas of patent prosecution, patent strategies and management, and licensing collaboration, and "recommended" in the corporate category. The rankings were based on a review of nearly 1,000 interviews and surveys completed by individuals active in the life sciences industry.

In addition, the firm ranked highly on several biotechnology and pharmaceutical league tables published by *BioPharm Insight* based on the volume and value of its licensing agreements in both the second quarter of 2013 and the preceding 12 months. Select rankings include the following:

- Ranked No. 2 by global volume and No. 4 by global value of biotech and pharma licensing agreements in Q2 2013
- Ranked No. 4 by global volume and No. 7 by global value of biotech and pharma licensing agreements in the 12 months preceding Q2 2013
- Ranked No. 5 by volume and No. 7 by value of biotech and pharma licensing agreements in North America in the 12 months preceding Q2 2013
- Ranked No. 2 by volume and No. 4 by value of biotech and pharma licensing agreements in the Asia-Pacific region in the 12 months preceding Q2 2013
- Ranked No. 6 by volume and No. 6 by value of biotech and pharma licensing agreements in Europe in the 12 months preceding Q2 2013

Upcoming Life Sciences Events

Phoenix 2013: The Medical Device and Diagnostic Conference for CEOs
October 10–13, 2013
The Ritz-Carlton, Dove Mountain
Marana, Arizona
www.wsgr.com/news/phoenix

Phoenix 2013 will serve as the 20th 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.

Wilson Sonsini Goodrich & Rosati's Biotech Board of Directors Reception
January 15, 2014
Clift Hotel
San Francisco, California

The Biotech Board of Directors Reception is an exclusive networking event geared toward executives and directors of biotech companies.

rEVOLUTION Symposium
May 7–9, 2014
Mandarin Oriental
Boston, Massachusetts
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

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.

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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