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Software Components of Digital Health Innovations Raise Unique Questions for Standard University Technology Licenses

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DIGITAL HEALTH REPORT

SPRING/SUMMER
Q2 2018

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PROFESSIONAL CORPORATION

Evaluating Prospective Partners When Scaling Your Digital Health Company (Part 1)

By Jake D. Gatof

Picture this: You have built a digital health company that could revolutionize healthcare delivery; upend diagnostic processes; accelerate data analysis; erase communication barriers between providers, patients and other participants; or perhaps replace entire medical records systems. You've proven your technology's functionality, raised an angel round of financing, created a pilot program, or maybe already launched a limited commercial deployment. Based on any one of these scenarios, you're ready to scale your company.

But now your next step forward is to evaluate prospective partners in the digital health industry that would best help your company, and you don't know where to start. The usual prospects—venture



investment, strategic technology players, payers, and providers—are unique entities with different priorities. It's also possible participants from each type of prospect would have views different from yours as to the overall objective, whether that is to land a unicorn valuation, procure deployment in a major healthcare system, integrate into a major tech platform, or overhaul the healthcare technology infrastructure.

You find a whiteboard and start making notes, outlining potential advantages and disadvantages of working with each partner. Meanwhile, you're also thinking about other challenges that lie ahead, like the payment and reimbursement landscape, regulatory uncertainties, data privacy concerns, and, of course, the company's significant capital needs.

This two-part article summarizes the key considerations that you may help point you to the right partner. Part one focuses

on venture investment and strategic technology players. Part two, which will appear in WSGR's next *Digital Health Report*, will focus on two other players—the payers and providers.

Partner Option 1: Venture Investment

Opportunities and Limitations

Agility and Disruption: Placing the daydreaming about unicorn-like valuations aside momentarily, you and your team agree that taking the traditional tech start-up path of venture first may provide you with the agility needed to overcome an inflexible healthcare system status quo. That has proven to be true in other entrenched industries such as transportation, communication, and banking. A directed focus to bring a refined and consumer-friendly product to market—without being overly concerned about

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the burdens of existing infrastructure or potentially lagging acceptance—is almost as enticing as the capital. In an industry synonymous with bureaucracy, there is a certain upside to the maxim that’s well-known in venture circles: *to the question of how you draw an owl: first, draw some circles, second, draw the rest of the owl.*

Core Competencies: Additionally, the shift to value-based care throughout the industry necessitates both (i) efficiency as an operating principle and (ii) a capacity to market to the public a broader awareness of the factors which constitute an individuals’ health. Because strategic efficiency and marketing are both commonly core skills that are demanded of venture-backed start-ups (especially where there has been a track record of success with other non-healthcare B2C technologies), there is significant appeal to applying the same concepts to healthcare, despite the complexity of the industry.

Healthcare Outsider: Of course, engaging with venture does raise the question of how to break through the healthcare industry’s significant barriers to entry. By itself, venture is not necessarily able to either drive adoption of technology by providers, or influence payer perspectives on the reimbursement or the “bundleability” of your technology in their payment structure. In this context it may seem difficult early on to not have a commercial or industry partner or champion. This also leads to the risk of attracting significant capital based on unproven potential, without having been forced to observe the real world application and acceptance of the technology, which may lead to the mismanagement of shareholder and investor expectations.

Exit Pressures: Venture may also be the instinctual first choice if you are looking to stand alone and remain unhindered by exclusive arrangements or obligations to a certain provider or payer. But when it comes to providing alone in the digital health arena, it is worth noting that there were no digital health IPOs in 2017 and only one in 2018: Chinese fitness

tracker and smartwatch maker, Huami, raised \$110 million in its IPO. While there has been significant M&A activity and consolidation, including some major testaments to the digital health investment hypothesis (e.g. Flatiron), a majority of the exits were to strategic acquirers, not financial acquirers. These market trends suggest that a stand-alone commercial path to an IPO may be less plausible for

most digital health companies, and that partnership and collaboration, even at the point of exit, will remain a hallmark of the industry for the foreseeable future.

Transactional Issues and Processes

Transactional Efficiency and Focus: A benefit of venture investment, at least relative to certain alternatives, is a

	Venture/ Financial Investors	Strategic Technology Partners (FAANG+)	Providers	Payer
Opportunities and Limitations				
Applicable Core Competencies	B2C experience with non-healthcare consumer products	Data security and data privacy expertise	Irreplaceable understanding of the provision of care	Irreplaceable understanding of the payment for care
Healthcare/ Insider Outsider	Outsider	Outsider regarding existing healthcare IT infrastructure, but Insider regarding IT deployments of like scale	Insider regarding provider workflow or quality of care, but not necessarily regarding payment	Insider regarding payment, but not necessarily provider workflow or quality of care
Interest in Digital Health Solutions and Compatibility	Returns/IRR	Become go-to/incumbent platform	Improvement of work flows and quality of care	Patient engagement and competition with other Payers
Corporate Strategy	Agility/Disruption	Technological Superiority/	Increase patient turnover and quality of care	Novel reimbursement strategies and cost-saving efficiencies
Deal Trade Offs				
Arduous Deal Terms	Dilution/Control	Rights of first refusal/offer/ negotiation and exceptions from drag-along in M&A context	Regulatory preparedness and established compliance	Rights of first refusal/offer/ negotiation in M&A context Exclusive licensing Arrangements
Expectations	Preferred treatment on liquidation; ability to guide business plan and growth	Technological integration and ongoing sharing of IP and know-how	Day-to-day assistive technology rather than status-quo-altering technology	Cost-reduction and improvement of customer experience
Process Related Concerns	Transactional Efficiency	Navigation of corporate structure and affiliate issues	Navigation of multi-stakeholder environment, where Provider may not have full decision-making authority	Desire for established and proven track record; focus on exclusive engagements

Potential Benefit
 Potential Challenge
 Potential Obstacle

certain predictability and transactional efficiency. While there is the usual negotiation of valuation, board seats, liquidation preferences, and all the other financing document requirements, certain matters that may otherwise be at play in a commercial deal or collaboration—regulatory approvals; the co-ownership, licensing, and co-development of intellectual property; or the integration into incumbent systems or existing technological architecture—would be tabled, at least temporarily.

Network and Preparedness: The ability to bring in sophisticated capital in the early growth stages, with limited back-and-forth as to regulatory strategy or IP crossover, is attractive. If the investor has ample industry experience, they should be able to provide introductions to other partners, which helps create an important bridge to end-users. However, venture deals should contemplate, incentivize, and be structured to anticipate strategic or commercial engagements with technology players, payers, or providers. Whether factored into protective provisions, milestone constructions, or other standard deal terms, investors and founders should facilitate future partnerships by including flexibility deal documents in anticipation of future collaborations.

Partner Option 2: Strategic Technology Players

Opportunities and Limitations

Acknowledgement of Market Opportunity: Here's a new scenario. Hypothetically, imagine your co-founder and CTO previously worked at [insert FAANG+ technology company here] before joining you at NewCo. She reminds the team that her former employer may be interested in a partnership or collaboration. You know it's no secret that many of the technology giants, including her previous employer, are interested in entering the healthcare space, and that a complete technological disruption of the healthcare status quo would benefit an advanced technology company like yours—not to mention the value of partnering with a market-leading technology giant.

Existing Engagement with Providers and Payers: You have also seen tech giants seeking to integrate with healthcare provider systems. The steps taken by big tech signals what their future roles may be in the healthcare space. It also reveals the advantages that could be derived from the exciting prospect of partnering with tech company platforms that have existing adoption among providers. For example, as reported by CNBC¹, Apple Chief Operating Officer Jeff Williams, has noted that “the willingness of health care institutions to work with Apple is a big deal, given the slow pace of change in medicine relative to other sectors...but what's more important about Apple's moves into the space is the mission behind it—view[ing] the future as consumers owning their own health data.” Google also recently launched the Cloud Healthcare API, which allows clinicians and researchers to collaborate with consumers. There's also exciting collaborations among technology players. For example Fitbit and Google announced a partnership in April to develop new consumer and enterprise digital health solutions.

Core Competencies: Partnering with an established technology company with strategic interests may also help your team develop the critical skills and competencies digital health companies need. Experience in areas like identity-driven solutions and systems (including blockchain solutions), data security, and privacy policies and related regulatory schemes could result in novel iterations of the technology and product, and also could help the strategic technology company involved deliver even greater value.

Healthcare Outsider and Exclusivity: Similar to what could transpire by taking the venture investment path, partnering with a technology leader, instead of a healthcare industry player could leave open the key questions of healthcare stakeholder engagement, including adoption and reimbursement. Plus, collaborating and integrating with specific technology players may limit future partnership options. And finally, if

you continue engaged in technological developments with a given big tech partner, you will need to balance your company's commitment to the existing partnership with the need for flexibility for future uses and deployments.

Transactional Issues and Processes

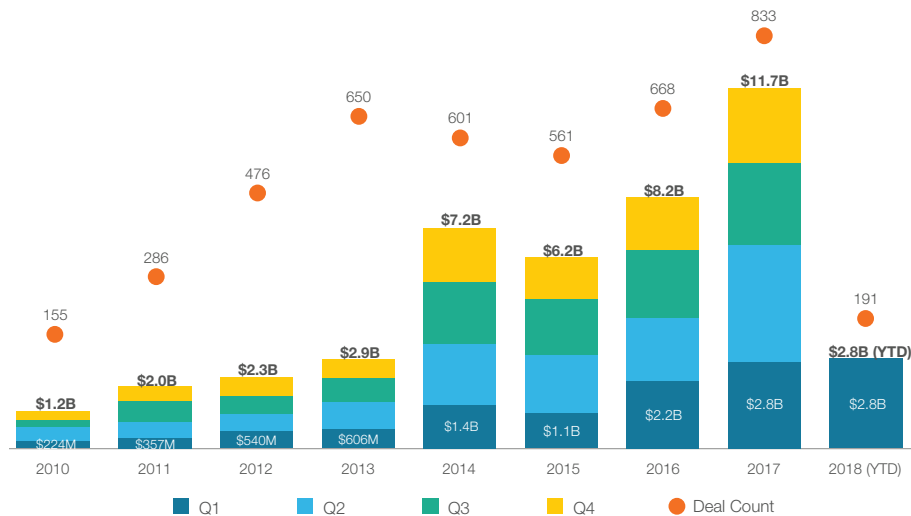
Detailed IP Negotiations: Engaging with a major technology player will inevitably lead to nuanced and complex negotiations around IP development, sharing, and ownership; the related know-how; and any related improvements. Whether in the context of an investment or a more comprehensive collaboration, negotiations with large, sophisticated technology companies may be uniquely challenging, and could lead to resource imbalances and deal leverage. Engagement with certain strategic technology partners also could prompt discussions of most-favored-nation commercial terms, or exclusivity for certain licenses or improvements developed during—or merely influenced by—the collaboration.

Special Strategic Rights: Strategic investment by technology players could also include related agreements regarding special rights in the context of an acquisition, including rights of first offer/rights of first refusal, carve-outs from typical drag-along obligations, nuanced confidentiality-sharing provisions, and acknowledgements of the strategic technology company's ability to engage with other partners without restriction.

Back to your whiteboard diagram, which is now starting to fill with marks and notes in different colors, you've now considered the first pair of prospective partners—procuring venture investment and collaborating with a strategic technology player. Soon enough, you'll want to add even more marks and notes to your diagram. In Part II of our two-part perspective, which we will publish in WSGR's next *Digital Health Report*, we'll discuss another pair of prospective partners in the healthcare industry—payers and providers.

¹<https://www.cnbc.com/2018/03/29/apple-health-records-product-expands-to-40-hospitals-implications.html>

Investment Trends in a Maturing Digital Health Market



Source: StartUp Health Insights Global Digital Health Funding Report 2018 Q1

By Brian Appel

Record Funding Pace in a Robust Ecosystem

The pace of investment in digital health companies continues to increase following a record-setting 2017, which saw more than \$11.7 billion of capital pour into the sector across 833 deals.¹ The torrid pace continued in the first quarter of 2018, as digital health companies closed on \$2.8 billion of investment in 191 deals, making it the biggest first quarter to date for the sector, with 60 deals more than Q1 2017.² The numbers reflect a continuing trend of steady growth since 2011, with investors becoming increasingly comfortable making larger investments in digital health companies as the sector matures.

While dollars invested in digital health in the first quarter of 2018 roughly match Q1 2017 numbers, if 2017's blockbuster \$914 million GRAIL deal is excluded, there would be approximately 47 percent

more investment in Q1 2018 compared to Q1 2017. The year 2018 is not lacking for megadeals either: the top ten digital health deals in the first quarter all involved fundraising in excess of \$50 million, constituting 42 percent of all dollars invested in the sector, and included four transactions surpassing \$100 million. This reflects a significantly increased pace compared to 2017, which saw only eight megadeals north of \$100 million, and only one such transaction (23andMe's \$250 million raise) occurring in the second half of 2017.

The record pace of funding is related to a greater number of maturing digital health companies in search of larger middle and late-stage financing rounds, but also reflects an increased number of active market participants. Data collected by StartUp Health, which tracks venture funding in the digital health sector, shows that the first quarter of 2018 recorded more repeat digital health investors than

ever before making a mix of new and follow-on investments, with more unique investors than in previous years. Forty investors participated in more than one digital health deal in the first quarter, with 33 of those participating in at least two deals. Founders Fund, NEA, and Khosla Ventures were the most active investors in the sector in the first quarter, logging five deals each. This was consistent with year-end 2017 numbers reflecting Khosla Ventures and Founders Fund along with GE Ventures, Sequoia, and YCombinator as the most active investors in the space.

A Maturing Market

Investment trends in 2017 and the beginning of 2018 indicate that the digital health sector continues to mature, with significantly more deals occurring at Series B and beyond. Year-end 2017 data from Startup Health indicates that for the first time since the platform began tracking digital health funding in 2010, double-digit deal counts were recorded at the Series B stage in each subsector tracked, with the exception of education and training. While most investment activity in Q1 2018 was still concentrated in early-stage deals, with Seed and Series A deals accounting for 61 percent of all first quarter deals, the number of mid-stage and late-stage deals saw increases as well. The average deal size of late-stage Series D+ deals increased by 60 percent in 2017, suggesting larger follow-on investments and increased investor comfort participating in larger rounds for mature companies with proven track records.³ This trend is consistent with a broader shift in healthcare investing towards expansion and later-stage deals. According to PricewaterhouseCoopers,

¹ StartUp Health Insights Global Digital Health Funding Report – 2017 Year End Report. See: <https://www.startuphealth.com/insights/>

² StartUp Health Insights Global Digital Health Funding Report 2018 Q1. See: <https://www.startuphealth.com/insights/>

³ RockHealth 2017 Year End Funding Report. See: <https://rockhealth.com/reports/2017-year-end-funding-report-the-end-of-the-beginning-of-digital-health/>

middle and later-stage transactions made up the majority of healthcare deals in the first quarter of 2018, though unlike the digital health sector, healthcare investing generally saw ongoing declines in early-stage activity.⁴

Certain subsectors within digital health have seen greater investment in later-stage financing rounds, with biometric data acquisition, wellness, and personalized health tallying the highest Q1 2018 numbers of mid-stage and late-stage investments. Increased later-stage activity in these subsectors is consistent with the emphasis prior to 2016 on delivering digital health solutions directly to the consumer, while early-stage investment in these areas has slowed as investors have increasingly concentrated on provider-focused solutions.

Ongoing Shift to Provider Solutions

In the first quarter of 2018, digital health companies offering provider-focused solutions received the most capital in financing rounds (\$1.42 billion), accounting for approximately 50.7 percent of the total dollars invested in the sector. This reflects an ongoing trend over the last two years: as investors have shifted from consumer wellness applications to solutions delivering tangible clinical impact, investment in monitoring, treating, and diagnosing diseases has increased significantly, as has investment in workflow functions designed to make healthcare practices more efficient. Strategic investors, in particular, have shifted their attention to clinically focused start-ups as they begin to see how technologies designed to affect patient behavior can generate better health outcomes and cost savings.⁵ In early 2018, investors poured

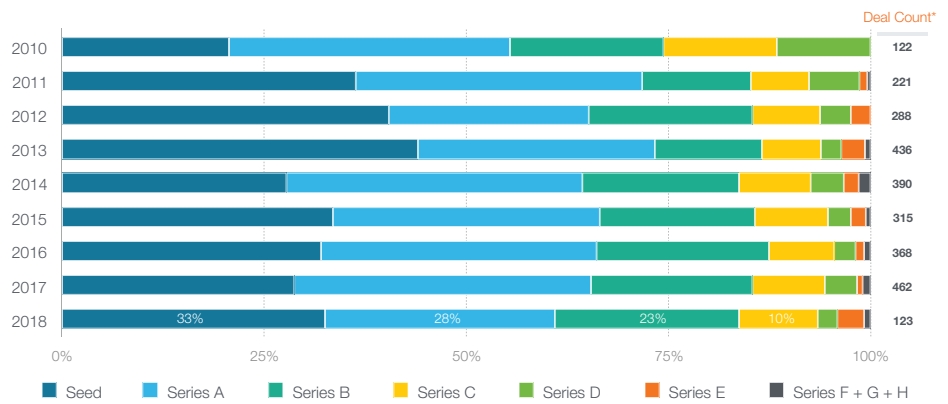
the most dollars into companies focused on biometric data acquisition (\$537 million, or 19.2 percent of the total dollars raised in the quarter), clinical workflow (\$472 million/16.8 percent), and administrative workflow (\$347 million/12.4 percent).

However, digital health companies focused on consumer health information accounted for \$1.6 billion of investment in 2017 (24.1 percent of all dollars invested in the sector) across 41 deals (7 percent of the total), suggesting that investors remained

support raised \$524 million, or 18.7 percent.

A Coming Uptick in Exit Activity?

The year 2017 saw no initial public offerings in the digital health sector, a somewhat surprising shift following successful recent IPOs of digital health pioneers like iRhythm and Teladoc. Mergers and acquisitions represent the other path for digital health liquidity events, but according to a report on digital health



Source: StartUp Health Insights Global Digital Health Funding Report 2018 Q1

convinced of the value proposition offered by B2C companies. In the first quarter of 2018, digital health companies providing a product or service to patients received \$949 million, or 33.9 percent of all dollars invested in the space—second only to provider-focused solutions. In terms of the most popular use cases for digital health technology in the first quarter of 2018, genomics applications received \$565 million, or 20.2 percent of total capital raised in Q1; diagnostic/screening start-ups raised \$539 million, or 19.3 percent; and companies providing clinical decision

trends by CB Insights, the number of M&A exits in the sector dropped significantly to 132 in 2017, down from 145 deals in 2016.⁶ Over the last two years, digital health M&A has been on the decline as a result of increasing available private capital (as detailed above), high valuations in the sector, and tentativeness from likely acquirers. According to data compiled by Silicon Valley Bank, this trend is contrary to patterns in other parts of the healthcare market, where M&A activity remains steady.⁷

⁴ PriceWaterhouseCoopers Healthcare MoneyTree Report Q1 2018. See: <https://www.pwc.com/us/en/health-industries/publications/assets/pwc-healthcare-money-tree-report-q1-18.pdf>

⁵ Silicon Valley Bank: Consumer Digital Health: How Market Shift Is Leading to New Opportunities. See: <https://www.svb.com/digital-health-report/>

⁶ CB Insights: 2018 Digital Health Trends. See: <https://www.cbinsights.com/research/briefing/trends-in-digital-health-2018/>

⁷ Silicon Valley Bank: Trends in Healthcare Investments and Exits 2018. See: <https://www.svb.com/healthcare-investments-exits-report/>

Investment Trends in a Maturing Digital Health Market *(continued from page 5)*

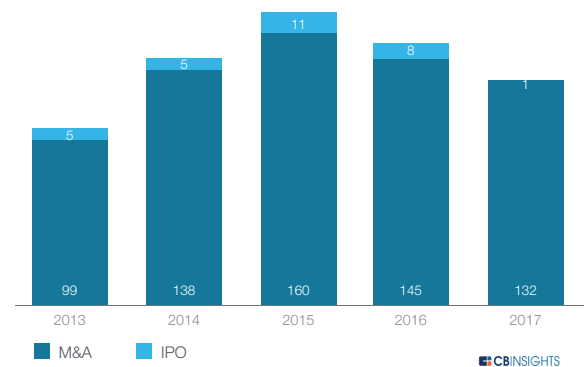
However, a few factors suggest that 2018 and 2019 may see a reversal of the trend. First, following the passage in late 2017 of federal tax reform legislation providing for cash repatriation at reduced rates, large tech and healthcare corporations such as Apple, Microsoft, Pfizer, Johnson & Johnson, and Merck are bringing significant sums of money back to the U.S. from overseas. While much of the repatriated funds have been used for stock repurchases and other purposes, large corporates can put some of the funds to work in mergers and acquisitions. Second, with digital health companies receiving more mid- and late-stage investment in 2017 and 2018 as detailed above, there may be increasing pressure for exit activity throughout 2018 and into 2019.

Since 2015, companies focused on enhancing electronic health record

functionality or improving clinical workflow have been the most popular acquisition targets for healthcare incumbents. According to market analysis by CB Insights, going forward in 2018, pharma corporates could target digital health companies to reach consumers directly and find AI expertise; medical device strategics could acquire digital health companies for their expertise in software, user experience and AI; while tech companies, such as Apple, Microsoft, and Amazon, could look at acquisitions to bolt on companies with expertise in healthcare analytics and data sources.

Whatever the case, the constant and increasing flow of venture capital into

Digital health first exits, 2013 - 2017



Source: CB Insights 2018 Digital Health Trends Report

the sector means more innovation in all subverticals of digital health, and no dearth of investment or acquisition opportunities for potential acquirers as they continue to make sense of the space and understand how digital health technologies fit within their existing product or service offerings.

Software Components of Digital Health Innovations Raise Unique Questions for Standard University Technology Licenses

By Rachel Landy

Imagine you have spent your graduate school years toiling away in a university research lab developing a groundbreaking digital health innovation. You and another lab worker are convinced that your latest discovery, a smart medical device with embedded software that connects to a mobile app, will forever change diagnostics. Having developed a prototype, including the embedded software and mobile app, you decide to form a company to commercialize the product. You have heard that the university will likely take ownership over

all of your intellectual property rights (you do vaguely recall seeing something to that effect in the paperwork you signed when you first enrolled), but will grant you a license on its standard terms so that you may pursue your dreams.

You approach the university tech transfer office to inquire about a license. You thought you'd be able to sign it without having to consult an attorney, but after discussing the product with the licensing officer, you become skeptical as the officer focuses on ascribing an appropriate value to the software code you have written while at the same time mentioning that

most of the office's deals don't involve a software component.

The line between life sciences (including traditional medical devices) and software companies has blurred in smart devices and in the digital health space, and as the officer indicated, many university licenses—which historically focused on patentable inventions—have failed to catch up. Many provisions in the form agreements that universities typically provide are not applicable to software licensing, resulting in far-reaching diligence and commercialization issues. Below, we highlight a few of the issues to address

when your university license includes a license to software.

1. *License Rights.* A typical university license grant mirrors a standard patent license grant, enumerating the rights afforded to patent owners (to make, have made, use, import, and offer for sale). Software, however, is primarily protected under copyright and therefore, the grant of rights should reflect the rights associated with a work of authorship: to reproduce, publicly display, publicly perform, create derivative works, and distribute to the public.
2. *Field of Use.* A typical patent license limits the licensee-company's exercise of the licensed patent rights to a specified field of use. For example, a licensee to a drug delivery technology conceived in a research lab may be limited to delivery of therapeutic agents for purposes of cancer treatment. In contrast, where licensed software is incorporated into a larger code base, it can be practically very difficult for a licensee-company to comply with field-of-use limitations that a university may wish to impose, as doing so would require the company to segregate, track and otherwise treat the licensed software code in its code base separately from all other portions of that code base. Making the problem worse, it is not unusual for a code from one product to find its way into other company products.
3. *Sublicensing Conditions.* University licenses often contain extensive conditions on the licensee-company's ability to grant sublicenses. These might include a requirement to provide copies of sublicenses to the university, taking on liability for acts of sublicensees, and requiring each sublicensee comply with the university license. Such conditions can make sense in a patent context, where sublicenses are limited in number and typically occur in connection with transformative business transactions. However, in the software context (where each unit of product is sold pursuant to an end user license), these conditions are neither appropriate nor scalable.

4. *Economics.* As noted above, university agreements may not be drafted in a way that recognizes the unique role of a license in the overall commercialization of software (as opposed to products sold pursuant to a patent license). This point is particularly salient when reviewing customary economic provisions in a university license, which distinguish between two different revenue sources: (i) royalties paid on the licensee-company's unit sales of products; and (ii) a percentage of revenues the licensee-company receives from sublicensees (referred to as "sublicensing revenues"). There can be a very significant difference in the two rates, with the latter being higher (most universities take the position that they should receive 20-50 percent of the sublicense revenues). A company should consider the following when negotiating these provisions:
 - a. Royalty rates are often set with the underlying notion that an exclusive patent license from the university gives the licensee exclusivity in the relevant market. However, that same exclusivity does not attach in a pure copyright license—a third-party developer could create the same or similar functionality without infringing the underlying copyright. As a result, the rate should be reduced to reflect the nature of the rights granted.
 - b. Many ordinary course commercial arrangements, such as "OEM" distribution agreements pursuant to which software code is incorporated into a third party product, could trigger a sublicensing revenue share, as opposed to a lower net sales royalty rate. Incurring royalty obligations under the higher sublicensing rate for these ordinary course transactions is likely to be commercially unworkable.
 - c. The company should ensure that any ordinary course end user licenses are subject to the unit sales royalty rate and not the sublicensing revenue rate, which is intended to capture value unrelated to sale of the underlying product.

5. *Rights upon Termination.* Upon termination of a university license, a patent licensee is usually prohibited from exercising further rights and may also be required to terminate all sublicenses. Again, that construct does not translate well to the software for a number of reasons. First, once software is incorporated into a code base, it cannot easily be replaced. Engineering snippets of code out could require a significant development expense. Second, once a license is granted to a user, it often cannot practically be terminated (particularly if the software is made available for download by customers). Once the code is downloaded, the company has no practical way to stop the consumer from using the code.
6. *United States Government Rights.* Under the Bayh-Dole Act (codified at 35 U.S.C. Section 200–212, and implemented by 37 C.F.R. 401), a university that receives federal grant funding may elect to take ownership of patentable inventions made with that funding, but in doing so becomes subject to various restrictions. These include retaining title to subject inventions and requiring that unless an exemption is obtained, all products that embody that invention must be manufactured substantially in the U.S. Universities often include extensive language regarding these terms in license agreements, all of which are largely inapplicable to copyright and, by extension, software. These should be deleted.

University licensing historically focused on patents, and as a result, university license agreements were drafted to apply to patents. However, as digital health becomes more prevalent, university licenses will increasingly need to contemplate software components and the distinct legal landscape in which software is licensed. Until then, licensing software from universities will require significant revisions to form license agreements.

Medical Device Conference 2018

Join us at WSGR's 26th Annual Medical Device Conference, which is scheduled to be held on **Thursday, June 21**, and **Friday, June 22**. This year's Conference will focus on strategies that can help medtech start-ups address the challenges they face today. Top industry CEOs, venture capitalists, industry strategists, investment bankers, and market analysts will offer their insights and expertise in a series of panels and presentations.

To register, or for more information about speakers and program topics, visit <http://mdc.wsgrvents.com/>.



The *Digital Health Report* is developed and reviewed by a team of attorneys from the firm's corporate, intellectual property, litigation, and regulatory departments, including the individuals listed below.

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