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# The valorization of non-patent intellectual property in academic medical centers

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**Abstract**

Turning university research output into useful products such as drugs, devices and diagnostics requires skills, knowledge, and resources traditionally attributed to private industry. When it comes to intangibles such as care delivery models, informatics and algorithms, and the software behind smart wearables, the commercialization challenges are even greater. With notable exceptions, Academic Medical Centers have typically not excelled in advancing commercialization of such non-patent intellectual property (IP). We believe that this is in part because the traditional closed form university IP policy, formulated since Bayh–Dole (1980), is ill-suited to non-patent IP. In this paper, we reflect on the evolving challenges that new forms of healthcare-related discoveries, specifically non-patent IP, are placing on the traditional university intellectual property and technology transfer regime, and to offer suggestions on how universities can begin to modernize their IP policies to support the valorization of non-patent IP.

**Keywords** Non-patent intellectual property · University technology transfer policies · Work-for-hire policy · Academic medical centers

**JEL Classification** L26 · M13 · O31 · O32 · O34 · O36

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## 1 Introduction

University researchers in academic medical centers (AMCs) generate the vast amount of basic knowledge on health and disease processes, forming the national bastion for scientific growth and education. In this process, universities expend a significant amount of federal dollars. In 2018, the National Science Foundation estimated total university spending of $79 billion, with about $42 billion originating from the federal government (NSF 2019). Johns Hopkins University (JHU), including the Applied Physics Laboratory (APL), led total expenditures by a single institution nationally, at approximately $2.6 billion. However, generating knowledge for the sake of promoting scientific advancement does not always translate into the commercialization of these discoveries and the pragmatic improvements they bring.

Turning research output into useful products such as drugs, devices and diagnostics requires skills, knowledge, and resources traditionally attributed to private industry. When it comes to intangibles such as care delivery models, informatics and algorithms, and the intelligent software behind smart wearables, the commercialization challenges from intellectual property management to venture funding are even greater. With notable exceptions, AMCs have typically not excelled in advancing commercial products. Indeed, the Association of University Technology Managers often notes gaps between research expenditures and commercialization success metrics such as licensing revenue and businesses creation (Silva and Ramos 2018).

The purpose of this paper is to reflect on the evolving challenges that new forms of healthcare-related discoveries, specifically non-patent IP, are placing on the traditional university intellectual property and technology transfer regime, and to offer suggestions how universities can modernize their IP policies to support the commercialization of non-patent IP. We make these observations from a combined 6 decades of experience in academic discovery commercialization, research and practice, founding half-a-dozen start-ups in the devices, diagnostics, therapeutic, and informatics domains, mentoring more than 2 dozen healthcare-related startups, and participating on faculty advisory boards of large university technology transfer offices.

## 2 Innovation commercialization in academic medical centers

The Bayh–Dole Act (P.L. 96-517), also known as the University and Small Business Patent Procedures Act of 1980, or the Patent and Trademark Act Amendments of 1980, was introduced to incentivize private investments for universities receiving federal dollars for research (AAUP 2014). The Act, designed to accelerate the commercialization of technologies, gave universities the right to *claim* ownership to inventions within their institutions that were supported by federal funds. Importantly, the Act did *not* automatically grant universities ownership of faculty inventions, a controversial issue that was challenged and upheld by the U.S. Supreme Court in 2011 in Stanford v. Roche (Valdivia 2013).

As a result, universities resolved the rights issue with their faculty by promulgating policies and procedures, sometimes without the input of faculty governance bodies. Usually, these procedures involve the faculty voluntarily disclosing their inventions in an explicit agreement to turn over the property rights to their discoveries, in exchange for support of the costly and time consuming process of establishing intellectual property, which individual faculty are not equipped to bear. University technology transfer offices (TTO) were formed to support faculty disclosure, patent processing and external licensing. Subsequent to the Act, patent and licensing numbers by AMCs increased, although conclusions regarding commercialization productivity has remained a disputed subject. TTOs have been characterized as dual agents, representing the university administration that give them their charters and the faculty body whose discoveries they are tasked to help commercialize (Phan and Siegel 2006). As we will discuss in a later section, because of the way University TTOs are structured and incentivized, they have become the *sole* agents of the university administration and deal with faculty discovery as works for hire.[1] Even so, studies have documented inconsistent results from TTOs, with as many as 87% not generating enough revenue to cover their own operating expenses (Godfrey et al. 2020). Critics have pointed out that the commercial impact of AMC discovery has been limited by the relative lack of expertise among faculty and the TTOs that commercialize their discoveries in late-stage technology development, lack of robust patent portfolios to broadly protect intellectual property, and lack of expertise in business model innovation (AAUP 2014; Feldman et al. 2007).

Studies of TTO performance that examined licensing revenue and start-up formation metrics have generally failed to demonstrate the consistent success of AMCs in technology commercialization after Bayh-Dole. In a recent study that evaluated the economic impact of university-licensed life science start-ups, researchers noted large differences in productivity and successes based on university locations regionally (Feldman et al. 2007). This suggests that geography and the supporting ecosystem around life science start-ups may have had more to do with their outcomes than the universities from which they were spawned. When evaluated based on the economic success of start-up liquidity events such as initial public offerings (IPOs), research has consistently reported a strong geographic influence in the U.S., with clear advantages associated with such hubs as Boston and the San Francisco Bay Area. The conclusions of these studies suggest that success metrics emphasizing longer-term economic outcomes, rather than the simple numeric tallying of patents, licenses, and start-up formation, may be more appropriate for university-originated technologies.

All this said, AMCs have admittedly generated notable discoveries with long term clinical and commercial impact, including the foundations of recombinant DNA that, provide a technology platform spanning products and industries (Pan and Chen 2017). In fact, the vast majority of commercial successes from AMCs have emerged from *biotechnology* advances, including some therapeutics. In the early 2000's, AMC innovations included some notable vaccines, specifically those preventing human papilloma virus (HPV) and rotavirus infections. Silva and Ramos (2018) suggest that vaccines originating from AMCs may be the logical result of the vast amount of host-pathogen knowledge generated by decades-long basic and translational studies, borne from single investigators scientific programs in AMCs; activities not frequently pursued by commercial interests (AAUP 2014), rather than from the presence of technology transfer offices. Again, it is notable that the top academic inventors were small in number and worked collaboratively in one center. For example, Carl June, David Porter, Michael Milone and Bruce Levine were co-awarded 9 patents on T cell therapies at the University of Pennsylvania, which became the basis for

[1] This is not the case for *all* universities, as illustrated in the University of Pittsburgh case, where faculty push back on a similar policy caused it to be withdrawn by the administration. See, https://techtransfercentral.com/reprints/ttt/1114-ip-assignment/ (accessed: 9/9/2020).

current immunotherapy models (Kesselheim and Avorn 2005). The importance and effect of star scientists have been documented in numerous studies, going back to, at least, Zucker and Darby (1996).

These observations suggest that that one way to improve commercialization success is for AMCs is to focus their discovery pipelines around star scientists and building knowledge clusters around them. Similarly, some researchers have suggested that AMCs strategically position commercialization efforts around specific programmatic scientific strengths, especially in universities not located within geographically defined "innovation hubs," such as the San Francisco Bay Area and Boston (Feldman et al. 2007).

Based on our reading of the literature, we find that successful university technology transfers offices address their missions in strategic, rather than purely financial, terms. Perhaps the best example is that of Stanford's licensing of recombinant DNA methods as part of the Cohen-Boyer licensing program (Pan and Chen 2017). Stanford licensed the technology to 468 companies, generating $255 million in licensing revenue over 25 years, which was in turn used to invest in growing research infrastructure (Pan and Chen 2017). Besides being an economic success, the strategy served to fulfill the four primary goals of the University in the 1970's, which were described by Feldman et al. (2007) as, congruence with public service priorities, incentives to commercialize for timely public benefit, manage to assure minimal biohazards, and provide income to the University for growing education and research. This licensing "gold standard" illustrates how an effective TTO strategy can grow institutional and regional innovation ecosystems. Indeed, the Stanford Office of Technology Licensing describes their current strategy as one that seeks broad overall use, not maximum financial return, with a focus on longer-term university gains that are broadly defined.[2] This approach is likely responsible for fostering a ubiquitous university culture of innovation that Stanford is so well known for.

The Stanford example, coupled with the fact that the productivity of U.S.-based university technology transfer offices are characterized by constant returns to scale, with the variations due to such factors as regional and institutional differences (Siegel et al. 2003), suggests that the purpose of the TTO should be to foster and support *faculty* in their pursuit of commercialization activities. This point is particularly relevant to our later discussion on non-patent intellectual property, in which the circumscription of property rights become more complex and difficult to manage. In sum, the singular focus on revenue generation through licensing or startup equity may be congruent with TTO performance objectives but is unlikely to help build a portfolio of successful commercial ventures at AMCs, since the required risky investments are unlikely to yield positive short-term (i.e., within the average tenure of a TTO officer) returns. Indeed, rather than financial returns, an explicit mission of supporting faculty activities in commercialization will likely have greater positive spillovers for faculty morale, societal perceptions of the usefulness of university research (see, Fraser et al. 2018), and foster a culture of innovation in universities (Guerrero and Urbano 2019).

## 2.1 Faculty inventorship and university intellectual property policy

The Bayh–Dole Act of 1980 temporally corresponded with the emergence and growth of the molecular biology and "genetic era", which further encouraged TTOs to become

[2] https://otl.stanford.edu/history-otl (accessed 3/15/2020).

proficient in the patenting and licensing of faculty-disclosed IP. Patents provide for an exclusive period of legal protection for any "new and useful process, machine, manufacture, or composition of matter" (Litan et al. 2007). Overtime, the definition of what was patentable changed, especially in the limiting of "upstream" molecular targets and genes (Van Norman and Eisenkot 2017). In the last decade, the scientific focus of academic researchers has expanded to include advances typified by the "digital era", involving software, databases, process improvements and educational tools. These inventions do not easily fit a patent regime that has been relatively static since the Method of Producing Potash, granted to Samuel Hopkins in 1790. These growing populations of non-patent IP, especially in AMCs, has challenged the work of TTOs. In Table 1, we summarize the characteristics of patent, trade secret and copyright IP, with examples of what are typical in AMCs. A glance tell us why we think that the growth of non-patent IP is so challenging to the traditional TTO business model. These non-patent IP are not severable and thus, not easily tradable.

More pointedly, many institutions of higher learning, such as JHU, consider faculty IP as products of "work for hire." That is, as part of employment contracts, faculty pre-assign to the university rights to all IP generated as part of, or related to, their work. In recent years universities have also migrated towards the broadest definition of IP; the JHU policy defines it as "any new and useful process, machine, composition of matter, life form, article of manufacture, software, copyrighted work or tangible property," including things like devices, chemical compounds, drugs, data sets, software, etc. that may, or may *not* be either patentable or copyrightable (Appendix 1). By accepting a faculty appointment, an individual acknowledges that the university owns the rights, title and interest to all her IP developed from, supported by, or channeled through the University. The original IP policy also stated that when an invention is conceived of and developed *in the absence of* university financial (or other) support, the individual retains ownership rights.

What is likely to be the subject of disagreement between universities and faculty inventors lies in the area of non-patent IP. When software or other unpatentable tangible research property (such as datasets) are developed with university support, JHU retains the rights, including copyrights. The same policy states that when a faculty member creates copyrightable works in written or electronic form that emerge from their teaching activities or research, including textbooks, and journal articles without support from the university or other sponsored research agency, rights are retained by the faculty member, and may be assigned elsewhere. "Without support" is disputable since faculty often write articles, teaching material, code, and conduct statistical analyses on university-provided computers. A subsequent clarification of the IP policy (expanded upon below), provides the university with broadened rights to ownership regardless of support, provided that the product is associated with faculty's role (expertise). Unfortunately, when faculty sign their employment contracts, they are routinely pointed to original IP policies, but typically remain unaware of the series of clarifications that have broadened University rights to faculty intellectual works.

One can envision yet more confusion arising from other interpretations. For instance, a university can clearly claim ownership of a potential druggable target discovered by a faculty in a university lab. Less clear is the search algorithm, coded by the faculty at home, validating the target against a chemical library. Should the latter be disclosed? The answer could be 'yes', based on the expanded definition of ownership and IP. In fact, the exception to a university's IP policy related to journal articles for example, result from the acknowledgement of tradition and precedent rather than a strict interpretation of Bayh–Dole or other legislation. At issue is the capturing of value from a faculty's intellectual capital,

**Table 1** Characteristics and AMC examples of patents, trade secrets and copyrights

| | Patents | Trade secrets | Copyrights |
|---|---|---|---|
| Protection of IP rights | Registration required for protection | Requires the owner to keep a secret | No registration required; material existence is enough proof of copyright |
| Innovations | New process, machine, manufacture or composition of matter, or new and useful improvement | Information and processes that are confidential that give the organization or business a competitive advantage | Creative works, including books, music, paintings, architecture, certain computer software |
| Common AMC IP | Drugs, devices, diagnostic tools or components thereof | Healthcare delivery processes, datasets, algorithms | Software, applications, educational material (books, videos, podcasts) |
| Requirements | Novel, useful, non-obvious | Confidentiality | Expressed in a tangible medium of expression (ex: written, recorded) |
| Duration of Protection | About 20 years | Until disclosure | 70 years beyond life of creator |

Adapted from Litan et al. (2007)

**Table 2** Valorization processes and needs in academic medical centers

| | Elements |
|---|---|
| IP protection | Faculty education, faculty disclosure, disclosure vetting (inventorship adjudication, novelty, prioritization), patenting (researching, drafting, submission, tracking) |
| IP management | Marketing, negotiation, licensing, milestone tracking, revenue tracking |
| Copyrighting | Faculty education, disclosure, registration |
| Faculty contracts and agreements | Materials transfer, confidentiality and non-disclosure |
| Corporate partnerships | External relations, programmatic alignments, contracts |
| Sponsored research | Contracts with industry |
| New venture creation | Ideation, team building, business model development, financing |
| Regional relationships | Networking, relationship management, agreements |

which is distinct from the product of her mental capacity (i.e., her ideas). While few universities historically sought to commercialize non-patent IP, the growth of digital platforms and innovations emergent from educational tools and software has more recently complicated IP policies and commercialization pathways, creating both opportunity and challenge.

## 2.2 The role of technology transfer offices in academic medical centers

In AMCs, employment contracts require faculty to disclose inventions and potentially protectable IP to the university TTO or equivalent office. Many of the processes to commercialize discoveries require skills outside of patent processing, to include business development, product and licensing strategy and interactions or negotiations with external entities. Following the example of such institutions as the Wisconsin Alumni Research Foundation (the TTO for the University of Wisconsin system), universities have expanded their TTO roles to embrace commercialization and external relations.[3] Such is the case with JHU, which developed Johns Hopkins Technology Ventures over the course of a decade to handle typical technology transfer, *and* business development and corporate partnership activities; more than doubling the personnel and budget devoted to these activities. These expansions have increased the ability of universities to support faculty discovery commercialization and to claim the value being created. Table 2 lists some of the many services and requirements of the commercialization process in AMCs.

There are many processes involved in commercializing patent and non-patent innovations, with skill sets required from multiple disciplines, including scientific, legal, and business. The model that most universities have established gives their TTOs central responsibility, if not a relative monopoly in decision–making if a faculty member chooses to use their support services. In a setting in which TTO personnel and resources are limited, many universities have made strategic and tactical errors in patenting and licensing. For example, limited finances often meant that Patent Cooperation Treaty (PCT) filings are delayed or not filed. In a 'first-to-file' regime, this problem limits the value of an invention

[3] https://www.marshallip.com/content/uploads/2018/03/IAM_the_-future-of-tech-transfer_2018.pdf (accessed 8/20/2020).

or worse, exposes it to dissemination risk by international competitors. Recognizing that innovation activities are larger than what can be enabled through a single office (recall that the JHU research enterprise is $2.6 billion a year), some universities have established programmatic initiatives and accelerators that attempt to integrate faculty research activities with business development and other aspects of entrepreneurship (Markman et al. 2012). We argue that such decentralized, and increasingly open, innovation activities with more faculty engagement is critical to the commercialization success of non-patent IP in AMCs, such as healthcare process improvements, health delivery models, and digital innovations.

Traditionally, TTOs have operated on a revenue maximization business model (Markman et al. 2012; Evans et al. 2015). Coupled with an *annual* budget cycle, this meant that TTO personnel are incentivized to focus on 'home runs' with immediate licensing potential. Some scholars have pointed out that such revenue models privilege short-term licensing gain at the expense of knowledge creation, societal impact, more expansive IP portfolio strategies, and inappropriately represents the commercialization path as a linear process, in which research leads to invention, disclosure, and licensing for revenue (Litan et al. 2007). This method of managing technology transfer overly simplifies the challenges that new academic entrepreneurs who must face and discourages them from fully engaging in the more realistic process of building value through strategic pivots, learning from failure, business modeling, and long-term planning; all the processes that are disproportionately vital for commercializing non-patent IP. Next, we discuss the unique challenges faced by AMCs to make a case for more liberal IP policies as the means of incentivizing the learning journey for faculty.

### 2.3 The unique aspects of non-patent intellectual property

Intellectual property refers specifically to the ownership rights that accompany the creation of knowledge subject matter. These rights that attach to *tangible* inventions, coming with a 'recipe' for production, are expressed as patents, which confer inventors the legal means to exclude or transfer to others for their use. Patents are, therefore, severable, just like any real asset. Against this backdrop are non-patent IP inventions that include works of authorship (books, journal articles), healthcare trade secrets (processes, data, delivery models), educational materials (books, recorded lectures, podcasts), and digital tools or software. Technology transfer offices have historically not considered these assets to be a fertile ground for generating short-term revenues, and so have either ignored them, not enforced disclosures, or simply back-assigned the rights to the faculty. Increasingly, and as a result of growth in the digital era, universities are interested in owning, and commercializing faculty non-patent IP. In fact, the Association of Universities in the Netherlands, following European Union practice, uses the word, "valorisation" or to make useful, in describing the rationale for commercializing university-based discoveries.[4] Valorization is broader than commercialization because it recognizes that value created from some discoveries can far exceed that of the immediate financial gain. Financial gain is the producer's surplus whereas the calculus of valorization includes the consumer surplus. In the case of non-patent IP, valorization makes more sense because value in, for example, teaching materials, exceeds the financial gain from tuition to the university to include the uplifting of societal capacity for future productivity. Similarly, the introduction of new health service models create value

[4] https://www.vsnu.nl/en_GB/f_c_valorisatie.html (accessed 9/1/2020).

beyond what can be billed to patients and payers to include spillovers into general community wellbeing and health. More significantly, we believe that among all types of IP, non-patent IP is particularly amenable to the benefits of open innovation (Carayannis and Meissner 2017). Open innovation involves a continuous learning process in which inventors, in interacting with users and other stakeholders (regulators, vendors, other inventors), collaboratively bring their inventions to the marketplace (Oliver et al. 2020). Open innovation therefore requires the unfettered participation of users, since it is only in their hands of that context-specific innovations, which characterize non-patent IP, find their first-best-use (Henkel and von Hippel 2004). Second, the maturation of entrepreneurial capabilities among inventors is accelerated in 'innovation spaces' (Kruger and Steyn 2019), which are open to the free flow of ideas from non-market stakeholders and market participants alike. Closed form (traditional) policies attached to patent IP do not support open innovation systems because the inevitable network of interests generated by these systems require the writing of complex ownership claims that increases the costs of participating in such collaborations. Take, for example, Massive Open Online Courses (MOOC).

The immense popularity of online courses supported by platforms such as EduX or Coursera have seen universities attempting to extend their non-patent IP claims into this domain (Schmidt 2013). These initiatives have yielded unique opportunities, and challenges to technology transfer offices and the technology transfer process in AMC environments. To explain this, we highlight the following relevant features of non-patent IP:

a. Non-patent IP is inextricably linked to faculty knowledge and experience, which creates overlapping issues regarding the faculty ownership of their ideas and employment obligations.
b. Success in commercializing non-patent IP is dependent on the business model that often requires the faculty's voluntary participation.
c. Success in commercializing non-patent IP is dependent on being administered in a decentralized technology dissemination model
d. Non-patent IP has a bigger potential for broader societal impact in an open-access environment, which a traditional patent-like regime (restrictions of dissemination rights, severability of asset rights, and so on) is likely to be ill-suited.

#### 2.3.1 Non-patent IP is inextricably linked to faculty knowledge

Unlike patent-protected IP, with severable rights and tradability, non-patent IP represents works of authorship, including books, articles, podcasts, recorded lectures, educational tools and materials, and software. This typically emanates from many years of scholarly work and knowledge; the value of the work is associated with dissemination, which is tied to the faculty-inventor as subject-matter expert in a scientific or healthcare field. The claiming of IP ownership by the university has implications for academic freedom. More importantly, limited avenues for monetization means that the restrictions on the right to freely disseminate, in a standard patent regime, is unlikely to be proportional to the potential commercial benefits.

Historically, faculty as authors retain non-patent IP rights for copyrighting or assigning the rights of work to another entity, such as when they publish journal articles or textbooks. With increased interest in retaining rights to certain types of non-patent IP, such as educational materials (lectures) and programmatic materials that can be presented in a scalable form, some prominent universities, including Johns Hopkins, have seen it necessary to clarify their IP policies to differentiate between types of non-patent IP. The JHU IP policy, clarified in 2014, states that the university distinguishes between literary (academic) works and educational materials ("Appendix 1"), such that it, "… does not consider educational materials to be traditional literary or scholarly works, and [that] Educational materials include online course materials, lecture materials, educational web sites, videos, and manuals (… not an exhaustive list) [and] the author will be granted a nonexclusive license to his/her own materials as a derivative in traditional works (such as books), but the university retains rights for commercialization in other media." This has enabled the university to enter into licensing agreements with online educational platforms such as Coursera, and to license digital tools that emanate from faculty academic programs focused on behavioral health, decision support, and so on. In some instances we are aware of,[5] the policy has resulted in faculty been administratively forced to enter into licensing agreements to commercialize their educational materials. As well, the policy makes faculty objections to the way the material were presented easily ignored. Interestingly, the commercialization of faculty generated content may work against the revenue models of tuition dependent academic units. No one has figured out how the licensing of faculty content to MOOC platforms limit the ability to charge high tuition dollars in the classroom.

In response to tensions over control of educational scholarship materials, the American Association of University Professors (AAUP) drafted a report in 2014. They point out that after the U.S. Supreme Court ruling in Stanford v. Roche (2011) the Bayh-Dole Act did not automatically grant the university rights to faculty scholarship, as had been claimed by many institutions (Valdivia 2013), and suggest that policies giving university ownership of scholarly works changes the employment relationship and restricts academic freedom. Specifically, "administrative efforts to control the fruits of faculty scholarship augur a sea change in faculty employment conditions, one too often imposed without negotiation or consent. Indeed, underlying those developments is an administrative conviction that faculty members are not independent scholars, teachers, and researchers but rather employees no different from those working in for-profit corporations that exist for the benefit of investors" (AAUP 2014, pg. 1). To balance the importance of university economic sustainability against academic freedom, we believe that universities must err on the side of academic freedom and faculty innovation, since this is the cornerstone of a university's raison d'être. From where we sit, the current model of technology transfer of non-patent IP rights overly weighs administrative control over faculty innovation.

### 2.3.2 Success in commercializing non-patent IP requires the faculty's voluntary participation

One may assume that decisions involving faculty works would necessitate agreement and collaboration by all parties, but this has not necessarily proceeded as such. First, informal conversations with colleagues in peer universities suggest that such policies have not been disseminated and distributed clearly enough for faculty to plan on and understand their implications, including the longer-term implications that can survive faculty departure from the university.

Consider a hypothetical in which a faculty member, a world-renowned expert in translational oncology and decision-support, creates a body of knowledge demonstrating that

[5] The sources have asked for confidentiality.

early detection of a specific biomarker predicts a high likelihood that a particular drug can be highly effective for those patients that express the marker. The university might consider exclusively licensing the dataset and algorithms to a therapeutic company to support their development of the drug and its subsequent marketing efforts. Such non-patent IP can potentially generate large revenues for the university but limit dissemination to other therapeutic companies, oncology specialty centers, and even general health providers. The secondary effect of such exclusivity is the slowdown in knowledge accumulation since decision support systems of this type become more accurate with accumulated use. More to this example; knowledge of the biomarker is in the public domain and not patentable, whereas the new data and digital algorithm can be replicated unless the data is protected, together with sequestration of the accompanying know-how (the faculty member's knowledge, experience, and insight). Accordingly, the licensee will require the faculty member's cooperation in implementing the biomarker into the final stages of drug development, and to 'lock in' the value of the drug by limiting the dissemination of further knowledge in the pathway. Being an expert in the field, this faculty member might have envisioned a broader impact of her work than what would have been realized in the licensing deal. This example illustrates how administrative decision making could dramatically alter the course of an academic career and the development of therapies with broad societal impact. In effect, an exclusive license would maximize the financial value of the discovery to the university while attenuating the value to society, whereas a non-exclusive license might maximize the value to society even though it would reduce the revenue for the university. This is the spirit in which valorization (rather than commercialization) as a strategic objective for non-patent IP technology transfer would operate.

In a number of settings, faculty have had little agency when TTOs have issued exclusive licensing for non-patent-protected products that require continued faculty feedback and cooperation to implement. This is particularly important when a certain amount of value in the license depends on faculty backing to assure product validity. For example, in digital health, platform companies often look for triage and diagnostic algorithms that add value to their platforms. These algorithms cannot be developed without the cooperation of clinicians or the patient data they generate from their practices. So these companies often look to AMCs for algorithms that have been proven effective in helping patients, or clinicians manage certain health conditions. Consider the behavioral health expert who accumulated a decade of data to validate a coaching algorithm for self-managing diabetes (Hill-Briggs et al. 2007). A licensee would like to pull the algorithm into its digital platform with support (and promotion) of the faculty member's expertise, because the value of the algorithm is as much, if not greater, with the faculty's brand attached to it. And since usage in a digital arena departs from the usual mechanism of validation in in-person settings, the coaching algorithm will require further iterative training to optimize. The company needs the faculty's input in development and optimization, while using her name and support during the commercialization process. This has caused some faculty stress by limiting the use of their work that was previously instrumental for research and creates new conflict of interest issues. TTOs may limit this problem by segmenting technology development from know-how, but this does not address the complexities created for the faculty member, as her university obligations have just expanded because of her relationship with a commercial entity, which can also change the trajectory of her academic career.

Inherent in this dilemma, we believe, is an administrative lack of appreciation of the importance of human capital, especially intellectual capital (knowledge, skills, experience) in successfully developing and implementing non-patent IP. In scientific domains, faculty are the harbinger of subject matter knowledge, and best understand how information flows through and outside the university to create new streams of knowledge, data, and solutions. Affording administrators oversight of commercialization activities misplaces decision-making power in the hands of those who do not necessarily have expertise in the subject area, threaten the sustainability of new initiatives and limit the context in which the university can make strategic decisions. We believe that faculty must be critical participants, and central architects, in innovation policy involving non-patent IP. They should cooperate with administrative officers and be accorded full transparency in the short and long-term implications of commercialization decisions. This challenges the current decision-making process in many universities, and calls for a less centralized and more distributive view of the commercialization process.

### 2.3.3 Success in commercializing non-patent IP is dependent on a decentralized technology dissemination model

Academic medical centers are historically ‘vertical’ organizations, with functional units created around clinical and managerial knowledge in support of a hierarchical structure and culture. Yet, much of the discovery work is done across such silos in multidisciplinary teams formed around programs of research. Technology transfer offices, or, broader, ‘commercialization’ units are faced with the challenge of understanding networks formed within and across these clinical and organizational silos. Even so, the organizational structure in AMCs is easier to navigate when commercialization processes originate from a capacitated scientific program, whereby a technology can be patented and neatly packaged in a license for export to outside organizations. Non-patent IP does not come with such well-defined processes. In fact, the likelihood of widespread dissemination in an academic setting is very high, and non-patent IP is particularly vulnerable to such risks. Consider the avenues through which this can happen, such as workshops, academic conferences, invited talks, Ph.D. seminars, the casual water-cooler converstion, and so on. This is because non-patent IP becomes more valuable with greater dissemination because others can rapidly build on the core ideas to improve, adapt, and widen the scope of application. This feature of open innovations makes non-patent IP particularly unique and the reason why scientists pursue active dessemination.

To valorize non-patent IP, inventors must engage in business model innovation, which involves the reimagining of revenue and cost relationships to exploit the promised efficiencies given by service enabling software, digital delivery systems, decision support algorithms, and so on. Business model innovation is an open process, which is grounded in organizational learning, requiring access to broad internal and external knowledge and social networks (Fleming and Waguespack 2007). The process is not unidirectional nor well formed at the beginning. It is one of trial and error.

Such dynamics ultimately lead to innovative cultures in organizations, which is no different for universities. We believe that the key to promoting non-patent IP and building an innovative culture relies on decentralizing the valorization process, whereby inventors’ social networks function to align scientific and business model expertise. Therefore, the way in which TTO can facilitate non-patent IP valorization is to enable open and decentralized communities of practice, which is contrary to the TTO nominal model of control and governance over faculty products of work for hire.

AMCs largely remain as vertical units defined by clinical specialty and management unit. This type of structure is generally less efficient and maladapted to respond to outside stimuli such as rapid market changes and emerging technological opportunities. Some of the most innovative institutions have attempted to solve these problems by aligning scientific programs, technology experts, and business model innovators to promote efficient innovation. Matrixing clinical units into 'service line' structures has been seen as a solution to creating more efficiency to deliver healthcare in certain fields that require specialized teamwork. While some centers, such as the Cleveland Clinic, have excelled in creating team-based delivery approaches, matrix organizations come with well-known problems and shortcomings (Weisbord et al. 1978).

Research in organizational processes and management have shown that flatter organizational structures, rather than matrixes, are better at facilitating innovation (Claver-Cortés et al. 2007). Flat organizational structures are used to foster entrepreneurial cultures, where faculty can be observers and contributors to the innovation process. The need to promote a flatter organization by distributing functional innovation teams is supported by research on human capital. Broadly speaking, human capital is composed of intellectual capital (knowledge in subject matter), structural capital (organizational and institutional knowledge), and relational capital (internal and external networks) (Evans et al. 2015). Effectively aligning all the components to develop and disseminate healthcare innovations involves a dynamic and organic team-based process, not centralized management.

In a recent review that summarized human capital in healthcare organizations (Evans et al. 2015), the authors focused on the results of three studies that evaluated capacity for health service innovation, which we consider to be most closely align with non-patent IP valorization. They concluded that relational capital played the strongest role, with three factors driving innovation: organizational culture and employee activities and attitudes around knowledge—sharing. The flat, team-based approach focused on strategic goals most effectively enables development of innovative human capital. This seems especially important to develop and valorize non-patent IP, as this type of work crosses functional units, involving databases, information technology, systems and strategic business model innovation.

Finally, we believe that it is critically important to understand how business models inform the successful delivery and adoption of non-patent IP, and to enable faculty entrepreneurs to develop their inventions in a team-based approach. Non-patent IP, especially that which uses digital platforms, should be commercialized with an eye toward value maximization (i.e., valorized), for example, in decisions about whether a company should *compete* directly, or *collaborate* with its competitors (Wiethaus 2006). One can envision that non-patent IP originating from AMCs can be best introduced into the commercial environment in a collaborative platform-supported business model, but this sometimes requires years of development and the foregoing of lucrative short-term licensing revenues. As an example, Google was born from Stanford engineering breakthroughs that enabled back-end web searching. In this situation, a powerful technology was used in a 'compete' strategy to launch the Bay Area company, which has gone on to support and grow the university's research enterprise. One could imagine an equal, if not more compelling, strategy could have involved an exclusive license to a software giant such as Microsoft or the building of multiple lucrative and impactful relationships with many other entities. These decisions must involve faculty inventors, for whom expertise, and problem solving are the prime drivers of their work.

### 2.3.4 Non-patent IP has potential for broader social impact in an open-access environment

In order to maintain alignment with their founding principles and fiscal responsibilities, AMCs must maintain a delicate strategic balance between the need to disseminate new knowledge to serve society and enhancing revenue by commercializing new products and services. This is particularly important in universities that house prominent researchers and programs that impact public health, such as at the Johns Hopkins University. In these settings, researchers routinely make very impactful discoveries to enhance the health of populations that may have little, or no commercial value because of constraints in delivery, institutional barriers and regulation, or financial capacity of the customer. TTOs have historically not seen their efforts as being relevant to that community, especially when goals and employee incentives are designed to maximize short-term revenue. In this setting, resource and personnel capacities drive priorities that leave less financially attractive innovations behind.

The exception to this rule is the system that has been developed by the University of California, Berkeley, which has been the prime architect of a socially responsible technology transfer policy. While maintaining over-arching IP policies aligned with the University of California, the office for Intellectual Property and Industry Research Alliances (IPIRA) has promulgated technology transfer that generated billions of dollars in revenue and the creation of IP policies that have supported the university's larger mission of promoting social impact. This "Socially Responsible Licensing Program" now serves as the gold standard for universities in the public health space (Mimura 2007).

Many universities, including Johns Hopkins, have less well formulated policies towards commercializing patent- and non-patent IP with lower perceived commercial value. As a result, inventors are frequently required to regain their IP rights from the university in order to continue the commercialization/ valorization process, or watch their discovery languish in the inboxes of the TTO. Consider the case in which a faculty inventor disclosed an algorithm and an application[6] that allowed HIV-providers to better understand medication risks, dosing and toxicities, and showed in funded research that it successfully reduced medication toxicities (Maddali et al. 2019). At the time of disclosure, the university TTO declined to commercialize the tool and after many attempts at negotiation and delay, eventually back-assigned the rights to the inventor. The team decided to valorize the algorithm through a non-profit but with little revenue, besides donations, to support further optimization and upkeep such as data collection, it's full potential remains unrealized. This example illustrates why we believe that transparent policies and multidisciplinary governance in technology transfer decisions may enable the successful valorization of inventions that may have more societal than financial impact.

## 3 Discussion

The need to promote innovation in non-patent IP has increased during the digital era, but perhaps never more so than now. The Covid-19 pandemic, which, at its height, reduced outpatient clinic visits to near zero, has upended the traditional mechanisms of healthcare

[6] https://www.hivassist.com/tool (accessed 9/9/2020).

delivery, and necessitated the creation of new methods to communicate, remote data acquisition, and service delivery. Telemedicine and digital healthcare before 2020 were considered aspirational and exploratory. Today, with support from payers such as the Centers for Medicaid and Medicare, as well as insurance companies, AMCs, with their technology partners such as electronic medical record companies, are investing in telemedicine and exploring new business models such as hybrid delivery using telemedicine-enabled satellite service units. We believe that universities, by affirmatively promulgating non-patent IP policies to support faculty ownership of their ideas, can significantly accelerate the invention and adoption of these new service and business models.

### 3.1 Recommendations

Universities will need to re-evaluate its non-patent IP policy by gathering faculty input and a taking multidisciplinary view towards maximizing the commercial potential of such assets, while guaranteeing faculty scholarship independence. For example, the current JHU IP policy on education materials, published in 2011, with clarification in 2014 (Appendix 1), could be construed as limiting faculty scholarship. As argued by the AAUP and other places[7] the policy of work-for-hire introduces a conditional aspect on employment, which junior faculty may not fully understand when entering into employment contracts early in their careers. We recognize the need for universities to monetize the value, and therefore take control, of non-patent IP, especially in the areas of digital technologies because they are easily disseminated, inadvertently or deliberately. Standard agency theory principles dictate that parties to a contract have the responsibility to enter with clear eyes and minds. However, when the principal (university) has control over the means needed by the agent (faculty) to perform the work, it is the former that bears the weight of ensuring clarity in the risks to the agent in the relationship. In particular, when it comes to junior faculty for whom the university shares responsibility for human capital development,[8] we recommend that the institution affirmatively limits its own control over faculty's rights to purse scholarly work. We believe that the writing of non-patent IP should involve grassroots faculty input, and that the thoughtful consideration of incentives, processes, and culture attending technology transfer offices will go a long way to accelerating faculty scholarly driven inventions. Some ways to do so are the following:

1. Review university non-patent IP policies to align with the principles of shared governance set forth in the AAUP Handbook.[9]
2. Extend shared faculty governance procedures to university technology transfer offices or restrict the ability of TTOs to claim ownership of non-patent IP without approval from a university's shared governance body.
3. Promote a program of ongoing education for faculty to ensure a complete understanding of contractual obligations in IP to support faculty entrepreneurship and innovation.
4. Affirmatively identify new non-patent IP domains, e.g., digital service delivery, to expand faculty ownership over their own scholarship.

[7] https://www.chronicle.com/article/whats-a-work-for-hire-and-why-should-you-care/ (accessed: 8/31/2020).

[8] For example, see Johns Hopkins Medicine's faculty handbook, https://www.hopkinsmedicine.org/som/faculty/policies/silverbook/index.html (accessed August 31, 2020).

[9] https://www.aaup.org/report/statement-government-colleges-and-universities (accessed July 28, 2020).

5. Create boundaries within which university technology transfer offices must negotiate with faculty for the use of their own non-patent IP, such as prohibiting exclusive licensing without faculty consent and involvement.
6. Create transparent protocols to manage conflict of interest and commitment concerns over the use of non-patent IP by faculty startups.
7. Create a university entity to support non-patent IP valorization efforts by faculty with appropriate outcome measures that go beyond financial gain.

## 4 Conclusion

In the world of innovation increasingly characterized by non-patent IP, universities and technology transfer offices have to rethink their policies on ownership, control, and agency in how they monetize such assets. Non-patent IP is seldom severable from the inventor, so it is not easily tradeable. For example, monetizing an online course or service business model without the input and participation of the creator, the faculty member, will not optimize its market value. In fact, separating the IP from the faculty commoditizes it, and debases the value of associated IP (all online courses offered by the university), making it challenging to differentiate the asset from that of its competitors, while weakening the case for tuition of the in-person versions of these courses. In short, as the share of non-patent IP is increasing with social, economic, and political forces pushing for the digitization of healthcare, we argue that there is a natural incentive for universities to protect the independence of faculty members in the valorization of non-patent IP and that a deep reconsideration of the supporting policies.

## Appendix 1: Extract of the Johns Hopkins University policy on the ownership and use of educational materials[10]

The Policy clarifies ownership of intellectual property (IP) created by faculty, staff and students of the University. In most cases, the University asserts its ownership rights to IP created by those working on behalf of the University. An exception is made for some “literary or scholarly works”, for which the University relinquishes ownership to the individual creator(s). This policy is meant to provide clarification on the ownership and use of educational materials by Johns Hopkins University School of Medicine (“JHUSOM”) faculty, staff and students working on behalf of JHUSOM (hereinafter referred to as “faculty”). JHUSOM does not consider educational materials to be traditional literary or scholarly works, and it is important that ownership of these materials be clearly understood in order to operate effective academic programs. Educational materials include online course materials, lecture materials, educational web sites, videos, and manuals (this is not intended to be an exhaustive list). Literary and scholarly works would include books, monographs, articles and similar work. This policy is not meant to change ownership rights for literary and scholarly works, as defined in the JHU IP Policy.

[10] https://www.jhu.edu/assets/uploads/2014/09/intellectual_property_policy.pdf (accessed 3/15/2020).

### Policy statement

1. By law under the work for hire principle, the University is the owner of intellectual property developed by faculty as part of their usual teaching, research, and service activities; developed with sponsored project support; or otherwise developed within the scope and course of employment.
2. Intellectual property owned by the University includes, but is not limited to, faculty developed teaching materials in electronic and print formats such as slides, lecture notes, lab exercises, web pages, audio and video recordings of the faculty, distance education materials, software, survey instruments, research and teaching data, assessment tools, manuals, and any current or future means of disseminating knowledge or expertise (hereinafter referred to as "Educational Materials").
3. Faculty who develop Educational Materials in performing their usual teaching, service, or sponsored project activities are granted a non-exclusive, no-cost license to use these materials as part of any of their teaching or scholarly functions either inside or outside of the University. The faculty are granted a non-exclusive, no-cost license to use these materials in developing traditional derivative works such as books, book chapters, journal articles, and electronic representations of these conventional works. The license to use the materials and develop traditional derivative works remains in effect if a faculty member leaves the University. Revenues from the distribution of these traditional derivative works shall remain entirely with the faculty authors. The University shall retain all other rights associated with these Educational Materials, including valorization. Specifically with regard to electronic works (such as videos and distance education materials), this section, and related sections concerning licenses back to faculty, refer to the faculty member's personal contribution only, and do not include a license to any portion of the entire work contributed by others.
4. In cases where Educational Materials are jointly developed by two or more faculty, each author retains the right to use the Educational Materials for teaching, research, or other scholarly functions. Development of derivative works such as books or journal articles shall be negotiated among the authors. Likewise, if one member leaves the University, the right to use material developed by others will need to be negotiated with the other faculty members. Disputes regarding use of Educational Materials or development of derivative works shall be referred to the Office of the Dean.
5. When faculty leave the University, or for any other reason are not available to teach a course they developed, the University continues to own the Educational Materials and retains the right to use and revise the traditional derivative works developed for the course. Where appropriate, authors of the materials may be involved in the development of revisions.

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