Examination of Intellectual Property and University-Industry Relations amid a Global Crisis

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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The outbreak of the Coronavirus Disease (COVID-19) led to a declaration of a global pandemic on March 11, 2020 by the World Health Organization (WHO) and is a global emergency due to the highly contagious nature of the COVID-19 virus and its severe complications for older and immunocompromised individuals. It is evident that the pandemic will have lasting social, economic, and political impacts, which will lead to the reinvention of classic innovation models, a phenomenon characteristic of periods following previous global crises such as world wars, famines, and other epidemics (Viale et al., 2020). Accelerated innovation has occurred in the months since the pandemic began, from the rapid development process of the COVID-19 vaccine to creative solutions for manufacturing personal protective equipment (PPE), a technology vital to halting the community spread of COVID-19 when social distancing is not possible. Additional examples of rapid innovation occurring during this global crisis include contact tracing mobile applications that operate via Bluetooth technology, robots that utilize UV light to sterilize surfaces, and virtual communication platforms for business and social interconnectedness.

The accelerated development of these technologies in response to an emergency requires an examination, framed by the New Political Sociology of Science (NPSS) theory, and the relationships of the three institutions—government, business, and university—that make up the triple helix model of innovation. Through the analysis of the influence of technical transfer offices and intellectual property regulations on innovation, the degree to which innovation can be considered a collective good or simply a technological change and how three spheres of influence inhibit or encourage innovation according to the NPSS framework will be determined. Further, the codification of boundaries among these institutions will be analyzed during periods with

destabilizing conditions and as well as possible future migrations of these boundaries when the destabilizing conditions are mitigated.

This analysis will largely be performed through reviewing academic articles and legal literature relating to the transformation of intellectual property and patenting policies throughout periods of destabilization. In addition, a case study will be performed regarding technical transfer at the University of Virginia, and more specifically the extent to which applied research is influenced by commercial objectives and how the University's goals align or differ from nationally competitive research universities. Important questions to consider in this analysis include: How is the innovation process altered in a global emergency, and what are the barriers or enablers to entry? To what extent are researchers in academia influenced by commercial objectives, and is this influence direct or simply profit-driven? How has the role of universities in society shifted over time, such as a shift from mission-oriented to profit-driven motivations, and how will this role be reconsidered following a global crisis? What role do patents play in the balance of power between academic, industrial, and government institutions? What role do patents play in a global crisis, when innovation is accelerated and should not be inhibited? What improvements need to be made to the intellectual property framework as innovations become increasingly political in nature?

Innovation, Institutions, and Public Good

The triple helix model of innovation is useful in codifying boundaries between innovation-producing institutions and emerged from World War II with the collaborative development of mission-oriented technologies to support the war effort. According to Leydesdorff and Etzkowitz (1998), "a seamless web of technology transfer and feedback loops" between the government, industry, and academia was sustained during this era. The triple helix model also addresses transformation within the aforementioned groups, for instance the increasing demand for academic

research in universities as academia shifts to an “amalgam of teaching and research, applied and basic, entrepreneurial and scholastic” (Etzkowitz & Leydesdorff, 2000, p. 112). Viale, Etzkowitz, and Fornaci (2020) suggest that global crises, such as the COVID-19 pandemic, reshape the triple helix model through evolutionary innovative leaps.

The triple helix model was redefined by Carayannis and Campbell to form the quadruple helix model, which according to Shutz, Heidingsfelder, and Schraudner (2019), addresses the interdependencies of four actors—science, policy, industry, and society—associated with the innovation process. This model is useful as it includes societal and cultural considerations in the innovation process which allows for research goals to be “legitimized among relevant publics, aim[ed] at positive public impact, and defined with the public’s help” (p. 129). The transactions between the public and the subsystems established in the triple helix model are facilitated through avenues such as user-centered innovation, open democracy, and transdisciplinarity. Improving the exchange of ideas and goals among the four spheres of influence—especially between the societal sector and the previously established institutions—through diverse and compelling participatory projects will allow for public preferences to influence commercial and academic institutions.

The aforementioned helix models relate to the NPSS theory and how NPSS may serve as a critical lens when examining the three main spheres of influence and their collaboration in order to support or impede technological advancements (Razak & White, 2015). NPSS as a framework explores the political nature of knowledge production institutions and “the dynamics of resistance and accommodation” associated with this power, and will be applied to this topic of the complexities of the university-industry relationship (Frickel & Moore, 2006, p. 5). There are three analytical considerations in this research that will be framed using NPSS including the boundaries

between innovation-producing institutions, external destabilizations and the transformations that ensue, and the classification of universities as economic or democratic institutions.

Technical Transfer Offices

The technical transfer between universities and industries—in the form of ideas, objectives, product development, clinical trials, and other forms of collaboration—is of interest as state-funded academic research is commercially driven and has the capacity to influence private-sector markets (Leydesdorff & Ivanova, 2016). Technology transfer offices serve as the bilateral relation between the academic and industry sectors, and their mission revolves around prioritizing commercial objectives in academic research environments by way of patents, licenses, startups, and other commercial avenues of transfer (Sanders & Miller, 2010). Technical transfer offices aim to rebrand academic research and development such that the R&D is most appealing to the industrial sector, while simultaneously aligning the goals of each institution and maintaining boundaries. This is useful in generating revenue for universities and stimulating regional economies (Bradley et al., 2013). It is important to consider how commercial objectives either align or infringe on a research university's mission, which generally involves the "creation, validation, and organization of information into new knowledge" (Jones & Strandburg, n.d., p. 7). This stresses the significance of a technical transfer office that determines the balance between academic freedom, commercial interests, and mission-oriented goals. In terms of notable research institutions and their associated technical transfer processes, the Massachusetts Institute of Technology's (MIT) Technology Licensing Office (TLO) seeks to "move innovations and discoveries from the lab to the marketplace for the benefit of the public and to amplify MIT's global impact" (MIT TLO, 2021), which is a standard mission statement for a technical transfer office that emphasizes the need for both bilateralism and boundaries.

The ability for universities to own patents and commercial licenses, permitted by the Bayh-Dole Act of 1980, is crucial as it allows not only for academic revenue generation through exclusivity but also for more successful government-funded, university inventions (Jones & Strandburg, n.d.). As academic institutions transform to have more industry-oriented objectives and vice versa, private intellectual property is emphasized and "leads to a re-interpretation and reframing of norms" (Sanders & Miller, 2010, p. 691) in both directions, such as industrial goals incorporating traditional academic values of serving the public good and universities becoming more entrepreneurial in nature. However, the increasing need for academic institutions to own intellectual property in order to maintain their competitive advantage among other research universities and profit-making businesses may contradict with their research missions which generally involve the public dissemination of information (Jones & Strandburg, n.d.). This overemphasis on the patenting process in university settings leads to a conversation on academic institutions and who they are innovating for. It is important to consider how their role in society may have transformed over time, from producing and freely distributing knowledge to privatizing information for market-driven and profit-seeking purposes (Bradley et al., 2013).

When modeling this transaction between universities and businesses, a traditional linear approach may include stages such as discovery, disclosing, patenting, marketing, licensing, and implementation (Bradley et al., 2013). This is of interest as the disclosure of a discovery to a technical transfer office will lead to a multidimensional evaluation of the invention to determine if it is patentable, through parameters such as revenue and licensing potential, academic field, competitiveness, and extensibility. This aspect highlights the power of technical transfer offices and how they influence academic pursuits. The aforementioned linear model may be deemed insufficient as it does not account for the variation in policies across universities, oversimplifies

the complex technical transfer process, and fails to acknowledge university cultures and reward systems to innovative faculty members. An alternative model that accounts for these insufficiencies is a complex web of stages that accounts for various potential inventors—from teams of scientists to single students—different sources of funding, which will in turn influence the invention process, and the option to bypass the technical transfer office disclosure stage.

The University of Virginia (UVA) Licensing and Ventures Group (LVG) utilizes a linear model for summarizing the process of commercializing university inventions which consists of six stages: discover, engage, protect, develop, accelerate, and impact. The LVG describes their mission as a partnership with "faculty, entrepreneurs, and investors to bring innovations discovered at UVA into the marketplace" (UVA LVG, 2021). In order to promote innovation during COVID-19, the LVG issued separate licensing guidelines, driven by the Association of University Technology Managers (AUTM), that involved the creation of a specific strategy for prioritizing rapid pandemic responses and the adoption of non-exclusive licenses to allow for the development and distribution of products such as PPE to prevent the spread of COVID-19. Notable contributions from UVA during this period of accelerated development facilitated by the relaxed guidelines include clinical trials with successful antibody cocktails and therapies and a contact tracing app programmed by computer science students (UVA, 2021). This departure from normal operating conditions in response to the destabilizing conditions created by the COVID-19 pandemic was common among research and commercial institutions, and highlights the university's prioritization of the common good through allocating resources and removing barriers to innovate in exchange for protecting intellectual property or maximizing profits.

The role of technical transfer offices relates directly to the NPSS framework and how the technical transfer offices influence the objectives of two of the three institutions within the triple

helix model in order to promote entrepreneurship and serve public interest towards a collective shared need. According to Frickel and Moore in *The New Political Sociology of Science: Institutions, Networks, and Power* (2006), NPSS "seeks to understand…how in the wake of these shifts, knowledge production systems respond adequately to the demands of the people" (p. 3). When presented with a destabilizing condition such as the COVID-19 pandemic, institutions such as UVA altered their intellectual property structure rendering inventions less exclusive and more susceptible to competitors in order to improve public health. This highlights one instance in which a global threat to public safety resulted in a transformation of knowledge production systems as barriers to innovate were removed and public demands were met. Following the conclusion of the COVID-19 pandemic when herd immunity is achieved as a result of the rapid vaccine development and distribution, it will be interesting to reflect on this period of rapid innovation and relaxed intellectual property policies. The boundaries between universities and industries will be reconsidered as a result of the global pandemic and new imaginaries will emerge.

Intellectual Property

Patents are one avenue in which technical transfer offices emphasize commercial interests in academic settings. As rapidly developing technology becomes increasingly political in contemporary societies, preexisting intellectual property policies and structures are challenged and deemed inadequate by actors from spheres of the triple helix model (Hilgartner, 2009). According to Hilgartner (2009), the new politics of intellectual property "centers on concerns about who governs technology and in pursuit of what goals" (p. 207). This statement is of interest as it relates to the NPSS framework and how powerful institutions—such as regulatory bodies determining patenting and intellectual property policies—have the capacity to infringe on citizens' ability to participate in the innovation process. This is particularly relevant during the COVID-19 pandemic

and how citizens with entrepreneurial mindsets sprang into action to innovate at accelerated rates for public good.

Experts may consider intellectual property policies as utilitarian incentive theories as they seek to maximize net social welfare while enticing authors to invent and produce novel works (Fisher, 1999). Experts in favor of the intellectual property system as it exists today argue that broad legal protection is required in a capitalist economic system given the substantial investments required for ventures, and that the incentive program is necessary for market proliferation and advancements in innovation (Beckerman-Rodau, 2011). In addition, those in support of the intellectual property system as-is maintain that patents serve as a "pull" for businesses by eliminating competition from the direct market for a set period of time, thus increasing demand and allowing businesses to charge higher prices due to the lack of competition (Sampat & Shadlen, 2021). Positive factors that experts also associate with the structure of intellectual property policies include cultural developments and human flourishing as a creative avenue is cultivated for inventors (Mandel, 2014).

There are critics of the intellectual property system as it exists today in the United States, partially due to the rapid technological evolution characteristic of the Digital Age and the corresponding challenges that these advancements presented when trying to apply existing, fragmented policies to digital technologies. In addition, proponents of limited intellectual property rights assert that the current system limits the free flow of ideas and information dissemination, thus inhibiting innovative advances and interfering with marketplace competition (Beckerman-Rodau, 2011).

Discussion

Given that accelerated rates of innovation were required to improve public health and resume essential or virtual operations during the COVID-19 pandemic, the intellectual property system and its barriers to entry in the form of processing time and legal fees presented a challenge for three of the four actors in the quadruple helix model: universities, corporations, and entrepreneurial laypeople. “Operation Warp Speed,” the government’s public policy response to the destabilizing conditions created by the COVID-19 pandemic, allowed for NIH funding as a “push” mechanism for enabling innovation (Sampat & Shadlen, 2021). Other aspects of this response consist of “pull” mechanisms like a limited accelerated patent examination program, which is of particular interest given the fact that a patent generally takes years to be filed, published, and granted. It is important to note that the mRNA therapeutic platform essential to the COVID-19 vaccination was widely patented prior to the pandemic, and will be protected in years to follow. Despite the unique acceleration program and predictive, pre-pandemic patenting for the vaccine base, the acceleration program offered limited availability and it is also possible that overlapping patents were filed, thus rendering claims worthless.

While some experts view the broad nature of the intellectual property system in the United States to be beneficial to the private sector due to its limit on competition as the technology is reserved by a single patent filer, and to be advantageous by cultivating a creative environment for inventors to protect their discoveries, the pandemic has highlighted the flaws in these arguments. First, while the U.S. government is subsidizing costs associated with the COVID-19 vaccine, patents artificially inflate prices associated with medications among other products—which is an active detriment to public health as individuals may not have access to the medications they need to survive—due to the fact that patents remove competition from the marketplace by prohibiting

companies from producing a drug aside from the intellectual property owner. Secondly, while the patenting process may seem appealing to an entrepreneurial layperson due to the ability to claim their inventions, the processing time and resources required to file and defend a patent ensures that corporations are able to maintain their share of intellectual property while individuals who sprang to action during the COVID-19 pandemic to benefit their communities will not receive intellectual property rights to their inventions in a timely fashion.

The accelerated rate of innovation in the COVID-19 pandemic highlights the interconnectedness of the four spheres of influence in the quadruple helix model and how barriers must be dissolved in order to successfully complete late-stage downstream product development processes such as vaccine creation and distribution. From the government's investment in R&D and purchase agreements for vaccines, to the development and distribution by pharmaceutical corporations such as Pfizer and Moderna, to Weissman and Karikó's establishment of the mRNA platform at the University of Pennsylvania, it is evident that all institutions contributed to the technological feat of creating and obtaining FDA approval of multiple COVID-19 vaccines (Moody, 2021). This aligns with the NPSS framework and how institutions transformed, collaborated, and accommodated despite destabilizing conditions in order to improve public health.

However, the destabilizing conditions created by the outbreak of this contagious disease have highlighted limitations in the innovation process that should be reconsidered in order for the United States to be better equipped for future crises. For instance, patenting reform is necessary in order to allow for greater access to the innovation process and may include features such as "compulsory licensing, patent pools, and exceptions to global patent laws" in the face of a global catastrophe (Sampat & Shadlen, 2021, p. 405). The manner in which technical transfer offices

removed barriers to entry in order to facilitate acceleration in the midst of the pandemic when faced with destabilizing conditions should serve as an example to other bilateral institutions within the triple helix model due to their flexibility in catastrophic scenarios. In terms of other transformations that will be evident following this period of destabilization, universities have the potential to maintain the mission and society-oriented approach to innovation—as they did when faculty members and students were called to action during the COVID-19 pandemic—provided that they reevaluate their role in society and realign values with mission-based objectives as opposed to commercially or profit-driven goals.

Conclusion

In this research, two bilateral structures—technical transfer offices and intellectual property policies—that connect spheres of influence in the triple helix model were examined in both normal operating conditions and disruptive conditions from the COVID-19 pandemic in order to understand their influence on the innovation process. It was determined that technical transfer offices may redirect university research topics to the point at which universities are producing knowledge for commercial institutions instead of society. This phenomenon will be reevaluated following the pandemic when universities realigned their objectives to improve public health during the crisis. In addition, it was determined that there are deficiencies in the patenting process, which were exacerbated by the global pandemic, as it creates barriers for entrepreneurs and excessive competition in the biomedical and pharmaceutical marketplaces. Given that this research primarily focused on university-industry relationships, and that global catastrophes lead to reconsiderations and lasting political, social, and economical change, a new opportunity for consideration is how the government will be restructured following the pandemic in order to be better prepared for catastrophes.

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