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Intellectual Property and Commercialising University Research in Japan: Comparative Perspectives from the US

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This article considers the incorporation of universities in the innovation ecosystem from a comparative perspective, investigating the development of the Bayh-Dole Act in the US and how this shaped the corresponding legislation in Japan. The article highlights the importance of the soft law features of these legal systems, the institutional factors and the broader innovation context to suggest that, while universities function, in practice, as important innovation institutions, their incorporation in this context is of a partial nature in Japan because of broader institutional dynamics.

Developments in medicine and medical technology have contributed significantly to the successful treatment of life-threatening and complex diseases, the foundation of which has often come from a publicly-funded university or hospital research context (Kraemer, 2020: 209). Intellectual property rights are a fundamental aspect of new medicines, but universities occupy a very specific position in this process because private enterprises have a long history of using university research to support patent applications that effectively privatise publicly funded work.[1]

This article presents a comparative analysis of the impact of reform in the context of universities and the commercialisation of intellectual property rights in the US and Japan to investigate how these reforms not only had an economic impact but changed the relationship between universities and private industry. While the legislative dimension of how patents and universities interact has been covered extensively,[2] this article provides a more critical analysis of the soft law aspect of the reforms through a comparative analysis of how universities – as actors in a political and economic context – responded to legislative changes and how their position shifted.

Legislative reform in both Japan and the US fundamentally changed the role of universities, but this is more accurately understood in the Japanese context as a partial transformation that operated mainly to formalise the participation of universities in the innovation ecosystem that manifests differently across both jurisdictions.

Universities have been fundamental contributors to technological advancement throughout history, in both direct and indirect ways. Universities have contributed indirectly by producing capable scientists who go on to work in private industry, though there is also the important work of spin-offs or non-commercial research produced by faculty.[3] The 1980s saw the beginning of the recontextualisation of universities in line with this more direct capacity that coincided with a national emphasis on intellectual property rights as a way of addressing economic stagnation. (Kato, 2009: 1).

The US and Japan (and by extension, their universities) have an especially important relationship to consider when investigating the impact of increased university activity and the role of private industry for several reasons. Japan and the US had a particularly contentious trade relationship throughout the 1980s and 90s that centred on the treatment of intellectual property rights in both jurisdictions (Harris, 2002: 74).[4] The turning point of this relationship was a series of legal transplants that occurred towards the end of the 1990s as Japan experienced the same type of

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1 With research tending towards more iterative versions of drugs in the pharmaceutical research context: Hain, 2015: 106.

2 See generally Garon, 2018: 637, 638.

3 One prominent recent example being the development of BiomeSense, an innovative company co-founded by a professor at the University of California San Diego that uses hardware, software, and data to improve microbiome data collection: BiomeSense <https://www.biomesense.com>.

4 Discussing the 'patent wars' that emerged between US and Japanese businesses: Lindgren and Yudell, 1994: 2, 3.

economic stagnation that had damaged the US economy ten years prior (Arai, 2005: 5). In responding to a severe downturn, Japan implemented a national policy that emphasised the role of intellectual property rights as an economic driver (Healy, 2005: 409), introduced a specialised intellectual property court (Pietari, 2016: 542), and transplanted almost identically the provisions from the US that promoted the commercialisation of intellectual property rights by universities (Kameo 2015, 178).

This article presents two major conclusions about the impact of policies that promote the exploitation of intellectual property rights, the first of which is that legislative reform in this area is fundamentally reliant on those within the university system for its success. Building on the difficulty of ensuring consistency between faculties and disciplines to realise these legislative objectives, the second conclusion is that this increased emphasis on the commercial potential of university research is in tension with the more complex social role that the university plays. While the discussion is focused on a comparative analysis of this development, there are some limitations that are important to highlight. This research relies almost exclusively on materials produced in English, and is not intended to present an internal perspective on the commercialisation of intellectual property, as if writing from the perspective of a Japanese or American university researcher engaged in industry/academia collaborations. Instead, it is intended as a response to the international presentation (and positioning) of university research emerging from Japanese and American universities. Intellectual property reform, in both a local and global sense, involves an aspect of 'signalling' – a demonstration of national values and priorities or a presentation of something more aspirational.[5] As such, the materials discussed here (a large proportion of which were written by academics with significant connections to Japan) form part of that international perception of Japanese intellectual property law. The comparative analysis is not intended to produce an entire account of Japanese and American intellectual property law in universities, but to investigate the degree to which these reforms appear to have been – from an external perspective – successful in situating universities as viable contributors to the innovation ecosystem and how the relationships between university, researcher, and industry are framed legislatively.

The first conclusion from the work explores how reform that encourages universities to obtain and then exploit intellectual property relies on the cooperation of individual researchers to support and actively uphold the values of the system. In this sense, the Japanese repositioning of universities is a clear example of a partial transformation, while the US demonstrates a more successful implementation. My comparative analysis reveals that efforts at national reform struggle in the context of a university because they cannot rely on a traditional corporate structure to ensure effectiveness.[6] Instead, there are systems of weak hierarchies (of professors, postdocs, assistants) that are supported by individual researchers who, for intellectual property exploitation or acquisition, may not necessarily support the broader objectives of the framework, particularly when this involves patent acquisition in medicine.

In this, it is the cultural context and the individual motivations of a researcher that contribute to the successful repositioning of a university as a formal innovation institution. The legislation in both Japan and the US focuses on the commercial dimension of research and the pursuit of profit,[7] something that stands in opposition to many contemporary scientific perspectives on 'open-science' and accessibility in a way that creates a variety of individual responses that range from a complete embrace of the commercial imperative to ones in which a researcher cooperates but at the minimum level required.[8]

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5 China's early adoption of WIPO provisions was considered to be a signal to the international community of their commitment to intellectual property obligations: Yu, 2006: 920, 921.

6 On the development of corporate hierarchies, particularly in the 1980s, and addressing the challenges that corporate bureaucracies must address to survive, see Smith, 2021: 197.

7 Particularly in the Japanese context, observing the large profits that (specifically pharmaceutical) patent licensing can bring: Ishii, 2017: 137.

8 'Open Science' is, itself, an umbrella term that can refer to many different arrangements and opens a 'multitude of battlefields, ranging from the democratic right to access publicly funded knowledge … or the demand for a better bridging of the divide between research and society …'. Fecher and Frieske, 2014: 17.

The second conclusion is that while this formalisation of universities in innovation is not inherently problematic, it presents a tension between the profit-driven objectives of private companies and the more complex institutional arrangements of a university that complicates how we understand the broader social and legal contributions of universities. Patent rights lend themselves particularly well to biotechnological and medical innovations, and universities have often attracted increased scrutiny of how these innovations are licensed or otherwise commercialised.[9] Universities involved in the exploitation of intellectual property rights must be evaluated more robustly than by their success in these purely commercial ventures. This is because emphasising the commercial potential of intellectual property rights can not only involve citizens essentially paying twice for an innovation (once through taxes to fund the research and then again in purchasing the product) (Rooksby and Pusser, 2014: 79), but also because this framing of research is being applied to health technologies. Understanding value in research from this economic perspective is particularly stark in a university setting because, as institutions, they have traditionally represented a more diverse set of values than just the profit imperative.[10]

Simply recasting universities as a commercial entity minimises the significance of the research being produced in universities across Japan and the US because not all disciplines fit easily within a framework that emphasises the economic application of their research. Increased scrutiny of the commercial activities of a university in the exploitation of intellectual property is required to both recognise the distinct heterogeneity in commercialised research output that is present in both Japan and the US, as well as to provide a more well-rounded evaluative perspective that incorporates non-economic considerations, such as contributions to human health and the broader accessibility of university outputs.

These non-economic considerations are particularly valuable as we see the increasing pressures on faculty (and universities themselves) to fit their research output in narrow, simplified categories to quantify their contributions. The pressure of metrics in academic research has been discussed extensively elsewhere, [11] although this narrow understanding of what makes a piece of research valuable highlights how disciplinary-specific the impact is in practice. While some sub-disciplines of engineering or science have clear outputs that can be readily commercialised, the humanities generally struggle to demonstrate the same type of industrial applicability.

Universities at the Crossroads of Medical Innovation and Education

On Universities and the Scale of Medical Technological Advancement

The role of patents

Patents have been an essential part of the continuing success of medical research and treatment, allowing companies to invest large amounts of money in the development of new therapeutic compounds with the security that a patent affords in terms of exclusivity (Hatch, 2000: 231). Patents immunise companies, at least partly, from the risk of 'free-riders' who would seek to use the output of the development process without incurring any of the associated costs, and can therefore market their products at a lower price (You and Katayama, 2005: 591). This is especially important for medicines, as an essential element is the disclosure of the innovation, [12] because medicines

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9 One notable example is the HIV/AIDS medication, d4T, that was developed at Yale and subsequently patented abroad. Significant student backlash about the cost of this medication in South Africa (where the existence of a South African patent prevented an offer from Indian generic producer Cipla from being accepted) eventually led to Yale and BMS stating that they would not enforce the patent: Adrangi, 2001.

10 On the development of universities as 'value spaces', with the current territory diverging from 'key concepts that … were those such as truth, understanding, personal development, inquiry, learning, critical thought …' to 'profit, innovation, economy, competition, knowledge transfer, markets, student-as-customer …' See: Barnett, 2019: 57.

11 On the pressures of academic publishing and the importance of metrics for evaluating faculty (and the corresponding rise in legitimate and less legitimate strategies to maximise these metrics), see: de Rijcke and Stöckelová, 2020: 101.

12 In the patenting of medicine, this could be a new compound or a dosing regime that addresses specific conditions. This mix between new and known uses in the patent system is criticised for enabling patent evergreening (where a patented

demonstrate a strong delineation in terms of function and chemical form (whereas a technology like software has patents that are notorious for providing effectively very little guidance as to what the invention actually is (Jaffe and Lerner, 2006: 57)). The presence of a patent, which is fundamentally territorial in nature and is only valid within the granted territory (Sender, 2002: 21), means that a company can charge above-market prices for it based on exclusivity in supply and has traditionally led to situations in developing countries where patented medications are so costly that they are unavailable to ordinary consumers (though in recent years the issue of medicine shortages has become more visible in both Europe and North America) (Truong, Rothe and Bochenek, 2019: 68). The territorial emphasis in patent law contrasts with both the expansive nature of disease outbreaks and the fundamental nature of universities and university-based research, which is grounded in faculties that collaborate across disciplines and geography. This collaboration represents a mobility (in both a physical sense and in terms of innovative approaches to problems) that does not translate easily to the geographic focus of the patent system.

A patent must be registered in each territory for which protection is sought, although a wide enough coverage will be effective in preventing parallel imports (except in intellectual property regimes that specifically restrict parallel imports or 'grey market' goods).[13] Once registered in these jurisdictions, the owner of the patent can use a system of price differentiation to maximise profit as it reaches the greatest number of consumers at the highest price point they are capable of paying (WIPO, 2020: 110). In this sense, despite the great contribution that patent law brings with its orderly record of technological advancement,[14] a modern world of rapid transportation and health advancements is undermined when the patent system itself provides a way for companies to split markets and, however unintentionally, undermine accessibility. This strategy of compartmentalisation is in contrast to the reality of modern health, where viruses and infections travel across borders easily and require a concerted cooperative effort to manage their impact internationally. The risk is that, with strict approaches to the accessibility of medicine, and an emphasis on maintaining strong patent rights, there will be cycles of reinfection where communities without access are marginalised as the drivers of mutations that then eventually reach the communities with access.[15]

The relationship between private industry and university research

Beyond the medical concerns, there is also a tension in the development of new pharmaceuticals that comes from the collaborative nature of university research At a general level and across all disciplines, university research relies on the willingness of faculty members to not only create and sustain their own research networks from an internal perspective (whether this is a laboratory hierarchy of professors, post-doctoral researchers and graduate students) but to also create and sustain research networks that operate internationally and represent truly interdisciplinary and collaborative methods of research.

Covid-19 is a clear example of this type of tension between how research develops (and the teams involved) and how the patent becomes a more singular expression of that research. The patents related to Covid-19 vaccines – and, in a similar way, to early research on HIV/AIDS that was partially supported by National Institutes of Health (NIH) grants (Goldstein, 2012: 462) – are controlled by private enterprises despite relying on basic research that was nationally funded.[16] The research that these products build on was produced in a variety of institutions and through networks of

compound essentially gains protection beyond the 20-year grant through small modifications to the compound or the application of the medicine in new contexts) Li, 2013: 520.

13 The US, specifically, has been pursuing this in its free trade agreements: Owoeye, 2015: 363.

14 Of the 'history of technology itself'. See: McJohn, 2008: 962.

15 On the discussion of 'herd immunity' that comes from a majority-vaccinated population, though this necessarily requires substantial access to the appropriate medicine/vaccines. See: Fentiman, 2017: 244.

16 Moderna reports that they received an award of approximately $955 million from the Biomedical Advanced Research and Development Authority (BARDA), a department of the US Department of Health and Human Services. See: Moderna, 2020.

researchers,[17] yet patent registrations by businesses in this context position a single commercial actor who controls the applications of this research internationally.

The increasing involvement of universities in pharmaceutical research – specifically because this form of research output relies so heavily on the protection afforded by a patent (even if defensively filed to prevent others profiting from it)[18] – is problematic because even without issues around funding and value-for-money, it positions the university structure as an active participant in the privatisation and compartmentalisation of research output. The university, as an institution, is then participating in a legal system that negatively impacts human health around the world in a way that contrasts with the earlier, more indirect, influence on private industry (such as producing graduates).

The elimination of costly risk for the private company in the development of new pharmaceuticals is also exaggerated when considered in the global context – a context in which the private company patent owner is free to trade internationally and secure patent registrations for follow-on inventions in foreign jurisdictions. In this, there is a distinct asymmetry in who exactly benefits from the use of public funding, and a disconnect between the investment and the reward that is so fundamental to the patent itself.

While citizens eventually benefit from the advancement of medical technologies funded in part through their taxes, this benefit does not accrue automatically and still relies on a level of wealth to access these treatments. In the US, the high cost of healthcare (even for more routine health issues) means that taxpayers may not necessarily have the insurance coverage to access these patented medicines.[19] Private businesses, on the other hand, benefit by eliminating some of the significant risks involved in the development of new pharmaceuticals *and* have a product that can be sold outside the territory that directly funded its development (although this does depend on the exact terms of the license negotiated with the university).[20] Rather than investing large amounts of money in research that may prove unsuccessful, private businesses can use the university-originated research as a foundation for further work without the risky initial steps. The citizens of the government that funded this research are therefore in a situation in which their taxes effectively subsidise private research and development costs and afford business a powerful commercial tool for trading internationally. This shift in burden away from private industry is particularly concerning because it is a process by which the university becomes, simultaneously, the place of the next generation of technical professionals, the advancement of research and, now, the active commercialisation of research outputs. This emphasis on the university as an active participant also extends to the exchange of risk, not only in functioning as the physical space in which research is conducted – something that is not particularly uncommon in the context of privately funded basic or applied research[21] – but in the commercialisation of research output. It is in the active pursuit of commercialisation and, by extension, profit, that the university becomes a vector in the innovation landscape by facilitating the privatisation of publicly funded research.

It is important to recognise that the issues that emerge from the territorial focus of patent law and pharmaceuticals are principally issues of accessibility and *not* expertise. Scientists can cross borders with relative ease and universities and research centres in the US have world-leading facilities and scientists that consistently produce high-quality research across all disciplines (though particularly in the context of medical research) (Mingst, 2003: 151). These high-quality research institutions have become an important part of the research and development process for private

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17 With authors highlighting how stakeholders worked 'so openly and collegially' in approaching Covid-19. See: Maher and Van Noorden, 2021: 316, 317.

18 An example in the context of software would be the Open Invention Network that obtains patents to then distribute them as freely as possible to its participants (on the condition that these patents are then not used to assert their patents against Linux). See: Parchomovsky and Mattioli, 2011: 239.

19 Even with the Patient Protection and Affordable Care Act 2010 in the US, the cost (and complexity) of coverage, deductibles, and premiums means that even those *with* insurance can struggle to access healthcare: Persad, 2020: 821, 822.

20 On the extreme costs of pharmaceutical development – Feldman, 2018: 592; though reflecting the generally non-linear nature of invention more broadly. See: Kline, 1985: 36.

21 As well as the fundraising elements that are important in the industry-university relationship. See: Hottenrott and Thorwarth, 2011: 535.

companies who, in the absence of wide-ranging research departments (Hassoun, 2011: 844), now rely on the foundational research carried out by universities (Fabrizio, 2006: 136). The Bayh-Dole Act reforms in this context were an important counterbalance because they specifically dealt with the issue of compulsory licensing as a way of ensuring access to federally funded research outputs (Lin, 2014: 177), as I now explain.

Codification and the Role of Universities

The impact of the Bayh-Dole Act

Implementation and Development of Bayh-Dole

The Bayh-Dole Act was introduced in 1980 as part of a broader 'pro-patent' initiative and economic response to the 1970s (Takenaka, 2009: 584).[22] It established a framework that structures the relationship between federally funded agencies and non-profit organisations or small businesses in terms of the patent rights that result from those projects (Takenaka, 2009: 584).

Prior to this, the Federal Procurement Regulation had mandated that patent rights emerging from federally funded research would be assigned to the US government, resulting in a situation in which many patents were held but there was a lack of consistent commercial exploitation (Mowery et al., 2015: 36). The most important – or at least, most contentious – provisions of the Bayh-Dole Act are the 'march-in' rights that allow the funding agency responsible to (at the request of a third party or of their own initiative) to issue a compulsory licensing for the patented technology.[23]

Universities are uniquely positioned in this legislative reform because they occupy a space that is at the crossroads of commercial development and research development, and are often the physical location of these interactions. As discussed previously, universities have long been centres of innovative output in terms of the training of a new generation of professionals and the innovative research output of faculty members.

With the shift towards the economic dimensions of intellectual property, that is, as a driver of economic growth, universities and their professors enter a space in which their patenting of new technologies can have serious ramifications outside of their initial intellectual property context, both in the broader human rights sense and in the personal career development of faculty members.[24]

Researchers now operate in a university context in which there is an expectation of commercialisation that marks not just a tonal shift from the historical operation of university research but centres the individual researcher in the active privatisation of their work. When considering how the Bayh-Dole Act affected the socio-legal position of universities more broadly, it is important to recognise that this conflict has taken on an additional dimension in recent years as universities face sustained criticism that the research outputs of their faculty are not accessible to ordinary citizens.[25]

The Bayh-Dole provisions outline four conditions under which a petition for march-in rights can be considered that predominantly centre on the usage of the invention and the actions of the patent assignee.[26] These provisions are intended to address, in part, the accessibility concerns that arise from the patenting of federally-funded inventions, going some way to tempering the extremes of this more formalised university-industry relationship. The most prominent of these tests has been whether the health and safety needs of the citizens are being met, providing the foundation for most of the challenges to the accessibility of HIV/AIDS medication (Pope, White and Malow, 2014: 286). The focus on HIV/AIDS accessibility is present in many of the petitions to grant march-in rights and

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22 The 'stagflation' of the US economy during the 1970s (economic stagnation and high levels of inflation) created a very difficult economic context: Blinder, 2013 :1, 2, 3.

23 USA: 35 U.S.C. §203(a).

24 From as early as postdoctoral level, patents obtained can be an important metric by which candidates can demonstrate research excellence in applications for funding and academic promotion: NIH, 2021.

25 Beyond the movement towards open access and 'open science', even universities struggle with the costs of subscribing to academic journals: Wired, 2019.

26 USA: 35 U.S.C. §203(1) – (4).

is significant not only for the complex legal and political position that HIV/AIDS occupies in the US,[27] but also because it reflects clearly how central universities are in this context (and particularly so in the context of pharmaceuticals).

Pharmaceuticals and the commercialisation of university research

The emphasis on pharmaceutical products that emerges when considering the patent activities of universities and industry becomes clear when considering the features that differentiate pharmaceutical research from other kinds of advanced technologies.[28] In contrast to software or artificial intelligence development (but like biotechnology), pharmaceutical research requires significant human and financial resources, as well as physical lab space to carry out research.[29]

The Bayh-Dole Act essentially shifted the risk for the development of new technologies to the university and its researchers, allowing private businesses to avoid the non-linear process of developing a new pharmaceutical compound, and step in as the patent licensee and follow-on innovator.[30] The shift in risk is not complete, however, because pharmaceuticals involve a much broader regulatory web that extends beyond intellectual property and requires extensive testing for safety and efficacy (a process which, itself, does not present a linear path from human trials to successful market launch) (Li and Lim, 2014: 246). The increased commercialisation of university research has therefore not resulted in a complete integration within the industrial product pipeline but, rather, functions as a significant offset to the traditional risks of product development.

The push towards broad-scale commercialisation of unused federal patent rights of the Bayh-Dole Act essentially changed the structure of modern industry in advanced technologies by repositioning universities as a direct source of patentable or patented innovations. Again, this repositioning is significant for pharmaceuticals because, particularly in the US, the extreme cost of healthcare as a result of patented medications can be traced (for specific medications) to compounds that were either produced in the context of university research or the safety of such pharmaceuticals was explored in publicly-funded experiments.[31]

The Bayh-Dole provisions were aimed at using the unexploited patents that had accrued to the government and the economic impact that this exploitation would bring (Mireles, 2007: 259; 263), specifically framed in terms of the economic effect that this would have. The economic focus of these provisions relies on the conventional justifications for technology licensing in that it is economically more efficient for multiple actors to use their expertise to develop or exploit specific elements of the patented technology.[32] Given the fundamentally economic rationale for the Bayh-Dole Act, it is surprising that the legislation included a reservation to compel a license in specific circumstances because the severity of the economic troubles throughout the 1980s meant that the legislators could have simply prioritised broad-scale exploitation as the sole objective (rather than considering accessibility at all), which was also clear in the framing of the Japanese legislation (Takenaka, 2005b: 28).

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27 Particularly the contentious position of the government regarding the funding of AIDS research early in the epidemic, while 'the political climate deterred any proactive federal response' and '[t]he social conservatives who helped elect [Ronald Reagan] recoiled from a disease publicly associated with gay men—a strongly marginalised and stigmatised social group': Padamsee, 2018: 1004.

28 In a study of the top 300 universities worldwide and their patenting considered in terms of discipline, patents in the field of chemistry far outweigh the other fields (such as mechanical engineering, electrical engineering, and instruments): Fisch, Hassel, Sandner and Block, 2014: 327.

29 Developing pharmaceuticals and scaling this up to commercial production requires physical, specialised space (in a way that does not appear to transfer directly to an experience of computer science research): Bharath, 2013: 89.

30 While there are obvious examples of this, such as HIV pre-exposure prophylaxis that culminated in a series of congressional hearings around access and the $50 million in federal funds granted to AIDS researcher Robert Grant. See: Haltiwanger, 2019. There are also more sinister manifestations such as the government-sponsored clinical trials of Remdesivir in the coronavirus pandemic, in which Gilead directly profits from federally-funded research on the basis that these tests did not produce anything inventive: Rowland, 2021.

31 With a significant proportion of the literature investigating the relationship between patents and high costs of healthcare, particularly in the US: Gold et al, 2009: 1.

32 On the procompetitive effects of licensing, see Dratler, 2005.

The fact that an exception *was* included is a strong indication that the commercial imperative should not be the only consideration. Despite the failure of the petitions for march-in rights so far and the significant disparities in US healthcare accessibility,[33] the Bayh-Dole's transformation of universities into an important input source for industry is fundamentally incomplete – it provides, at least in theory, a way in which accessibility *could* be rebalanced through a successful application for compulsory licensing.

Universities have had their role in the broader innovation ecosystem formalised by Bayh-Dole and, while it is a role that in practice has been explicitly commercial, there exists the potential for a more active approach to the march-in rights process to be developed in the future that might prevent universities from being fully subsumed by industry and industry interests.

Facilitating the Commercial Exploitation of Innovation

Technology Licensing Organisations (TLOs) and Technology Transfer Offices (TTOs)

One of the most significant changes that the Bayh-Dole provisions introduced was with the positioning of universities as *owners* of intellectual property, something that was mirrored in the similar international legislation. Making universities licensors of the patented technologies that they helped develop was a significant enough development, but it also came with a formalised institutional framework that supports a more complex role for the university – primarily with the introduction of Technology Licensing Organisations (TLOs) in the Japanese context and Technology Transfer Offices (TTOs) in the US, though universities in both countries now appear to use a mix of these terms almost interchangeably (and with some variation, such as MIT's Technology Licensing Office).

The TLOs have been prominent institutions themselves within the university, although the revenue distribution considered across all TLOs in Japan and the US, is highly skewed and this asymmetry can be seen particularly acutely at universities that are less research-intensive or have less funding.[34]

Under the Bayh-Dole Act, TLOs were primarily aimed at facilitating a process of technology transfer by which intellectual property rights could be exploited by private companies for commercial purposes (Ream, 2008: 1343). Taken from this broad perspective, the implementation of specific university administrative structures to help researchers to first secure and then successfully license their research would appear to be a natural development rather than a dramatic corporatisation of the university.[35]

As discussed previously, universities, through their contribution of skilled professionals and equipment, have long engaged in the processes of technology transfer (Young, 2004: 21). Before Bayh-Dole (or more broadly, the active involvement of universities in the production of intellectual property), technology transfer from university to private industry occurred through the ordinary activities of university researchers, from producing scholarship in peer-reviewed journals, presentations at conferences, or engaging in collaborative research through research groups (Young, 2004: 21). An important distinction, then, is that Bayh-Dole did not formalise all forms of technology transfer and instead narrowly constructs 'technology transfer' to mean the commercial application of intellectual property.

The commercialisation dimension of a university TLO is not inherently problematic when it is an explicit collaboration with a private business, with clear parameters regarding the registration of any resulting intellectual property and subsequent licensing. But the ethos of research universities in the dissemination of knowledge, and the transfer of that knowledge to the public, is undermined significantly when not only the basic, research foundation of the commercialised product is out of

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33 The petitions for march-in rights have been consistently denied (which, given the earlier discussion of HIV/AIDS response by the US government, is particularly significant. See *In the Case of Fabrazyme* (2010); *In the Case of NORVIR* (2004)): Craddock, 2007: 286.

34 On the extreme concentration of wealth generated through technology transfer at specific universities: Orozco, 2019: 161.

35 It is also important to remember that intellectual property was not always in the modern consciousness in the way that it was now, researchers 30 years ago were not necessarily preoccupied with the process of applying for patents on their research: Young, 2004: 20.

reach,[36] but the product itself – for reasons of money or physical supply (Hoffman, 2012: 2–3) – has also become inaccessible.

Beyond pharmaceuticals, TLOs fulfil several functions for both universities as a whole and on the level of individual faculty, allowing universities to recruit high-quality staff and establish an effective interface between academia and private industry (Young, 2004: 21). Considering TLOs from this more structural perspective reveals a more utilitarian aspect of university administration bodies, reflecting the pressure of economic growth that was key to the Bayh-Dole legislation at its conception and has become more explicit within universities themselves in recent years.[37]

Constructing TLOs as a fundamental element of economic growth at both a regional and national level necessarily involves recontextualising the role of a university and pushes it further away from the traditional themes of service and dissemination of knowledge. In the commercialisation of pharmaceutical innovations, this emphasis on national economic growth appears to be particularly sinister given the history of manufacturers generating extraordinary profits from products that originated in government-funded research and are the result of exploiting the ill-health of American citizens.[38]

The shaping of a TLO in such a way fundamentally alters the position of a university in a socio-legal context because the process of commercialisation which the Bayh-Dole provisions formalised is, in its practical impact on ordinary citizens, so incredibly divergent from how universities have typically functioned.[39]

Diversity in TLOs and the economic framing

The important role of TLOs in national economic growth is also concerning from a different perspective, considering the distinctly heterogeneous impact at a national level.[40] The establishment of TLOs has created an additional factor in how universities are perceived and evaluated in terms of their industrial impact which, in turn, reinforces the divide between the successful TLOs with high revenue or famous products and more small-scale operations. Once again, the objectives of knowledge dissemination and service to the public are subverted by a system that reinforces financial disparities not only in terms of its accessibility of commercialised products but also at a disciplinary level, in which smaller colleges or less directly commercial specialties are considered less attractive or worthy from an economic growth perspective.[41] Success in licensing technology and the patenting of technology has essentially become a new metric for analysing the performance of university departments and assigning funding. It has the potential to skew the research priorities towards more profitable endeavours such as the development of pharmaceuticals.[42]

A research skew towards pharmaceuticals also reflects the broader technological heterogeneity in US patent law, specifically from an enforcement perspective. While a technologically unitary regime in principle,[43] several studies have shown that the treatment of a patent in court is affected

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36 Although this is being addressed through wide-ranging commitments to open access publishing: Ross-Hellauer, Schmidt, and Kramer, 2012: 2.

37 Intellectual property rights in the development of Bayh-Dole were explicitly framed in terms of their contribution to economic growth: Hamilton, 2003: 406. The Japanese context also demonstrates that the priority was the exploitation of intellectual property rights for national economic growth, and therefore TLOs aiming for profit is not necessarily a distortion of the original legislation: Saegusa, 1999: 3.

38 One particular example that stands out is Gilead's PrEP medication, which is under patent in the US but not elsewhere, resulting in an annual cost to US citizens of $21,360: Simmons-Duffin, 2019.

39 For the development of non-profit hospitals in the US, as well as the important role of free clinics, both of which run counter to the profit orientation of the pharmaceutical industry, see BBC, 2019.

40 The highly asymmetric output of TLOs should be seen in the context of a similarly unbalanced distribution of resources across universities that are essential in producing the research in the first place: Lafuente and Berbegal-Mirabent, 2019: 779.

41 Despite the fact that producing profit is supposed to be one of the lesser reasons for implementation of TLOs in universities: Young, 2004: 22.

42 Given the growth of biomedical patents versus non-biomedical patents, this skew has been a feature of US university research for a significant period already: Hamilton, 2003: 408.

43 In that patent law does not have separate patent systems for different technologies, and all are protected under an essentially identical 'patent'.

substantially by the type of technology that it is related to.[44] For universities, and from the perspective of enforcement, pharmaceuticals have a fundamental advantage in this context because they represent a specific compound at a therapeutically effective dose that can very easily be depicted graphically and chemically. By contrast to patent claims in software and computer-implemented inventions,[45] pharmaceutical patent claims are clear in what they cover and the bounds of its protection. This gives universities a great degree of clarity in their licensing, especially considered in the context of a petition for march-in rights.

The issue with this model of evaluating the success of universities is that it reinforces the dominance of research-intensive universities that have successfully licensed their technologies, which then receive more research funding and gain in university rankings, to then attract other talented professors to develop new technologies. The reality is that many TLOs are not sustainable for the majority of universities, particularly in light of the reinforcing cycle of elite university output just described. The costs involved with running a TLO should be considered as a normal part of the university budget rather than providing funding with an expectation that the TLO will become profitable. A move away from this profit expectation of TLOs would deemphasise the unusual large successes and also draw focus to the valuable services that they provide for researchers.

This push towards commercialisation and generating income also has a sub-disciplinary perspective. A clear divide can be identified between Science, Technology, Engineering, and Maths (STEM) subjects and humanities, but even within STEM there are departments that are currently struggling precisely because they lack the type of immediate application that characterises the research produced by TLOs. Pure maths – with impact that may emerge 'perhaps decades or centuries later' (Rowlett, 2015: 67) – highlights that, even within STEM, not all disciplines can be easily reconfigured in this commercial framing.

Law schools also represent, even within humanities or social sciences, a particularly vulnerable position regarding commercialisation of output or research. Law schools suffer – in both the US and the early-2000s transplants in legal education in Japan[46] – because there is an emphasis on the practice of law and achieving the skills required of a lawyer.[47] Clinical legal education is one example of how law schools can produce a concrete application of the discipline, yet it does not generate income in the same way that a TLO does and is also subject to the type of ideological criticism that is not present with STEM subjects.[48] What is lost in the expansion of TLOs and the broader commercial framing of research is that, considered here in the context of law, so much of the discipline's 'value' (for students and society) is left behind. The legal education reforms in 2004 in Japan could introduce similar provisions but not transplant the dynamics of US law schools, especially the latter's involvement in outreach (Adams, O'Meara and McCarthy, 2020: 339), advocacy (Paoletti, 2015: 286) and environmentalism,[49] both of which represent important forms of non-economic or non-commercial value.

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44 Patent law in practice is extremely technology-specific: Burk and Lemley, 2002: 1156-57.

45 On the technology-specific features that permit a degree of ambiguity in claim drafting for software inventions, see Cotter, 2018: 118.

46 On the 2004 reforms in Japan and the shift away from undergraduate law, see: Riles and Uchida, 2009: 3. On the tensions in US law schools between teaching students 'legal skills' and 'producing law students capable of practicing law', see Valentine, 2009: 179.

47 '…this undergraduate education did not truly prepare graduates for legal practice' and was instead a source of future civil servants and businesspeople': Saegusa, 2009: 371.

48 Especially in contexts where legal aid budgets are reduced and legal clinics are important services: Blackburn, 2018: 179. Particularly in the US at Harvard, students involved with the Federalist Society argued for the establishment of more conservative legal clinics that highlight the more ideological dimension that can attach to these activities: Carrel, 2019.

49 Engaging with environmental issues has a long tradition at particular law schools in the US: Young, 2010: 43.

The Socio-economic Context of Bayh-Dole in Japan

Lost in Transplantation

The Japanese context pre-2000

The potential of intellectual property in encouraging technological and economic growth was highlighted by the radical emphasis on the strengthening of patent rights towards the early 2000s. Then Prime Minister Koizumi in his address to the National Diet in 2003 declared that Japan would become an 'intellectual property-based nation' and set in motion a reform effort that was envisioned as an attempt at replicating the pro-patent age of the Reagan administration in the USA (Tani, 2004: 120).

This was not the first time that the Japanese patent law framework had actively mirrored that which appeared in the USA, with the 1999 reforms to the Industrial Revitalization Law introduced by Prime Minister Obuchi entrenching almost identical provisions to the Bayh-Dole Act and building on the earlier 1998 Act on the Promotion of Technology Transfer from Universities to Private Businesses (Ogose, 2010: 12). This emulation of US policy appears particularly significant when considered in its historical context, given that intellectual property rights – even just a decade earlier – were the source of intense trade tension between the US and Japan.[50] Conflict emerged as a response to the different perceptions and treatment of intellectual property rights, specifically patents, in the two countries. This led to a situation in which US businesses felt that Japan, along with some of the ordinary difficulties of operating in a foreign legal system,[51] was specifically targeting US-owned intellectual property rights for undermining.[52]

Japanese businesses, in contrast, appeared to downplay the importance of patent rights into the late-1980s in an approach that emphasised market competitiveness through manufacturing rather than with artificial restrictions from patents and patent enforcement.[53] This dramatic shift in policy and the positioning of intellectual property rights is stark because it not only represents a completely opposite construction of the role of intellectual property rights as an essential tool for economic growth but actively aligned Japanese economic policy with that of its trade rival. In fact, Japan was dealing with the same problem that had emerged in the US over a decade earlier, in which the innovative research that was conducted in universities was patented but then failed to be commercialised (Hata and Miyazaki, 2015: 173).

Besides the more developed history of industry-university collaboration in the US and the tendency towards in-house basic research in Japan (Mireles, 2007: 266), the Japanese regulatory approach to universities prevented professors from engaging in commercial activities and they could not hold positions of private employment outside the university (Mirowski, 2011: 134).

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50 The Young Report, while discussing the potential of patents as engines of economic growth, also highlighted the need to deal with foreign infringement of US intellectual property. With the rapid expansion of Japanese companies in overseas markets and the US falling behind (globally) in manufacturing, frequent patent-related disputes emerged during the 1980s between the US and Japan: Suzuki, 2010: 43; 55.

51 The Ministry of International Trade and Industry takes a central role here, facilitating technology transfer from abroad to Japan. The difficulty of navigating the Japanese legal system concerned US businesses. It was a combination of manufacturing strength (whereby leased intellectual property from the US would return to the US in more competitive, Japanese, products) and concerted behaviour of Japanese firms reminiscent of a cartel that provoked trade tensions between the two countries: Ajemian and McHardy Reid, 2010: 423.

52 Again, drawing on the central role of Ministry of International Trade and Industry, the 1960s saw a consistent pattern of behaviour of Japanese firms relying on government intervention. One controversial example of the was grant of a patent to a Japanese business, even though the JPO had previously found it to be infringing a US patent: Wolfson, 1993: 546.

53 In the 1980s, the dependence on patents that characterised the disputes between the US and Japan was seen by Japanese businesspeople as a crutch for industries that could not compete on either the innovativeness of their products or manufacturing: Rousso, 2001: 813.

The broader institutional impact of TLOs

The TLO system in Japan was intended to facilitate the licensing and management of university-developed technologies,[54] although it is important to note that in the context of the Japanese reform it created *registered* TLOs and did not affect the activities of non-registered offices (which merely remain ineligible for the benefits outlined by the legislation) (Ishii, 2017: 137).

The 1998 Act introduced TLOs to Japanese universities to promote and facilitate the collaboration of universities and private industry so that research outputs could be developed and contribute to the growth of national industries.[55] The TLO of a university is to establish a strategy that promotes technology transfer to industry, specifically through the patent mechanisms of licensing and assignment, although their role is more expansive than it would first appear. TLOs were also, eventually, a fundamental part of the efforts of the JPO to promote patent licensing by sending skilled licensing advisors and encourage private enterprises to license university-owned patents (Kashiwara, 2007: 7). It is therefore clear that the strategy of reforming the functional relationship between universities and intellectual property was not simply a promotion of licensing itself, but rather a concerted institutional approach focused on the TLO to shape the macro-dynamic (of the relationships between the university as a creator of intellectual property and private enterprise licensees) as well as the micro-dynamics (providing support for researchers in actually obtaining intellectual property rights, ensuring that appropriate funding is available for obtaining the patent, and then licensing that patent right).[56]

While the TLO is a key element in the transfer of intellectual property rights to private business, they also fulfil an important role as a coordinator for joint and funded research ventures (Ishii, 2017: 145). This is significant because it demonstrates the more complex function of the TLO outside simple licensing agreements and provides another way in which the university is integrated into the broader enterprise context. As will be discussed, the differences in academic research contexts between the US and Japan meant that, in the Japanese context, the inclusion of a TLO as something of a 'third party' in the relationship between university researchers and industry complicated the efficient technology transfer that the legislation was intended to facilitate. The resulting arrangement of the parties further distinguishes the Japanese context from that which the Bayh-Dole Act creates in the US. The difficulty (particularly from a management perspective) is that because of the incorporation of the Japanese national universities, researchers are formally required to report all inventions that they generate as employees of the university and this would create an enormous burden if adhered to exactly.[57]

The apparent lack of will in surveillance under both the older regime of lab donations and the modern TLO approach must be understood in the broader economic context of the reform. The issue in the US context was that the government had accrued many patents that it could not use because the right was assigned by default when the invention was produced with federal funding (So et al., 2014: 201). In the US context, it was not that the professors were legally prevented from assigning the intellectual property rights arising from their research, but instead it was more that the commercial value – in line with the Bayh-Dole Act being an attempt at promoting economic recovery[58] – was going unexploited. Even before the Bayh-Dole Act was passed, elite universities were already pushing the potential of individual labs to partner with businesses and generate profit (Orozco, 2019: 126, 127).

The informal (or at least, more unstructured) relationships between laboratories and industrial partners in the Japanese context did not require elaborate formal governance structures because the

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54 Japan: art 5, Act on the Promotion of Technology Transfer from Universities to the Private Business Operators (1998). Available at: https://www.wipo.int/edocs/lexdocs/laws/en/jp/jp193en.pdf.

55 Japan: Article 1, Act on the Promotion of Technology Transfer from Universities to the Private Business Operators (1998).

56 Previously, researchers had self-funded their own patent applications and TLOs, therefore, have an important role in facilitating the acquisition of patents over new technologies: Kandachi, 2004: 623.

57 This would also only cover a narrow portion of the TLOs responsibilities. Beyond just processing applications, the TLO would also be responsible for how the royalties from the technology would be shared and other aspects specific to the licensing agreement (which raises the issue of when, exactly, the TLOs would effectively negotiate and contact potential foreign licensees): Kandachi, 2004: 623.

58 And other associated legislation like the Economic Recovery Act 1981. See: Wolfe, 2013: 124.

universities (and also the professors) were unable to be assigned the intellectual property rights in their research, although they were still officially recognised as the inventor of the technology (Kameo, 2015 :186). Under the old system, Japanese professors would have had little to gain from frustrating the industrial partner registering intellectual property rights in the research. The lack of surveillance or enforceable obligations in a system that relied on donations comes at least partially from the fact that the economic potential of the research was only one aspect of its value. As in the case of the disciplinary impact of the increasingly commercial framing of research, particularly in Japan, the legislation failed to capture the non-economic aspects of the relationship between universities and businesses.

United States universities had already emphasised the commercial framing of research before the Bayh-Dole Act was used to, essentially, codify practice at elite universities in a way that strengthened the normative foundation of institutional commercialisation. Japan lacked this type of experience, and so the promotion of commercialised university partnerships took one aspect of the old regime and elevated it – with commercialisation becoming the central value of collaboration.

The introduction of TLOs marks an important departure for Japanese universities and signals an explicit incorporation of intellectual property in the fundamental mission of a university. The Japanese government and its approach to intellectual property underwent several transformations as Japan evolved politically and economically, but the central role of the university and its relationship with intellectual property – positive or negative – has been consistent throughout modern Japanese history.[59]

The Japanese Bayh-Dole Act is indeed a significant turning point in how universities operate and the relationship of researchers to industry, although there was a shift throughout the twentieth century that gradually started to recognise individual researchers as the creators and owners of resulting intellectual property rights.[60] Post-War Japan saw increasing support for the uncoupling of universities from intellectual property rights because universities had been co-opted by the military (Hisa, 2004: 46), although this built on the earlier sentiment in an academic context that research involving private interests was not an academic pursuit (Hisa, 2004: 46).

Changes within the university environment

While the difficulty of reconciling intellectual property ownership in this difficult historical context could be considered from an employment law perspective, it is more comprehensively understood as a tension emerging from the intersection of universities, their previously informal role in innovation, and the pursuit of national industrial and economic growth. The US offers several notable examples of how the relationship between the production of skilled individuals and technological growth (particularly in advanced technologies) can develop. Silicon Valley is perhaps the clearest example, sparking investigations around the world as to how this type of environment could be copied (Fenwick, Vermeulen and Corrales, 2018: 94; 95). The dominance of Silicon Valley over what was a comparatively skilled concentration of universities on the East Coast was due, at least in part, to the more liberal employment practices of California, which allowed the free flow of skilled professionals.[61] The interconnected nature of US universities, start-ups and technical experts is one of the primary drivers of innovation in the US. While not explicitly presented as such, the fact that the Japanese Bayh-Dole Act was very clearly an attempt at replicating this dynamic would suggest

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59 The Iwakura Mission of the Meiji Restoration reflects the origins of modern Japanese industrial policy, investigating the types of institutional reform needed to make Japan competitive (of which the patent system, as observed in the US and implemented in 1885, was a core element). See: Manata and Ottervik, 2019: 897; 898.

60 Specifically, the shift in the 1970s, in which the Ministry of Education allowed researchers the right to their invention in three specific circumstances. See: Hisa, 2004: 46.

61 Ministry of International Trade and Industry tried to replicate a similarly vibrant business atmosphere in the 1960s by offering subsidised loans from governmental financial institutions that, in the 1970s, evolved into a policy of (very restricted) venture capital. See Vogel, 2018: 107. For specific analysis of the labour policy of California (specifically covenants on post-employment competition) that contributed to the distinctly mobile and flexible workforce of early Silicon Valley (and why Massachusetts/East Coast did not achieve the same industrial prominence), see: Gilson, 1999: 575.

that its objectives were not only the exploitation of government intellectual property, but a broader realignment of universities relative to private businesses.

The policy of preventing civil service employees from holding external posts is a core element of how this policy became more fully realised in Japan (Carraz, Nakayama and Harayama, 2014: 229). While the US, at the time of the reform, already had universities committed to the commercialisation of their faculty's research output (Orozco, 2019: 127) – and therefore well prepared to extend this approach to federally-funded research – the Japanese system operated in a much stricter regulatory context, which meant that the sharp transition that introduced TLOs was disruptive to existing systems of university research.

The restrictions of the Japanese system allowed a system of informal rules and paradigms to develop that established the parameters of industry and university collaboration, with these dynamics not necessarily addressed by the Japanese Bayh-Dole legislation. This shift in how universities operate relative to private industry, as well as changes to the very framework that facilitated that relationship, was profound because it conflicted with an existing complex system of self-regulation. The absence of legislation to truly address the forces beneath this transition towards commercialisation of university research seems to have contributed to the inefficiency of Japanese TLOs and, by extension, the incomplete transformation of Japanese universities as innovation institutions.

The Partial Repositioning of Japanese Universities

The limitations of the patent as a legal and economic instrument

It is often overlooked in discussions about the march-in rights framework that has come to define the modern discourse around the Bayh-Dole provisions that these rights are only a single element of the reform that helped to revitalise the US economy. For Japan, it was this economic aspect that was prioritised because it had successfully been used to restart the US economic recovery (Lechevalier, 2011: 126). This led to Japanese reform that focused on the economic aspects of recovery and not necessarily a comprehensive approach to intellectual property rights.

The experience of the Japanese Bayh-Dole Act and the reform of universities to maximise their technology transfer for patent exploitation demonstrates that, even if the provisions were to be exactly transplanted, any reform in this field needs to also address the significant cultural dimension of the institutions involved and their practices. It is clear that in both Japan and the US there are soft law components that have led to some significant weaknesses when promoting the commercialisation of university output, as well as the clear imbalances that exist in terms of ensuring access to these outputs. However, while patent rights are indeed central to modern innovation – in terms of legal protection and providing a structured representation of knowledge and progress[62] – they are fundamentally limited in providing a comprehensive understanding of an invention. This takes on a discipline-specific dimension when considering the difficulties in accurately and completely capturing an innovation in a patent document, something that disproportionately affects software or other computer-implemented inventions.[63]

Focusing on the process of technology transfer through a formalised route like patent licensing can further skew future research agendas towards those fields of technology that match most closely with the patent system. This could be not only in terms of how this technology can be depicted effectively as discussed previously, but also in a more disciplinary-specific sense that is related to how the process of collaboration or group research work in that area. Effective technology transfer relies not only on the transmission of a patent in the legal sense of disclosure and licensing, but also

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62 The ability for patent law to help with the 'orderly development of broad prospects' was described as a potential strength for incorporating software within the patent system: Campbell-Kelly, 2005: 247.

63 On the patenting of non-chemical innovations and the important role of tacit knowledge, see Kingston, 2004: 458. University patents have been described as 'embryonic' in that they are likely to operate in a context in which the associated knowledge has not yet been codified and can exacerbate the existing issues with the disclosure function of the patent: See Larrimore Ouellette and Weires, 2019: 23.

on a strong sense of tacit and contextual disciplinary understanding.[64] Particularly in the Japanese context, the more tacit elements of technology transfer were significantly affected by the introduction of TLOs because the reform sought to formalise industry/university relationships and was central in contributing to the partial or incomplete nature of the repositioning of universities. By firmly positioning the TLO between university researchers and their partnerships with private businesses, the more human aspects of that relationship are harder to maintain. The relationship between researcher and business is more than just that of licensor/licensee, and it is this personal quality that is essential in communicating the type of tacit knowledge that is not captured in a patent document. This also highlights the heterogenous nature of university commercialisation, as high-performing universities like Tokyo and Kyushu still demonstrate a strong research output (Ishii, 2017: 141), while the disruptive impact of the TLO is more damaging to universities with younger or emerging research departments. The regulatory context suggests that, rather than the informal transferal of intellectual property rights to industry partners as purely the result of a mutually beneficial relationship, it was instead an industry-led instance of private ordering to meet some deficiency in the regulatory framework.

For universities and university researchers, before the reform that formally incorporated the universities and allowed them ownership of their intellectual property rights, informal 'donations' to labs were not simply in exchange for the resulting rights in the laboratory's research but instead had an important function in moderating their relationship (Kameo, 2015: 185). This funding was often used to allow researchers to present their work internationally because the government agency did not allow research funds to be used for international travel.[65] Importantly, however, this funding was maintained even outside active research projects and provided a form of consistent support for a professor and his or her lab. (Kameo, 2015: 185).

In short, the bureaucratic framework created a system in which the relationship between research labs and industry partners has been exceptionally slow to change and still relies to a great degree on the goodwill of professors and industry partners (Kameo, 2015: 183). In this respect, Japan suffers from a dual problem in their transplantation of the Bayh-Dole provisions that must be addressed by any future solution, the first of which is this informal or personal foundation of industry/university cooperation.

The challenge in measuring the impact of TLOs in Japan

March-in rights are a controversial area. The reality is that an application for march-in rights suggests, inherently, a conflict between the major stakeholders involved. In Japan, with the emphasis on informal relationships and the perceptions of TLOs, pursuing this type of action could permanently damage the long-standing relationship between the university and the business – particularly if this decision is taken by an actor *outside* the research context, such as an administrator. TLOs have already been characterised as an interfering third party and the impact of even a failed application – as would be likely given the experience in the US – could further complicate the relationship of the TLO with both industry partners and the individual faculty researchers. This, however, assumes that TLOs have a meaningful impact on university research and relationships with industry partners. It is not my intention to suggest that researchers understand their work primarily as it relates to TLOs or that march-in rights have an impact on the everyday working of researchers at universities in Japan or the US. Instead, I would suggest that critiques of TLOs and march-in rights that question how passive – or underdeveloped (Chan-Tiberghien, 2010: 47) – they are, actually highlight a more fundamental failing in how universities have been integrated with more commercial settings. This is a significant issue for the Japanese system because, when viewed through the lens of the US experience with Bayh-Dole, it becomes clear that even a system without such a complex role of personal relationships does not automatically

64 On discussing the interaction between innovators as a key element to the dissemination of tacit knowledge, see Ghosh, 2010: 90.

65 One key example is use of these donations to fund international travel because the Ministry of Education, Culture, Sports, Science and Technology did not allow the use of grants-in-aid to be used for international travel: Kameo, 2015: 185.

guarantee increased accessibility. As clearly demonstrated in the US example of the National Institutes of Health (NIH),[66] the existence of a framework and specific criteria for a compulsory license cannot ensure successful petitions.

March-in rights were intended to facilitate commercialisation but retain a degree of control by the government as an extension of the taxpayer (Basheer and Guha, 2010: 271, 272). The fact that the threat of using march-in rights is not a concern for businesses demonstrates a crucial legislative failure. The solution is perhaps not as simple as just implementing more permissive standards for review,[67] but it is clear that the workings of compulsory licensing through this mechanism need to be revisited. The discussions in the context of Covid-19 highlight this tension because, 40 years on from its introduction and the failure to demonstrate a single successful petition, the Bayh-Dole legislation remerged in discussions around vaccine accessibility (Paradise, 2020: 1, 2). In both Japan and the US, march-in rights are central features of the legislative frameworks that reframed university research and commercial partnerships, and should be a central consideration when universities are collaborating with industry partners. The absence of impact here suggests a fundamental mismatch between the mechanisms provided for in the legislation and the actual functioning of universities as research institutions.

A second weakness is related more specifically to the Japanese university context, though it certainly shares some overlap with the US system. The TLOs of Japanese universities have been supported extensively by the Japanese government in much the same way that the US universities are in the context of supporting start-ups[68] – although this can be seen not only in direct government support for TLO activities but also in the reduced fees and accelerated patent process offered by the JPO.[69] The support provided to Japanese TLOs by the Ministry of Education, Culture, Sports, Science and Technology and the JPO must be seen in the broader patent context of Japan, an environment that already provides competitive patent costs compared to the US (van Pottelsberghe de la Potterie and François, 2009: 492). The fact that Japan already has a generally affordable patent system in terms of patent acquisition and enforcement (specifically in the calculation of damages: Pietari, 2016: 994) raises questions about the role of the TLOs. If, even with these systemic advantages, the TLOs are not considered central actors in shaping the commercialisation of university research, then that is a sign that their responsibilities and activities need to be revisited. The prevailing concern around this is a question over whether these universities, particularly ones with a less significant research output, will be self-sustaining once government support has stopped.[70] However, a larger issue is the broader landscape in which the TLOs and universities find themselves, where the US has a significant advantage: start-ups and venture capital (Mashima, 1999: 126). As the system of industry and university collaboration has developed in the US, start-ups and spin-offs have become clear and effective ways of maintaining researcher input, while still contributing to the exploitation of patented technology that the Bayh-Dole Act was intended to encourage.[71]

Japan has lacked a strong venture capital scene historically and working patterns have not generally been conducive for start-ups,[72] although the government[73] – centrally, and increasingly, at the Prefectures level – has made important, if tentative, steps towards liberalising this approach and

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66 The NIH are aiming the prominent funders of research undertaken in public institutions, as public entities and are therefore central in the functioning of march-in rights and their petitions: Cimoli et al, 2014: 507.

67 There are moves to make the process more restrictive, with the National Institute of Standards and Technology proposing some clarifications, one of which is to 'include a provision that march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from the practical application of the invention': NIST, 2021.

68 Japan: Small Business Research and Development Act (PL 102-564 S. 2941, 1992).

69 Including preferential examination fees and annual fees for a specified lifespan of the patent: Hatori, 2016: 17.

70 There is concern that TLOs are not sustainable yet in Japan because filing and defending patents costs more than they earn from licensing (mirroring the situation in most US TLOs): Takenaka, 2005: 34.

71 On the important role of spin-offs in a university context, see Ito, Kaneta, and Sundstrom, 2016: 7.

72 Specifically, the difficulties of recruiting technical and non-technical staff in a context in which 'long-term attachment' to big companies is common and mobility is generally low, although improving,: Odagiri, 2007: 168.

73 'By international standards, Japan is very short of venture capital. Japanese venture capital organizations prefer to invest what capital they have in development finance rather than start-ups': Coyle, 2000: 19.

using tax incentives for the formation of new innovative start-ups with the support of central government.[74]

Conclusion

The development of medical technologies in recent decades has brought significant advances from a technological perspective and in actual health outcomes for ordinary citizens around the world. Universities have always been a fundamental aspect of industrial development, producing technically proficient graduates and offering a space in which students can explore their professional interests and aspirations.[75] Particularly in the context of medicine, with historical and contemporary examples, universities have long existed at the intersection of practical medicine and the teaching of new medical professionals in a broader educational sense.[76]

The rise of intellectual property rights has changed the role of universities as actors in the innovation ecosystem, although this appears to have occurred in two distinct waves. The first was a general consciousness of intellectual property rights as an economically valuable asset, distinguishing a nation's development beyond the earlier agricultural or manufacturing-focused expertise. This development affected individuals and industry equally, bringing a popular awareness of intellectual property rights, which had previously been considered a more specialised area of law.[77]

The second wave saw the role of universities take on a more formalised dimension that resulted in the partial transformation of their position as an *active* innovation actor. This period of reform, involving the Bayh-Dole Act in the US as an early example, was specifically intended to release the value held in stores of government-owned intellectual property and reshape universities as active participants in the commercialisation of government-funded technologies. This shift reflected the general importance of intellectual property, but the US legislation (and later, the modified Japanese transplant) is actually part of a larger, more consistent, pattern of exploiting intellectual property as a way of responding to economic challenges.[78] The Bayh-Dole Act created new institutions within universities to facilitate the commercialisation of intellectual property rights resulting from their research, although some notable universities had already implemented TLO for this purpose. One of the strengths of US universities has typically been the success with which their innovations are commercialised through either a licensing agreement with industry or the spinning-out of a company that involves university faculty members, meaning that the legal reform was, at least for some universities, more of a baseline standardisation than the more sweeping change that the Japanese reform brought.

The Japanese context presents a much more partial transformation as a result of the Bayh-Dole legislation because of several factors that are unique to the Japanese academic and legal context. Academic culture specifically relating to the negotiations and funding relationship between Japanese universities and industry have typically been created through informal processes of mutual support, emphasising both the passive role of universities in innovation (namely, proposing particular graduates to industrial partners) and sustaining these relationships even in the absence of active

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74 Though not yet passed into law, Fukuoka is actively advertising special tax rates as one of the 'National Strategic Special Zones' to incentivise the creation of start-ups: Fukuoka, 2020.

75 Beyond the general perception of universities and the value of the student experience, liberal arts education (specifically in Japan and Asia more broadly) is fundamentally about providing a wide breadth of disciplinary experience to develop the personal interests of the students: Jung, Sanderson, and Fajardo, 2019: 9.

76 On the important role of teaching hospitals in the US, specifically through the twentieth century with the move from for-profit hospitals with few ties to local hospitals to a more regulated medical education that takes place outside of the medical school itself, see Cooksey and York, 1999: 24. On the historical context of hospitals pre-Reformation in England as primarily monastic institutions, see Thomson, 196: 749.

77 'Before the introduction of intellectual property rights into the international trading framework through the TRIPS Agreement, intellectual property was still the domain of specialists and intellectual property rights producers': Guan, 2018: 111.

78 On the development of pre-modern protection for innovation, Meiji Restoration, and the borrowing of legal concepts in this area from Germany, see Cunningham, 2017: 677.

research.[79] Because of this, Japanese universities and their employees post-Japanese Bayh-Dole Act found themselves in a similar position officially to their US counterparts, although the practical reality means that universities occupy a difficult middle-point in which TLOs can often function as a too explicitly commercial element in negotiations that undermine effective cooperation between industry and faculty.

In both Japan and the US, the repositioning of universities from the passive or more informal innovation production model to active participants in the commercialisation of technology has profound implications for the future of university research. These implications appear in the two contexts of the accessibility of products emerging from publicly funded research and the modes by which we evaluate universities and their research output. From the perspective of accessibility, the shift towards a university's active involvement in the commercialisation of medical research brings a problematic dimension that is not present in the previous, more informal routes, of technology transfer. Concerns over accessibility in terms of cost are well documented in developing countries, although recent years have seen difficulties over the price of medication extend to the US.[80] As a direct result of the Bayh-Dole legislation, prominent US universities have already contributed to the creation of an environment in which ordinary American citizens are being priced out of access to essential medicines. This is occurring both through the creation of private enterprises with university faculty involvement and through university researchers producing the actual foundations of commercialised pharmaceuticals.[81]

The second context in which the formalisation delivered by the Bayh-Dole Act in both Japan and the US is problematic relates to the broader shift in how universities themselves are evaluated and assessed. Recent years have seen an increased emphasis on evaluating universities through quantifiable metrics (Muller, 2018: ch 7), extending not just to measuring graduate success with employment statistics but reducing faculty members' performance assessment to their impact metrics.[82] The focus on commercialisation of their research, reinforced by the importance of patent acquisition more generally as a metric in scientific disciplines, provides an additional variable through which academic staff can be assessed. This not only further incentivises research that can be successfully commercially exploited but, given the robustness of intellectual property rights specifically for pharmaceuticals, encourages a disproportionate investment in pharmaceutical research and commercialisation. This is exacerbated by the heterogenous success of TLOs in both Japan and the US where only the vast minority of elite universities have seen significant profits. The majority of TLOs in the US do not produce noteworthy applications of research, while Japanese TLOs rely heavily on government subsidy to continue their operations. This effect is magnified in the Japanese context because of the comparatively fewer universities in Japan and the historical strengths of the national universities.

Finally, reflecting on the limitations of the work presented here, in my view further research could be used to investigate the issues more empirically. The materials produced for international consumption – that is, in English and distributed in easily accessible databases – may not necessarily reflect the experience of Japanese and US researchers. Perceptions of the TLO system could be investigated empirically through interviews with investigators leading research laboratories, perhaps by looking into researcher attitudes in (and how they differ between) high-ranking and lower-ranking universities. Either way, further research could be used to confirm that dynamics in university laboratories are different for US and Japanese researchers or, perhaps more significantly,

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79 'Most commonly, firms would ask scientists to serve as their informal consultants regarding scientific questions, to introduce the best students in the lab to the firm when they went on the job market, and plug them into international scientific networks': Kameo, 2015: 185).

80 It has also seen the emergence of a healthcare system that is almost defined by its relationship to wealth, considering medicines, physicians, and incentives for dispensing specific medicines from a comparative perspective: Garber and Skinner, 2008: 43.

81 The patent for HIV treatment owned by Yale is one significant example, in which the cost was higher in sub-Saharan Africa, and Yale later helped to reduce its price: Hemel and Ouellette, 2017: 4; and Ouellette, 2010: 309. This is to say nothing of the fact that it was in the context of significant public backlash and that it relies on external pressure and voluntary action by the university to achieve more accessible prices.

82 In terms of professional research outputs, advertising university rankings, graduation rates of students, and the value of faculty achievements all become brochure materials, see: Muller, 2018: 71, 76, 77.

that there exists a significant divergence between the internal perception of the TLO system and the generally critical tone of the literature available in English.

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