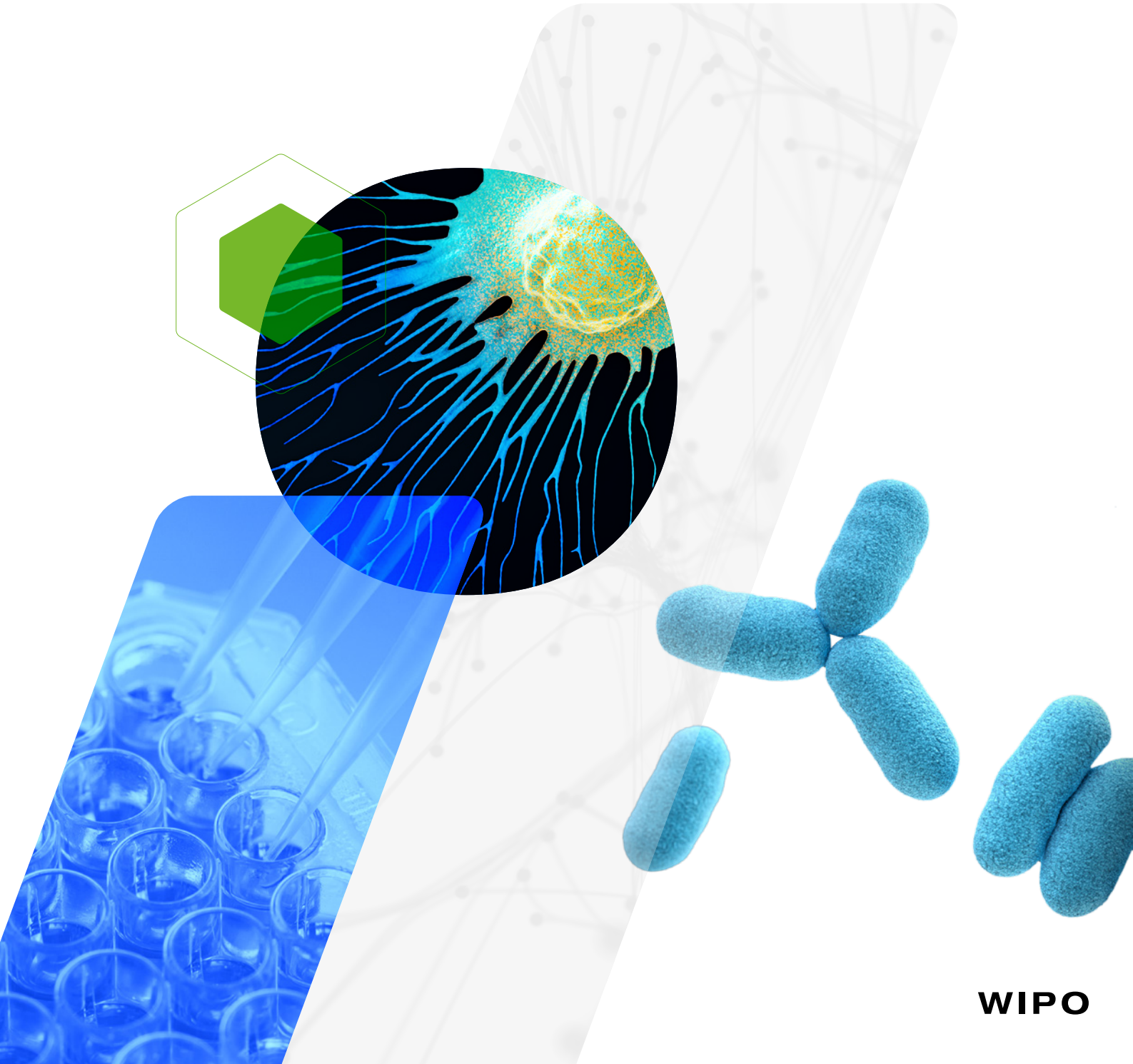
Discussion Paper on the Interplay between Patents and Trade Secrets in Medical Technologies



WIPO

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APPENDIX

A questionnaire and interview-based snapshot assessment of practical interplays of patent and trade secret systems for certain medical device and technology innovators from the Federative Republic of Brazil during the pandemic caused by the SARS-CoV-2 virus

Background of the Discussion Paper on the Interplay between Patents and Trade Secrets in Medical Technologies

prepared by the WIPO Secretariat

1. The need for COVID-19 vaccines, medicines and related technologies have raised renewed interest in better understanding the impact of patent and trade secret protection on development and dissemination of medical technologies. While the benefits and shortcomings of these two protection mechanisms have been well documented, how these mechanisms interact with each other throughout the innovation process and product value chain in the field of medical technologies are less explored. In addition, medical technologies relate to a wide range of products (from pharmaceuticals to digital medical devices), where the interplay between patents and trade secrets may vary as well.

2. Accordingly, as one of the activities under WIPO's COVID-19 Response Package, the WIPO Secretariat commissioned Professor Tanya Aplin, The Dickson Poon School of Law, King's College London and Dr. Johnathon Liddicoat, Senior Lecturer, The Dickson Poon School of Law, King's College London to prepare a discussion paper on the interplay between patents and trade secrets in medical technologies (the Paper). The Paper was peer reviewed by Professor Andrew Christie, Chair of Intellectual Property, Melbourne Law School, The University of Melbourne.

3. The Paper aims to facilitate a better understanding of the issues through analyzing and synthetizing the literature on the interplay between trade secrets and patents in the field of various medical technologies at the policy, law and practical levels, while proposing specific areas for follow-on research. As its title suggests, the Paper is intended to facilitate discussions on this complex issue with a view to further the development of an enabling environment for innovation and technology transfer, and to support the use of technology to address global health challenges.

4. In order to supplement the Paper based on literature review, a survey-based depiction of the practical interplay between patents and trade secrets in Brazil was prepared by Mr. Benny Spiewak, Partner, SPLAW Advogados, and is appended to this document.

5. The WIPO Secretariat expresses its high appreciation to the authors for the preparation of their contributions annexed to this document and to the peer reviewer for his thorough review of the Paper.

Disclaimer: The views and opinions expressed in the papers attached to this document are those of the authors, and do not necessarily reflect those of WIPO or its Member States.

Discussion Paper on the Interplay between patents and trade secrets in medical technologies

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I. Acknowledgements

This Discussion Paper has been co-authored by Professor Tanya Aplin (tanya.aplin@kcl.ac.uk) and Dr Johnathon Liddicoat (johnathon.liddicoat@kcl.ac.uk), from the Dickson Poon School of Law, King's College London. The authors are grateful to Dr Nazanin Aslani for her valuable research assistance and to Professor Andrew Christie, Melbourne Law School and Ms Tomoko Miyamoto, WIPO, for their perceptive and helpful comments on an earlier draft of this Paper. Any errors or omissions are, of course, the authors and comments on this Paper are welcome.

II. Executive Summary

An overlooked issue in intellectual property law is the interaction between patents and trade secrets protection. This is particularly the case when it comes to medical technologies. **This Discussion Paper analyses the key literature dealing with the interplay of patents and trade secrets protection in relation to medical technologies to help identify a future research agenda and areas of focus for policy debate.**

The Paper (in section IV) contextualises medical technologies by setting out the main characteristics of their innovation cycles. In relation to the cost of developing pharmaceutical drugs, generally studies do not distinguish between biologics and small molecules, although it is often generally accepted that biologics are more expensive. Even so, the stages for development tend to be the same and include: i) discovery and development; ii) pre-clinical research; iii) clinical research; iv) regulatory review; and v) post market safety monitoring.

In the case of drug repurposing – i.e., finding new uses of existing authorised drugs – there are similar stages, albeit discovery and development is often not necessary and pre-clinical research might be skipped in certain cases. There is little concrete evidence that the innovation cycle for drug repurposing is different compared to developing new drugs, but repurposing is generally considered to be faster, cheaper and more likely to receive an authorisation.

When it comes to medical diagnostics the stages of development differ from drugs. Some differences to highlight are that prototypes of a device are developed and tested in laboratory settings and the pathway to approval and regulatory review for devices is often split into different categories depending on possible health risks. The most onerous of these is for the devices that pose the most significant health risks, which require pre-market approvals that are somewhat involved in nature.

Finally, in relation to other medical innovation, such as surgical techniques, non-diagnostic tools and behavioural interventions, there is much less information about their innovation cycles.

The Paper (in section V) reviews the justifications and policy goals of patents and trade secrets protection. While patent protection sometimes draws support from natural rights rationales, particularly when it comes to recognising inventors on the patent specification, the more popular justification is utilitarian or economic in nature. Specifically, patent law is said to incentivise the creation, commercialisation and disclosure of inventions. As well, some commentators see patent protection as a means of reducing the wasteful duplication of inventive activities.

Trade secret law is sometimes justified based on commercial ethics (to prevent unfair competition) or to protect national economic interests. However, the dominant rationale also tends to be economic in nature, namely, to incentivise innovation, to incentivise the limited sharing of information and to reduce wasteful expenditure on protective measures to maintain secrecy.

While economic rationales for both patents and trade secrets tend to dominate the literature, they are also subject to criticisms, mainly around whether there *is* the said incentive effect.

The Paper (in sections VI and VII) offers a detailed consideration of the interplay between patents and trade secrets protection in relation to different medical technologies, **in particular pharmaceuticals (small molecules and biologics), drug repurposing, drug manufacturing, medical diagnostics, and medical machine learning.** While there is a traditional view that patents and trade secrets protection are alternatives, in fact the better view seems to be that they operate in a complementary fashion, especially from the perspective of interplay between the regimes. It is this complementary operation that can, at times, cause tensions.

Our review of the literature suggests that the interaction of patents and trade secrets for small molecules and generics generally works well. However, a significant area of concern is the extent to which clinical trial data and clinical protocols are not disclosed because they are protected as trade secrets and the harmful impact this can have on subsequent access and innovation.

Another major concern is the way in which the interplay between patents and trade secrets affects the authorisation of biosimilars (i.e., copies of biologics). In particular, originators of biologics can use trade secrets to protect the manufacturing processes for biologics. This likely delays those looking to manufacture biosimilars, not least because reverse engineering of biologics is a difficult process that only reveals limited information.

Drug repurposing can also be thwarted by protection of clinical trials protocols and data by trade secrets.

When it comes to innovation in drug manufacturing, it seems that while patent protection might be available, it is not always utilised, with a preference instead for trade secrets protection. Thus, the incentive function of patent law may be queried here.

Trade secrets may also be used to protect actual drug prices, and this can shield companies from regular market forces.

In relation to medical diagnostics, there is a concern that patent protection enables the patentee to create a database of useful information about improvements to the diagnostic which they can then protect as trade secrets.

For surgical methods, there is little research on whether exclusion from patentability (or not) impacts innovation. There is also little study of the interplay between patents and trade secrets when it comes to development of surgical and other medical (non-diagnostic) devices.

Machine learning and medical innovation is a growing area of interest. An uncertainty is the extent to which machine learning applications are patentable and, if so, whether they are fully disclosed in the patent specification. As such, there may be a gravitation towards trade secrets protection, which in turn may block transparency and follow-on innovation.

The Paper (in section VIII) also examines how the interplay between patents and trade secrets protection affects public policy goals, such as accelerating innovation, access to medical technologies and a "knowledge commons" of medical technologies. These sections consider some of the interplay issues at a higher level of abstraction than the preceding sections. The section on medical innovation considers whether the overlap of trade secret and patent protection (amongst other forms of protection) are sufficiently balanced to encourage innovation and follow-on innovation. This section points to several areas of research to help better understand the issues as stake.

The section on access to medical technologies considers whether trade secrets might be preventing access to technologies after patents expire. The section also considers how trade secrets might hamper authorised access to patented technology without permission from the rights holders. For example, a third party might obtain a compulsory licence for the patented invention but be unable to use the technology due to trade secrets protection. This paper calls for more research on flexibilities in TRIPS Article 39 that might permit sharing of trade secrets.

The section on a "knowledge commons" considers how trade secrets and patents might inhibit the development of medical information that is publicly accessible. Empirical evidence on these topics is still emerging. This section considers, amongst other things, how patent specifications may insufficiently describe inventions for experts to practice the inventions and to reliably know that they work. This section points to the need for more empirical research on these topics because studies have only started to uncover the depth and breadth of the issues.

Finally, the Paper (in section IX) identifies the areas that are ripe for further research and policy debate. These are as follows:

i. The desirability and impact of increased disclosure of clinical trial data and protocols for drugs in the case of both small molecules/generics and biologics/biosimilars;
ii. Whether there are sufficient incentives for medical diagnostics, surgical treatment methods, and innovations in drug manufacturing;
iii. The extent to which drug prices are kept secret, the impacts that may arise as a result of this practice and how to address them;
iv. The extent to which datasets that are generated as a follow on to patented medical diagnostics and medical machine learning applications are protected by trade secrets and whether this impacts follow-on innovation;
v. Tracking the extent to which medical machine learning applications are protected by patents and trade secrets and whether sufficient incentives exist for innovation in this new area of technology;
vi. Whether the disclosure mechanisms under patent law can be improved in relation to certain kinds of medical technologies (e.g., biologics and medical machine learning inventions);
vii. On the desirability, nature and form of compelled disclosure of trade secrets by regulatory authorities and the role that regulatory protection may play alongside such disclosure, including in instances of public health emergencies, such as the Covid-19 pandemic;

viii. Deeper analysis of the situations in which Article 39 TRIPS permits compelled disclosure of trade secrets and state sharing of regulatory data, particularly in the case of public health emergencies.

III. Introduction

This Discussion Paper aims to facilitate a better understanding of the interplay between patents and trade secrets protection in the field of medical technologies and to highlight the opportunities for further debate and future research. The Paper examines how these two legal mechanisms work together in different areas of medical technologies and illustrates how interactions between patents and trade secrets law contribute to the attainment of public policy goals relating to medical innovation and access to and dissemination of medical technologies.

The Paper begins in section IV by contextualising medical innovation through a description of the main characteristics of its innovation cycles. It then considers in section V the key features of patents and trade secrets protection and the policy goals of these legal regimes. The Paper next turns in sections VI and VII to a detailed consideration of the interplay between patents and trade secrets law, both generally and more specifically in relation to different medical technologies, including pharmaceuticals (small molecules and biologics, and drug manufacturing), medical diagnostics and medical machine learning. After this, the Paper in section VIII considers how the interplay between patents and trade secrets law affects medical innovation, access to medical technologies and a 'knowledge commons' of medical innovations. Finally, in section IX the Paper concludes by highlighting issues for further consideration and future research.

Patent protection is understood to refer to exclusive rights, for a limited duration, in respect of inventions that are new and non-obvious and capable of industrial application. These exclusive rights, which include the ability to make and use the invention, are acquired through a process of registration. Trade secrets protection, by way of contrast, refers to legal protection against various types of unauthorised acquisition, disclosure or use of commercially valuable *secret* information, for as long as the information remains secret. This protection is not dependent on registration.[1]

Given that the focus of this Discussion Paper is the interplay between patents and trade secrets when it comes to medical technologies,[2] a wide range of mainly, but not exclusively, legal literature in the form of books, book chapters, journal articles and policy papers were consulted. These resources were accessed via open access sources or subscription-only databases. The focus is on published *research* regarding the interplay between patents and trade secrets in the medical sphere rather than seeking to map the international, regional and national legal instruments relating to patents and trade secrets law.

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[1] Generally, for an introduction, see <https://www.wipo.int/patents/en/> and <https://www.wipo.int/tradesecrets/en/> accessed 30 September 2023.

[2] The terms 'patent(s)' and 'trade secret(s)' are used in this Paper as shorthand to indicate *either* patent protection and trade secret protection via patents and trade secrets law or the *object* of that legal protection. The sense in which these terms are used will hopefully be apparent from the context.

While the Paper has sought to be comprehensive in its review of this literature, it is inevitably restricted by its focus on English language publications, which tend to discuss the position in the United States and Europe. As well, rather than citing all literature that was identified, this Paper focuses on the key literature. What is provided is a map of the major issues regarding the interplay of patents and trade secrets in relation to medical technologies. It is hoped that this mapping exercise will help governments, policymakers, scholars, and researchers to shape their discussions and focus their priorities.

IV. A description of the characteristics of innovation cycles in medical technologies

This section describes the innovation cycles in medical technologies in order to contextualise the role of patents and trade secrets as innovation levers. From this discussion, we see that patents and trade secrets may be more or less relevant at different stages of the innovation cycle and that investment in research and development will differ depending on the type of medical innovation. But, also, that there is a lack of comprehensive evidence of costs involved in the innovation cycle for medical technologies, other than pharmaceutical drugs.

Innovation cycles are models used to describe the continuous processes of research and development (R&D). Models, by definition, are simplified accounts that aid understanding. Innovation is perhaps more typically modelled linearly (e.g., Figure 2). However, the point of the innovation cycle is to emphasise the continuous, dynamic nature of R&D. Most successful products are improved over time, and almost all successful products are eventually displaced by superior ones.

The cycle in Figure 1 has previously been used in other reports but has a different use here. One earlier use is to emphasise the demand aspect; if no demand exists (or demand is dampened by low incomes, small markets, or low sales volume), the cycle can breakdown.[3] The utility of seeing R&D as a cycle is to emphasise that patents and/or trade secrets may operate at every stage of the process.

[3] World Trade Organization, World Health Organisation and World Intellectual Property Organization, 'Promoting Access to Medical Technologies and Innovation' (2020, 2nd edition) 144–147 <https://www.wto.org/english/res_e/publications_e/who-wipo-wto_2020_e.htm> accessed 30 September 2023.

The roles that patents and trade secrets play can vary throughout the cycle. A standard, simplified account is that innovators patent at the stages of discovery (e.g., finding a new compound), development (e.g., optimising the compound) and manufacturing (e.g., designing systems to scale-up production). This simplified account continues that innovators keep *some* trade secrets at manufacturing (these secrets complement manufacturing patents; *some* innovations are hard to reverse engineer and can easily be kept secret behind factory doors, meaning patents are less desirable), at delivery (e.g., client lists and logistics), and demand for improved products (e.g., market research and feedback from patients). Even though this account is simplified, one can see how patents and trade secrets play complementary and overlapping roles, impacting, for example, what information is made available to the public.

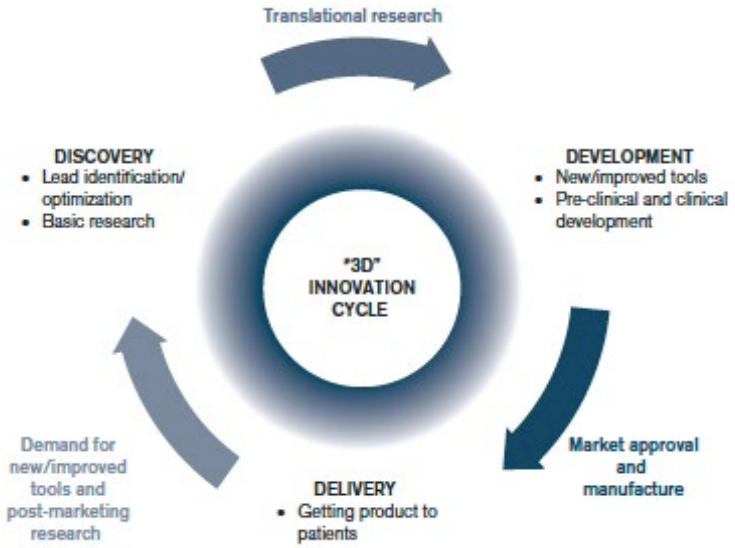

Figure 1 The Innovation life cycle (source: WHO (2006, p23)).

This Paper explores the uses of patents and trade secrets for different medical technologies throughout their innovation lifecycles. The Paper focuses on the development of: i) pharmaceutical drugs, including small molecules and biologics; ii) 'repurposing' of pharmaceutical drugs; iii) medical diagnostics; and iv) other medical technologies, including surgical methods and medical machine learning applications. The innovation cycles for these technologies vary significantly; for example, the cost of developing these products can range from several million to several billion ($US). The next section explores these cycles.

The cost and timelines described below are based on published articles and reports. Technology can progress quickly, which means, inescapably, the costs and timelines are based on old technology. Perhaps cutting-edge technology, such as machine learning, will reduce costs and hasten timelines. However, all the technological improvements over the past 60 years have not been able to stop timelines lengthening or costs increasing.[4] Thus, any new technology would have to alter a profound historical pattern.

[4] Jack W. Scannell et al, 'Diagnosing the decline in pharmaceutical R&D efficiency' (2012) 11 Nature Reviews Drug Discovery 191, 191–192.

A. Pharmaceutical drugs

1. Introduction and timelines: biologics v small molecules

Regulators and commentators typically divide drugs into two categories: i) biologics; and ii) small molecules. The United States Food and Drug Administration (FDA) defines biologics to include vaccines, blood, tissues, and recombinant proteins, which are created using genetic material from different sources. Biologics can consist of sugars, proteins, or genetic material and are isolated from natural sources or produced by biotechnological methods using living organisms. In contrast, small molecules are chemically synthesized. Small molecules are generally much smaller, too, hence their name. Scientists can typically characterise the structure of small molecules in terms of atoms and their arrangement, whereas biologics are much more complex and not easily characterised.[5]

This Paper's analysis of patents and trade secrets often distinguishes between biologics and small molecules; however, the systematic studies on the cost of developing drugs (described below) generally do not distinguish between the two. Nevertheless, commentators argue biologics are more expensive to develop, primarily because more research is required, and the reagents and manufacturing are more resource intensive.[6] This expense is borne out in the prices to treat patients with biologics; for example, some vary between US$10,000 to $40,000 per patient annually.[7]

Despite the high prices of biologics compared to small molecules, the timelines for their developments are effectively the same. A recent study examined the time from when new compounds are initially patented, which usually occurs towards the end of several years of Discovery & Development (Figure 2), until market authorisation. The study found the median time was 12.4 years for *both* small molecules and biologics.[8] This result makes some sense because patent life motivates research: once a compound is patented, each day without a product on the market sacrifices a day of the protection period.

[5] FDA, 'What are "Biologics" Questions and Answers' (FDA, 02 June 2018) <https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers> accessed 30 September 2023.

[6] Favour Danladi Makurvet, 'Biologics vs. Small Molecules: Drug Costs and Patient Access' (2021) 9 Medicine in Drug Discovery 100075, 4–5.

[7] Makurvet (2021), 6.

[8] Reed F. Beall, Thomas J. Hwang and Aaron S. Kesselheim, 'Pre-market Development Times for Biologic Versus Small-molecular Drugs' (2019) 37 Nature Biotechnology 708, 708–709.

2. Stages of development & costs

The FDA breaks down drug development into five stages (Figure 2).[9] This Paper refers to many FDA processes and other aspects of United States ('US') law because it is the most discussed and often seen as standard. The first stage, **Discovery & Development**, may include creating and analysing thousands of compounds, looking for new therapeutic effects in those compounds, and looking for new treatment options by studying disease processes. **Pre-clinical Research** refers to early research in animals, microorganisms and cells that mimic human disease. Pre-clinical work focuses on toxicity and potential drug dosing in humans. **Clinical Research** is split into three phases of clinical trials: phase I trials often involve 20 to 100 *healthy* volunteers and focus on safety and dosing; phase II trials typically include several hundred patients with the disease and focus on efficacy and side effects; and phase III trials involve hundreds or thousands of patients and focus on efficacy and the significance of the adverse events (commonly known as side effects).[10] **FDA Review** involves regulators evaluating whether the drug is safe and effective.

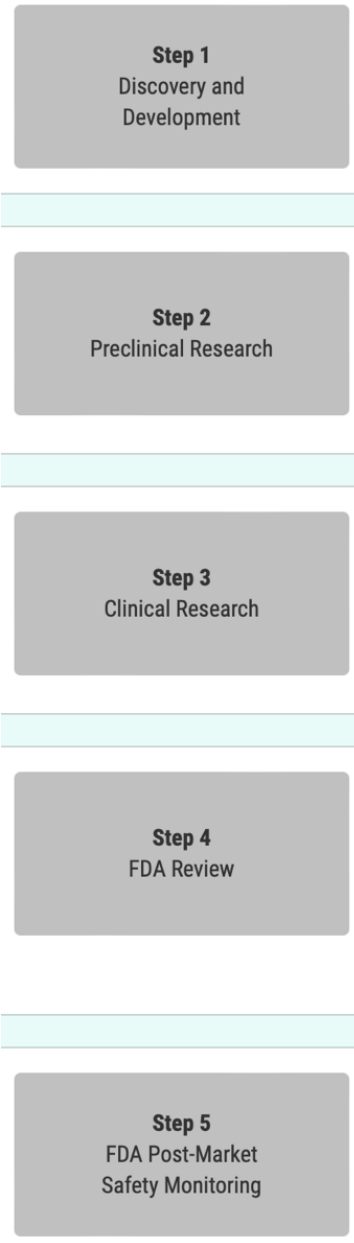

Figure 2 The drug development process (source: FDA.gov, The Drug Development Process)

A study published in 2021 conducted a systematic review of peer-reviewed articles examining how much it costs to develop a new drug. The study found 19 applicable studies and converted the values into US$ as of 2019. As the cost of drug R&D has increased over time, it is sensible to consider articles from the 10 years before this study only (2010–2020), in which case the study found 11 relevant studies. The studies found the out-of-pocket expenses of developing a drug varied between US$321 million and US$1.54 billion.[11] The authors pointed out there was significant variation in the methods and data used in the studies that could account for some of the variation. For example, the chance of authorisation for drugs varied in the studies from 3% to 25%. The 11 studies also inconsistently included: disease areas (e.g., the data indicates cancer therapeutics are some of the costliest); ratios of small molecules and biologics; and post-authorisation costs (phase IV in Figure 2).[12]

[9] FDA, 'The Drug Development Process' (FDA, 4 January 2018) <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process> accessed 30 September 2023.

[10] FDA, 'Step 3: Clinical Research' (FDA, 4 January 2018) <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research> accessed 30 September 2023.

[11] Michael Schlander et al, 'How Much Does it Cost to Research and Develop a New Drug' (2021) 39 PharmacoEconomics 1243, 1247–1250. These values do not include developing orphan drugs.

[12] Schlander et al (2021), 1262–1263.

Post-authorisation costs generally fall in the last of the FDA's five stages, **Post-Market Safety Monitoring**. This last stage refers to the reality that, despite rigorous testing, 'the true picture of a product's safety actually evolves over the months and even years that make up a product's lifetime in the marketplace'.[13] Thus, depending on various factors, including the type of drug and the disease, the FDA might require ongoing clinical or non-clinical studies after a drug is authorised.

B. Drug repurposing

Drug 'repurposing' typically refers to the process of finding new uses for (already) authorised drugs, although various other terms are sometimes used (e.g., repositioning, reprofiling). Repurposing includes most of the steps in Figure 2, albeit *sometimes* the first few steps can be shortened or skipped. The discovery part of 'Discovery & Development' typically is *not* necessary, as the compound is already known. That said, the development part might be necessary, particularly if the compound is altered for different administration (e.g., orally instead of intravenously). Pre-clinical research might be skipped if the same compound is used in the same presentation. However, depending on the changes to the compound, the new disease, or changes in dosing, some pre-clinical work might be required. The same goes for phase I; it could be skipped or needed for similar reasons.[14] Otherwise, phase II and III trials will almost always be necessary because rigorous studies on efficacy and side effects are required for authorisation.

Commentators frequently suggest that repurposing is faster, cheaper and has a higher chance of receiving authorisation than developing *new* drugs. But the evidence on these points is scarce. No systematic review exists. The best evidence available consists of estimates and anecdotes, except for on the success of progressing a new use from phase I all the way to authorisation. One study of clinical trial success rates found that repurposing had a 20% chance of progressing from phase I to authorisation, whereas *new* compounds had a 10.4% success rate. In short, the evidence suggests repurposing has twice the chance of authorisation.

The evidence on cost and timeline is patchier. A high-profile review of the process of repurposing suggested that it took 3-12 years.[15] But this estimate was made without data. On cost, a 2008 estimate stated at least US$100 million,[16] and a 2016 estimate said around US$300 million.[17] A pharmaceutical company also made a statement to the US Supreme Court saying it is 40% cheaper (than developing a new drug).[18] But these claims were all made

[13] FDA, 'Step 5: Post-Market Drug Safety Monitoring' (FDA, 4 January 2018) <https://www.fda.gov/patients/drug-development-process/step-5-fda-post-market-drug-safety-monitoring> accessed 30 September 2023.

[14] Donald E. Frail and Michael J. Barratt, 'Drug Repositioning: The Business Case and Current Strategies to Repurpose Shelved Candidates and Marketed Drugs' in Michael J. Barratt and Donald E. Frail (eds), *Drug Repositioning* (Wiley 2012) 39–40; Michael Hay et al, 'Clinical Development Success Rates for Investigational Drugs' (2014) 32(1) Nature Biotechnology 40, 42 and 45, noting that non-new molecular entities often skip phase I clinical trials.

[15] Ted T. Ashburn and Karl B. Thor, 'Drug Repositioning: Identifying and Developing New Uses for Existing Drugs' (2004) 3 Nature Reviews Drug Discovery 673, 675.

[16] Henry G. Grabowski and Jeffrey L. Moe, 'Impact of Economic, Regulatory and Patent Policies on Innovation in Cancer Chemoprevention' (2008) 1(2) Cancer Prevention Research 84, 85.

[17] Nicola Nosengo, 'Can you Teach Old Drugs New Tricks' (2016) 534 Nature 314, 315.

[18] Brief for Allergan, Inc et al. as Amici Curiae supporting Respondents, 8 in *Caraco Pharmaceutical Laboratories Ltd v. Novo Nordisk A/S,* (2012) 566 U.S. 399.

without data too. The cost will depend on various factors, including the size and duration of clinical trials, which means it depends on the disease being treated and any 'head start' gained from the first authorised use. Perhaps a fair summary is that repurposing is between 40-90% cheaper than developing new drugs. This range is wide but is based on the estimates above and builds in the range of variables at play.

C. Medical diagnostics

The FDA breaks down the development of medical diagnostics into five stages.[19] These stages differ from those for drugs. The first stage, **Device Discovery and Concept**, begins with identifying an unmet need. From there, researchers develop a 'proof of concept', a document outlining steps to determine whether the concept is workable. The second step, **Pre-clinical Research – Prototype**, features researchers building prototypes tested in controlled laboratory settings (not on humans). The third step is identifying the **Pathway to Approval,** which flows into the fourth step, **FDA Review**. Therapeutic drugs have a well-established process of clinical trials (phases I-III), but the FDA uses a *different* pathway for diagnostics. Indeed, medical diagnostics do not have their own regulatory pathway. They come under the umbrella term 'devices', which is split into three categories.[20]

The first category, Class 1 devices, poses the lowest health risks, and most devices in this class are exempt from regulatory review. Products in Class 1 include items such as tongue depressors, bandages, and dental floss. Class 2 devices pose moderate health risks and require 'premarket notification'. They might also have to meet FDA standards, and developers might have to conduct post-market surveillance or keep patient registries. Class 2 devices typically include X-ray systems, insulin syringes and hearing aids. Class 3 devices pose the most significant health risks. They help support or sustain life, including preventing harm. The types of devices in this class include digital mammography and non-invasive glucose testing devices. Medical diagnostics are typically in Class 3; consequently, they must obtain 'pre-market approvals' (PMAs).[21]

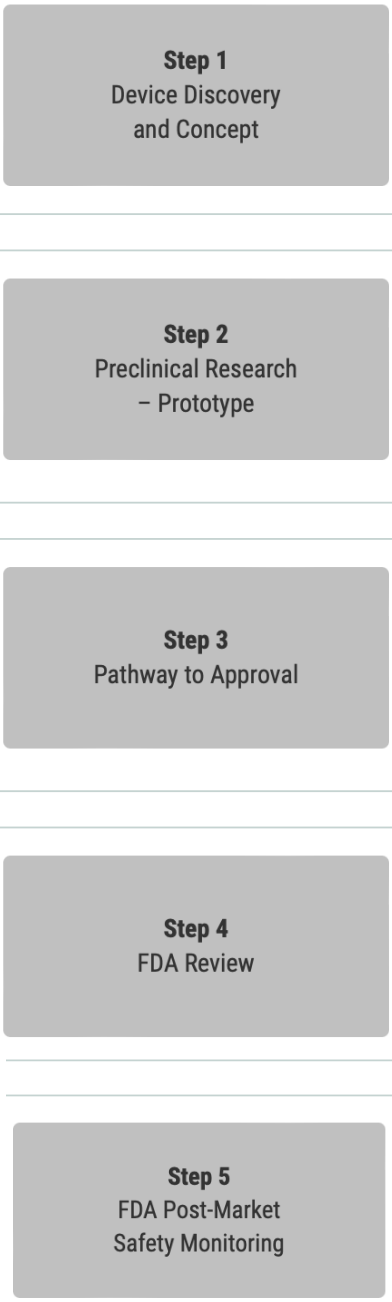

Figure 3 The device development process (source: FDA.gov, The Device Development Process

[19] FDA, 'The Device Development Process' (FDA, 4 January 2018) <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/device-development-process> accessed 30 September 2023.
[20] FDA, 'Step 3: Pathway to Approval' (FDA, 4 January 2018) <https://www.fda.gov/patients/device-development-process/step-3-pathway-approval> accessed 30 September 2023.
[21] ibid.

PMAs are the most involved regulatory processes for medical devices. PMAs require:

1. scientific evidence that the possible benefits of a device outweigh the possible risks [, and]
2. that the device will significantly help a large portion of the target population.[22]

New medical diagnostics will typically have to conduct clinical trials to satisfy these requirements, which raises the prospect of high costs akin to those for drugs. The cost of developing medical diagnostics is less well-studied compared to drugs. But commentators have described the process as being separated into: i) a pilot phase, with fewer than 100 patients to gauge safety; and ii) a pivotal phase, which is a much larger trial and designed to show safety and effectiveness comprehensively.[23] Four diagnostic executives were asked at a conference in 2013 how much it costs to develop new diagnostics. The values ranged from US$12.1–55.0 million.[24] These values were largely confirmed in a 2020 interview study. Six company executives gave estimates ranging from US$1–150 million.[25] The executives also estimated the development time to range from 2-30 years.[26] One of the reasons for the shorter and cheaper diagnostics in the study was that the interviewees considered diagnostics that might be new in the sense that they were more convenient to use rather than a diagnostic based on new biomarkers (e.g., proteins or DNA).

The fifth step of the process is **Post-Marketing Device Safety Monitoring**. Like drugs, the FDA might require post-approval studies to validate a PMA. These studies could be clinical or non-clinical studies to ensure the safety and efficacy of the diagnostic.[27]

1. Laboratory developed tests: an exception to the requirements for clinical trials

Laboratory developed tests (LDTs) are a sub-type of diagnostics, 'designed, manufactured and used within a single laboratory.'[28] Some companies generate large turnovers based on LDTs, performing tests on samples sent to them, perhaps from around the world. The significance of LDTs is that they are (currently) subject to significantly *less* regulatory scrutiny. Indeed, the FDA has 'generally not enforced premarket review and other applicable FDA requirements' because LDTs have traditionally consisted of simple lab tests.[29] However, some LDTs have become complex with advancing technology, diagnosing or indicating diseases that might

[22] ibid.

[23] Aaron V. Kaplan et al, 'Medical Device Development: From Prototype to Regulatory Approval' (2004) 109 Circulation 3068, 3070.

[24] Peter Keeling, 'Mystery Solved! The Cost to Develop and Launch a Diagnostic Test' (Diaceutics, 15 January 2013) <https://www.diaceutics.com/articles/mystery-solved-what-is-the-cost-to-develop-and-launch-a-diagnostic> accessed 30 September 2023. Perma link: https://perma.cc/HAQ4-RB7N. It is interesting to note that another $20.1–106 million is necessary to *drive commercialisation*, including marketing and health technology assessments.

[25] Johnathon Liddicoat, Kathleen Liddell and Mateo Aboy, 'The Effects of *Myriad* and *Mayo* on Molecular-Test Development in the United States and Europe: Interviews from the Frontline' (2020) 22 Vanderbilt Journal of Entertainment & Technology Law 785, 805–806.

[26] Liddicoat et al (2020), 805.

[27] Centre for Devices and Radiological Health, 'Procedures for Handling Post-Approval Studies Imposed by PMA Order' (FDA, 7 October 2022) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-handling-post-approval-studies-imposed-pma-order> accessed 30 September 2023; see also, Kaplan et al (2004), 3069 and 3072.

[28] FDA, 'Laboratory Developed Tests' (FDA, 27 September 2018) <https://www.fda.gov/medical-devices/in-vitro-diagnostics/laboratory-developed-tests> accessed 30 September 2023.

[29] ibid.

warrant significant medical intervention (e.g., detecting the risk of breast cancer). In short, they can provide similar information to other diagnostics that have passed PMAs.

The FDA has found several problems with some marketed LDTs and has been considering updating its policy on reviewing LDTs. The problems with the tests include insufficient evidence, incorrect results, and falsified data.[30] The FDA began a process to revise its policy on LDTs in 2010 and produced a discussion paper in 2017, but no changes have yet occurred.[31] If LDTs were reviewed, the costs of developing the evidence to satisfy PMAs for many diagnostics would be significant, as the evidence would likely require clinical trials. We can gauge the significance of this cost by comparing i) the cost of developing Class 2 devices, which only require pre-market notification without clinical trials, with ii) Class 3 devices which require PMAs (and trials). A 2010 survey of device manufacturers, which included diagnostics amongst other devices, found that developing Class 2 devices cost, on average, US$31 million, and Class 3 devices cost US$94 million.[32] The cost of producing Class 2 devices, which often do *not* require trials, is over US$60 million cheaper.

The discussion of LDTs provides nuance on the development of diagnostics in the US. The discussion is also illustrative of the situation in the rest of the world. Many countries require the equivalent of PMAs for the authorisation of medical diagnostics. But inevitably, countries classify devices at different levels of risk and have different regulatory regimes. The reality is that the same diagnostic might have varying levels of regulatory oversight in different countries and, therefore, cost more or less to develop.

D. Other medical technology

A cornucopia of other medical technology exists, ranging from surgical techniques, stents, hearing devices, and medical imaging devices to behavioural changes or non-surgical interventions (e.g., diets or sleeping habits). The cost of developing Class 2 devices gives an indication of developing hearing devices and some imaging devices (US$31 million), and the cost of developing Class 3 devices gives an idea of stents (US$94 million). However, these costs will vary considerably because the technology is diverse. On the other hand, no reliable source could be found for developing behavioural changes or non-surgical interventions. These advances could perhaps be best described as medical *innovations* rather than *technology.* Regardless of their term, however, these innovations will still be considered below because they raise issues at the interface of patents and trade secrets.

The term 'medical technology' could also be stretched to include technology *ancillary* to drugs, diagnostics, and other technology. For example, it could include teleconferencing with patients, software for managing patient records or insurance and scientific reagents. However, this Paper will *not* discuss these types of technologies, although it will consider medical machine learning applications.

[30] ibid.
[31] ibid.
[32] Josh Makower, Aabed Meer and Lyn Denend, 'FDA Impact on US Medical Technology Innovation' (Nov 2010) 6–7 and 28 <https://perma.cc/5FYL-X9GS> accessed 30 September 2023.

V. Patents & trade secrets: justifications and roles in innovation

In this section we review the justifications for patent and trade secrets protection and their role in innovation. While there are several possible justifications, economic or incentive-based justifications tend to dominate, albeit they are not without criticism.

A. Justifications for patent protection

There is much literature on the justifications for the existence and scope of the patent system. While natural rights justifications based on labour and personality theories feature in the literature, incentive or economic-based rationales tend to dominate the discussion and are the more standard justifications used by scholars and policymakers.

Before turning to the standard accounts of why we have patents, this section will briefly deal with natural rights justifications. According to a labour theory, patents are granted because they are a reward for the intellectual labour of creating inventions.[33] Various criticisms have been raised, but two key ones are that: i) a property right may not be an appropriate reward and there are alternative types of rewards, such as prizes, grants, state assistance, acknowledgment or market-based lead times;[34] and ii) it is unrealistic to assume that an invention is solely the result of individual labour, rather it is likely to flow from collaborative labour, which builds upon previous innovation.[35] Nevertheless, a Lockean labour theory has been relied upon to support the existence of experimental use exceptions in patent law, consistent with the provisos to leave 'enough and as good' in the commons and not to waste products.[36]

Another natural rights-based justification is the personality theory, which itself draws upon Kant and Hegel, where the difference is whether the invention is an expression of personality or an exercise of the will in actualising itself in the world.[37] Some scepticism has been expressed about this justification vis-à-vis technological innovation, on the basis that technological or functional works are less likely to have room for expressing personality than aesthetic works.[38] Further, one can raise the objection that the premise of individual self-expression does not map onto the reality of collaborative teams working towards innovation and that collective self-expression is not easily recognised in patent law. While there is a

[33] Fritz Machlup and Edith Penrose, 'The Patent Controversy in the Nineteenth Century' (1950) 10 Journal of Economic History 1, 17-21; Ofer Tur-Sinai, 'Beyond Incentives: Expanding the Theoretical Framework for Patent Law Analysis' (2012) 45 Akron Law Review 243, 257-262 (basing this on the Lockean labour theory).

[34] Edwin C. Hettinger, 'Justifying Intellectual Property' (1989) 18 Philosophy and Public Affairs 31, 41 writes: 'Alternatives include fees, awards, acknowledgment, gratitude, praise, security, power, status, and public financial support'; and Machlup & Penrose (1950), 18-19 referring to the argument that an innovator's 'head start profits' should suffice as a reward and also alternative types of rewards such as prizes or bonuses. See also Robert Burrell and Catherine Kelly, 'Public Rewards and Innovation Policy: Lessons from the Eighteenth and Early Nineteenth Centuries' (2014) 77 Modern Law Review 858 (discussing the system of state rewards in England in the 18th and 19th centuries in detail and arguing for serious consideration to be given to their utilisation in today's innovation landscape).

[35] Hettinger (1989), 38-39; Tur-Sinai (2012), 260.

[36] Tur-Sinai (2012), 265-273.

[37] For Kant, see Peter Drahos, *A Philosophy of Intellectual Property* (Routledge, 1996), 80-81; for Hegel see Drahos (1996) ch 4; Margaret J. Radin, 'Property and Personhood' (1982) 34 Stanford Law Review 957; and Justin Hughes, 'The Philosophy of Intellectual Property' (1988) 77 Georgetown Law Journal 287, 330 et seq.

[38] Hughes (1988), 340-343. See contra Tur-Sinai (2012), 280-281.

recognition of joint inventorship, this tends to be a narrow conception that hinges on who supplies the 'inventive concept'.[39] Nonetheless, commentators have drawn on personality theory to justify why it is that inventors are attributed *as* inventors on the patent specification.[40] This occurs even if entitlement to the invention is vested in an employer or assigned to a third party.[41]

The far more popular justifications for the existence and scope of patent law are utilitarian or economic in nature. There are two main types of 'incentive' justification.[42] The first is that patents provide necessary incentives for inventing – the incentive-to-invent rationale. The argument is that, without the exclusive property rights granted by patents, third parties would free ride on inventions (because of their non-excludable quality) and drive down price, which in turn would affect recoupment of investment by the inventor. The second is the incentive-to-disclose rationale, i.e., the patent system provides incentives for inventors to *disclose* the invention rather than to maintain secrecy and such disclosure is beneficial to society.[43] This has often been characterised as a social contract – one 'in which the inventor agreed to disclose his secret and the state agreed, in exchange, to protect the inventor for a number of years against imitation of his idea.'[44]

Another dominant economic rationale, complementary to the incentive-to-invent rationale, is the prospect theory.[45] This theory sees opportunities to develop technological innovation as 'prospects', which can be carried out by multiple actors, with the risk that each pursues these prospects and expends resources simultaneously and in secret. The patent system, through allocating exclusive rights shortly after discovery of a prospect, is seen as encouraging more efficient allocation to these prospects – in other words, the patent system helps to reduce the (wasteful) duplication of inventive activities. The features of the patent system that align with the prospect theory include that the scope of patents exceeds what is necessary to incentivise investment in invention; rules – such as priority rules – which encourage an early patent application and the fact that patents are granted well before commercialisation is feasible.[46]

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[39] A conception that really is an extension of individual inventorship: see, e.g., Patents Act 1977 (UK), s. 7 as interpreted in *University of Southampton's Applications* [2006] EWCA Civ 145, where the Court looked for who had supplied the inventive concept.

[40] Tur-Sinai (2012), 283-287. For a detailed discussion of the 'moral rights' of inventors see Nari Lee, 'Inventor's Moral Right and the Morality of Patents' in Ysolde Gendreau (ed), *Research Handbook on Intellectual Property and Moral Rights* (Edward Elgar, 2023), ch 6, available at <https://ssrn.com/abstract=3716247> accessed 30 September 2023.

[41] See Paris Convention on Industry Property 1883 (revised 1979), art. 4ter: 'The inventor shall have the right to be mentioned as such in the patent'.

[42] Machlup & Penrose (1950), 21-28.

[43] This latter incentive-to-disclose rationale has been promulgated by William M. Landes & Richard A. Posner, 'The economics in patent law', in *The Economic Structure of Intellectual Property Law* (Harvard UP, 2003), 294-333.

[44] Machlup & Penrose (1950), 26.

[45] First proposed by Edmund Kitch, 'The nature and function of the patent system' (1977) 20 Journal of Law & Economics 265.

[46] Kitch (1977), 267.

Each of these rationales has attracted criticism. This is not unusual whenever one tries to use an all-encompassing descriptive or normative explanation for law, including patent law.[47] We briefly turn to consider the criticisms.

In relation to the incentive-to-invent rationale, a core criticism is that mechanisms other than property rights can operate effectively as incentives. These may be market-based lead times, internal motivations (linked to status and reputation),[48] or monetary awards sourced from the state or elsewhere. In addition, critics point to the social costs of the patent system, including channelling research into those areas that enjoy patent protection (and neglecting other areas that are important); the costs of administering the patent system; and the economic disadvantages of a temporary monopoly being granted.[49] It is fair to say that there is a lack of empirical evidence about the efficacy of patents as incentives and that any incentivising effect may depend on the sector. Scholars point out that there are some industries, such as the software industry, which do not rely heavily on patents in order to prevent free-riding, whereas other sectors, such as pharmaceutical drugs, do.[50] How those incentives may operate for drugs – and the differences between biologics and small molecules - is considered in sections IV.A.1, VII.A-B and VII.D.1. Certainly, in the area of methods of medical treatment (for which there is an exclusion from patentability in European patent law) there is disagreement about whether patents are necessary to incentivise innovation in medical methods or whether other types of incentives suffice and the harmfulness or costs of allowing such methods to be patented.[51] Here, it may be necessary to distinguish between different methods, with diagnostic methods possibly having a stronger case for an incentive-to-invent rationale than, say, surgical methods (see section VII.F.1).

It is also worth noting that the debate about the effectiveness of patents as incentivising innovation resurfaced during the Covid-19 crisis. Some commentators argued that the patent-centric model 'may result in underinvestment in promising treatment opportunities until a crisis is upon us' and called for a different approach in future, one where serious consideration is given to how to design prizes for innovation.[52] While, for others, the social cost of the patent monopoly and the barriers it caused to the manufacture and distribution of Covid-19 vaccines was the focus of criticism and contributed to calls for an IP waiver – the incentive rhetoric being challenged as just that.[53] In response, there were those who staunchly maintained the

[47] It also explains why some scholars have sought to move away from universal accounts of IP law, or patent law in particular, by adopting a pluralist approach that searches for common principles or values across the various justifications: see e.g., D B Resnik, 'A Pluralist Account of Intellectual Property' (2003) 46 Journal of Business Ethics 319 and Robert P. Merges, *Justifying Intellectual Property* (Harvard UP, 2011).

[48] See Jessica Silbey, *The Eureka Myth: Creators, Innovators and Everyday Intellectual Property* (Stanford UP, 2014), ch 4.

[49] Machlup & Penrose (1950), 22-24.

[50] Landes & Posner (2003), 312-313.

[51] See Alexandra Sims, 'The case against patenting methods of medical treatment' [2007] 29 European Intellectual Property Review 43 and Sven J. Bostyn, 'No cure without pay? Referral to the Enlarged Board of Appeal concerning the patentability of diagnostic methods' [2005] 27 European Intellectual Property Review 412.

[52] Robert Burrell and Catherine Kelly, 'The Covid-19 pandemic and the challenge for innovation policy' (2020) 71 Northern Ireland Quarterly Review 1.

[53] Siva Thambisetty et al 'Addressing vaccine inequity during the COVID-19 pandemic: the TRIPS intellectual property waiver proposal and beyond' (2022) 81 Cambridge Law Journal 384, 411-412.

role of patents as incentives for drug innovation, such that the notion of an IP waiver was considered harmful.[54]

When it comes to the incentive-to-disclose rationale, there are some key objections. These include that the patent system only encourages those inventions that cannot be concealed to be patented – it does not necessarily encourage inventions that are able to be kept secret to be patented. Further, there are few inventions that can be kept secret for very long and, even if they are able to be concealed, the same or similar innovations are likely to be developed independently. Finally, there is the argument that the patent system encourages secrecy in the early stages of invention, and, without patents, inventors would speed up the dissemination of their ideas in order 'to secure recognition and fame, and this would hasten technological progress on all fronts'.[55]

The prospect theory has also come under scrutiny. It has been argued that the patent system does not reduce wasteful duplication of innovation efforts but rather may intensify them and shift them to earlier in time because of the value attached to being the first to obtain the patent, particularly in new areas of technological innovation. Further, even where a patent is granted, this does not preclude further competition because third parties may seek to improve upon the patented technology.[56] As such, scholars have sought to justify the prospect theory on a different basis, namely, that rivalry leading to earlier patenting will mean that there is less time for the patentee commercially to exploit the invention, and the invention will enter the public domain sooner. More specifically, 'the race to claim patent rights becomes a race to diminish the patentee's rents by dedicating the invention to the public sooner'.[57]

Finally, we consider another justification for the patent system - one that connects patents and trade secrets. Scholars argue that patent law is 'a response to economic problems inherent in trade secrecy and market structure'.[58] More specifically, they argue that patent law 'combats' the desire to keep the invention secret[59], in part by requiring publication of the patent specification and because the patent monopoly offers broader protection than trade secrets law and 'saves the inventor the cost of keeping his invention secret'.[60] Licensing for manufacture is also more straightforward with patents than with trade secrets because, in relation to licensing trade secrets, there is a risk of accidental or deliberate leakage of information, which could destroy the secrecy of the information and so the basis for protection.[61] Other commentators also evaluate patent law from the perspective of avoiding the drawbacks of trade secrets protection and suggest that trade secrecy 'does not permit

[54] Reto Hilty et al., 'COVID-19 and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021' (May 7, 2021). Max Planck Institute for Innovation & Competition Research Paper No. 21-13, <https://ssrn.com/abstract=3841549> accessed 30 September 2023.
[55] Machlup & Penrose (1950), 26.
[56] John Duffy, 'Rethinking the Prospect Theory of Patents' (2004) 71 University of Chicago Law Review 439, 442-443. See also Landes & Posner (2003), 319-320.
[57] Duffy (2004), 444.
[58] Landes & Posner (2003), 294.
[59] Landes & Posner (2003), 294.
[60] Landes & Posner (2003), 295, 328.
[61] Landes & Posner (2003), 329.

society to efficiently assess the value of inventions' whereas patents do.[62] As well, a patent system also reduces 'the enormous transaction costs that trade secrets involve'[63] and, via disclosure of the invention in the patent specification, encourages third parties to invent around.[64]

This interplay between the justifications for patent and trade secrets protection leads us to consider more squarely the rationales for trade secret law.

B. Justifications for trade secret protection

A variety of justifications have been raised for trade secrets protection and this plurality contributes to the impression of a less coherent or compelling basis,[65] as compared with patent law. Similar to patents, the basis for trade secrets protection has been seriously called into question by some scholars[66] and there is a tendency to focus primarily on economic rationales.[67]

The first economic justification is that trade secrets law provides an incentive to innovate. The argument is that trade secrets protection acts as an incentive to innovate because it 'gives the developer of new and valuable information the right to restrict others from using it, and therefore the prospect of deriving supracompetitive profits from the information'.[68]

The more dominant rationale, however, is that trade secret law incentivises *sharing* of information and saves on wasteful expenditure in maintaining secrecy. The presence of legal protection for secret, commercially valuable information means that holders of such information are more likely to share it, albeit on a restricted basis, because there is default protection in the event of misuse. Further, trade secret protection operates as a substitute for physical and technical precautions adopted to maintain secrecy, thus saving a holder of information from having to use such precautions.[69] This is the case even though there is a requirement of secrecy since this 'serves to channel inventors into the appropriate form of IP protection' and preserves 'robust competition'.[70] Further, the fact that the definition of a trade secret requires 'reasonable steps to maintain secrecy' does not detract from this

[62] Nuno Pires de Carvalho, 'The Primary Function of Patents' (2001) University of Illinois Journal of Law, Technology & Policy 25, 44.
[63] Carvalho (2001), 44.
[64] Carvalho (2001), 49.
[65] For a discussion of the plurality of rationales see Tanya Aplin et al, *Gurry on Confidence: The Protection of Confidential Information* 2nd edition (OUP, 2012), ch 3 and for the argument that there is no coherent justification for trade secrets protection see Robert G. Bone, 'A New Look at Trade Secret Law: Doctrine in Search of a Justification' (1998) 86 California Law Review 241.
[66] Bone (1998); see also Hettinger (1989), 46, 50, 52.
[67] Michael Risch, 'Why Do We Have Trade Secrets?' (2007) 11 Marquette Intellectual Property Law Review 1, 26; Mark A. Lemley, 'The Surprising Virtues of Treating Trade Secrets as IP Rights' (2008) 62 Stanford Law Review 311; William M. Landes and Richard A. Posner, 'The Economics of Trade Secrecy Law' in *The Economic Structure of Intellectual Property Law* (Harvard UP, 2003), ch 13, 354-371; and David Friedman, William M. Landes and Richard A. Posner, 'Some Economics of Trade Secret Law' (1991) 5 The Journal of Economic Perspectives 61. See also the US Supreme Court in *Kewanee Oil Co v Bicron Corp.,* (1974) 416 U.S. 470, 484.
[68] Lemley (2008), 330. See also J. R. Thomas, 'The Role of Trade Secrets in Innovation Policy' (2014) Congressional Research Service, R41391 and *Kewanee,* 484 where the Court observes that the incentive function of patent law is not threatened by the incentive function of trade secrets law.
[69] Lemley (2008), 333-336; Risch (2007), 43; Landes & Posner (2003), 365: noting that trade secrets protection is an 'attractive substitute' for 'costly defensive' measures to preserve secrecy.
[70] Lemley (2008), 338 and 343.

argument because without it 'trade secret owners would under-protect information in some instances' and because this requirement is focused on 'efficient protection measures'.[71] As well, such steps arguably operate as a signal that the secret has value and is in fact secret.[72]

We have also seen commentators consider the justification of trade secrets *vis-à-vis* patents. It has been observed that:

> 'rational inventors choose trade secret protection when they think that patent protection is too costly in relation to the value of their invention or will yield them a profit substantially less than that value…either because it is not patentable or because the length or breadth of patent protection is insufficient'.[73]

It has also been argued that innovators will sometimes prefer trade secrets to patents because this involves less cost and the absence of a disclosure requirement, and so to abolish trade secrets protection would undermine incentives to innovate.[74]

Scholars observe that the limitations on trade secrets protection - in particular the requirement of derivation and the permissibility of reverse engineering - 'weaken the trade secret right sufficiently that it does not entice inventors to choose secrecy over patent protection'.[75]

Despite these economic justifications, criticisms of trade secrets protection abound. For example, some scholars point to the lack of 'socially beneficial public disclosure' (as compared with patents) and the stifling effect secrecy can have on competition;[76] along with the restrictions that trade secrets law places on employee mobility.[77] Even those that view trade secrets positively raise the question of whether some limitation on the duration of protection might be desirable.[78]

This critique has led some commentators to rely on alternative justifications, based on commercial ethics and morality.[79] Support for such an 'unfair competition' type rationale also derives from international patent law, in the form of Article 10bis Paris Convention on Industry Property 1883 (revised 1979) and Article 39 of the Agreement on Trade Related Aspects of Intellectual Property Rights.[80] The difficulty with an unfair competition justification is that it is based on norms of commercial ethics and morality and yet there is little empirical

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[71] Risch (2007), 45.

[72] Risch (2007), 45. Contrast Lemley (2008), 348-350 arguing that reasonable steps to preserve secrecy does not make sense as a separate requirement but only as evidence of secrecy or scienter.

[73] Landes & Posner (2003), 359.

[74] Landes & Posner (2003), 360.

[75] Lemley (2008), 40.

[76] Hettinger (1989), 50, 52.

[77] Hettinger (1989), 46-47.

[78] Lemley (2008), 353.

[79] See Lynn Sharp Paine, 'Trade Secrets and the Justification of Intellectual Property' (1991) 20 Philosophy & Public Policy 247 (referring to common morality and fair competition). See also Harry Wingo, 'Dumpster Diving and the Ethical Blindspot of Trade Secret Law' (1997) 16 Yale Law and Policy Review 195, 196 (noting that 'promoting commercial ethics is one of trade secrets law's fundamental purposes'); Risch (2007), 37 (arguing that enforcement of 'commercial ethics' can be justified as 'populist' or 'democratic') and Thomas (2014), 3-4. *Kewanee*, 481 ('The maintenance of standards of commercial ethics and the encouragement of invention are the broadly stated policies behind trade secret law.')

[80] See Sam Ricketson, *The Paris Convention for the Protection of Industrial Property: A Commentary* (OUP, 2015), paras 13.56, 13.61 et seq.

data to support the existence of such norms.[81] Moreover, even if there was this evidence, commentators have queried whether legal norms should automatically mirror commercial morality and behaviours. Further, while there may be marginally greater compliance with the legal norm, this could involve significant litigation costs. Finally, there is the risk of incorrect recognition of the commercial norm and that it will become rigid and inflexible.[82]

One final justification to address is that of national economic interest. This justification was apparent in the adoption of the US Economic Espionage Act 1996 and in the EU Trade Secrets Directive.[83] In relation to the US legislation, the main rationale was to stem the increasing tide of foreign espionage.[84] In the case of the EU Trade Secrets Directive, protecting regional economic interest was a key concern. Specifically, recital 8 refers to the need to remove fragmentation of trade secrets protection between Member States because such differences make 'cross-border network research and development, as well as innovation-related activities…less attractive and more difficult within the Union, thus also resulting in Union-wide innovation-related inefficiencies.'

VI. The interplay of patents and trade secrets

A. General interplay issues

This section makes a few general observations before turning to look at the interplay of patents and trade secrets in terms of alternative and complementary uses.

The first observation is that while the interplay between patents and trade secrets has received some attention in the literature,[85] it has not received as much attention as other overlaps or interplays[86] compared, say, with copyright and designs[87] or trade marks and

[81] Bone (1998), 246.
[82] Bone (1998), 295-296.
[83] [2016] OJ L157/1.
[84] See Statement of Louis J. Freeh, Director FBI before the House Judiciary Committee Subcommittee on Crime, Hearing on Economic Espionage, May 9, 1996 <https://irp.fas.org/congress/1996_hr/h960509f.htm> accessed 30 September 2023.
[85] Lionel Bently and Tanya Aplin, 'Patents and Trade Secrets' in Neil Wilkof, Shamnad Basheer and Irene Calboli (eds), *Overlapping Intellectual Property Rights* (OUP, 2023), ch 3; Andrew Beckerman-Rodau, 'The Choice between Patent Protection and Trade Secret Protection: A Legal and Business Decision (2002) 84 Journal of the Patent and Trademark Office Society 371; Karl F. Jorda, 'Patent and Trade Secret Complementariness: An Unsuspected Synergy' (2008) 48 Washburn Law Journal 1; Michael R. McGurk and Jia W. Lu, 'The Intersection of Patents and Trade Secrets' (2015) 7 Hastings Science & Technology Law Journal 189, with some literature specifically focussing on medical technologies: see Brenda M. Simon and Ted Sichelman, 'Data Generating Patents' (2017) 111 Northwestern University Law Review 377 and W. Nicholson II Price and Arti K. Rai, 'Manufacturing Barriers to Biologics Competition and Innovation' (2016) 101 Iowa Law Review 1023.
[86] It is noticeable, for example, that the few major texts on overlaps in intellectual property rights minimally address the issue (see the one chapter by Bently and Aplin in Wilkof, Basheer & Calboli (2023)) and passing references in Estelle Derclaye and Matthias Leistner, *Intellectual Property Overlaps: A European Perspective* (Hart, 2011), 172 (stating that decisions dealing with patent and trade secret protection are rare in France) and 316 (suggesting publication of source code in software patent applications to solve the 'highly problematic' overlap between patents and trade secrets in the case of computer programs); and some discussion in R. Tomkovicz, *Intellectual Property Overlaps: Theory, Strategies and Solutions* (Routledge, 2012), ch 2, section 2.2. Only fleeting reference is made in Estelle Derclaye, 'Overlapping Rights' in Rochelle Dreyfuss and Justine Pila (eds), *The Oxford Handbook of Intellectual Property Law* (OUP, 2017), ch 22, 618-651 at 620, 625.
[87] E.g., Estelle Derclaye, *The Copyright/Design Interface: Past, Present and Future* (CUP, 2018).

copyright.[88] Second, international IP law is relatively silent on the question of IP overlaps generally, addressing only the overlap between patents and plant variety rights and, to some extent, also copyright and designs.[89] Notably, international IP law is entirely silent on the overlap or interplay between patents and trade secrets. Third, while there is an increasing empirical literature on the relationship between patents and trade secrets,[90] this still lags behind the empirical literature on patents due to the lack of available data on trade secrets.[91] Finally, it appears that trade secret protection is especially relevant to the manufacturing and service sectors[92] and preferable for process innovations, whereas patents tend to be preferred in the case of product innovations.[93]

The next section considers the traditional view that patents and trade secrets are alternatives and then considers the emerging view that they are in fact complements. It is particularly as complements that we see the interplay between patents and trade secrets becoming potentially problematic.

B. Alternative uses

Commentators often discuss patents and trade secrets as alternative forms of protection and present the relevant considerations for making an informed choice between the two regimes.[94] In thinking about these factors, the nature and scope of patents versus trade secrets protection, is relevant.[95]

Patents are registered rights and as such involve acquisition and maintenance costs. They offer strong monopoly rights (against making, use, sale and importation of the patented

[88] E.g., Irene Calboli, 'Trademarking Creative Works: Trends and Negative Effects on the Copyright Equilibrium,' in S Frankel and D Gervais (eds), *Evolution And Equilibrium: Copyright This Century* (CUP 2014), ch 3, 52-80.

[89] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (WTO) (1994) (in force since 1995) ('TRIPS'), art. 27(3)(b) and Berne Convention for the Protection of Literary and Artistic Works (rev, 1971), arts. 2(7) and 7(4). See Derclaye (2017), 624.

[90] A. Arundel, 'The relative effectiveness of patents and secrecy for appropriation' (2001) 30 Research Policy 611-624; Paul Belleflamme and Francis Bloch, 'Dynamic Protection of Innovations Through Patents and Trade Secrets (12 November 2013), <https://ssrn.com/abstract=2537248> accessed 30 September 2023; D. Crass et al, 'Protecting Innovation Through Patents and Trade Secrets: Evidence for Firms with a Single Innovation' (2019) 26 International Journal of the Economics of Business 117; K. Hussinger, 'Is Silence golden Patents versus secrecy at the firm level' Governance and the Efficiency of Economic Systems (GESY), Discussion Paper No 37 (March 2005); Elisabetta Ottoz and Franco Cugno, 'Choosing the scope of trade secret law when secrets complement patents' MPRA Paper No. 27195 available at <https://mpra.ub.uni-muenchen.de/27195> accessed 30 September 2023, Nathan Wajsman, Francisco García-Valero, et al, 'Protecting Innovation through Patents and Trade Secrets: Determinants and Performance Impacts for German Firms' (September 2016, European Union Intellectual Property Office).

[91] Nicola Searle, 'The Economic and Innovation Impacts of Trade Secrets' (2020) available at <https://ssrn.com/abstract=3686478> accessed 30 September 2023.

[92] Searle (2020), 13.

[93] Arundel (2001); Wesley M. Cohen, Richard R. Nelson and John P. Walsh, 'Protecting Their Intellectual Assets: Appropriability Conditions and Why US Manufacturing Firms Patent (or Not)' (NBER Working Paper Series No 7552, February 2000), <https://ideas.repec.org/p/nbr/nberwo/7552.html> accessed 30 September 2023; Crass et al (2019).

[94] Simon & Sichelman (2017) and W. Nicholson II Price, 'Expired Patents, Trade Secrets, and Stymied Competition (2017) 92 Notre Dame Law Review 1611, 1616-1617 describing this 'traditional view' and see Beckerman-Rodau (2002), 388-404; McGurk & Lu (2015), 200-209 on the factors affecting this choice.

[95] See also Derek E. Bambauer, 'Secrecy is Dead – Long Live Trade Secrets' (2016) 93 Denver Law Review 833, 835-836.

product or of products directly resulting from the patented process) in return for disclosure of the invention in the specification and a limited term of 20 years protection.[96] Whereas, trade secrets are unregistered rights[97] and thus offer informal and cheaper protection by comparison. Trade secret protection also has the potential to last longer than patents, assuming secrecy of the information can be maintained. However, the scope of protection is weaker since trade secret law only protects against misappropriation and does not prohibit third parties from independently generating the same information or acquiring it legitimately through reverse engineering.[98] There are also complications in how trade secrets are licensed as compared with patents[99] and a certain precariousness to whether secrecy is maintained because of the risks of accidental or deliberate leakage by employees or third parties. When it comes to enforcement, there may be differences in remedies depending on the jurisdiction. This is the case in the US, for example, where there is the possibility of 'treble damages'[100] for patent infringement but only 'double damages' in the case of wilful and malicious appropriation of trade secrets.[101] By comparison, this sort of disparity is not apparent in the EU.[102]

The traditional thinking when it comes to 'election' between patents and trade secrets assumes they are substitutes 'to the extent that the subject matter can either be patented or potentially kept a secret.'[103] What may influence the 'choice' is nicely summarised thus:

> 'Inventors and firms will typically consider the duration of protection, likelihood of reverse engineering, likelihood of independent invention, detectability of infringement, and the cost of procuring and enforcing the rights inherent in the protection sought.'[104]

[96] See TRIPS, arts. 28, 29 & 33.
[97] See TRIPS, art. 39(2).
[98] E.g., see EU Trade Secret Directive, art. 3(1).
[99] Because trade secrets protection does not create a property right as compared with patents, which do.
[100] 35 USC, s.284.
[101] UTSA, s. 3(b) and 18 USC s.1836(3)(C).
[102] As a result of the Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights ('Enforcement Directive') OJ L157, 30/04/2004 p. 45, arts.9-15 and EU Trade Secrets Directive 2016/943 [2016] OJ L157/1, arts. 9-15, although this is not to suggest that there are not some differences. For a discussion see: Tanya Aplin, 'A critical evaluation of the proposed Trade Secrets Directive' (2014) IPQ 257, 276-277 who points out that they are comparable apart from three key differences, which relate to: i) the persons entitled to seek measures, procedures and remedies; ii) the absence of remedies in the Trade Secret Directive for preserving evidence or for obtaining orders regarding the origin and distribution networks of infringing goods (as we see in art. 8 Enforcement Directive); and iii) the fact that the Trade Secret Directive has explicit factors for the court to consider when determining proportionate remedies.
[103] Simon & Sichelman (2017), 386.
[104] Simon & Sichelman (2017), 387. McGurk & Lu (2015), 200-209 refer to patentability, term of protection, enforcement, remedies, disclosure, prior user rights and costs. Beckerman-Rodau (2002), 388-404 has a longer list of market and business considerations: i) market life of the subject matter; ii) likelihood of reverse engineering; iii) likelihood of independent development; iv) extent to which you want to educate your competition; v) type of subject matter; vi) difficulty of maintaining subject matter as a secret; vii) cost of maintaining secrecy versus the value of the subject matter; viii) economic barriers to competitors entering the market; ix) number of persons who need access to the subject matter; x) expense and time to obtain patent versus trade secret protection; xi) economic effect of trade secrecy being lost; xii) employee mobility; xiii) internal versus external use of technology; xiv) consequences of bringing a patent action.

Whether this choice is problematic was considered by the US Supreme Court in *Kewanee v Bicron.*[105] The court held that a choice between patents or trade secrets protection was *not* problematic and, as such, patent law did not constitutionally pre-empt trade secret law.[106] The court categorised trade secrets into three types: i) where the owner knows the trade secret is not patentable; ii) where the trade secret has doubtful patentability; and iii) where the owner believes the trade secret constitutes a patentable invention.[107] As for the first category, there would be no point trying to seek a patent and therefore opting for trade secret protection would be an obvious choice. In such a situation, the court held it would make sense to maintain trade secret protection since '[t]rade secret law will encourage invention in areas where patent law does not reach'.[108] For the second category, the court held that doubts about patentability might dissuade inventors from applying for such protection, in which case '[t]rade secret protection would assist those inventors in the more efficient exploitation of their discoveries'.[109] As for the third and final category, where the invention is clearly patentable, the court noted the advantages of patent protection over trade secrets protection and concluded that the possibility that an inventor would opt out of the former was 'remote'.[110] Further, in the rare situation trade secret protection was nevertheless preferred, the court saw this as unproblematic because 'there is a high probability that [the invention] will be soon independently developed'.[111]

However, commentators have challenged the view that patents and trade secrets are substitutes. They have argued that it is misguided to treat them as such because patent claims are often broader than what is disclosed in the specification, with it sufficing to disclose an embodiment of the invention. There are also the 'watered down' disclosure requirements of US patent law, where the failure to disclose the best mode of performing the invention is no longer a ground of invalidity.[112] As such, not all of the technologically and commercially valuable information about an invention will be disclosed and this will be protectable as a trade secret.[113] Other commentators have doubted the assumed preference for patent protection, in light of changes to US patent law affecting the scope of patentable subject matter, increasing the range of prior art, introducing a prior use defence and increasing the costs of enforcement.[114] Thus, the literature indicates a firmly held view that patents and trade secrets should be seen as complementary, which we now examine in further detail.

[105] *Kewanee Oil Co v Bicron Corp.,* (1974) 416 U.S. 470, 484.

[106] For a critique of the decision see Sharon K. Sandeen, 'Kewanee Revisited: Returning to First Principles of Intellectual Property Law to Determine the Issue of Federal Preemption' (2008) 12 Marquette Intellectual Property Law Review 299.

[107] *Kewanee,* 484.

[108] *Kewanee,* 485.

[109] *Kewanee,* 487.

[110] *Kewanee,* 490.

[111] *Kewanee,* 491.

[112] Simon & Sichelman (2017), 387-388.

[113] Simon & Sichelman (2017), 389. See also Brian J. Love and Christopher B. Seaman, 'Best Mode Trade Secrets' (2012) 15 Yale Journal of Law & Technology, 11 suggesting that the removal of the 'best mode' requirement and the introduction of prior user rights in US patent law will lead to an increase in reliance on patents and trade secrecy and at 15 indicating that the change undermines the disclosure-for-limited monopoly bargain of patent law.

[114] Bambauer (2016), 837-840.

C. Complementary uses

One type of complementary use is relying on trade secrets protection *prior* to patenting. That trade secrets would be used in this way follows from the novelty and industrial application requirements under patent law. The fact that an invention must have industrial application,[115] i.e., a plausible practical use or concrete benefit,[116] means that there may be a delay between an inventive breakthrough and a patentable invention. Further, inventions will be assessed as against the prior art and thus it is important that the inventor does not destroy the novelty of her invention by disclosing it prior to filing a patent. This is where trade secrets protection can be useful as a means to maintain the confidentiality of an invention until the inventor is ready to file for a patent.[117] Of course, there remains the risk of misappropriation of the trade secret, which could be novelty destroying, although some patent systems (such as in the UK) exclude disclosures from the prior art where they are the result of trade secret misappropriation or breaches of confidentiality.[118] In this situation, patents are the primary vehicle for protecting the invention and trade secrets are used in a complementary way in order to preserve the ability to obtain patent protection.

Additionally, trade secrets are often used in tandem with patented products. Trade secrets may protect the product's method of manufacturing, along with how to commercialise and market it.[119] Further, relevant information about how best to practice the invention may not be disclosed in the patent specification,[120] but held back and licensed through specific agreement, in which confidentiality or non-disclosure obligations are imposed.[121] As scholars observe, 'commercial embodiments of inventions developed well after patenting often substantially differ from what is disclosed in a patent' and can be protected by trade secrets.[122] There is the concern that this complementary use 'arguably thwarts the goals of the patent system'.[123] However, the main concern lies with 'data generating patents', which 'often generate information apart from the invention itself' and which are increasing in the big data era.[124]

An example relates to Myriad Genetics which, due to their patent rights, was the sole provider, for many years, of genetic tests for the BRCA1 and BRCA2 genes that are markers of breast cancer. Despite some of Myriad's patent claims being invalidated by the US Supreme Court, the corporation nevertheless was in a position (while those patents were considered valid) to accumulate a private database of patients' genetic information generated from use of the patented diagnostic tests. As a result, Myriad is now able to offer a lower rate of

[115] TRIPS, art. 27(1).
[116] *Human Genome Sciences v Eli Lilly & Co* [2011] UKSC 51.
[117] Jorda (2008), 10-11.
[118] See Patents Act 1977 (UK), s. 2(4), but only where those disclosures occur six months prior to the filing date.
[119] Price (2017), 1618 referring to the example of a patented drug and the method of making it as a trade secret.
[120] Price (2017), 1618. Kyoungbo Sim, 'Optimal use of patents and trade secrets for complex innovations' (2021) 79 International Journal of Industrial Organization 102788, <https://doi.org/10.1016/j.ijindorg.2021.102788> accessed 30 September 2023 giving the example of how Wyeth extended its monopoly position even after expiry of the patent for Premarin, a patented hormone therapy for menopausal women because of its trade secrets for the process of extracting estrogen.
[121] Virender Chandel, 'Confidential information (know-how) licensing' [2019] 41 European Intellectual Property Review 714.
[122] Simon & Sichelman (2017), 405.
[123] Simon & Sichelman (2017), 406.
[124] Simon & Sichelman (2017), 391.

variants with unknown significance because it can interpret diagnostic test results in light of its large, private database. This, in turn, gives it a competitive advantage.[125] Other examples of 'data generating patents' are patented algorithms for search engines and facial recognition technology and patented smart medical devices.[126] Again, the concern is that the multiplicity of data that is generated by use of these patented technologies allows the patent holder not only to improve their invention but also to gain leverage in secondary markets. This is because the data that is generated is not just about the invention itself and its uses, but about its users.[127] Moreover, traditional safeguards in trade secrets law, such as reverse engineering or independent creation, are foreclosed for the period of the patent.[128] As a result, there is a concern that data-generating patents may 'hinder downstream innovation' and 'extend deadweight losses to consumers after the underlying patent expires or is invalidated'.[129]

Commentators have observed various ways in which patents and trade secrets may be used in a complementary fashion[130] and flagged the concern that such use does not distort the principle of open competition that is meant to occur once the patent has expired. This distortion may be less problematic where 'the protected aspects of the invention are different and separable' but more problematic where they are not.[131] There are three scenarios of concern. The first is where information necessary to make an interchangeable version of the patented product is kept secret. An example is biologics, where competition for interchangeable products has been thwarted by trade secrets protection for the methods of manufacture, and where, because of the complicated nature of biologics, the relevant information is not discernible from reverse engineering the product.[132] The second scenario is where other innovations or components needed to use the patented invention are protected by trade secrets.[133] The third scenario is where a patented invention is used 'to generate information closely linked to the patented invention…that enables the effective functioning of the underlying invention for consumers'.[134] This relates to the Myriad Genetics example discussed above.[135] A suggestion for addressing this tension is to introduce a requirement of 'economic enablement', although the means for doing so under either patent or trade secrets law may not be straightforward.[136]

Of course, the challenge is how to assess when such complementary use of patents and trade secrets *is* harmful to competition. In the case of data-generating patents, one suggestion is to consider the extent to which the patent allows for data collection not directly related to the market for the patented invention and the degree of impact of competition in the market regarding the data.[137]

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[125] Simon & Sichelman (2017), 394-395.
[126] Simon & Sichelman (2017), 396-404.
[127] Simon & Sichelman (2017), 406.
[128] Simon & Sichelman (2017), 407-408.
[129] Simon & Sichelman (2017), 413.
[130] W. Nicholson II Price, 'Expired Patents, Trade Secrets, and Stymied Competition' (2017) 92 Notre Dame Law Review 1611.
[131] Price (2017), 1620.
[132] Price (2017), 1623-1626. The concrete example he gives of this phenomenon is the drug Premarin.
[133] Price (2017), 1626-1627.
[134] Price (2017), 1629.
[135] Price (2017), 1630-1631.
[136] Price (2017), 1632-1640.
[137] Simon & Sichelman (2017), 420 et seq.

Having outlined these important, general issues concerning alternative and complementary uses of patents and trade secrets, we turn now to consider more specific interplays between these two regimes of protection in relation to medical technologies.

VII. Specific interplay issues in medical technologies

A. Small molecules and generics: a system working well but with a salient history

Commentators generally believe the system of trade secrets and patents fits well for the production of new small molecules.[138] Innovators use trade secrets to protect new molecules until patenting them, and patents offer broad protection for innovators to recoup costs and make a profit, despite the high costs (described in section IV.A).[139] However, this system belies an important history that shapes issues for other technologies, especially biologics.

Today, small molecules are generally regarded as easy to copy. Copies of small molecule drugs are known as 'generics' and are typically 'substitutable' with the originators' versions, which means the generic can be substituted for an originator's drug with no little or no meaningful differences in therapeutic effect.[140] However, this ease and substitutability are only recent phenomena ushered in by scientific and regulatory advances.

The scientific advances primarily relate to analytical science. In the early 1960s, scientists had limited tools to evaluate the similarity of an originator's drug with a competitor's generic version.[141] These limited tools were underpinned by the fact few standards existed for testing the similarity of compounds.[142] Indeed, this period in the US is underpinned by political and scientific struggles to show that two small molecules were 'bioequivalent', meaning two drugs have substantially the same effect in human bodies.[143] Many scientists and politicians disagreed on whether generics *could* be equivalent to originators' products. Ultimately, the FDA took the lead in 'defining a methodology of measuring therapeutic equivalence in terms of biological availability that worked to develop explicit protocols for bioequivalence',[144] and by '1978, bioequivalence had become a more coherent object within the FDA, a regulatory science of similarity'.[145]

These advances in science are linked to legislative and regulatory change. In 1984, the US passed the Drug Price Competition and Patent Term Restoration Act, often called the Hatch-Waxman Act.[146] The Act has also been called the 'grand compromise' because it seeks to

[138] See e.g., Dan L. Burk and Mark A. Lemley, 'Policy Levers in Patent Law' (2003) 89 Virginia Law Review 1575, 1616–1617.
[139] The perennial issue of whether originators charge *too* much for patented drugs is relevant here, especially from a policy perspective. However, to the extent that the prices purely rely on patent protection is beyond the scope of this Paper, which focuses on the *interplay* between patents and trade secrets.
[140] Price & Rai (2016), 1028; Robin Feldman, 'Trade Secrets in Biologic Medicine: The Boundary with Patents' (2022) 24(1) The Columbia Science & Technology Law Review 1, 24.
[141] Jeremy A. Green, *Generic: The Unbranding of Modern Medicine* (Johns Hopkins University Press 2014) 103–105.
[142] Green (2014), 103-105.
[143] Green (2014), 110-120.
[144] Green (2014), 120.
[145] Green (2014), 122.
[146] Drug Price Competition and Patent Term Restoration Act of 1983, Pub. L. No. 98-417, 98 Stat. 1585.

balance promoting innovation with enabling generic entry.[147] Three elements of the Act are relevant to this discussion, and the first two are favourable to generic companies. First, the Act allows the authorisation of generics *without* conducting extensive clinical trials. Before the Hatch-Waxman Act, generic companies often had to repeat many of the clinical trials conducted by originators.[148] However, under the new Act, which continues today, generic companies only have to show their products are bioequivalent, which generally means they can avoid conducting clinical trials.[149] The finding of bioequivalence has a significant impact on clinical medicine because it allows pharmacists to substitute an originator's version of the drug for a cheaper generic.[150]

Second, the Act introduced an exemption to patent infringement for generic companies to test and develop generic drugs for authorisation.[151] Before this, companies risked infringing patents if they started experimenting with how they would produce generic drugs. The exemption allowed generic companies to conduct R&D during the lifetime of patents and, therefore, to launch generic versions as soon as the relevant patents expired. The third element is a benefit for originators. The Act grants regulatory protection to originators when they have a product authorised. The Act stops the FDA from authorising generics that rely on originators' clinical-trial data for 5 years.[152]

These three elements have been reproduced in many countries and have been broadly successful in encouraging generic entry and increasing the uptake of low-cost generics.[153] This Paper will regularly refer to the authorisation of generics (and other types of drugs), which rely on originators' data. It will also return to issues surrounding regulatory protection.

1. A system working well with two exceptions

Although the system of small molecules and generics works well, two related issues query whether the system could work better. The issues concern disclosing clinical trial data and protocols. In the US, manufacturers have claimed the protocols used to run clinical trials (i.e., the procedure) as trade secrets. They have also claimed the data produced by trials as trade secrets.[154] In both instances, the justification for trade secret protection is that competitors could use the information to make competing products.[155]

Trade secrets on clinical trial data and protocols can adversely affect follow-on innovation and access. Before these effects are described, though, the trade secrets must be put in the

[147] Ernst R. Berndt and Murray L. Aitken, 'Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation' (2010, National Bureau of Economic Research, Working Paper 16431) 2.
[148] N. Danchev and I. Nikolova, 'Generics – Present and Future' (2007) 21 Biotechnology & Biotechnological Equipment 94, 94.
[149] 21 CFR § 314.108(b)(2).
[150] Feldman (2022), 24; whilst this statement is generally true, various territories have different approaches to permitting substitutability for generics, see e.g., Chana A. Sacks et al, 'Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologics Substitutions' (2021) 181 JAMA International Medicine 16, <doi:10.1001/jamainternmed.2020.3588> accessed 30 September 2023.
[151] 35 USC § 271(e).
[152] 21 USC 355 § (c)(3)(E)(ii).
[153] Henry G. Grabowski et al, 'Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act' (2011) 30(11) Health Affairs 2157, 2157.
[154] Feldman (2022), 39.
[155] European Ombudsman, 2560/2007/BEH against the European Medicines Agency, 2010 [80].

context of disclosures made by regulators or mandated by laws governing clinical trials. These disclosure requirements are different in the US and the EU.

First, in the US, FDA authorisation decisions include descriptions of clinical data and are published publicly; however, the data are often only a summary of the key clinical studies, which can exclude information such as patients' clinical outcomes, mortality, withdrawal and adverse events.[156] Second, anyone who runs a clinical trial must report certain data, but what must be reported is limited: trialists must only describe the study design (i.e., the number of treatment arms) and summarise the results.[157] Moreover, a study found that for approximately 1 in 3 completed trials in the US the sponsor organisation failed to report any results for their trials in breach of their legal obligations.[158] One could downplay the significance of these results because scientists will likely publish the results in a journal. However, there are benefits to publishing on official clinical-trial websites. For example, the websites use a common format that enables comparisons across trials, which journals do *not* do, and many people access the websites (e.g., clinicaltrials.gov receives 215 million views per month).[159]

Commentators have argued that the absence of accessible clinical trial data and protocols has three negative impacts. First, the lack of data stops third parties from reviewing the data, which could reveal flaws or safety issues missed by regulators. Second, the data is helpful for governments and other health insurers/payors that decide how much they will pay or reimburse for a drug, which affects patient access. Third, if the trial results and protocol are not disclosed, other companies may trial the drug, not knowing it has been trialled before or not knowing how to improve upon the earlier trial, wasting resources and perhaps putting patients at needless risk.[160]

The disclosure requirements are different in the EU. In 2015, the EMA started publishing the data analysed in their reports, which allows, amongst other things, researchers to re-assess the data.[161] Yet, the published data is aggregated data, not *patient*-level data, which means the *raw* data is still unavailable (that said, the EMA is pursuing the idea of publishing patient-level data in the future).[162] Further, the EU passed a Regulation in 2014 that significantly changed the landscape. The Regulation requires that all documents submitted to the EU concerning clinical trials are published, *except* for commercially confidential information. This

[156] Barbara Mintzes et al, 'Clinical Trial Transparency: Many Gains but Access to Evidence for New Medicines Remains Imperfect' (2015) 116 British Medical Bulletin 43, 46.
[157] 42 USC § 282(j)(2)(A)(ii) and 282(j)(3)(B)–(c).
[158] Charles Piller, 'FDA and NIH let clinical trial sponsors keep results secret and break the law' (*Science*, (13 January 2020) <https://www.science.org/content/article/fda-and-nih-let-clinical-trial-sponsors-keep-results-secret-and-break-law> accessed 30 September 2023.
[159] ibid.
[160] See e.g., Feldman (2022), 40-41.
[161] EMA, 'Publication of Clinical Trial Reports' (EMA, 2 October 2014) <https://www.ema.europa.eu/en/news/publication-clinical-reports> accessed 30 September 2023.
[162] ibid.

publication policy means that applications to conduct clinical trials, which include the protocols,[163] are published.[164]

The extent of the negative impacts created by trade secrets has not been examined. Researchers have not examined how frequently the three negative effects identified above arise nor the magnitude of the problems (e.g., the cost of not revealing them). Nor have researchers considered if the greater disclosure created by the EU Regulation overcomes some of the problems in the US; are most trials listed on both EU and US clinical trials registries, meaning protocols are typically published (because they could be obtained from the EU website)? Similarly, do the data published in the EU reports provide sufficient information for third parties to analyse (e.g., when reviewing efficacy and making reimbursement decisions)? Or will only patient-level data suffice?

B. Biologics and biosimilars: one of the greatest areas of tension between patents and trade secrets

1. An introduction to biosimilars and the different regulatory systems in the US and EU

The term 'generics' describes competitors' copies of small molecules. However, a different term is used to describe competitors' copies of biologics: 'biosimilars'. The reason the term 'biosimilar' is used relates to the complexity of biologics (outlined in section IV.A.1). As explained above, small molecules are relatively simple molecules, typically made using well-established laboratory processes and are usually easy to represent using pen and paper.[165] Moreover, the advances in science from the 1960s to today have meant that generic companies can produce generics relatively cheaply, for as low as US$1-2 million.[166] In contrast, biologics are more complex, made in living organisms.[167] They are *not* typically easy to represent using a pen and paper, nor can they be easily made. This complexity makes it more challenging for competitors to make bioequivalent compounds. Indeed, the term *biosimilars* effectively admits complexity: the compounds are *not* identical. They are only similar. Commentators estimate it takes up to 8 years to create a biosimilar at a cost of US$100–250 million.[168]

Broadly speaking, many countries use similar systems for authorising generics as they do for biosimilars. However, there are key differences. Whereas generics are authorised if they are bioequivalent, in the US and EU, biosimilars are authorised if they are 'highly similar' and display 'no clinically meaningful differences' to the biologic.[169] The EU and US have similar standards here but diverge elsewhere. In terms of regulatory protection, originators in the EU are granted the same regulatory protection as small molecules. That is, 8 years of data

[163] In a decision, the European Ombudsman found that clinical study reports and protocols do not constitute trade secrets, see, European Ombudsman, 2560/2007/BEH against the European Medicines Agency, 2010 [79]-[80].

[164] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on Clinical Trials on Medicinal Products for Humans Use, and repealing Directive 2001/20/EC [2014] OJ L158/1 art 81 ('Clinical Trials Regulation').

[165] Price & Rai (2016), 1028.

[166] For a brief review, see, Price & Rai (2016).

[167] Price & Rai (2016), 1032–1033.

[168] Price & Rai (2016), 1028.

[169] 21 USC §§ 355(j)(2)(A)(i)–(v); Directive (2001/83) on the Community code relating to medicinal products for human use [2004] OJ L311/67, art 10(4) and Annex 1 '2. Essentially Similar Medicinal Products'; EMA, 'Biosimilar Medicines: Marketing Authorisation' (EMA, 19 August 2019) <https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview> accessed 30 September 2023.

protection followed by 2 years of market protection.[170] Data protection stops companies from applying for a generic that relies on the data submitted by the originator, whereas market protection allows the authorisation of generics but stops companies from marketing them.[171] In the US, biologics obtain 12 years of data protection.[172]

Another important difference concerns the interchangeability of biosimilars for biologics. The EMA considers that once they authorise a biosimilar, it is interchangeable with the biologic.[173] That is, pharmacists can substitute biosimilars for biologics without clinically meaningful impacts. But the situation is different in the US. Biosimilars are *not* automatically interchangeable there. To obtain a designation as interchangeable, biosimilar companies must conduct 'switching studies', which involves *switching* ill trial participants during the trial from the originator's compound to the biosimilar.[174] These studies are ethically dubious because many are not expected to show any additional benefit. A 2022 study found only two unique biosimilars had been authorised as interchangeable in the US.[175] In contrast, 19 unique biosimilars have been authorised as interchangeable in the EU.[176]

2. Three interplay issues that (possibly) delay biosimilars

The authorisation of biosimilars and their substitutability is where the issues at the interface of patents and trade secrets begin. There are three problems, and these could facilitate biosimilar manufacturers strategically using trade secrets to delay biosimilars beyond the patent life on the original compounds (including any patent term extension or supplementary protection certificate).

The first problem involves quality control processes which regulators might impose. For example, in the US there are Current Good Manufacturing Practices that are enforced by the FDA.[177] These set out minimum requirements 'for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product' to ensure their safety along with the identity and strength of compounds.[178] If an originator keeps secret their particular

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[170] Regulation 726/04 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency [2004] OJ L136/1, 726/04 art 14(11); Directive (2001/83) on the Community code relating to medicinal products for human use [2004] OJ L311/67, art 10(1).

[171] ibid.

[172] 42 USC § 262(k)(7)(A); Henry Grabowski, Genia Long and Richard Mortimer, 'Data Exclusivity for Biologics' (2011) 10 Nature Reviews Drug Discovery 15, 15.

[173] EMA, 'Biosimilar Medicines: Overview' (EMA, 29 October 2019) <https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview> accessed 30 September 2023. Note: some EU Member States might take different stances on interchangeability.

[174] FDA, 'Considerations in Demonstrating Interchangeability with a Reference Product Guidance for Industry' (FDA, 2019) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-demonstrating-interchangeability-reference-product-guidance-industry> accessed 30 September 2023; see also, Yaniv Heled, 'The Case for Disclosure of Biologics Manufacturing Information' (2019) 47 Journal of Law, Medicine and Ethics 47, 57.

[175] Feldman (2022), 24.

[176] 'Biosimilars Approved in Europe' (Generics and Biosimilars Initiative, 12 05 2023) <https://www.gabionline.net/biosimilars/general/biosimilars-approved-in-europe> accessed 30 September 2023. The 19 compounds are unique compounds, not two or more biosimilars of the same biologic. In total, 75 biosimilars have been authorised by the EMA; many of which reference the same biologic.

[177] <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations> accessed 30 September 2023.

[178] <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations> accessed 30 September 2023 and Feldman (2022), 44.

processes that seek to comply with these minimum requirements this can potentially delay the entry of biosimilars. The delay arises because biologic manufacturers must spend significant time reverse engineering these processes or inventing their own, which might take over 200 days.[179] Originators *could* patent some of these processes; however, the exemptions from patent infringement for developing biosimilars (and generics) limit their value.[180] Thus, originators have a strong incentive to keep these processes secret.[181]

The second problem for biosimilar entry concerns the absence of clinical trial data and protocols. These issues were outlined above in the context of small molecules, describing how the lack of data and protocols potentially obscured flaws in the data and reimbursement decisions, amongst other things. However, the issues for biosimilars are different. If biosimilar manufacturers must conduct clinical trials to show interchangeability, as they do in the US, manufacturers will want to produce similar data using similar protocols. However, biosimilar entry may be delayed or prevented if these are unavailable.

The third problem is probably the most acute and concerns manufacturing biologics. Manufacturers typically patent biologics as a *compound*, but the complexity of biologics means that manufacturing them is challenging. Manufacturers can patent manufacturing methods, but they have a strong incentive to keep them as trade secrets because it may provide them with longer protection. Biosimilar manufacturers aim to create 'highly similar' compounds with 'no clinically meaningful differences', but the problem is that there are numerous ways to make the compounds in living organisms, and even small differences can significantly impact safety and efficacy.[182] Patents that claim the compound do have to disclose how to make the compound. Yet, instructions on how to make compounds in patents, which include claims for the compounds themselves or how to make them, are often described in broad terms for many variables (such as temperature, concentration, cell lines or reagents), meaning that significant research is needed to find which combinations of variables are best.[183] Moreover, the instructions are, on average, over 12 years old from when the patent application was filed (see section IV.A.1), meaning the process has almost certainly improved, and commentators argue it is difficult, if not impossible, to reverse engineer these processes.[184] Some of the areas of uncertainty for biosimilars include genetic vectors (used to transfer DNA between organisms), cell lines (artificially created living cells that produce the biosimilar) and growth conditions.[185] These challenges can delay, stop and disincentivise biosimilar entry.

[179] W. Nicholson Price II, 'Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing (2014) Boston College Law Review 491, 503-504.

[180] Feldman (2022), 45 also noting that such exemptions facilitate the development but not commercialisation of biosimilars.

[181] These processes would have to be reviewed by regulators as part of the authorisation processes. However, the FDA and other regulators have a broad policy of not revealing manufacturers' commercially valuable techniques, see, 5 USC § 552(b)(4); 21 USC § 20.61(b); Feldman (2022), 26–28.

[182] See e.g., Erika Lietzan, 'A Solution in Search of a Problem at the Biologics Frontier' (2018) 2018 University of Illinois Law Review Online 19, 25; Price & Rai (2016), 1023, 1035-1036.

[183] Feldman (2022), 27.

[184] Feldman (2022), 34; W. Nicholson Price II and Arti K. Rai, 'Are Trade Secrets Delaying Biosimilars?' (2015) 348 Science 188, 188.

[185] Price & Rai (2016), 1046.

Commentators have described several examples of biologics that were patented as compounds yet have never had a generic authorisation, despite the attempts of generic companies. One example is Premarin, authorised in the US in 1942, which garnered over US$1 billion in sales in 2016.[186] A competitor tried to produce a generic but was stopped because a court in 2003 found that the competitor had misappropriated a trade secret from the originator.[187]

The challenges of making biosimilars are likely significant. A 2017 survey of pharmaceutical manufacturers shows that they use trade secrets *more* frequently than patents.[188] However, this survey does *not* distinguish between small-molecule and biosimilar manufacturers. Indeed, this empirical fact underpins a problem with the arguments surrounding biosimilar entry: the regulatory and scientific challenges are cogent, but there is a shortage of empirical data explaining the significance of the problem. Critical questions include how often companies decide *not* to pursue a biosimilar due to trade secrets. And on average, how much longer do biosimilars take to get to market compared to generics? An interview study with 8 EU national medicines agency regulators and 17 company executives found that manufacturing techniques protected by trade secrets were *generally surmountable*.[189] This result indicates the problems with trade secrets are not as severe as some commentators suggest, but the study consisted of a relatively small sample. Thus, any conclusions should not be drawn too quickly.

The interplay of patents and trade secrets in the circumstances of Covid-19 vaccines are described below in section VIII.B.3.

3. Patent thickets: a US issue easily conflated with delays caused by trade secrets

The expression 'patent thickets' is typically used to describe high numbers of patents with overlapping subject matter.[190] The significance of thickets is that it can be costly to identify all the relevant patents, raising the spectre of infringing multiple patents.[191] Consequently, patent thickets surrounding biologics can delay biosimilar entry and make them more expensive.

One study sought to evaluate whether patent thickets for biologics are observable in territories beyond the US. The study compared the number of patents protecting 30 biosimilars submitted for authorisation in the US, the UK and Canada.[192] The study found far

[186] Matej Milukic, 'Top 20 Health Products for Women in the U.S. Based on Revenue in 2016' (Statista, 28 January 2020) <https://www.statista.com/statistics/312282/revenue-from- top-20-womenhealth-products-in-the-us/> accessed 30 September 2023.

[187] *Wyeth v Natural Biologics Inc*, 2003 WL 22282371, at *25–26 (D Minn, 2 October 2003).

[188] Nathan Wajsman and Francisco García-Valero, 'Protecting Innovation Through Trade Secrets and Patents: Determinants for European Union Firms' (July 2017, European Union Intellectual Property Office) 35.

[189] Louise C. Druedahl et al, 'A Qualitative Study of Biosimilar Manufacturer and Regulatory Perceptions on Intellectual Property and Abbreviated Approval Pathways' (2020) 38 Nature Biotechnology 1253, 1254.

[190] Carl Shapiro, 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting' in A. Jaffe, J. Lerner and S. Stern (eds), *Innovation Policy and the Economy* (MIT Press, 2001), 119.

[191] One must be careful when discussing overlapping patent rights/claims. Some overlap is permitted by patent law, whilst some is not. It is beyond the scope of this Paper to discuss the precision of the term in detail. For more information, see the papers cited in this section. See also, Andrew F. Christie and Chris Dent, 'Non-overlapping Rights: A Patent Misconception' (2010) 32 European Intellectual Property Review 58.

[192] But only nine reference biologics, see, Rachel Goode and Bernard Chao, 'Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem' (2022) 9(2) Journal of Law and the Biosciences lsac022, 7, <https://doi.org/10.1093/jlb/lsac022> accessed 30 September 2023.

fewer patents protecting drugs in Canada and the UK compared to the US. On average, the study found 12 times more patents in the US than in the UK and 9 times more in the US than in Canada. The study also looked at a subset of the patents to evaluate whether they overlapped. The study found significantly more overlap in the US than in the UK and Canada. Consequently, the study concluded patent thickets were an 'American problem'.[193]

Patent thickets are problems that generally do *not* involve trade secrets. Nevertheless, patent thickets are described in this study because any delays to biosimilar entry *may* be due to, or primarily due to, them. Indeed, the interview study described above that examined the role of trade secrets on biosimilar entry found that patent thickets were a more significant problem than secrets on manufacturing processes, stating 'patents protecting originator biologics were considered a greater obstacle given their large number and difficulty in identification'.[194]

4. Manufacturing patents applied for *after* they were used commercially for a year or more

The discussion of biosimilars and manufacturing trade secrets above concentrated on when the processes are *permanently* kept secret (or at least until they are reverse-engineered or independently created). But originators may also develop manufacturing processes and only keep them confidential for a period. Originators can patent manufacturing processes they previously kept secret, but the circumstances in which they can do so vary between territories.

The European Patent Convention (1973) allows patentees to protect innovations as trade secrets for as long as they want and to patent them later, assuming the innovations do not form part of the prior art.[195] However, the situation is different in the US. The commercial use of an invention in the US, even if secret, counts as prior art.[196] US law does provide a 'grace period', however, which allows inventors to make prior art disclosures in the year prior to filing their patent applications.[197] However, once the prior art (i.e., trade secret) has been used for a year, the grace period is no longer relevant and the prior art invalidates the patent for lack of novelty, even if it is secret and only becomes public knowledge later.[198]

The issue of filing patents for manufacturing trade secrets used for over a year was explored in a 2021 study of US biosimilar litigation. The study analysed 34 cases of patent enforcement that involved 259 manufacturing patents.[199] Of these patents, 192 (74%) were filed more than one year *after* the FDA authorised the drug. The authors point out that either these patents are invalid (i.e., the inventions were used secretly for more than a year) or the originator must have used a different method when the drug was first authorised. If the originator used a different method when the drug was first authorised, the biosimilar company should be able

[193] Goode & Chao (2022), 1.
[194] Druedahl et al (2020), 1254.
[195] European Patent Convention (1973), art. 54.
[196] 35 USC § 102(a)(1); *Helsinn Healthcare v Teva Pharmaceuticals*, 139 S Ct 628, 630 and 634 (2019); Arti K. Rai and W. Nicholson Price II, 'An Administrative Fix for Manufacturing Process Patent Thickets' (2021) 39 Nature Biotechnology 20, 21.
[197] 35 USC § 102(b)(1).
[198] 35 USC § 102(a)(1) and b(1); *Helsinn Healthcare v Teva Pharmaceuticals*, 139 S Ct 628, 630 and 634 (2019); Rai & Price (2021), 21.
[199] Rai & Price (2021).

to make the compound *without* infringing the patent, assuming they have sufficient technical expertise.

It is possible that all the patents found in the study were validly granted: originators often need an entire factory to make biologics, with various components and processes that could be improved. For example, manufacturers could increase the size of batch processes, find better ways to monitor production, improve safety equipment, improve conditions for the cells/organisms (that make the drugs) or design new purification processes.[200] Nevertheless, the authors suggest that the large numbers of patents on manufacturing processes indicate that at least some are invalid.[201]

C. Drug repurposing

One issue for repurposing arises at the interface of patents and trade secrets. This issue concerns the disclosure of clinical trial protocols and data, particularly summaries of results. This Paper has already discussed issues involving protocols and data for small molecules and biosimilars, but the problems here are different. They concern the publication of clinical trial protocols and data *preventing* patents for repurposed uses.

The issues surrounding the publication of protocols and data have gained prominence in light of the EU Clinical Trial Regulation. Clinical trials cannot be run in the EU (as in most territories) without prior authorisation,[202] and the application to conduct a clinical trial must include a protocol, which includes the trial's objective, design, methodology, purpose and statistical considerations.[203] The EU Regulation also states that all information submitted in the application should be accessible on an EU database,[204] and it is this requirement for publication on the database that causes issues.

Commentators argue the publication of protocols creates a problematic position for patenting. If a patent application for a new therapeutic use is filed *before* the clinical trial details are published, the trial will not count as prior art against the application. The lack of prior art is good for patentees wanting to satisfy the novelty and inventive step requirements. However, it is less desirable from the point of view of sufficiency (the equivalent of enablement in the US), which requires the use of the drug and its therapeutic effects to be described in a clear and complete way to be performed by the person skilled in the art.[205] Yet, patent applicants cannot submit data from the clinical trial with their application because they do *not* yet have it. Some new-use patents have been granted without clinical data, but others have not,[206] raising the need to wait for the results. Yet, if a developer waits for the results before patenting, the protocol will be published by the time the developer gets the

[200] K. Ho, 'Manufacturing Process of Biologics' (ICH, 2011) <https://www.ema.europa.eu/en/documents/presentation/presentation-manufacturing-process-biologics-kowid-ho-afssaps_en.pdf> accessed 30 September 2023.
[201] Rai & Price (2021), 22.
[202] Clinical Trials Regulation, art 4.
[203] Clinical Trials Regulation, annex I 14.
[204] Clinical Trials Regulation, arts. 81(1) and (4).
[205] European Patent Convention (1973), art. 83.
[206] See, Lorenz Kallenbach and Marco K. Vallazza, 'Are the New Clinical Trial Transparency Rules Incompatible with the Patentability Requirements in Europe?' (2018) 36 Nature Biotechnology 928, 928.

results, raising the possibility of anticipation (lack of novelty) and, perhaps more importantly, obviousness (lack of inventive step) because the protocol will foreshadow the results.[207]

The EU Regulation does allow for commercially confidential information to be redacted.[208] However, commentators suggest this might not be enough: the people conducting the clinical trials might *not* know to redact certain information.[209] Other commentators suggest the current system is not sensitive enough to patenting issues; for instance, there is no clear way to conceal the identity of the drug in a trial.[210] These issues, however, remain empirically untested. These issues might arise a lot or not at all. Indeed, there is room to think the problems are *not* too significant, as patents for repurposed drugs have increased over the past decade.[211] Moreover, an early assessment of the Regulation suggest that EMA grants generous deferrals for publishing clinical trial data and errs on the side of caution when allowing organisations to permanently redact commercially confidential information.[212]

D. Important but often overlooked aspects of drug development cycles: manufacturing & pricing

1. Drug manufacturing

Drug manufacturing was described above concerning biologics and follow-on innovation. The issue here, though, is more general. The problem, in short, is that there are insufficient incentives to encourage advances in drug manufacturing techniques. For instance, company executives have described how chocolate, potato chip and soap manufacturers use more advanced manufacturing processes than drug companies.[213] In theory, more advanced manufacturing processes would lead to fewer recalls for defective products and, perhaps, cheaper drugs.[214] However, the argument is that patents, trade secrets and even regulatory protection periods may not encourage, or even inhibit, advances in manufacturing.

Patents are available for new manufacturing processes. However, commentators argue they are ineffective. Manufacturers might be reluctant to obtain patents for two reasons. First, patents disclose to competitors their new technology. Second, patents on manufacturing processes are often hard to enforce because patentees do not know with certainty if a competitor is using their method, and it is expensive and risky to find out if they are.[215] Companies can use trade secrets, but they are challenging to enforce for the same reason as patents.[216] Moreover, even if manufacturers use trade secrets to protect their innovations,

[207] Kallenbach & Vallazza (2018), 928–930.
[208] Clinical Trials Regulation, art 81(4)(b).
[209] W. Nicholson Price and Timo Minssen, 'Will Clinical Trial Data Disclosure Reduce Incentives to Develop New Uses of Drugs' (2015) 33(7) Nature Biotechnology 685, 686.
[210] Kallenbach & Vallazza (2018), 930.
[211] Mateo Aboy et al, 'Mapping the European Patent Landscape for Medical Uses of Known Products' (2021) 39 Nature Biotechnology 1336, 1338; Mateo Aboy et al, 'European Patent Protection for Medical Uses of Known Products and Drug Repurposing' (2022) 40 Nature Biotechnology 465, 467.
[212] Żaneta Zemła-Pacud and Lenarczyk, 'Clinical Trial Data Transparency in the EU: Is the New Clinical trials Regulation a Game-Changer?' (2023) 54 International Review of Intellectual Property and Competition Law 732, 758.
[213] W. Nicholson Price II, 'Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing (2014) Boston College Law Review 491, 491–492, fn 1.
[214] Price (2014), 504—509.
[215] Price (2014), 526–528. It should also be mentioned that regulatory protections are irrelevant for manufacturing methods because they do *not* protect innovative methods.
[216] Price (2014), 536–538.

the nature of trade secrets means that manufacturers hide their innovations, preventing cumulative innovation, where everyone builds on each other's advances.[217] The absence of cumulative innovation can hamper the development of more efficient ways to make the *same* compound. It could also hamper developing related compounds. For example, it is plausible that if companies making mRNA vaccines for Covid-19 shared their manufacturing techniques, they could have accelerated the manufacturing process or found ways to increase yields. That said, the effects of trade secrets on cumulative innovation are speculative and have not been empirically explored by researchers.

Two aspects of the industry also operate to slow or stop innovation. First, manufacturers are wary of regulators refusing to authorise new processes, which would mean they could not implement techniques they have spent resources developing.[218] Second, de-facto–standards often arise in the industry, making it much cheaper and easier to follow the standard than create a new process. These standards arise because regulatory bodies, such as the FDA, will publish guidelines or follow-on innovators will emulate pre-existing methods to maximise the chance of regulatory compliance. Of course, de-facto–standards can be updated, but this takes time and resources and runs the risk of non-compliance.[219]

Relatively few people have studied advances in drug manufacturing, and the key article in this area was published in 2014. The arguments above are supported by some surveys and anecdotes. A key survey found that pharmaceutical companies reported that 68% of process innovations could be effectively protected by secrecy, but only 36% by patents.[220] However, this survey is from 1994, almost 30 years old. The age is a problem because regulators have expressed interest in modernising all aspects of drug development and regulation over the past decade. For example, the FDA has taken steps to remove and stop de facto standards from arising, for instance removing examples of manufacturing techniques described in their documents.[221] It also began a 'Quality by Design' (QbD) initiative. Traditionally, drugs were manufactured according to specific methods, and batches were tested at the end to identify sub-standard products. However, QbD is different, featuring real-time monitoring and adjustments of the manufacturing process, resulting in a product that is market-ready off the production line. In short, where traditional manufacturing focuses on the method and end-product testing, QbD focuses on real-time testing and adjustments, permitting more flexibility with manufacturing processes.[222] No commentators have explored the effects of these modernisations on incentives for improving manufacturing.

Another problem with arguments about the lack of incentives for manufacturing is that they potentially conflict with the discussions above. For example, the empirical findings on large numbers of manufacturing patents on biologics (see section VII.B.4) conflict with the idea of poor incentives for improvements. It is possible that only some areas of manufacturing or types of drugs see few manufacturing advances. It is also possible that manufacturing innovation is only slightly slower than it could be because generic and biosimilar

[217] Price (2014), 536.
[218] Price (2014), 512–514, 516–519.
[219] Price (2014), 514–516, 517–519.
[220] Cohen et al (2000), 34 (Table 2). It is also interesting to note that pharmaceutical manufacturing is *not* alone in relying heavily on trade secrecy to protect process: across all industry over 50% of process innovations can be protected by secrecy and only 23% by patents.
[221] Price (2014), 516.
[222] For a review of this idea, see Price (2014), 544–546.

manufacturers develop new ways to develop their products, improving on originators' processes. They might be driven to innovate because competition for generics and biosimilars can be fierce, forcing them to update any de-facto standards and undercut competitors on price. Alternatively, it could be that manufacturing innovation is slower than it could be, but this is a natural consequence of an industry that relies heavily on regulation and generics/biosimilars, which are designed to be copies of originators' drugs.

2. Drug prices as trade secrets

IP commentators often discuss patents on drug compounds and trade secrets on manufacturing methods. Yet, one area they often overlook is that manufacturers frequently keep drug prices as trade secrets. The issue is beginning to gain traction in IP circles but has been on the agenda of other disciplines for much longer. Whether drug prices qualify for enforceable protection as trade secrets is debated.[223] Regardless of whether they are protectable, though, many prices are kept secret and commentators argue that companies do this so they can opportunistically charge higher prices.[224]

Typically, it is hard to keep prices secret. However, secret drug prices can arise due to information asymmetries and other factors that blunt competitive forces.[225] How drugs are distributed, sold, prescribed, and dispensed varies between countries. It is beyond the scope of this Paper to discuss the detail of any one country. However, it is interesting to note that in the US, this involves patients, doctors, pharmacists, insurers, pharmaceutical companies, and pharmaceutical benefit managers (PBMs). PBMs play a particularly important role. In short, PBMs are intermediaries; they negotiate prices with pharmaceutical companies on behalf of the government and other payors (e.g., insurers and governments). PBMs also help set the 'formularies', which dictate the terms of access (i.e., what patients get which drugs and under what conditions).[226]

The drug prices publicly known in the US are often called 'list prices'.[227] But these prices are not what anyone pays. Rather, they are the drug companies' opening bids in negotiations.[228] The actual prices paid are the product of negotiations and closely guarded secrets, and an extra layer to this situation is that the negotiations typically include a rebate for PBMs, which are kept secret too.[229]

Commentators argue that secret pricing shields companies from regular market forces. Healthcare providers, insurers, and governments, amongst others, do not have access to the prices paid by each other to inform their decision-making, and some of the outcomes created by the information asymmetry can be perverse. One reported example is that patients have been forced to pay more for a generic's drug than the originator's.[230] Another reported example is that rebates for insulin (the treatment for diabetes) to PBMs have increased to

[223] See e.g., Robin Feldman and Tait Graves, 'Naked Price and Pharmaceutical Trade Secret Overreach' (2020) 22 Yale Journal of Law & Technology 61, 84–89.
[224] See e.g., Feldman & Graves (2020), 63; Cindy Bors et al, 'Improving Access to Medicines in Low-Income Countries: A Review of Mechanisms' (2015) 18 Journal of World Intellectual Property 1, 8.
[225] Feldman & Graves (2020), 71.
[226] Feldman & Graves (2020), 72-73.
[227] Dylan Scott, 'Inside the Impossibly Byzantine World of Prescription Drug Prices' (STAT, 21 Dec 2015) <https://www.statnews.com/2015/12/21/prescription-drug-prices-confusion/> accessed 30 September 2023.
[228] ibid.
[229] Feldman & Graves (2020), 71–73.
[230] Feldman & Graves (2020), 72.

half the list price.[231] The secret nature of prices can also hamper investigations into price fixing and price gouging.[232]

Governments have implemented initiatives to increase the transparency of prices, and a 2020 study examined whether these have been effective.[233] The study found many countries had begun initiatives, yet the study also said that the effects of the initiatives were inconclusive because they had insufficient evidence.[234] Amongst the problems faced in the study was that many of the prices paid before the study commenced were secret.

E. Medical diagnostics

Two issues concerning medical diagnostics have attracted significant commentary. The first issue concerns improvements to diagnostics during the lifetime of patents, which can accrue to patentees as trade secrets. The second concerns recent shifts in patentable subject matter case law in the US that potentially push innovators towards trade secrets or deciding not to develop innovations.

1. Patents, trade secrets and private databases accrued *after* patenting

If a company develops a new medical diagnostic, they are able to build a database of information on improvements to the diagnostic, especially if they are the sole provider of that test. From one perspective, identifying improvements to a diagnostic is no different to any other market product: companies are welcome to collect information on how the product performs and seek input on how to improve the product. Indeed, customers often encourage companies to do this, and companies usually keep the information as trade secrets with little complaint. However, the situation is slightly different for modern medical diagnostics.

Modern diagnostics often focus on proteins, genes and other biological compounds in human bodies. Sometimes diagnostics focus on, for example, only one gene or even one short section of a gene. However, most biological compounds that can act as markers of health (commonly known as 'biomarkers) exist in a complex milieu of other biomarkers, including different sections of the same gene.

A famous example of this complex milieu is testing for breast and ovarian cancer via analysing the BRCA1 and BRCA2 genes. In the early 1990s, scientists found that variations in these genes indicated that patients were predisposed to developing breast and ovarian cancer,[235] and these variations were patented. However, the variants initially found were not the only ones, and over time, the patentee, Myriad Genetics Inc, was able to identify new variants. Indeed, Myriad even offered free testing to patients that had new variants.[236] Myriad initially contributed its genetic data to a public database, but this changed in 2004 when it chose to keep the data as a trade secret.[237] Myriad's policy of not publishing its data became more acute in 2013 when the US Supreme Court invalidated several of its foundational patents on

[231] Ryan Know, 'Insulin Insulated: Barriers to Competition and Affordability in the United States Insulin Market' (2020) 7(1) Journal of Law and the Biosciences lsaa061, 10–11.
[232] Feldman & Graves (2020), 74–75.
[233] Nur Sufiza Ahmad, Mohd Makmor-Bakry and Ernieda Hatah, 'Drug Price Transparency Initiative: A Scoping Review' (2020) 16 Research in Social and Administrative Pharmacy 1359.
[234] Ahmad et al (2020), 1368.
[235] Robert Cook-Deegan et al, 'The Next Controversy in Genetic Testing: Clinical data as Trade Secrets?' (2013) 21 European Journal of Human Genetics 585, 585.
[236] Cook-Deegan et al (2013), 586.
[237] Cook-Deegan et al (2013), 586.

the isolated BRCA genes.[238] The invalidation meant that Myriad had accumulated its database of genomic variants based on an incorrectly granted patent. If Myriad had never been granted the patent, it could have still offered genetic tests and generated a database, however, competitors likely would have offered competing tests sooner and, therefore, Myriad's lead time on developing its database would have been reduced.

Since the patents in the US were invalidated, numerous organisations have tried to gather all the data on variants in BRCA1 and BRCA2 and publish them in a public database. A 2021 article stated that over 60,000 variants have been identified in the genes, and over 58,000 remain unreviewed.[239] However, as long as Myriad keeps its database secret, whether the public database has better information remains unknown.

Other providers of medical diagnostics have created private databases,[240] and the issue is similar in principle to some of the problems described below on machine learning.[241] Commentators have described patents that can be used to create private databases as 'data-generating patents'.[242] However, the researchers have not empirically examined the extent to which these patents create a de facto monopoly when the patent expires (or is invalidated) or the extent to which the secrets hamper follow-on innovators.

Not all providers of medical diagnostics can create databases protected by trade secrets *after* patenting. Trade secrets are useless if a diagnostic is self-revealing or can be reverse-engineered. The revealing nature of a diagnostic is limited by, amongst other things, how it is provided to the market. For instance, it is easier for companies that offer LDTs (when doctors send samples to a company that performs the test in-house), which is how Myriad accumulated its database. It is less easy for companies that send test kits to, for example, hospitals that perform the tests *and retain the results* in the hospital.

2. Patentable subject matter & trade secrets

The *Myriad* decision is also key to the issue of patentable subject matter and trade secrets, although it is not the only relevant decision. Two other US Supreme Court decisions in the 2010s significantly reshaped diagnostic innovation and have possibly pushed innovators towards using trade secrets *instead* of patents or not innovating at all.[243]

Myriad concerned whether isolated, naturally occurring DNA qualifies as patentable subject matter. The US Patent & Trademark Office had granted patents on isolated DNA for decades, but the US Supreme Court reversed this practice. The Court held that isolated, naturally-

[238] *Association for Molecular Pathology v Myriad Genetics Inc*, (2013) 569 US 576, 596.
[239] Mary A. Majumder et al, 'Challenges to Building a Gene Variant Commons to Assess Hereditary Cancer Risk: Results of a Modified Policy Delphi Panel Deliberation' (2021) 11 Journal of Personalized Medicine 646.
[240] Sarah E. Ali-Khan and E. Richard Gold, 'Gene Patents Still Alive and Kicking: Their Impact on Provision of Genetic Testing for Long QT Syndrome in the Canadian Public Health-Care System' (2017) 19 Genetics in Medicine 1253, 1255.
[241] Christi J. Guerrini, Amy L. McGuire and Mary A. Majumder, 'Myriad Take Two: Can Genomic Databases Remain Secret? (2017) 356 Science 586, 587.
[242] Simon & Sichelman (2017).
[243] The European Patent Convention (1973), art. 53(c) excludes patents on 'diagnostic methods practiced on the human or animal body'. However, this exclusion is generally not seen as affecting innovation because the exclusions can be drafted around by patent attorneys.

occurring DNA did *not* constitute patentable subject matter because it was not 'markedly different' from naturally occurring DNA.[244]

The second decision, *Mayo Collaborative Services v Prometheus Laboratories Inc*, concerned methods for optimising dosages of drugs for treating autoimmune diseases.[245] The patent was based on a correlation in human bodies between a drug metabolite (a product of the drug produced in the body) and the efficacy of the drug. In short, the information in the patent allowed doctors to know whether to give patients more of a drug or withhold it, depending on the concentration of the metabolite.[246] The information was, and is still is, valuable to medical practice; however, the US Supreme Court held the claim invalid because it included a natural correlation without adding 'significantly more' (i.e., other inventive activity).[247]

The third decision, *Alice Corporation v CLS Bank International*,[248] did not concern a patent on a medical diagnostic, but the reasoning in the decision has profound implications for diagnostics. The patent claimed a method for exchanging financial obligations using a third-party intermediary and a computer system to carry out the method.[249] The US Supreme Court rejected the claim, stating the claims were directed to an abstract idea (which is not patentable) of using an intermediary, and merely implementing the idea through a computer did not make it patentable.[250] The decision affects diagnostics because, for example, it affects patents that claim mathematical algorithms.[251]

Each of the three decisions narrowed what constitutes patentable subject matter in the US,[252] and several commentators argue the lack of patent protection stops innovation or forces innovators to rely on trade secrets instead of patents.[253] Two interview-based studies have examined whether diagnostic innovators have turned to trade secrets *instead* of patents. One interview study with patent practitioners, legal academics and scientists found an increased

[244] *Association for Molecular Pathology v Myriad Genetics Inc*, (2013) 569 U.S. 576, 591–593. The reasoning in *Myriad* has been interpreted to apply to biological material *beyond* DNA, see, Mateo Aboy et al, 'Was the *Myriad* Decision a 'Surgical Strike' on Isolated DNA Patents, or Does it have Wider Impacts' (2018) 36 Nature Biotechnology 1146, 1148–1149.

[245] *Mayo Collaborative Services v Prometheus Laboratories Inc*, (2012) 566 U.S. 66, 72–73.

[246] *Mayo,* 73–74.

[247] *Mayo,* 78–70.

[248] *Alice Corp Pty Ltd v CLS Bank International*, (2014) 573 U.S. 208.

[249] *Alice Corp,* 212–214.

[250] *Alice Corp,* 218, 219–222.

[251] Mateo Aboy et al, 'How Does Emerging Patent Case Law in the US and Europe Affect Precision Medicine?' (2019) 37 Nature Biotechnology 1118, 1119.

[252] The Australian equivalent of the patents litigated in *Myriad* were also litigated there. The High Court, Australia's apex court, invalidated the patents for slightly different reasons, see, *D'Arcy v Myriad Genetics Inc* [2015] HCA 35.

[253] Arti K. Rai and Jacob S. Sherkow, 'The Changing Life Science Patent Landscape' (2016) 34 Nature Biotechnology 292, 294; see generally Bambauer (2016); David O. Taylor, 'The Supreme Court's Revolution in Patent Eligibility Law: Alternative Protections for Biotechnology' (2019) 37 Nature Biotechnology 227, 229. It is also interesting to note that *Myriad* actually applied to few other patents in prosecution (see Mateo Aboy et al, 'After *Myriad*, What Makes a Gene Patent Claim "Markedly Different' from Nature?' (2017) 35 Nature Biotechnology 820, 822) and that the numbers of gene-related patents increased after the decision (see Mateo Aboy et al, '*Myriad's* Impact on Gene Patents' (2016) 34 Nature Biotechnology 1119, 1120–1121). It is also interesting to note that *Mayo* has affected prosecution, but many applicants can draft valid claims (see Mateo Aboy et al, '*Mayo's* Impact on Patent Applications Related to Biotechnology, Diagnostics and Personalized Medicine' (2019) 37 Nature Biotechnology 513, 516).

interest in trade secrets but no instances of parties using trade secrets as a substitute for patents.[254]

The second study interviewed six managers at university technology transfer offices, seven patent practitioners and six executives at diagnostics companies.[255] All 19 interviewees were based in the US.[256] No managers at university technology transfer offices said they had chosen to use trade secrets instead of patents; indeed, they emphasised that trade secrets are generally the antithesis of their universities' missions.[257] Nor did any practitioner say they knew of a client who had made the decision.[258] That said, one company said they had chosen to keep a new method a trade secret in response to the decision.[259] The company offered the test as a LDT; as such, it was relatively easy to implement. Thus, there is evidence of using trade secrets instead of patents, albeit one example from a relatively small sample.

The interview study that found one company had chosen to keep a diagnostic method a trade secret instead of filing for a patent also found something closely related. One company had initially planned to launch a LDT and a kit. However, the *Mayo* decision weakened their patent position, and, therefore, they were thinking that they would forgo launching the kit to keep aspects of the test hidden.[260] The decision was not yet made when the interview was conducted, but the interviewee thought they would probably forgo the kit.

Commentators also argued that *Myriad*, *Mayo*, and *Alice* might *stop* innovation. The argument, in short, is that the incentive offered by trade secrets is too weak to make up for the absence of patent rights. The interview study that found one company had decided to use trade secrets *instead* of patents also found some organisations had chosen not to develop tests. The study found four university technology transfer offices had decided to forgo developing tests because the tests were difficult to patent, and they did not think trade secrets were sufficient.[261] They added that one of the key reasons for obtaining patents was they helped attract partners.[262] The study also found that one company had decided not to acquire a test from another organisation because the judicial narrowing of patentable subject matter probably meant the patents were invalid.[263]

A later study investigated the extent to which diagnostic innovators can obtain patents in light of the US Supreme Court decisions. The study found that diagnostics developers have found

[254] Christi J. Guerrini et al, 'Constraints on Gene Patent Protection Fuel Secrecy Concerns: A Qualitative Study' (2017) 4 Journal of the Law & the Biosciences 542, 553.
[255] Liddicoat et al (2020), 803–804.
[256] Liddicoat et al (2020); the study also involved similar numbers in Europe, but these numbers are excluded from this discussion.
[257] Liddicoat et al (2020), 809.
[258] Liddicoat et al (2020), 814.
[259] Liddicoat et al (2020), 821.
[260] Liddicoat et al (2020), 821.
[261] Liddicoat et al (2020), 823.
[262] Liddicoat et al (2020), 808–809.
[263] Liddicoat et al (2020), 820–821.

ways to patent innovations by linking them to treatments,[264] amongst other strategies.[265] Thus, patenting of medical diagnostics has continued.

F. Other medical technologies

As stated above, a cornucopia of other medical innovations exists, including surgical techniques, stents, hearing devices, medical imaging and behavioural changes or non-surgical interventions (e.g., diets or sleeping habits). It is impossible to cover all these technologies in detail. Moreover, it may not be possible to say anything of interest because relatively little (compared to drugs and diagnostics) has been written about them.

Instead of attempting to cover the gamut of technologies, this section will proceed in two parts. First, this section will describe the commentary on surgery, which has attracted a relatively large amount of interest. In some territories, surgical methods are either unpatentable or, if patents are available, they are unenforceable. This variability in patentability and enforcement has attracted various doctrinal and empirical analyses at the interface with trade secrets. The analyses outline various themes on topics instructive on other technologies, and the second part of this section examines these topics for various other innovations (e.g., diets).

1. Surgical methods

Patent protection for surgical methods differs between the US and European Patent Convention ('EPC') countries. In the US, a patent for cataract surgery was enforced against a surgeon in the 1990s.[266] The lawsuit attracted outrage from the medical community,[267] culminating in new legislation that provided an immunity from infringement liability for medical practitioners performing 'medical or surgical procedures' and 'related health care entities'.[268] The immunity is quite broad, covering all medical practitioners and their employers.[269] In contrast, the EPC excludes 'methods for treatment of the human…body by surgery' from patentability altogether.[270] The precise boundaries of the EPC exclusion have been subject to various judicial decisions and commentary.[271] However, for the sake of simplicity, surgical methods on humans are excluded from patentability in EPC territories if done for curative purposes and, in some instances, non-curative purposes.[272]

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[264] Mateo Aboy et al, 'One Year After Vanda, are Diagnostics Patents Transforming into Methods of Treatment to Overcome *Mayo*-based Rejections' (2020) 38 Nature Biotechnology 279. Although note that this strategy may be effective in the US because there is no explicit statutory prohibition on patenting methods of medical treatment practiced on the human body as there is in Europe under European Patent Convention (1973), art. 53(c).

[265] Aboy et al (2019), 516.

[266] *Pallin v Singer*, 93-CV-202, 1996 WL 274407, at *1 (D Vt, 28 March 1996).

[267] For a brief review, see William D. Noonan, 'Patenting Medical and Surgical Procedures' (1995) 77 Journal of the Patent and Trademark Office Society 651, 651–652.

[268] 35 USC § 287(c)(1)–(2).

[269] Jonas Anderson, 'Nonexcludable Surgical Method Patents' (2020) 61 William & Mary Law Review 637, 657.

[270] European Patent Convention (1973), art. 53(c).

[271] See eg., European Patent Office, '4.2.1. Surgery' (Guidelines for Examination in the European Patent Office, March 2023) <https://new.epo.org/en/legal/guidelines-epc/2023/g_ii_4_2_1_1.html> accessed 30 September 2023; Lionel Bently et al, *Intellectual Property Law* (Oxford, 2023) 530–533 and Eddy D. Ventose, *Medical Patent Law – The Challenges of Medical Treatment* (Edward Elgar, 2011).

[272] *Shell/Blood flow*, T182/90 [1994] EPOR 320, 322-333.

Commentators have argued that the lack of enforceable patents forces innovators to keep the methods as trade secrets or to refrain from innovating.[273] Commentators have also argued surgeons are unlikely to use trade secrets because patients and other people in medicine (e.g., hospital administrators) need to know what is happening for insurance and other purposes. Thus, perhaps a more robust argument is that patents and trade secrets provide no incentive and, therefore, a sub-optimal amount of surgical innovation is occurring. Yet, to the authors' knowledge, no one has systematically examined these arguments: no one has assessed whether surgeons are keeping techniques as secrets, nor has anyone assessed whether surgeons are failing to innovate or to promote or commercialise their innovations.[274]

Although no studies exist on the effects of the US and European laws, surgical techniques have continued to advance. New surgical procedures are described in the popular press frequently. Moreover, numerous journals exist specifically on surgery (e.g., the British Journal of Surgery and the JAMA Surgery, published by the Journal of the American Medical Association). Incentives *beyond* patents likely explain these innovations and publications. Many physicians subscribe to sharing knowledge to improve medical care, and new advances and publications promote their careers and individual prestige.[275] Indeed, a 2020 study on patents in the US found many on surgical techniques that were unenforceable.[276] The author argues that people pursue these patents to signal their capability and because they see the inventions as extensions of their personalities.[277] Another explanation is that many physicians take pride in their work and derive satisfaction from improving techniques to treat patients.[278]

Although significant innovation occurs in surgery without enforceable patent rights in the US and EPC countries, one could query whether the right incentives are available for the optimal amount of innovation. Designing empirical studies that could answer this question with certainty is challenging. However, without any evidence, answering this question is impossible.

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[273] Emily C. Melvin, 'An Unacceptable Exception: The Ramification of Physician Immunity from Medical Procedure Patent Infringement Liability' (2007) 91 Minnesota Law Review 1088, 1089.

[274] At least one case of when a patent on a surgical *device* helped promoted a surgical technique that otherwise was *not* used much has been reported. However, it is difficult to separate increase in use of the technique from the incentive to commercialise the invention provided by a patent from the technical improvement provided by the patent. See Linda Judge, 'Issues Surrounding the Patenting of Medical Procedures' (1997) 13 Computer & High Technology Journal 181, 206.

[275] These justifications and incentives, broadly fall into a theory of innovation known as 'open science', see, Paul A. David, 'The Economic Logic of "Open Science" and the Balance Between Private Property Rights and the Public Domain in Science Data and Information: A Primer' in Julie M Esanu and Paul F. Uhlir (eds), *The Role of Scientific and Technical Data and Information in the Public Domain* (National Research Council, 2003) 21–23.

[276] Jonas Anderson, 'Nonexcludable Surgical Method Patents' (2020) 61 William & Mary Law Review 637, 662–663.

[277] Anderson (2020), 669–677.

[278] This explanation is often called 'user innovation': see Eric von Hippel, 'Democratizing innovation: The evolving phenomenon of user innovation' (2005) 55 Journal für Betriebswirtschaft 63, 68 <https://link.springer.com/article/10.1007/s11301-004-0002-8> accessed 30 September 2023; see also Eric von Hippel, *Free Innovation* (MIT 2017) 4–6, 30–31. Indeed, there is some evidence of 'user innovation' by clinicians in relation to drug repurposing: see Harold J. DeMonaco, M. S. Ayfer and Eric von Hippel, 'The Major Role of Clinicians in the Discovery of Off-Label Drug Therapies' (2006) 26 Pharmacotherapy 323 <https://ssrn.com/abstract=780544> accessed 30 September 2023.

2. Other technology

By way of contrast, devices used *during* surgery, as well as other medical devices (such as hearing aids or medical imaging), are patentable, and the patents are enforceable in the US and EPC countries. The EPC exclusion on surgery states that only *methods* are excluded,[279] which means devices are patentable. The law in the US is different but has a similar outcome. The US immunity stops enforcement of all patents against medical practitioners (and their employers); however, it does not stop enforcement against *manufacturers* of devices. [280]

Although patent protection is available for developers of surgical devices and other medical devices, few commentators have considered how these technologies raise interplay issues (between patents and trade secrets). The commentary to date describes some of the possibilities the interplay might bring (e.g., trade secrets *could* extend the patent exclusivity), but detailed assessments of specific technologies are lacking.[281] This is an area that researchers in the future should consider.

Behavioural changes and non-surgical interventions, such as diets or sleeping habits, are innovations that have attracted little commentary too. That said, some of the themes above are applicable here. For instance, innovators might find it challenging to patent diets because they are not inventive, especially if the diets are based on published advances in nutrition. Even if patents on diets were obtained, patentees would likely find them difficult to enforce because once the details of the diet are published in the patent or communicated to people, people can share the details with others. Moreover, patentees would likely find it challenging to enforce their patents against large numbers of individuals, especially since each would provide a small financial reward and the patentee would have poor evidence of what the individuals do in their private lives.[282]

One could argue the absence of enforceable patent rights on diets and sleeping habits could force innovators to rely on trade secrets. Alternatively, one could argue the absence compels innovators to refrain from commercialising their innovations because they are unlikely to recoup their costs. These arguments are effectively the same arguments raised above for surgical methods, and like the arguments on surgical methods, we are in the same position: new diets and sleeping habits are continually advertised, but we effectively have no empirical evidence on whether innovators are refraining from inventing or commercialising. Perhaps the biggest difference between non-surgical and surgical innovations is that these non-surgical innovations have attracted less commentary.[283] The lack of commentary suggests that the problem is not as acute or, at the very least, does not rouse much interest.

[279] European Patent Convention (1973), art. 53(c).

[280] It is also worth noting that if a specialised but unpatented tool is claimed in a patented method in the US, the patentee can enforce the method against a manufacturer of the tool. The surgeon will be directly infringing the patent, but the patentee cannot pursue them because of the immunity. Instead, the patentee can pursue the manufacturer as a contributory infringer. For more detail on this scenario, see, Anderson (2020), 667–668.

[281] See e.g., Simon & Sichelman (2017), 401–407, 414–420.

[282] Some territories also have defences for 'private acts', which may further complicate infringement actions, see e.g., Patents Act 1977 (UK), s. 60(5)(a).

[283] Some commentators have considered these types of issues, albeit not focussing on the interplay with trade secrecy, see, Amy Kapczynski and Talha Syed, 'The Continuum of Excludability' (2013) 122 Yale Law Journal 1900, 1909, 1921–1941.

G. Specific interplay issues in related technologies

1. AI & Medical Innovation

Artificial Intelligence (AI)[284] and its subfield of Machine Learning (ML)[285] has attracted a lot of attention in IP scholarship in recent years.[286] The focus of enquiry has tended to be on patent and copyright issues and to a much lesser extent on trade secrets.[287] In relation to patents, there has been extensive debate about inventorship of machine-generated inventions[288] and also discussion of whether to adapt core validity principles – such as inventive step and sufficiency – for such inventions.[289] In the case of copyright, authorship and ownership of AI generated creations has been debated extensively,[290] along with whether the processes of ML infringe copyright in the content that is used as training data.[291] When it comes to trade

[284] 'AI is best understood as a set of techniques aimed at approximating some aspect of human or animal cognition using machines.' See Ryan Calo, 'Artificial Intelligence Policy: A primer and Roadmap' (2017) 51 U.C. Davis Law Review 399, 404. See also Ryan Abbott, *The Reasonable Robot: Artificial Intelligence and the Law* (CUP, 2020), 22, defining AI as 'an algorithm or machine capable of completing tasks that would otherwise require cognition' and observing at 24 that 'all modern AI is narrow or specific' in that it 'focuses on discrete problems or works in specific domains'. For an overview of the technical aspects of AI, see Josef Drexl and Reto Hilty, et al, *Technical Aspects of Artificial Intelligence: An Understanding from an Intellectual Property Law Perspective* (October 8, 2019). Max Planck Institute for Innovation & Competition Research Paper No. 19-13, <https://ssrn.com/abstract=3465577> accessed 30 September 2023.

[285] David Lehr and Paul Ohm, 'Playing with the Data: What Legal Scholars Should Know About Machine Learning' (2017) 51 U.C. Davis Law Review 653 (noting that legal scholars tend to oversimplify and focus on the machine-learning algorithm as deployed, rather than the complex, prior data stages and that, even when scholars discuss the data stages, it is with a focus mainly on problem definition and data collection, omitting further stages such as data cleaning, summary statistics review, data partitioning model selection, and model training. As well, they observe that for the most part legal scholarship discusses supervised machine learning.) Note that machine learning can be divided into supervised, unsupervised and reinforcement learning: see Drexl & Hilty et al (2019).

[286] E.g., see European Commission, Directorate-General for Communications Networks, Content and Technology, Hartmann, C., Allan, J., Hugenholtz, P., et al., *Trends and developments in artificial intelligence : challenges to the intellectual property rights framework: final report*, Publications Office of the European Union, 2020, <https://data.europa.eu/doi/10.2759/683128> accessed 30 September 2023 and Jyn-An Lee, Reto Hilty and Kung-Chung Liu (eds) *Artificial Intelligence & Intellectual Property* (OUP, 2021).

[287] E.g., see Lee et al (2021) and Ryan Abbott, *Research Handbook on Intellectual Property and Artificial Intelligence* (ed) (Edward Elgar, 2022).

[288] See *Thaler* v. *Vidal,* 43 F.4th 1207, 1210 (Fed. Cir. 2022) (United States); *Thaler v The Comptroller-General of Patents, Designs and Trade Marks* [2021] EWCA Civ 1374 (on appeal to the UK Supreme Court) (United Kingdom); *Thaler v Commissioner of Patents* [2021] FCA 879; overturned by *Commissioner of Patents v Thaler* [2022] FCAFC 62 (Australia). See also USPTO Request for Comments on Patenting Artificial Intelligence Inventions, 84 FR 44889 (August 27, 2019) which led to the report *Public Views on Artificial Intelligence and Intellectual Property Policy* (Oct 2020) and UK IPO Consultation on Artificial Intelligence and Intellectual Property: copyright and patents (29 October 2021) and the Government response to that consultation (28 June 2022).

[289] Lisa Vertinsky, 'Patents and Thinking Machines' in W. Barfield and U. Pagallo (eds), *Research Handbook on Law and Artificial Intelligence* (Edward Elgar, 2018), ch 18, available at <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3036030> accessed 30 September 2023; Dan Burk, 'AI Patents and the Self-Assembling Machine' (2021) 105 Minnesota Law Review Headnotes 301 <https://ssrn.com/abstract=3628791> accessed 30 September 2023.

[290] E.g., Jane C. Ginsburg and Luke A. Budiardjo, 'Authors and Machines' (2019) 34 Berkeley Technology Law Journal <http://dx.doi.org/10.2139/ssrn.3233885> accessed 30 September 2023.

[291] E.g., Rossana Ducato and Alain Strowel, 'Limitations to text and data mining and consumer empowerment: making a case for a right to "machine legibility"' (2019) 50 International Review of Intellectual Property and Competition Law 649; Rossana Ducato and Alain Strowel , 'Ensuring Text and Data Mining: Remaining Issues With the EU Copyright Exceptions and Possible Ways Out' [2021] 43 European Intellectual Property Review 322; and Maryna Manteghi, 'The insufficiency of the EU's text and data mining exceptions for using artificial intelligence' [2022] 44 European Intellectual Property Review 651.

secrets, the main issues that have been raised are applicability of trade secrets to AI training data,[292] whether trade secrets law facilitates sharing of data[293] and the use of trade secrets to block transparency of AI innovations, thus exacerbating the so-called 'black box' quality of AI innovations.[294]

There is the potential for AI and ML in particular[295] to have transformative effects across multiple sectors and this includes health.[296] Commentators have discussed the potential for AI (and specifically ML) to radically change 'personalised medicine', which is 'a practice of medicine that uses an individual's genetic profile to guide decisions made regarding the prevention, diagnosis and treatment of disease'.[297] For example, there is EyeDiagnosis's IDx-DR software, which assists with diagnosing diabetic retinopathy by allowing non-specialist medical practitioners to take simple images of the retina which is then compared against a database of retina images.[298] Another example is IBM's Watson Oncology which uses ML to study patient records in order to then provide treatment recommendations.[299] Further, there is the potential for ML to assist with developing new therapeutic uses of existing drugs,[300] both in terms of identifying novel therapeutic uses[301] and holding more precise clinical trials (where patients are selected according to DNA profiling to provide biomarkers for targeted treatment).[302] For example, there is BERG's AI Interrogative Biology which uses ML to identify possible drug treatments from its vast dataset of tissue samples and BenevolentBio's

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[292] Ana Nordberg, 'Trade secrets, big data and artificial intelligence innovation: a legal oxymoron?,' in Jens Schovsbo, Timo Minssen and Thomas Riis (eds), *The Harmonization and Protection of Trade Secrets in the EU, An Appraisal of the EU Directive* (Edward Elgar, 2020), ch 11, 194-220 and Sharon Sandeen and Tanya Aplin, 'Trade Secrecy, Factual Secrecy and the Hype Surrounding AI' in R. Abbott, *Research Handbook on Intellectual Property and Artificial Intelligence* (ed) (Edward Elgar, 2022), ch 24, 442-459.

[293] Tanya Aplin, Alfred Radauer, Martin Bader and Nicola Searle, 'The role of EU trade secrets law in the data economy: an empirical analysis' (2023) International Review of Intellectual Property and Competition Law <https://doi.org/10.1007/s40319-023-01325-8> accessed 30 September 2023.

[294] Frank Pasquale, *The Black Box Society: The Secret Algorithms that Control Money and Information* (Harvard UP, 2015), 193 '[t]rade secrecy protection effectively creates a property right in an algorithm without requiring its disclosure' and 217 '[t]rade secrecy, where it prevails, makes it practically impossible to test whether their judgments are valid, honest and fair'.

[295] Christian Lovis, 'Unlocking the Power of Artificial Intelligence and Big Data in Medicine' (2019) 21 Journal of Medical Internet Research e16607 <doi: 10.2196/16607> accessed 30 September 2023.

[296] See generally, Pavel Hamet and Johanne Tremblay, 'Artificial intelligence in medicine' (2017) 69 Metabolism S36 <https://doi.org/10.1016/j.metabol.2017.01.011> accessed 30 September 2023 and Anmol Rora, 'Conceptualising Artificial Intelligence as a Digital Healthcare Innovation: An Introductory Review' (2020) 13 Medical Devices: Evidence and Research 223 <https://doi.org/10.2147/MDER.S262590> accessed 30 September 2023.

[297] Mubashir Hassan et al, 'Innovations in Genomics and Big Data Analytics for Personalized Medicine and Health Care: A Review' (2022) 23 International Journal of Molecular Sciences 4645 <https://doi.org/10.3390/ijms23094645> accessed 30 September 2023. See also W. Nicholson II Price, 'Black-Box Medicine' (2015) 28 Harvard Journal of Law & Technology 419, 425-434.

[298] Price (2019), 75.

[299] Price (2019), 76.

[300] Price (2015), 436; Hamet & Tremblay (2017).

[301] E.g., see Lincoln Tsang et al, 'The Impact of Artificial Intelligence on Medical Innovation in the European Union and United States' (2017) Intellectual Property & Technology Law Journal available at <https://www.arnoldporter.com/-/media/files/perspectives/publications/2017/08/the-impact-of-artificial-inteelligence-on-medical-innovation.pdf> accessed 30 September 2023.

[302] Kurt Benke and Geza Benke, 'Artificial Intelligence and Big Data in Public Health' (2018) 15 International Journal of Environmental Research and Public Health <doi:10.3390/ijerph15122796> accessed 30 September 2023.

Judgement Correlation System which uses ML to analyse millions of scientific research papers with a view to generating novel hypotheses.[303] Another fairly well known application of AI in medicine is in relation to image analysis.[304] Somewhat more remotely, but perhaps as important, is the potential for AI to assist with hospital administration systems, 'to improve system efficiency or to increase the volume of care provided'.[305] There has also been talk of the potential for medical AI to 'democratize medical expertise', i.e., to enable a wider range of health care providers to offer a certain standard of patient care.[306] AI also manifests itself in physical objects, such as 'carebots' and robots used in surgery, or as teaching tools.[307] Some areas, however, such as neurocritical care, have yet to see the benefits of AI applications.[308]

When it comes to AI and ML applications in medicine, there is a plurality of data that may be drawn upon including genetic, genomic, epigenomic, transcriptomic, metabolomic data, medical images, biobank data, electronic health records and scientific literature.[309] This variety is a strength, but also poses challenges in terms of accessing data, data quality, data formatting and storage, and data privacy.[310]

Aside from the significant challenges pertaining to data, there are other obstacles to successful development of AI and ML innovations in medicine. One issue relates to how to regulate AI software that is used in a healthcare setting[311] - for example, should it be regulated as a 'medical device' and thus subject to the relevant safety and performance validation within a particular jurisdiction and, if so, is this thwarted by a lack of expertise and resources of the regulator.[312] Another is that AI applications can be very context dependent. One commentator discusses that many AI tools are developed in 'high-resource hospitals' but that this, in turn, poses 'translational challenges'. More specifically, there will be difficulties in using AI tools developed in high-resource hospitals in lower-resource settings because there might be real differences in the patient populations, and substantial differences in resources

[303] Tsang et al (2017).
[304] D. Douglas Miller and Eric W. Brown, 'Artificial Intelligence in Medical Practice: The Question to the Answer?' (2018) 131 The American Journal of Medicine 129.
[305] W. Nicholson Price II, Rachel E. Sachs and Rebecca S. Eisenberg, 'New Innovations Models in Medical AI' (2022) 99 Washington University Law Review 1121, 1127. See also W. Nicholson II Price, 'Medical AI and Contextual Bias' (2019) 33 Harvard Journal of Law & Technology 65, 71-72 referring to automation of routine tasks.
[306] Price (2019), 73-79.
[307] Hamet & Tremblay (2017).
[308] Giuseppe Citerio, 'Big Data and Artificial Intelligence for Precision Medicine in the Neuro-ICU: Bla, Bla, Bla' (2022) 37 Neurocrit Care S163 and Valentina Bellini et al, 'Big Data and Artificial Intelligence in Intensive Care Unit: From "Bla, Bla, Bla" to the Incredible Five V's' (2022) 37 Neurocrit Care S170.
[309] Hassan et al (2022). See also Price (2015), 431.
[310] Hassan et al (2022); Lovis (2019). See also Price (2015), 438 referring to '[g]athering, cleaning, and assembling high-quality health information from many different sources' as 'an expensive endeavor' and at 454 et seq discussing privacy concerns; and Indes Reinecke et al, 'Assessment and Improvement of Drug Data Structuredness From Electronic Health Records: Algorithm Development and Validation' (2023) 11 JMIR Medical Informatics e40312 <doi: 10.2196/40312> accessed 30 September 2023.
[311] See Nicolas Terry, 'Of Regulating Healthcare AI and Robots' (2019) 21 Yale Journal of Law & Technology 133.
[312] Tsang et al (2017); Lovis (2019). See also Benjamin Chin-Yee and Ross Upshur, 'Three Problems with Big Data and Artificial Intelligence in Medicine' (2019) 62 Perspectives in Biology and Medicine 237, 246 lamenting the lack of certification standards for AI tools in medicine; and Price (2015), 440-442, 460 discussing how the opaque and dynamic nature of AI models makes validation harder and at 458-460 discussing the awkward fit of black-box medicine for the FDA.

which can influence the optimal treatment recommendations.[313] An important means of addressing these problems is having representative datasets, which in turn could be supported by public funding, and for regulatory bodies to play a role.[314] A further issue is the extent to which there is the expertise within the medical profession to deploy AI/ML tools effectively.[315]

An important challenge – and one most relevant to this Paper - is whether patent and trade secrets operate as incentives for AI and ML medical innovation. Scholars have suggested that patent incentives are inadequate (at least in the US) because of Supreme Court decisions that narrow the range of patentable subject matter and the problems in addressing the disclosure requirement.[316] Moreover, those Supreme Court decisions will also nudge AI innovation towards 'companion diagnostics and paired devices, rather than pure algorithms and data'.[317] However, a study indicates that these initial fears about the unavailability of patents for medical ML innovations are not borne out by the empirical data.[318] Indeed, there has been a rapid growth in medical ML inventions since 2013 in both Europe and the US. These inventions have tended to have relatively conservative claims and to focus mainly on measurement, analysis, detection and classification, rather than fully automated diagnosis.[319] Monitoring patenting in this area would be worthwhile.

Trade secret protection would seem to be very apt for ML algorithms, given their 'black-box' nature,[320] which makes them less accessible via reverse engineering. However, trade secrets protection for the datasets used to develop medical ML innovations may be problematic because this places the dataset holder with a 'robust competitive advantage' and 'slows cumulative innovation and promotes duplicative investment'.[321] Scholars also regard trade secret protection as being ineffective when it comes to 'validation' of medical ML, i.e., ensuring that the particular ML model is able to be scrutinised to check that it is operating accurately. However, trade secrets protection does not promote this kind of transparency because complete openness about the model would destroy its secrecy and thus the basis for protection.[322]

To the extent that open-source ML supports medical innovation the role of both patents and trade secrets is problematic because this type of protection is incompatible with the central spirit of open-source sharing, which is not to have exclusivity.[323]

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[313] Price (2019), 90-98.
[314] Price (2019), 107-108, 110-113.
[315] Benke & Benke (2018); Lovis (2019).
[316] Price (2015), 443-445. For a more detailed discussion see Price et al (2022), 1152-1157.
[317] Price (2015), 445.
[318] Mateo Aboy, W. Nicholson Price II and Seth Raker, 'Mapping the patent landscape of medical machine learning' (2023) 41 Nature Biotechnology 461
[319] Aboy et al (2023), 466-467.
[320] Price (2015), 446.
[321] Price (2015), 447-8.
[322] Price (2015), 440-442, 448.
[323] For a discussion see: Keerthi B Harish, W. Nicholson Price II and Yindalon Aphinyanaphongs, 'Open-Source Clinical Machine Learning Models: Critical Appraisal of Feasibility, Advantages, and Challenges' (2022) 6 JMIR Formative Research e33970 <doi: 10.2196/33970> accessed 30 September 2023.

VIII. The roles of patents and trade secrets in attaining public policy goals

This section considers the interplay of patents and trade secrets in achieving public policy goals. Three policy goals are considered in turn: i) accelerating the development of medical technologies; ii) providing access to medical technologies; and iii) building a 'knowledge commons' about medical technologies.

A. Accelerating the development of medical technologies

One of the primary goals of patents and trade secrets protection is to accelerate the development of new technology (see section V). This section considers this goal from three perspectives. First, this section recaps issues from section VII for specific technologies. The second part considers the topic of overlaps between patents and trade secrets. Some commentators query whether patents and trade secrets are *both necessary* for innovation and whether a layer of trade secret protection could be removed. The third part considers the opposite of overlap: when patents and trade secrets provide weak incentives or are unavailable. This unavailability can occur for medical innovations such as surgical techniques (discussed in section VII.F.1). This section considers whether society should provide *additional* incentives to realise these innovations.

1. Recap of specific instances where the interplay of patents and trade secrets might *not* accelerate new medical technology

Sections VII.A–G identified several instances where the interplay of patents and trade secrets might not accelerate medical innovation. These areas include: i) trade secrets on clinical trial protocols and data hampering follow-on drug R&D; ii) patents and trade secrets providing weak incentives for improvements in drug manufacturing; iii) patents and trade secrets providing weak incentives for medical diagnostics, especially in the US, where the Supreme Court narrowed what constitutes patentable subject matter; iv) patents and trade secrets together providing weak incentives for surgical innovations; and v) whether medical ML is being sufficiently incentivised by patents and trade secrets.

2. Overlaps between patents and trade secrets: a balancing act?

a) Patents and trade secrets overlap for drugs; should society compel disclosure of trade secrets on clinical trial data and protocols?

Commentators query whether the overlapping protection of patents and trade secrets is desirable for drugs.[324] Indeed, for most territories, drugs have a third layer of protection because they receive some form of regulatory protection, too (the US provides 5 years for small molecules and 12 years for biologics). The desirability of all this protection is queried because patents and regulatory protection might be *sufficient* to incentivise R&D on drugs.

If trade secrets protection is unnecessary, this extra layer of (legal) protection might slow follow-on innovation. One example (discussed above) of trade secrets slowing innovation is trade secrets on clinical trial data and protocols. In short, if a drug has been used in a clinical trial, follow-on innovators will want to know the protocols used in that trial and the results. If the clinical trial protocols and data are unavailable, follow-on innovators lack information on what has previously failed, nor can they improve on previous clinical trial protocols.

[324] See generally, Feldman (2022); Heled (2019); Price & Rai (2016).

Commentators query whether trade secrets on trial protocols and data are necessary or logical. A study on the prospect of greater disclosure found that innovators would continue to invest 96-99% of their research budget if full safety and efficacy data were disclosed.[325] Albeit, the study was published in 1980. Perhaps modern econometric methods would yield a different result, but the idea is also backed by ethicists, who argue clinical trial data and protocols should be published to minimise extra trials on humans.[326]

Two legal arguments can be made to support greater disclosure of clinical trial data and protocols, one from the perspective of patent law and one from regulatory protection. The patent argument is simple: patents are premised on describing how an invention works. Consequently, all data relevant to a compound and its claimed applications should be disclosed.[327] This argument is complicated by the fact that patents are often applied for (and granted) many years before a drug is marketed. Commentators who support this argument have started exploring some form of ongoing disclosure.[328] The argument from regulatory protection is similar: protection is premised on the innovator providing sufficient information on the treatment.[329] This argument is complicated by the fact that regulatory protection was never premised on disclosing information *to the public*. Yet, commentators who support greater disclosure argue regulatory protection should be premised on disclosure to the public.[330] The difficulty with such an argument is whether it complies with Article 39(3) TRIPS which mandates that regulatory data shall be protected against unfair commercial use and disclosure, 'except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use'. This has led some commentators to suggest that disclosure of regulatory data in a crisis, such as the Covid-19 pandemic, would be justified.[331] But that perhaps the disclosure of trade secrets might be on a restricted basis rather than generally available to the public.[332]

Pharmaceutical companies would have at least three responses to oppose these calls for disclosure. The first is based on the idea of trade secrets as a 'backup'. Patents are probabilistic in the sense that many are invalid, and regulatory protection periods are often short (e.g., 5 years for small molecules in the US). Thus, the extra layer of trade secret protection helps innovators when patents are found invalid and regulatory exclusivity periods expire. The second argument is that developing drugs (especially biologics) is expensive, and the extra protection helps developers earn a profit. The third argument is that some trade secrets are critical to other drugs in development. For example, some data might indicate the drugs could be repurposed for other diseases. This repurposing issue was raised in section VII.C. As stated there, no systematic evidence indicates whether it is a significant issue.

[325] Fay H. Dworkin, 'On Estimating the Economic Impact of Regulations: A Case Study on Trade Secret Disclosure' (1980) 1 Economics of the Pharmaceutical Industry 197, 199–200.
[326] See e.g., Heled (2019), 58.
[327] Feldman (2022), 52.
[328] Price & Rai (2016), 1050–1053.
[329] Feldman (2022), 52.
[330] See e.g, Feldman (2022), 52–54.
[331] Olga Gurgula and Luke McDonagh, 'Access Denied: the Role of Trade Secrets in Preventing Global Equitable Access to COVID-19 Tools' (June 19, 2023) <https://ssrn.com/abstract=4484507> accessed 30 September 2023.
[332] Gurgula & McDonagh (2023), although specifically suggesting this in relation to compulsory licenses of trade secrets.

These three responses should be looked at in greater detail. The second argument about profit might be challenging to maintain because the drug industry is one of the most profitable.[333] However, the remaining two are under-explored and should be the focus of future studies.

b) Trade secrets can encourage third parties to innovate: lessons from generics

Another factor that should be considered in the overlap is that trade secret protection *can* prompt third parties to create new technology to overcome secrets. A primary example is the acceleration of science surrounding small molecules and generics, especially in analytical chemistry. Section VII.A.1 describes how the FDA and other scientists led efforts to develop technology to identify whether small molecules and generics were bioequivalent. Without these innovations, the generic market as we know it would not exist.

The advances in science that enabled the generic industry are most directly relevant to biosimilars. Indeed, several commentators argue that these scientific advances are in motion for biosimilars and that, perhaps, trade secrets will *not* be such an obstacle for biosimilars in the future.[334] However, whether society will realise these scientific advances is debatable. Moreover, in considering whether to require more disclosure, it is difficult to weigh the *prospect* of these advances in science against the follow-on innovation that greater disclosure would entail.

c) Medical diagnostics and other technologies

The same arguments made for drugs about manufacturing and clinical trial data and protocols could be made for medical diagnostics and other technologies. In short, not publishing and keeping the information secret hampers follow-on innovation. However, few, if any, commentators have made this argument. Instead, commentators have focussed their attention on drugs.

The issues at stake for the acceleration of medical diagnostics and other technologies are similar to those for drugs (e.g., greater disclosure would accelerate follow-on innovation but remove a layer of protection for innovators). That said, there are three key differences. First, the diagnostic industry (as well as other medical technologies) is less profitable than the drug industry. The lack of profitability hints that perhaps the extra layer of trade secret protection is necessary, otherwise innovators may choose to pursue other innovations. Second, the authorisation of medical diagnostics and other technologies does *not* attract regulatory protection. The absence of regulatory protection means that if developers had no trade secret protection, they would only have patents for protection. Thus, the argument concerning the probabilistic nature of patents has greater weight here because, without patents, innovators have no other backup protection.

The third difference concerns scenarios in which society has no disclosure of information on diagnostics is challenging because no one but the developers have the information. Two such scenarios are LDTs and other technology not reviewed by the regulators for efficacy (e.g.,

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[333] United States Government Accountability Office, 'Drug Industry: Profit, Research and Development Spending, and Merger and Acquisition Deals' (Report to Congressional Requesters, November 2017) 20.

[334] See e.g., Teddy Henriksen, 'Trade Secrets: Promoting Innovation in Biosimilars' (2021) 31 Australian Intellectual Property Journal 262; Rebecca Weires, 'Recent Advances in Biologics Manufacturing Diminish the Importance of Trade Secrets: A Response to Price and Rai' (Written Description, 4 March 2019) <https://writtendescription.blogspot.com/2019/03/recent-advances-in-biologics.html> accessed 30 September 2023.

Class 1 medical devices in the US). The absence of reviewing this data means that regulators do *not* have any data to disclose. Thus, society cannot rely on regulators to obtain and publish the data. Moreover, LDTs allow companies to pursue commercialisation strategies where they do *not* patent anything or only patent self-revealing parts of their invention. Thus, companies could avoid disclosure by providing LDTs and not patenting or limiting their patenting self-revealing innovations. Therefore, if society wanted to ensure disclosure, it would have to obtain it by methods other than patents or submissions to regulators.

3. Weak or non-existent incentives for medical diagnostics, surgical technical techniques, and drug manufacturing in general

This Paper described three technologies that arguably have weak or non-existent incentives: i) surgical techniques; ii) medical diagnostics (created by judicially narrowed patentable subject matter in the US); and iii) drug manufacturing in general. This section will analyse surgical techniques and medical diagnostics together before considering drug manufacturing in general.

The absence of incentives for surgical techniques and medical diagnostics arose from ordinary legal processes. In the case of surgical procedures, US and EPC legislators decided to protect medical practitioners from patent infringement actions. Thus, the legislators knowingly chose to remove the patent incentive for these technologies. In the case of medical diagnostics, the US Supreme Court decided a series of cases knowing that it was narrowing patentable subject matter law. Given these processes created the current situation, commentators suggest legislative amendments to change the law.

If the law were to be amended, then better evidence of the problems created by the absence of incentives would be desirable (some key questions were described in sections VII.E.2–F.1). However, what was *not* described above was that evidence of the *benefits* created by these laws should also be considered. For instance, how much does society benefit from medical practitioners performing surgical methods without fear of patent infringement?

The benefits ushered in by the US Supreme Court's narrowing of patentable subject matter should also be considered. One of the Court's justifications for altering the patentability of medical diagnostics was that developers were trying to tie up the 'basic tools of scientific and technological work'.[335] If the Supreme Court was correct, research should have flourished in some areas. Unfortunately, no researchers have looked for acceleration caused by these decisions.[336] The absence of this research means we cannot tell if the adverse effects of the decisions (i.e., organisations forgoing the development of tests) are outweighed by positive effects elsewhere.

The absence of incentives for drug manufacturing differs from the situation for surgical techniques and medical diagnostics. The absence of incentives for drug manufacturing is not due to legislation or case law narrowing protection: patents and trade secrets are available for new manufacturing techniques. Thus, any solution to the problem will have to come from different areas of law and policy. Some suggested solutions include regulatory exclusivities for manufacturing innovation, more dynamic regulatory agencies, and publicly publishing all manufacturing processes at regulatory review (which would probably compel manufacturers

[335] *Association for Molecular Pathology v Myriad Genetics Inc,* (2013) 569 U.S. 576, 589.
[336] That said, it has arisen accidently, see Liddicoat et al (2020), 835–836.

to patent their innovations).[337] Before considering these solutions, however, systematic evidence on the scale and breadth of the problem should be obtained.

B. Access to medical technologies

Accelerating the development of medical technology is useless without access on reasonable terms. This section considers access issues at the interplay between patents and trade secrets in three parts. First, this section recaps access issues identified in sections VII.A-G. Assuming these access issues are substantial, the second and third parts consider arguments aimed at removing a layer of trade secret protection to enable greater access. The second part builds on the acceleration arguments (in section VIII.A above) by pointing out that many of the arguments for greater access are similar to those for encouraging the acceleration of new technologies (e.g., disclosing trade secrets might enable greater access to technology, but there are concerns it will remove the initial incentive to create it). However, greater access also raises some new arguments, which this part considers. The third part considers access once a *TRIPS flexibility*[338] is executed, such as a compulsory licence. TRIPS flexibilities raise new access-related arguments that strengthen the case for disclosure, such as access to medicines during health emergencies.

1. Recap of specific instances where the interplay of patents and trade secrets might hamper access to new medical technology

Sections VII.A–G identified several specific instances where the interplay of patents and trade secrets *might* hamper access to medical technology. These areas include: i) trade secrets on prices (if prices are kept high, then this hampers access); ii) trade secrets on clinical trial protocols and data, which can affect decisions on what patients are eligible for the drug as well as insurance and reimbursement decisions; iii) imperfect patent disclosure and trade secrets on quality control processes and manufacturing processes for biosimilars; and iv) trade secrets on databases for medical diagnostics, which, after the patents expire, stop the entry of competitors and therefore keep prices high.

2. Removing a layer of trade secret protection to enable better access: how the arguments differ from removing a layer of trade secret protection to accelerate innovation

Section VIII.A above on accelerating new medical technology considered many issues surrounding the overlapping and consecutive uses of trade secrets. Many of the issues raised there are equally relevant here. For example, section VIII.A considered whether trade secret protection on clinical protocols and data was necessary to encourage innovation at the expense of delaying follow-on innovation. One of the arguments here is whether society could compel disclosure of prices or manufacturing processes to enable better access. Another argument is whether we should compel better disclosure of quality control and manufacturing processes to enable more biosimilar entry. Many of the arguments, both for and against, are the same, but there are different elements.

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[337] Price (2014), 541–561.

[338] The phrases 'TRIPS flexibility' and 'TRIPS flexibilities' do not have an official definition. WIPO describes 'TRIPS flexibilities' as flexibilities concerning the method of implementing TRIPS obligations, substantive standards of protection, mechanisms of enforcement and areas not covered by TRIPS: see <https://www.wipo.int/ip-development/en/policy_legislative_assistance/advice_trips.html> and <https://www.wipo.int/ip-development/en/agenda/flexibilities/database.html> accessed 30 September 2023. In this Paper we are using the phrase to refer to *flexibilities in substantive standards of protection*, in particular exceptions to rights, compulsory licensing, government use and parallel importation.

One different element is that access generally involves a shorter-term effect. For example, disclosing prices would relatively quickly lead to less government expenditure and more treatments. Likewise, manufacturing methods for biologics would likely enable more competition, which would mean lower prices and more treatments. Access is distinct from the concept of accelerating new technology, which has more distant impacts on society because it relies on innovators taking on information and producing new products, which can take more than a decade.

Many of the same counterarguments could be raised against greater disclosure (i.e., backup protection, the extra protection is necessary for adequate profits, and some of the information is necessary for other innovations). That said, at least one unique consideration concerns databases on improvements to medical diagnostics. As explained above (see section VII.E.1), commentators have described some patents on medical diagnostics as 'data generators', in the sense that, whilst providing the patented test, the rights holders will generate data on how to improve the test or perhaps how the test relates to other aspects of human health. These improvements will be in the data they accumulate, and many diagnostic providers might want to patent them. Manufacturers might oppose greater disclosure because they want to patent the improvements. However, this interest need not permanently stop greater disclosure. For example, *if* diagnostic providers were obliged to contribute anonymised patient data to a public database, it might be prudent to give providers the option to withhold data for a few years if they are planning on using the data in a patent application.[339]

3. Authorised access and use without permission from rights holders

Sometimes parties seek authorised access to innovations without permission from rights holders. 'Authorised access and use' here refers to courts or other decision-makers awarding, for example, compulsory licences. Access and use might be sought when the price is too high, there is a shortage of the invention, or rights holders refuse to grant access. To the authors' knowledge, no one has tried to evaluate what percentage of medical patents (or drugs or other innovations) are subject to an application for access and use without permission from rights holders. However, researchers have assembled a non-exhaustive database of instances when 'authorities have invoked, planned to invoke, or have been asked to invoke a TRIPS flexibility for public health reasons'.[340] The database contains 172 entries beginning from 2001. Of these 172, 130 were executed, and another 14 are pending. The most common entries are for HIV treatments, but other drugs include treatments for cancer (e.g., docetaxel) and H1N1 influenza (oseltamivir).

TRIPS flexibilities include compulsory licensing, government use and parallel importation.[341] The scope of the provisions in TRIPS and how they are implemented in various territories is beyond the scope of this Paper.[342] Instead, this discussion focuses on how the interplay of

[339] The idea of data-generating patents is applicable to other technologies, such as machine learning, but has primarily been discussed with reference to medical diagnostics.

[340] 'The TRIPS Flexibilities Database' (Medicines Law & Policy) <http://tripsflexibilities.medicineslawandpolicy.org> accessed 30 September 2023.

[341] TRIPS, art 31; Declaration on the TRIPS Agreement and Public Health, Doha WTO Ministerial, 2001: TRIPS, WT/MIN(01)/DEC/2, adopted 14 November 2001, paragraph 5(d).

[342] Indeed, the interpretation of some provisions might be subject to significant uncertainty, see generally, Johnathon Liddicoat and James Parish, 'Ironing Out the Wrinkles: Reforms to Crown Use and Compulsory Licensing to Help Prepare the Patents Act 1977 for the Next Health Crises' (2021) 4 Intellectual Property Quarterly 245.

patents and trade secrets might affect these mechanisms. TRIPS flexibilities provide access to make, use and import patented inventions. However, as explained below, trade secrets could hamper this access and use, raising an extra barrier to using patented technologies.

The prime example of trade secrets protection hampering authorised access to, and use of, patented inventions relates to vaccines for Covid-19. Territories worldwide, especially those with low vaccine rates, can exercise TRIPS flexibilities to make or import various medicines or take advantage of the WTO Covid-19 Ministerial Decision,[343] which provides a waiver for patent rights on Covid-19 vaccines. However, the flexibilities and Ministerial Decision are likely useless in many circumstances because of trade secrets on aspects of the technologies, which are especially time and resource intensive to independently create or reverse engineer.[344] Indeed, one pharmaceutical company has even alleged that a manufacturer it contracted with to make a vaccine flatly refused to share its manufacturing secrets.[345] The contractor refused to reveal how to make the vaccine, saying it would involve disclosing trade secrets, whilst the pharmaceutical company argued the information should be transferred to them pursuant to their contract. The company also suggested the contractor was trying to squeeze more money from them by not disclosing the method of manufacture.[346]

The manufacturing-trade secret arguments for Covid-19 vaccines are similar to those discussed above for biosimilars (vaccines are typically biologics). However, there are three crucial differences. First, whereas biosimilars concern a technology patented 20 or more years ago, the issue for Covid-19 vaccines (and any other medicines still covered by patents) is that the technology has been on the market for less time. Thus, the technology is less well studied, and people have had less time to reverse engineer the marketed products or to independently discover the information that is protected as trade secrets.

Second, manufacturers typically launch biosimilars when patents (on the original compounds) expire, whereas access via TRIPS flexibilities typically arises in unusual circumstances. In the case of Covid-19, it was a health emergency. In other circumstances, compulsory licences might be granted because a patentee cannot meet demand or refuses to license on reasonable terms. These are situations in which legislators or policymakers have decided people should have access *without* the rights holder's consent. However, trade secrets can operate to frustrate these policy decisions.

Third, the unusual circumstances might activate other TRIPS flexibilities. Some commentators, for example, argue that Article 39 of TRIPs, in its own right, and read in conjunction with Article 73, permits governments to establish compulsory licenses or other compelled transfers of trade secrets to deal with public health crises. Such trade secrets might

[343] World Trade Organization, 'Ministerial Decision on the TRIPS Agreement' (Adopted on 17 June 2022 WT/L/1141) <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True> accessed 30 September 2023.

[344] Gurgula & McDonagh (2023).

[345] Cynthia Koons and Susan Decker, 'Inovio Tells Court Supplier is Holding Covid Vaccine "Hostage"' (Bloomberg, 3 June 2020) <https://www.bnnbloomberg.ca/inovio-tells-court-supplier-is-holding-covid-vaccine-hostage-1.1445259> accessed 30 September 2023.

[346] ibid.

relate to data on drugs submitted as part of regulatory or marketing authorisation processes or to the manufacturing processes for drugs.[347]

a) A complicating factor: regulatory protections

TRIPS flexibilities, such as compulsory licensing and government use, foresee third parties applying to use patented technologies. Yet, even if a third party obtains, for example, a compulsory license, legislation may still block them from using the technology due to regulatory protections. As described above, many territories provide regulatory protection, lasting up to 12 years, preventing the authorisation of generics and biosimilars. Put another way, the issue here is that third parties may have a compulsory license; however, regulatory protections could prevent regulators from authorising a generic or biosimilar.[348]

The issue of market or data exclusivities preventing the authorisation of generics and biosimilars garnered significant academic commentary during the Covid-19 pandemic in Europe.[349] It is addressed, albeit very generally, in the WTO Covid-19 Ministerial Decision.[350] The EU Commission has proposed reform to remove this barrier during public health emergencies,[351] and other countries removed this barrier before the pandemic, such as Malaysia, Chile and Colombia.[352] However, not all countries have removed the barrier.

C. Building a 'knowledge commons' of medical technologies

Building a 'knowledge commons'[353] of medical technologies is of benefit to the public since it can facilitate scientific understanding and progress. Patent law aims to support this goal by

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[347] See David S. Levine and Joshua D. Sarnoff, 'Compelling Trade Secret Transfers' (December 25, 2022), forthcoming in Hastings Law Journal, <https://ssrn.com/abstract=4311880> accessed 30 September 2023; Gurgula & McDonagh (2023).

[348] See generally, Ellen F.M. 't Hoen, Pascale Boulet and Brook K. Baker, 'Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: *A Proposal for Greater Coherence in European Pharmaceutical Legislation*' (2017) 10 Journal of Pharmaceutical Policy and Practice 19, <https://doi.org/10.1186/s40545-017-0107-9> accessed 30 September 2023.

[349] See e.g., Ellen 't Hoen, 'Protection Against Market Exclusivity in the Fight Against COVID-19' (2020) 26 Nature Medicine 813; Dhanay Cadillo Chandler, 'Uh-oh We are in Trouble! Compulsory Licences v Data Exclusivity in the EU: One More Challenge to Overcome in the Race to Find a COVID-19 vaccine?' (2020) 42 European Intellectual Property Review 539; Sven J.R. Bostyn, 'Access to Therapeutics and Vaccines in Times of Health Pandemics: How Exclusivity Rights can Affect such Access and What We can do About It' (2020) 4 Intellectual Property Quarterly 227, 266–267.

[350] Paragraph 4: 'Recognizing the importance of the timely availability of and access to COVID-19 vaccines, it is understood that Article 39.3 of the Agreement does not prevent an eligible Member from enabling the rapid approval for use of a COVID-19 vaccine produced under this Decision.' For a brief discussion see Andrew D. Mitchell, Antony Taubman & Theodore Samlidis, 'The Legal Character and Practical Implementation of a TRIPS Waiver for COVID-19 Vaccines' (2022) 33 Fordham Intellectual Property, Media & Entertainment Law Journal 100, 125-126.

[351] Proposal for a Directive of the European Parliament and of the Council on the Union Code Relating to Medicinal Products for Human Use, and Repealing Directive 2001/83/EC and Directive 2009/35/EC, art. 80(4).

[352] See 't Hoen et al (2017), 4–5.

[353] We use the term 'knowledge commons' here to indicate a shared information resource whose use is not restricted by intellectual property rights. We acknowledge that there are different and complex understandings of 'commons' and the associated term 'public domain': e.g., see James Boyle, 'The second enclosure movement and the construction of the public domain' (2003) 66 Law & Contemporary Problems 33; A. J. van der Walt & M. du Bois, 'The Importance of the Commons in the Context of Intellectual Property' (2013) 24 Stellenbosch Law Review 31 and Séverine Dusollier, 'The commons as a reverse intellectual property – from exclusivity to inclusivity' in Helena R. Howe and Jonathan Griffiths (eds) *Concepts of Property in Intellectual Property Law* (CUP,

having a patent register and requiring that patent specifications describe inventions well enough for a person skilled in the art to make and use them.[354] One of the justifications for trade secrets law is that it incentivises innovation and *limited* sharing of protected information. This section explores the interplay between patents and trade secrets, focussing on how information can be kept from the public, including the idea that disclosure in patent specifications is imperfect.

This section is divided into two parts. This section begins by recapping specific issues for medical technologies discussed above, and the second part considers issues at a higher level of abstraction. It considers problems associated with imperfect patent disclosure. Then it considers evidence indicating that vast numbers of patents are granted for inventions that do *not* work, yet the information that they do not work remains hidden.

1. Recap: clinical trial data and protocols, manufacturing, and medical diagnostics

Sections VII.A–G described various instances of patents and trade secrets (or lack of patents and trade secrets) combining to potentially prevent the creation of a knowledge commons about medical innovation. These include: i) incomplete disclosure of clinical trial data and protocols for drugs; ii) trade secrets on manufacturing methods for biologics; iii) trade secrets on improvements to medical diagnostics; and iv) lack of transparency regarding medical ML.

2. Disclosure in patent law

Many territories have different approaches to information that must be disclosed in a patent specification. For example, the EPC states that patent applications must 'disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art',[355] and US law demands 'written enablement' that includes 'clear, concise and exact terms', including the 'best mode' of practising the invention 'contemplated by the inventor'.[356] Regardless of the precise disclosure requirements, though, commentators are concerned that the disclosure in patents is imperfect, in the sense that skilled people in the area *cannot* practice the invention. The requirements of sufficiency and written enablement are designed to ensure skilled people *can* practice the invention, but there is no guarantee these requirements are effective.[357]

Commentators have articulated three reasons for imperfect disclosure.[358] The first is that patents are primarily drafted by patent attorneys concerned about the legal impacts of their words, potentially veiling technical details. Second, the more a patentee discloses in a patent specification, the more information they provide to competitors, who might design competing products or services. Thus, patentees have an incentive to limit disclosure. Third,

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2013), ch 11, 258-281. On the idea of 'medical information commons' see Juli M. Bollinger et al, 'What is a Medical Information Commons' (2019) 47 Journal of Law, Medicine & Ethics 41, <doi: 10.1177/1073110519840483> accessed 30 September 2023.

[354] Jeanne C. Fromer, 'Patent Disclosure' (2009) 94 Iowa L Rev 539, 549 explains that patent disclosure can encourage 'inventing around, improving upon, and inspiring both during and after the patent term, and for copying after the patent term'. Although Alan Devlin, 'The Misunderstood Function of Disclosure in Patent Law' (2010) 23 Harvard Journal of Law & Technology 401 argues that the disclosure function is ancillary to the main purpose of patent law, which is to incentivise innovation and its commercialisation.

[355] European Patent Convention (1973), art. 83.

[356] 35 USC §112.

[357] See Fromer (2009); Devlin (2010).

[358] For a review of all three, see, Alexandra K. Zaby, Diana Heger and Marek Giebel, 'Strategic Non-disclosure in Patents' (SSRN, 28 February 2022) <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3314108> accessed 30 September 2023.

patent claims are typically drafted at a high level of abstraction to increase the scope of their protection. This abstraction potentially obscures what has been invented, and patentees can protect the omitted information as a trade secret. For example, a patentee might know that several variations of a drug might be therapeutically better than others. The law might require them to disclose one in detail (otherwise, their patent might be invalid for lack of disclosure), but the patent might claim tens or hundreds of variations (if not more).

Imperfect disclosure can have two negative impacts. First, it can affect follow-on innovation in terms of market products. Limited disclosure affects the information available to competitors, which, in turn, could affect the quality and type of products they produce. Second, imperfect disclosure can affect the development of scientific knowledge, which is often *not* directed to market products. Legal scholars have assumed that few people, other than patent attorneys, read patent specifications.[359] However, increased access to patents through various websites has changed this: a 2017 survey found that only 22% of researchers in the academic, government and non-profit sectors had *never* read a patent, i.e., 78% of them *had* done so.[360] These results emphasise the value of the corpus of scientific or technical information available in patent specifications to researchers.

The breadth of imperfect disclosure (e.g., is it across patents in all areas of technology?) and the magnitude of its effects (e.g., how do follow-on innovators respond to the lack of disclosure?) are beginning to be explored. That said, our knowledge is very much incomplete. One study analysed rejections at the USPTO due to the lack of disclosure (written enablement). The study found that reluctance to provide more information resulted in narrower claims, indicating that examiners sometimes detect imperfect disclosure.[361] The study also found that reluctance to provide disclosure resulted in fewer citations of the patent, suggesting the invention is less relevant to follow-on innovators.[362] However, researchers have yet to analyse how often imperfect disclosure is *undetected* by examiners, whether third parties can get the omitted information from elsewhere and, perhaps more importantly, even if disclosure meets the legislative requirements, how often can skilled people practice the invention.

a) Disclosure, the replicability crisis and negative data

In science, the replicability crisis refers to the idea that nearly 90% of studies in reputable, peer-reviewed journals are *not* replicable, in the sense that follow-on scientists cannot reproduce the results.[363] While the concept of a 'replicability crisis' originated in scientific research, it has now made its way into patent scholarship.

Patent specifications often contain experimental data, which patentees use to justify their claims. One study has begun empirically to examine the replicability of data in patent specifications. The researcher randomly analysed 500 medical patents with pre-clinical data, scoring their methods against widely accepted methodological criteria.[364] Studies have shown that poor methodologies are strongly linked to low replicability, and the study found that the

[359] Fromer (2009), 560-562.
[360] Lisa Larrimore Ouellette, 'Who Reads Patents?' (2017) 35 Nature Biotechnology 421, 421.
[361] Zaby et al (2022), 18-19.
[362] Zaby et al (2022), 18-19.
[363] See e.g., C. Glenn Begley and Lee M. Ellis, 'Raise Standards for Pre-clinical Cancer Research' (2012) 483 Nature 531, 532.
[364] Janet Freilich, 'The Replicability Crisis in Patent Law' (2020) 95 Indiana Law Journal 431, 448–455.

methodological quality of patent specifications was *worse* than in scientific papers, indicating that the replicability crisis is *worse* in patents than in scientific journals.[365]

The replicability issues for patented inventions overlap with various trade secret issues. One critical problem concerns *negative* data (i.e., information that something does *not* work; for example, that a drug does *not* treat a disease). If a claimed invention does *not* work, the negative data showing the invention does not work will unlikely be published. This negative data can be kept secret and protected as a trade secret, depriving the public of valuable information. However, if it is true that up to 90% of patented inventions are *not* replicable and do *not* work, society might want to reconsider whether its corpus of patent knowledge is actually a wasteland of bad ideas. Information on which patents do not work would be helpful for follow-on innovators and academic researchers.

That said, the magnitude of the negative effects created by the replicability crisis in patents has not been empirically examined. It is possible that most of the negative effects that overlap with trade secrets are minimised because holders of inventions that do not work abandon their rights (through non-renewal of the patent) or let their rights expire, and scientists that do read patent specifications complement their reading with various other sources. It should also be noted that the evidence of the replicability crisis in patent law is only beginning to be understood.

IX. Summary and issues for further consideration

This Discussion Paper has focused on a previously under-explored area – the interplay of patents and trade secrets in relation to medical technologies. It has brought together a range of literature in order to explore how patents and trade secrets affect innovation of different medical technologies, including drugs (both for small molecules and biologics), drug manufacturing, diagnostics, surgical methods, medical devices and medical machine learning applications. Importantly, innovation cycles and the impact of patents and trade secrets on those cycles may differ depending on the type of medical technology. This Paper has also considered the ways in which patents and trade secrets interact to affect medical innovation, access to and use of medical technologies and the knowledge commons about medical technologies.

Further, we have seen that there is generally agreement on the main rationales for patents and trade secrets protection. These tend to focus on incentives to disclose and innovate, in the case of patents, and incentives to innovate, to reduce expenditure on security mechanisms and to share information, in the case of trade secrets. However, the extent to which these rationales are borne out in practice is a complex matter and needs: i) to take into account the particular type of medical technology; ii) to acknowledge that patents and trade secrets are often used in a complementary fashion rather than as substitutes; and iii) more empirical investigation and evidence in many cases. Any future research should also include the interplay between patents, trade secrets *and* regulatory protection when considering incentives for, access to, and the 'knowledge commons' of, medical technologies.

[365] Freilich (2020), 434.

In summary, this Paper suggests that it would be fruitful to conduct further investigation and research on the following topics:

i. The desirability and impact of increased disclosure of clinical trial data and protocols for drugs in the case of both small molecules/generics and biologics/biosimilars;
ii. Whether there are sufficient incentives for medical diagnostics, surgical treatment methods, and innovations in drug manufacturing;
iii. The extent to which drug prices are kept secret, the impacts that may arise as a result of this practice and how to address them;
iv. The extent to which datasets that are generated as a follow on to patented medical diagnostics and medical ML applications are protected by trade secrets and whether this impacts follow-on innovation;
v. Tracking the extent to which medical machine learning applications are protected by patents and trade secrets and whether sufficient incentives exist for innovation in this new area of technology;
vi. On the desirability, nature and form of compelled disclosure of trade secrets by regulatory authorities and the role that regulatory protection may play alongside such disclosure, including in instances of public health emergencies, such as the Covid-19 pandemic;
vii. Whether the disclosure mechanisms under patent law can be improved in relation to certain kinds of medical technologies (e.g., biologics and medical ML inventions).

In addition to the above areas, there are matters of International IP Law that are worthy of further consideration. There is scope for deeper analysis of the situations in which Article 39 TRIPS permits compelled disclosure of trade secrets and state sharing of regulatory data, particularly in the case of public health emergencies. While this issue has had important, early consideration by some scholars,[366] there is the opportunity for more debate and discussion, including an assessment of the effectiveness of state practices (e.g., in Malaysia, Chile and Colombia) of removing market or data exclusivities during public health emergencies.

[366] See Levine & Sarnoff (2022); Gurgula & McDonagh (2023).

APPENDIX

A Questionnaire and Interview-based Snapshot Assessment of Practical Interplays of Patent and Trade Secret Systems for Certain Medical Device and Technology Innovators from the Federative Republic of Brazil during the Pandemic Caused by the SARS-CoV-2 virus

Benny Spiewak, Partner, SPLAW Advogados

Abstract

The extraordinary context of the pandemic influenced aspects of the decision-making process of specific innovative research centers, which repurposed pre-existing confidential information into patent subject matter. Implementing a particular fast-track patent system for COVID-19-related innovation has also influenced their decision to file patent applications and disclose their invention rather than maintain their secrecy.

I. Foreword

1. Strategic and systematic management of a medical device and technology company's intellectual assets enhances its competitive advantage[1], protects its innovations, and maximizes its value. Effective intellectual asset management can be critical, as companies increasingly rely on their intangible assets to gain a competitive edge and drive innovation in the highly competitive market of healthcare products.

2. Critical aspects of intellectual asset management include[2] (a) understanding and cataloging intellectual assets; (b) taking necessary measures to safeguard intellectual property rights ("IP") through protection systems, e.g., patents or trade secrets; (c) assessing the value of intellectual assets and developing strategies to leverage them to generate revenue; (d) encouraging and supporting research and development efforts; (e) establishing collaborations to enhance the company's IP portfolio or access external innovations; (f) identifying and managing risks associated with intellectual assets, such as loss of trade secrets; (g) aligning the management of intellectual assets with the overall business strategy; and (h) raising awareness about the importance of intellectual assets, their protection, and the role they play in the company's success.

3. Specifically, in the context of the IP system, patents and trade secrets interact in a dynamic set of situations experienced by innovators in the medical products and technology sectors (jointly the "*Sector*")[3], as the two mechanisms offer relatable protection for their associated organically intangible nature. Concept, structure, overall goals, enforceability, costs, and length of protection are components considered by innovators willing to choose a path for protection. Innovators, including those from the Sector, experience similar decision-making processes. Patents and trade secrets may allow companies to protect and leverage their IP throughout the research, development, regulatory, and commercialization processes.

4. Whether trade secrets and patents are seen as overlapping or complementary depends on the specific situation and the type of innovation or IP setting involved. Sector-focused businesses often employ a combination of IP strategies, using patents for inventions and trade secrets for others to create a comprehensive and robust IP portfolio.

5. Sector-based innovators strategically determine the balance between patents and trade secrets based on factors such as the level of innovation, the potential for reverse engineering, and market competition.

6. At times, they may opt for one route instead of the other due to the maturity of their innovation. At others, they will follow a specific path due to the lack of options, e.g., strategic information may need to remain secret as it could not meet patentability requirements.

7. Hypothetically, would extraordinary contexts affect such logic or the structure upon which Sector-based innovators decide whether to seek the patent or trade secret route? If so, how does an unexpected scenario influence their decision-making process?

1 J. Open Innov. Technol. Mark. Complex. 2022, 8(3), 163; https://doi.org/10.3390/joitmc8030163.
2 Bismuth, A. (2006), "Intellectual Assets and Value Creation, Implications for Corporate Reporting," OECD, Paris.
3 Caenegem, W. V. (2014). Trade secrets and intellectual property: Breach of confidence, misappropriation, and unfair competition. Kluwer Law International; Cao, Y. and Zhao, L., 2011. Intellectual property management model in enterprises: a technology life cycle perspective. International Journal of Innovation and Technology Management, 8(02), pp.253-272.

I.1. Justification

8. While attempting to address such questions, the old saying, "*A crisis is an opportunity to ride a dangerous wind,*" came to mind. Such a legendary proverb may have been tested during the coronavirus disease pandemic ("*COVID-19*"). I noted how the extraordinary context and *momentum* of COVID-19 led Sector innovators to swiftly review their ongoing innovation protection strategies vis a vis the renewed context, opportunities, and structural tools.

9. Empirically, I noted that innovative Sector-based enterprises actively managed and reviewed their innovation portfolios and strategies to tackle COVID-19 and consider its inherent marketing opportunity. Checking plans, systems, and pipelines identified initiatives more likely to succeed and become opportunities to face gigantic challenges.

10. COVID-19 has highlighted the role of a structured IP system, as it has facilitated battling COVID-19-related challenges[4]. It has also *tested* how innovative Sector companies decided between the secrecy and the patentability systems.

11. I took part in and supported several decision-making processes. I have sometimes drafted and implemented mechanisms leading to decisions and formulated the questions supporting such choices. Ultimately, I guided decision-makers and stakeholders in the Sector while they were selecting how to protect their innovation.

12. Based on professional experience, I suggested that Brazil-based agents of the Sector have relied on existing innovative expertise to repurpose their offerings by benefiting from otherwise confidential information and trade secrets to accelerate the development of healthcare-oriented products and solutions, such as diagnostic, sanitation, and ventilation innovation. Also, I have noted that Brazilian innovation centers and innovators *swiftly* changed their IP-driven goals and have enjoyed changes rapidly made to the Brazilian IP structure, i.e., COVID-19-dedicated fast-track.

13. Nonetheless, a questionnaire-based snapshot assessment was designed to openly inquire about the standpoints of individual innovators effectively taking part in the decision-making processes leading to the route toward protecting their Sector-related innovation, i.e., whether to follow the secrecy or the patentability systems. Such questions considered in the questionnaire were generally presented during my professional liaisons with like-minded decision-making individuals and based on which patentability or secrecy routes were elected.

II. Innovation in the Medical Device and Technology Sector

14. Sector-based innovation plays a vital role in healthcare systems worldwide, supporting medical professionals in delivering high-quality patient care, improving patient outcomes, and enhancing the overall healthcare experience. The Sector is diverse, including large multinational corporations, mid-sized enterprises, small startups, individual innovators, and research centers.

4 Hilty, Reto and Batista, Pedro Henrique D., and Carls, Suelen and Kim, Daria and Lamping, Matthias and Slowinski, Peter R., COVID-19, and the Role of Intellectual Property: Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021 (May 7, 2021). Max Planck Institute for Innovation & Competition Research Paper No. 21-13, Available at SSRN: https://ssrn.com/abstract=3841549 or http://dx.doi.org/10.2139/ssrn.3841549

15. The Sector generally refers to the industry involved in designing, developing, manufacturing, and distributing a wide range of medical devices and technology used in healthcare. Medical devices are instruments, apparatuses, machines, or implants intended to diagnose, monitor, treat, or alleviate medical conditions, injuries, or disabilities. They play a crucial role in modern healthcare, supporting medical professionals in delivering accurate diagnoses and effective treatments and enhancing patients' quality of life. That was true during COVID-19.

16. Medical devices and technology encompass a broad spectrum of products and solutions, including but not limited to diagnostic equipment, i.e., devices used for identifying medical conditions and diseases; surgical instruments, i.e., Instruments used during surgical procedures, implantable devices, i.e., devices designed to be implanted into the body to provide support, monitoring, and life support equipment, i.e., devices used for continuous patient monitoring and life support, assistive devices, i.e., devices designed to assist individuals with disabilities or limitations, in-vitro diagnostic devices or IVDs, i.e., devices used to analyze biological samples, and software (SaMD) intended to be used for medical purposes that meet the definition of a medical device according to regulatory authorities.

17. Medical devices and technology-related innovations must meet strict safety and performance standards to ensure they are safe and effective in healthcare settings. Regulatory agencies, such as the U.S. Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA) in the European Union, and the National Health Surveillance Agency (ANVISA) in Brazil, oversee medical device approval and post-market surveillance.

II.1. Innovation Cycle

18. From a practical standpoint – and while variations may occur depending on the specific innovation or company, the primary innovation cycle in the Sector somewhat mirrors those of other innovation-intensive segments and can be outlined[5] as follows:

a. **Identifying Needs and Opportunities:** The first step in the innovation cycle is identifying needs and opportunities for new medical devices. This involves gathering insights from healthcare professionals, patients, market research, and technological advancements to understand the unmet needs and potential opportunities.

b. **Conceptualization and Ideation:** In this stage, ideas and concepts for new medical devices are generated based on the identified needs and opportunities. Cross-functional teams, including engineers, designers, clinicians, and business experts, brainstorm and collaborate to develop potential solutions.

5 Guerra-Bretaña RM, Flórez-Rendón AL. Impact of regulations on innovation in the field of medical devices. Res Biomed Eng. 2018. DOI: 10.1590/2446-4740.180054; Bonutti PM, Seyler TM, Bianco PD, Ulrich SD, Mont MA. Inventing in orthopedics: from idea to marketed device. J Bone Joint Surg Am. 2008; 90(6):1385-92. http://dx.doi.org/10.2106/JBJS.G.01407. PMid:18519334.; European Commission. Working Group on new and emerging technologies in medical devices. Report on nanotechnology to the medical devices expert group, Findings, and recommendations [Internet]. Brussels: European Commission; 2007a [cited 2018 Feb 21]. Available from: http://ec.europa.eu/enterprise/newsroom/cf/_getdocument.cfm?doc_id=4865.

c. **Feasibility Assessment:** The ideas generated in the previous stage are evaluated for their technical feasibility, regulatory compliance, market potential, and economic viability. Prototypes or proof-of-concept models may be developed to assess the practicality and functionality of the proposed medical device.

d. **Design and Development:** Once a feasible concept is selected, the actual design and development of the medical device begin. This stage involves detailed engineering, prototyping, and iterative testing to refine the design and ensure it meets safety, performance, and regulatory requirements.

e. **Regulatory Compliance and Clinical Trials:** Medical devices must comply with various regulatory standards and undergo clinical testing to demonstrate their safety and effectiveness. This stage involves obtaining regulatory approvals (e.g., FDA or ANVISA clearance or CE marking) and – at times - conducting clinical trials to gather data on the device's performance and safety in real-world scenarios.

f. **Manufacturing and Production:** The medical device enters the manufacturing and production phase after successful regulatory approval and clinical validation. This involves scaling up the production process to meet market demand while maintaining consistent quality and adherence to regulatory standards.

g. **Market Launch and Commercialization:** The medical device is officially launched into the market, and commercialization efforts begin. Marketing, sales, and distribution strategies are employed to promote and sell the device to healthcare providers, hospitals, and other end-users.

h. **Post-Market Surveillance and Feedback:** Once the medical device is in use, post-market surveillance and continuous monitoring become crucial. Feedback from users and clinical data are collected to identify potential issues, safety concerns, or areas for improvement. This information helps refine the device, address shortcomings, and ensure ongoing regulatory compliance.

i. **Continuous Improvement and Innovation:** The innovation cycle does not end with the product launch. Medical device companies continually seek opportunities for improvement and innovation based on user feedback, technological advancements, and changing market needs. This feedback loop feeds into the next round of creativity and refinement, restarting the innovation cycle.

III. Patents and Trade Secrets: A view of their interplay in the Sector

19. Trade secrets and patents are two distinct forms of IP protection that may foster innovation and encourage business growth in medical devices and technology. While they serve different purposes, there are interplays and considerations that businesses need to consider when deciding how to protect their valuable inventions, technologies, and innovations.

20. From a practical standpoint, medical device and technology enterprises may decide to keep relevant information undisclosed until a further decision is confirmed regarding its practical use, e.g., will it be sold to a third party, continuously used as a trade secret, or associated with a patent application? The path to choose between the protection mechanism requires an assessment of items concerning the IP protection item itself, including those discussed herein below, i.e., concept, protection mechanisms, procedures, and periods.

III.1. A Brief Conceptualization

21. A patent is a government-granted exclusive right that gives an inventor the authority to exclude others from making, using, selling, or importing an invention for a limited period, i.e., 20 years from the filing date in Brazil. Patents require disclosing the invention's details in a publicly available patent document.

22. A trade secret is confidential and proprietary information that provides a competitive advantage to its owner. Unlike patents, trade secrets are not publicly disclosed. They can include formulas, manufacturing processes, customer information, or confidential business information.

23. To obtain patent protection, inventors must disclose the details of their invention to the patent office and the public. This promotes the spread of knowledge and helps others build upon existing innovations after the patent expires. Trade secrets rely on maintaining confidentiality. The owner must take reasonable measures to keep the information secret (e.g., non-disclosure agreements, restricted access, and physical safeguards). Once the secret is exposed or no longer confidential, protection is lost.

24. The maximum term for a patent is typically 20 years from the filing date. After this period, the invention enters the public domain, and others can freely use it. Trade secrets can provide indefinite protection, i.e., if the information remains a secret and the owner takes appropriate steps to protect it, it can be maintained indefinitely.

25. Generally, patents give the owner a monopoly over the patented invention, preventing others from making, using, or selling the claimed invention without permission. Trade secret law prevents unauthorized acquisition, use, or disclosure of confidential information. However, it does not stop others from independently developing and using the same information. The kind and degree of protection offered by the trade secret and the patent differ significantly, impacting inventors' decision-making.

26. Inventions must fulfill the criteria of novelty, usefulness, and non-obviousness to qualify for patent protection. The level of trade secret protection is less stringent. To meet the requirements for protection under general trade secret legislation, an innovation must (i) not be known or readily accessible, (ii) be protected from disclosure, and (iii) confer a distinct competitive advantage onto its proprietor.

27. Two types of patents are protected under Brazilian law: patents of invention ("*PI*") and utility model ("*UM*"). A PI is granted when an invention is novel, involves an inventive step, and is capable of industrial application. A UM may be granted when the object has an industrial use, presents a new shape or layout, and involves an inventive act that results in functional improvement in use or manufacture.

28. Trade secrets are protected under Brazilian law regardless of any formality or registration, and the term of protection is unlimited, lasting as long as confidentiality. Confidentiality of such information may be perpetual if its holder manages to keep it from disclosure.

29. Although Brazilian law does not establish any specific requirements for the protection of trade secrets, Brazilian courts usually apply the list of Article 39.2 of the TRIPS Agreement: a) the information must be secret; (b) the data must be valuable; and (c) the holder must take reasonable precautions to keep the information secret.

30. In the context of trade secret protection in medical devices and technology, the extent to which inventors can effectively control the dissemination of their technological information determines the level of disclosure of their innovation. Once the innovative content is disclosed in the wake of patenting procedures, it will eventually become usable by third parties once the term of protection expires or if the patentability is revealed as impracticable for its failure to meet statutory requirements.

III.2. Fast-track of COVID-19-related patent applications

31. The National Institute of Industrial Property ("*INPI*"), the body responsible for issuing patents in Brazil, developed a priority or fast-track system for patent proceedings linked to innovations that may be utilized against COVID-19 to encourage the development and licensing of innovative technology. This was done to combat the effects of COVID-19. INPI has set the "COVID-19 fast-track" on April 3, 2020, via Ruling 149. Following amendments, the program remained valid until December 31, 2022.

32. Before "COVID-19-related fast-track", INPI implemented nine (9) other fast-track mechanisms to expedite the prosecution of patent applications, including those (a) filed by senior inventors, (b) sub judice patent applications, i.e., ongoing litigation concerning the likelihood of infringement, (c) filed in the wake of patent prosecution highways, (d) environmentally-sound-oriented patents, i.e., green patents, and (e) claiming protection for innovative treatments aimed at battling AIDS, cancer or rare diseases.

33. Impacts[6] of the fast-track system generally considered the time elapsed between the application filing and its material review by examiners of the INPI. The INPI successfully responded to the public health emergency by awarding patents on an average of five point three (5.3) months following the fast-track request. This period is much shorter than the required time for typical procedures, which may be up to ten times higher[7].

III.3. The *standard* interplay between patents and trade secrets

34. The decision to protect innovations through trade secrets or patents depends on the nature of the invention, business goals, budget, and the level of protection desired. Companies must carefully balance the benefits of exclusivity and disclosure when choosing between these two forms of intellectual property protection.

6 Pessôa RF, Corrêa EG, Vasconcellos AG. Concessão rápida de patentes para enfrentamento da COVID-19 no Brasil. Rev Panam Salud Publica. 2022;46: e149. https://doi.org/10.26633/RPSP.2022.149

7 Krafuni, Simone. August 2020. Citing References. [online]. Available from: https://www.correiobraziliense.com.br/economia/2020/08/4872191-a-dificil-arte-de-ser-inventor-no-pais.html [Accessed 20 September 2023].

35. Given COVID-19, Sector companies considered such decision-making components in conjunction with the extraordinary context of the pandemic[8] whenever evaluating trade-offs, comparing alternatives, and ensuring that the chosen course of action delivers the best possible outcome.

36. When deciding between trade secrets and patent protection, COVID-19 was a crucial component supporting the choice of the most appropriate strategy for protecting and exploiting innovative ideas, i.e., if not for the pressing challenges of COVID-19, Sector companies could have decided on other IP-protecting paths. While the decision-making process varies substantially, Sector innovators – like other innovators - generally consider the following components when assessing whether a Sector-focused innovation will be patented or kept under secrecy:

a. **Term of protection**: Opting for trade secret protection means the medical device or technology company may keep its innovation confidential indefinitely and potentially gain a competitive edge in the long run. For instance, a company from the Sector may decide to keep its strategic know-how associated with equipment maintenance and problem-solving confidential, albeit it could be a patentable process. Also, the diagnostic and image-based devices of the Sector are designed to operate for years, even decades, i.e., their anticipated operational lifespan may exceed the statutory term of patent protection.

b. **Risk of Disclosure**: One of the main risks with trade secrets is losing protection if the information is disclosed, which could have competitors catching up, e.g., it is practically and statutorily legal and possible that otherwise *secret* servicing processes, routines, algorithms, or operating mechanisms become known by an expert via observational or trial and error-type assessments.

c. **Cost and Complexity**: Obtaining and enforcing patents may be cost-sensitive and time-consuming. Sector companies may opt for trade secrets, assuming that the overall protection cost is inferior to that of patents. While it may prove true, ensuring secrecy requires substantial investment, training, and structure.

d. **Innovation Pace:** The patent system may not suit Sector segments with rapidly changing technologies, as patents can take years to be granted. This is relevant to the Sector, where solutions commonly combine hardware and software components. For instance, securing patent rights for software based on or connected to specific hardware configurations or workflow might be irrelevant. Such specifications or workflow will likely evolve when the patent is granted.

37. Sector innovators carefully assess each option when choosing between trade secrets and patents. As noted, factors to consider include the nature of the innovation, the competitive landscape, the industry's pace of innovation, potential risks of disclosure, enforcement capabilities, and the overall business strategy. Also, the short-term advantages, long-term benefits, risks, and potential impacts on innovation and competition should be added to the decision-making process.

8 Opportunity cost is a fundamental economic concept that refers to the value of the best alternative foregone when deciding. It summarizes the concept that when – for instance - a medical device or technology chooses one option, it will give up another option's potential benefits.

38. Will the *standard* interaction between patents and trade secrets change during extraordinary settings, i.e., COVID-19? Do specific Governmental-influenced changes to patent proceedings, e.g., fast-track, affect the patent or trade secret decision-making outcomes? To investigate such questions and test the hypothesis of I.1 above, a short questionnaire was sent to Sector stakeholders, including companies and research institutions. A round of online interviews followed the questionnaire.

IV. The Questionnaire

39. From June 12 to July 10, 2023, representatives of fifty-seven (57)[9] patent applicants were asked to participate in a questionnaire-based survey concerning their views on the interplay between patents and trade secrets in the Sector.

40. The targeted audience was comprised of the following fourteen (14) individuals:

a. Publicly identified by open databases as inventors, co-inventors, or representatives of patent applications exclusively filed during the initial period of the COVID-19-related fast-track, i.e., April 3, 2020, to December 31, 2022, and which claimed[10] expedited review under such system; and

b. Associated with, contracted, or employed by Brazilian research institutions (and their innovation centers) and enterprises *without* corporate associations with international enterprises, i.e., Brazilian subsidiaries of foreign enterprises, were excluded from participation.

41. Of the initially contacted audience, twenty-two (22) responded and have been given access to the online-based questionnaire. Fourteen (14) of such responders[11] answered the questionnaire. They confirmed that they were (i) familiar with the concepts of patents and trade secrets and (ii) directly involved in the decision to file the relevant patent application. Results follow:

IV.1. The online form

42. The online form contained the following wording and the questions. For all questions, the percentage data shown in their results are calculated on the basis of the total number of respondents of the online questionnaire (14 individuals).

9 Such an audience was selected out of one hundred (100) patent applications filed in the wake of the INPI´s COVID-19-related fast track. Please refer to Schedule I for additional information.

10 The international patent classification ("IPC") was considered while assessing relevant applications. The IPC was established by the Strasbourg Agreement of 1971. It sets a hierarchical system of language-independent symbols for classifying patents and utility models according to the different technical fields to which they belong. The system contains about 70,000 entries, classification symbols, and codes that can be allotted to patent documents. Symbols are arranged in a hierarchical, tree-like structure. At the highest level are the eight sections corresponding to broad technical fields. Divisions are subdivided into classes and then into more than 600 subclasses. Medical technologies patents relate to IPC classes A61 [B, C, D, F, G, H, J, L, M, N], which include instruments, implements, and processes for diagnostic, surgical, and person-identification purposes, including obstetrics, tools for cutting corns, vaccination instruments, finger-printing, psycho-physical tests; and H05G, which include essential electric elements, which cover all electric units and the general mechanical structure of apparatus and circuits, including the assembly of various crucial components into what is called printed circuits and also cover to a certain extent the manufacture of these elements. Classes and subclasses were considered for the current assessment.

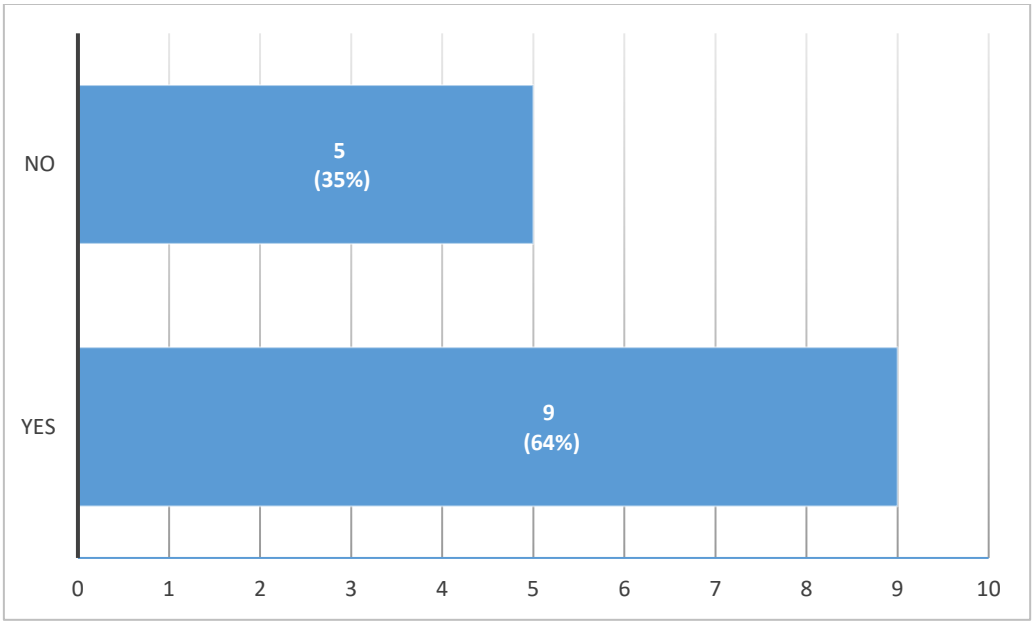
11 Eleven (11) of such interviewees asked for their identity to remain undisclosed, as they were uncertain as to the implications of their participation in the assessment. In the abundance of care, the essence of all interviewees will remain undisclosed.

Dear Participant,

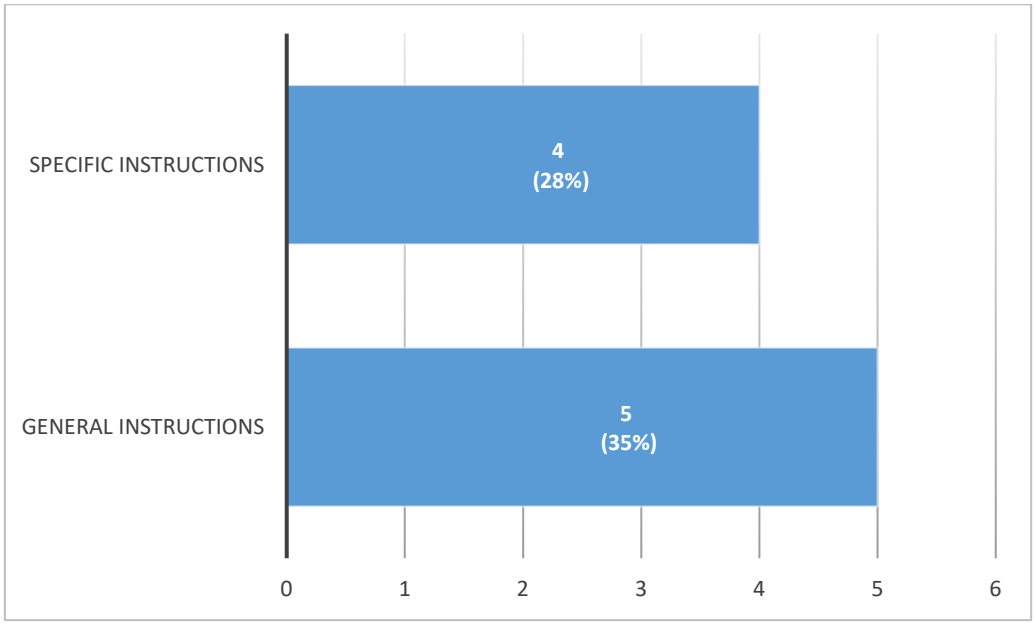
Thank you for participating in this short research. Addressing all questions should ask for 30 minutes of your time. As informed in the cover e-mail, your answers will help me assess how trade secrets and patents interplayed during the pandemic. You have been selected to participate because your identity is connected to the Brazilian patent application [].

Whenever discussing Intellectual Property protection mechanisms, innovative enterprises generally – but not necessarily or mandatorily - opt between filing a patent or keeping the information confidential and undisclosed. I am interested in learning how innovative centers like yours decided during the pandemic on the future of the creative knowledge associated with the application above. While choosing mechanisms may involve a comprehensive set of criteria, I want to understand if the pandemic has affected your decision-making process and associated extraordinary relevance. Based on such context:

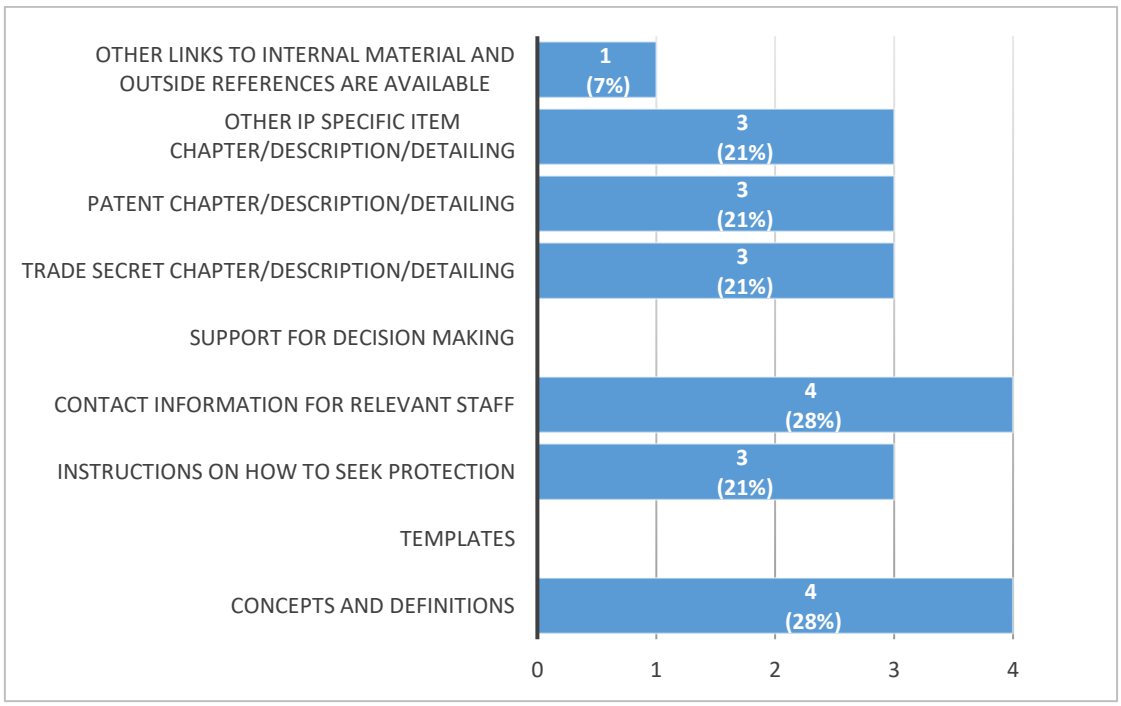
1. Does your center keep active IP-oriented guidelines, policies, or standard operation procedures?



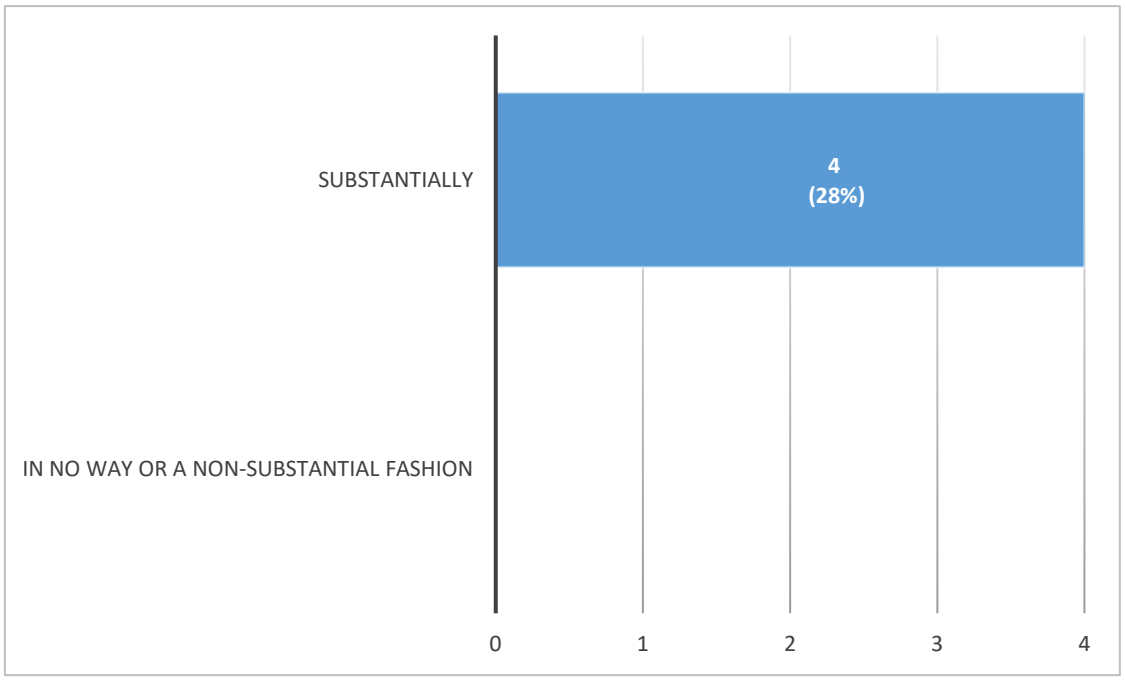
1.A. If question 1. was answered "Yes", which aspects are covered by the referenced instructions?



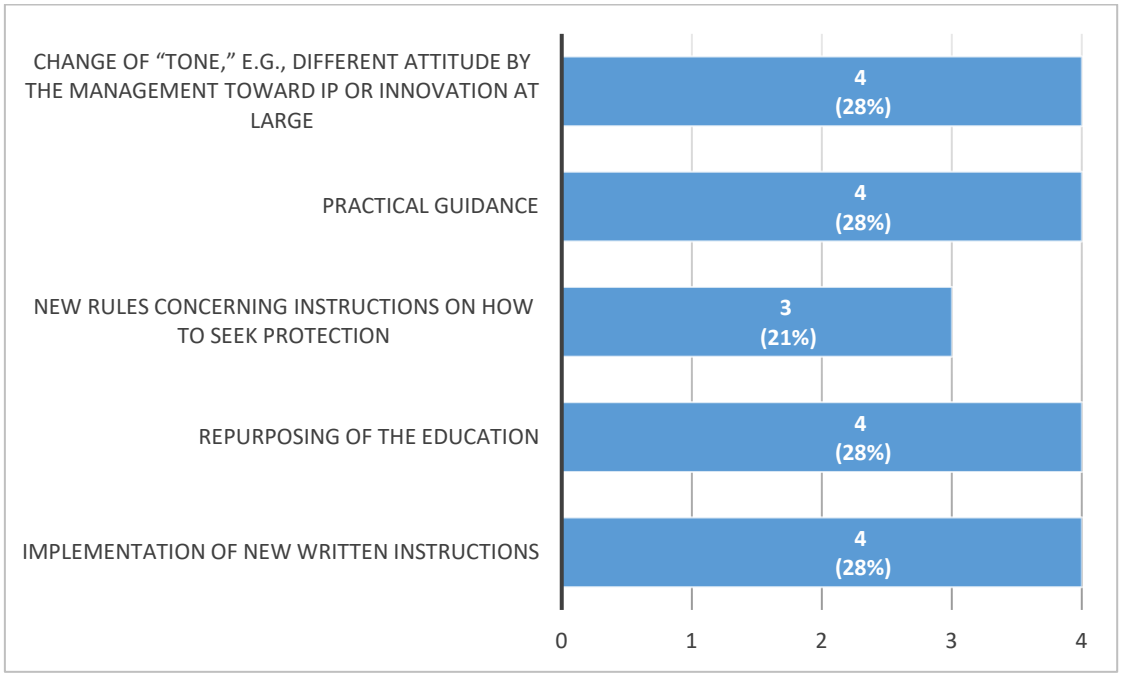
1.B. If specific instructions are provided, what elements are covered by such instructions?



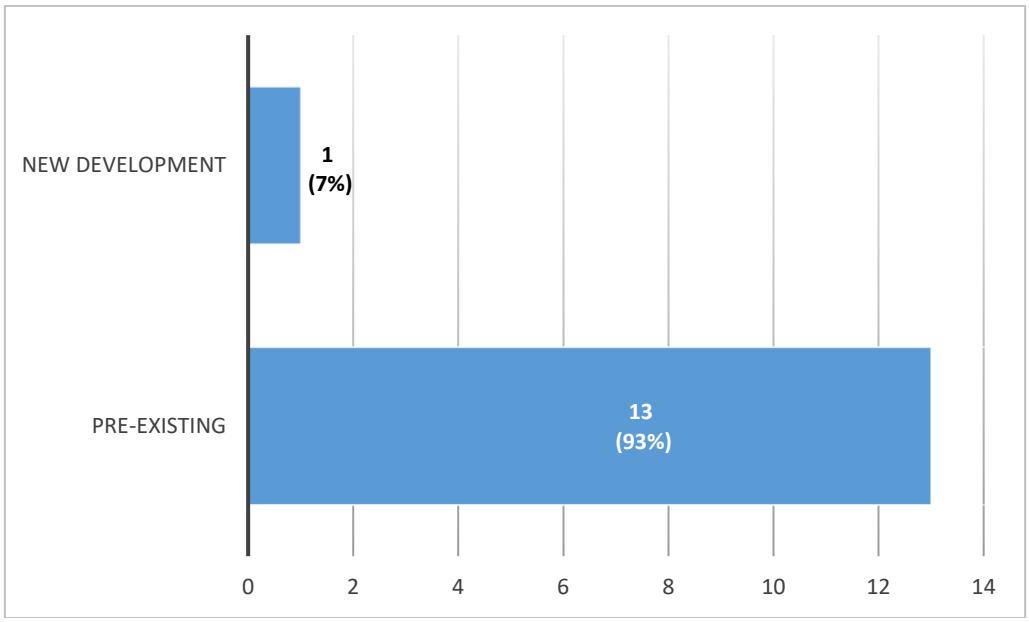
2. Did COVID-19 (associated context and aftermath) affect such instructions? You may select all applicable options.



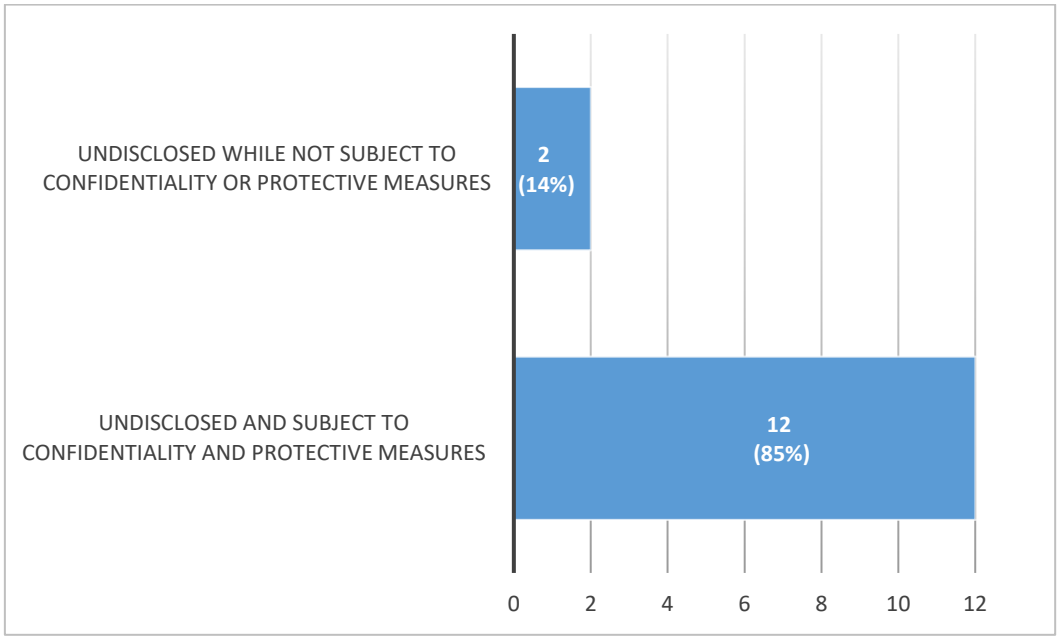
2.A. In what way did COVID-19 substantially affect the instructions? You may select all applicable options.



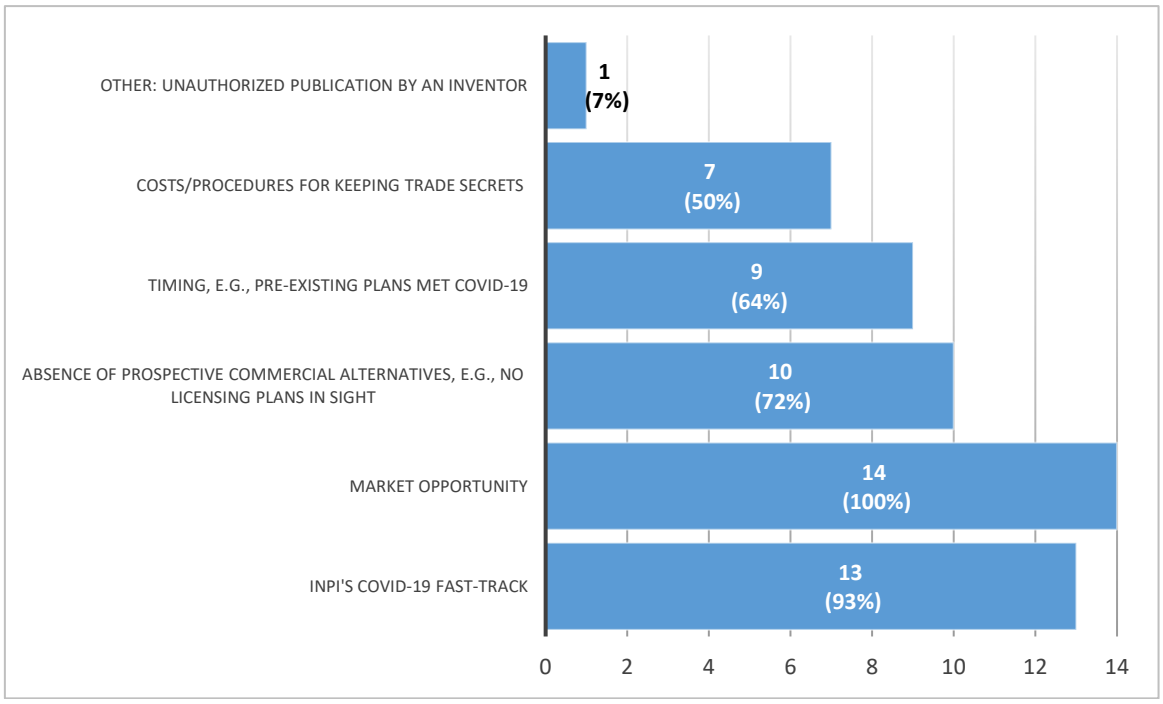
3. Was that patent application subject matter innovation based on pre-existing knowledge of your enterprise, or was it specifically developed/implemented because of COVID-19 (and associated context)?



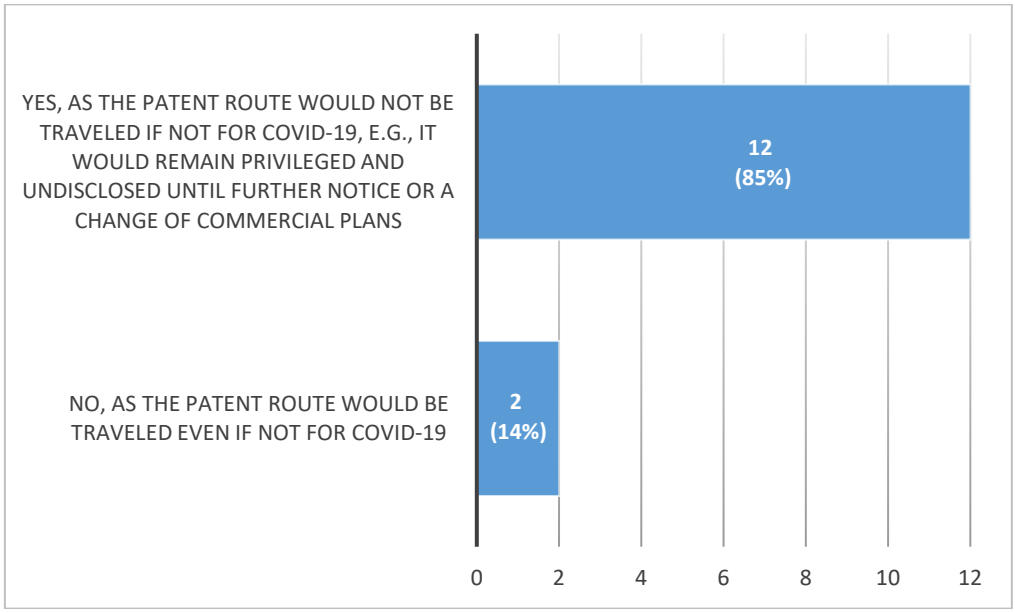
3.A. If you selected the "pre-existing knowledge" response previously, please inform us how you kept that information before associating it with a patent application.



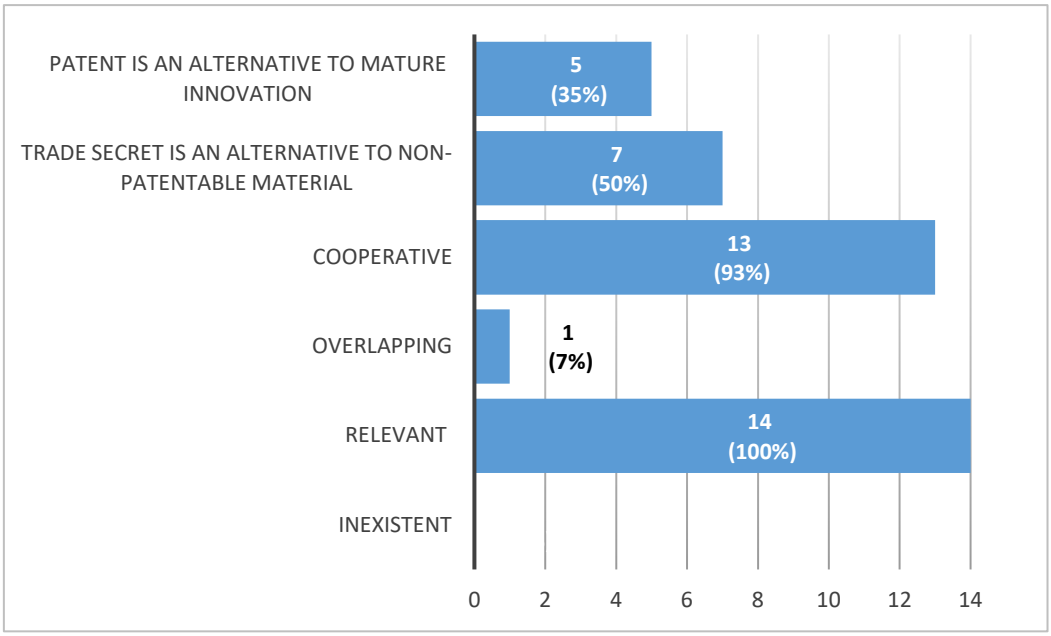
4. When deciding to file the application, which of the following components have you (and the team) considered? You may select all applicable options.



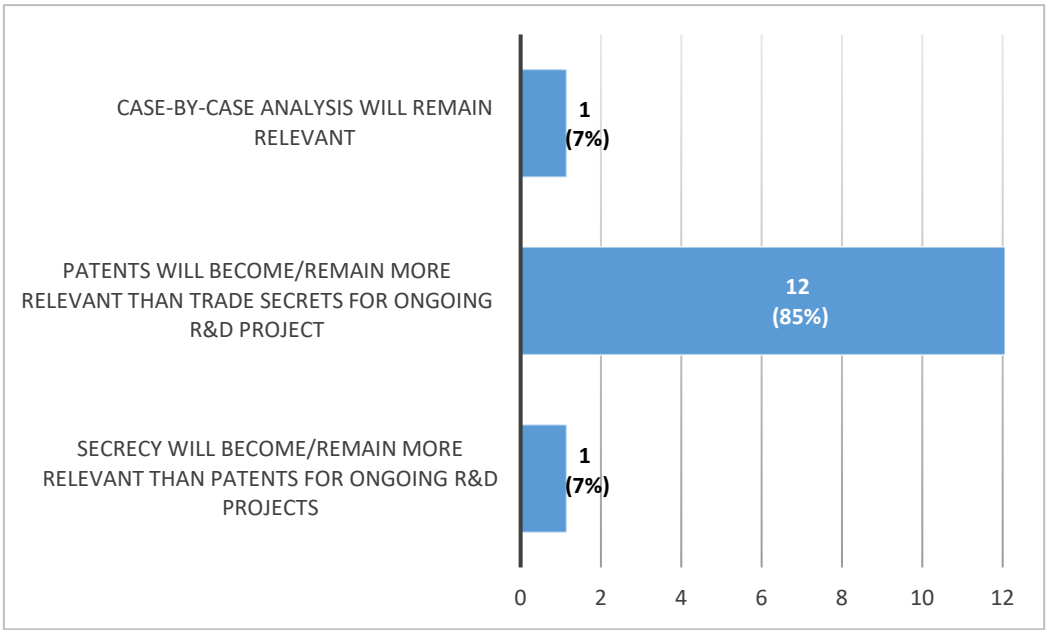
5. Did COVID-19 (and associated context) influence your decision to file a patent?



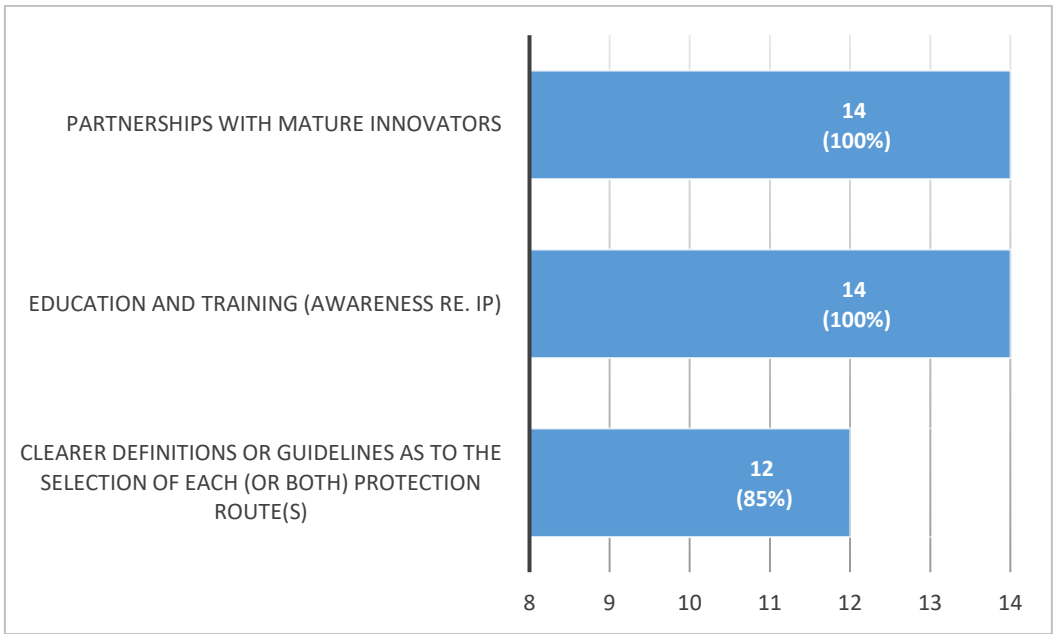
6. How do you perceive the current interaction between patents and trade secrets? You may select all applicable options.



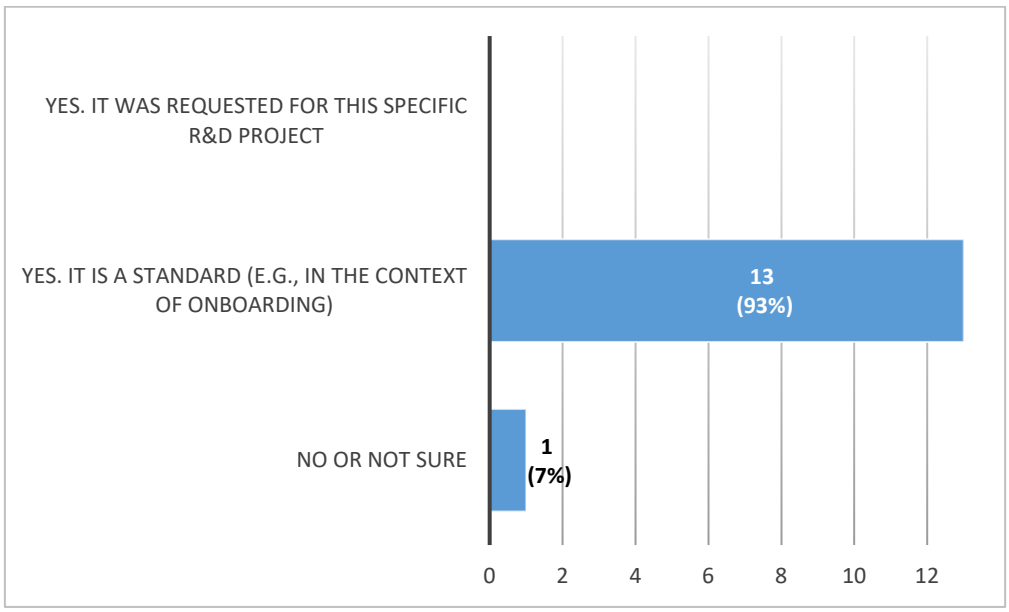
7. What are the anticipated interactions between patents and trade secrets at your center? You may select all applicable options.



8. If it were up to you, which of the following components would improve the interplay between patents and trade secrets at your enterprise? You may select all applicable options.



9. Do you currently have an active NDA signed with your enterprise?



IV.2. Consolidation of the results

43. The questionnaire's amplitude, features, and results may limit the ability to establish definitive solutions for the interplay between trade secrets and patents in the Sector.

44. Yet, a snapshot assessment of the results hints at the practical components and underlying rationale Sector research centers considered when assessing their options for protecting their innovation during COVID-19. The results of the questions above and the results of the post-questionnaire interview[12] demonstrate that:

a. Respectively, per answers to Q1, Q1A, and Q1B, IP-oriented guidelines, policies, or standard operating procedures ("instructions") apply for 64% of the respondents' research centers, and 28% have specific rather than broad instructions.

b. Per answers to Q1A and Q1B, (i) 28% of the respondents' research centers provided specific instructions that contained information about concepts and definitions and contact information for relevant staff; and (ii) 21% instructed on how to seek protection and contained specific chapters for patents and trade secrets. No respondent selected "*templates*" or "*support for decision-making*."

c. Per answers to Q2 and Q2A, COVID-19 affected existing instructions for 28% of the respondents. It led them to (i) implement new instructions and (ii) repurpose the education/training content and practical guidance, including as to how to seek protection. In addition, it changed their attitude towards managing IP or innovation.

d. Per answers to Q3 and Q3A, 93% of the relevant patent applications, i.e., filed by the research center to which the respondents are associated, considered pre-existing knowledge of the research center rather than resulting from *new* development in the wake of COVID-19. Per answers to Q3A, 85% of the respondents protected such pre-existing knowledge from disclosure through confidentiality or protective measures.

e. Per answers to Q4, 100% of the respondents informed that the decision to file their patent application considered the market opportunity associated with COVID-19[13]. The decision by the research centers was influenced by factors such as (i) INPI's COVID-19 fast track (93% of respondents), (ii) the inexistence of prospective commercial alternatives (72% of respondents[14]), (iii) the market opportunity of COVID-19 matched those of pre-existing plans

12 Seven (7) individual 20M phone calls were organized with certain respondents. Such individual respondents responded positively to question 10, which inquired about their willingness to receive a call to discuss the results. During the interaction, the respondents were asked for their opinions on the results of the questionnaire, rather than asking for inputs on their specific selections or responses, e.g., what are your thoughts and comments based on the information that 85% of the respondents highlighted the need for more precise definitions or guidelines on choosing between patents and trade secrets.

13 Per answer to Q5, 86% of respondents said COVID-19 influenced their research center´s decision to file the patent. Such figures may conflict with their response to Q4, when 100% of the respondents selected COVID-19 as a driver of their decision to file a patent.

14 The COVID-19-related market opportunity was construed as the option for the research centers to bring their innovations to the market, as they did not have mature or prospective alternatives, e.g., no licensing or offers to be considered.

to file the patent application (64% of respondents), (iv) costs or procedures for safeguarding trade secrets (50% of respondents), and (v) the unauthorized publication of the novel knowledge by an author (7% of the respondents).

f. Per answers to Q5, 85% of the respondents informed that COVID-19 (and associated context) influenced their decision to file a patent, i.e., seeking patent protection would not have occurred if not for COVID-19 and the relevant, innovative content would have remained privileged and undisclosed until further notice or a change of commercial plans.

g. Per answers to Q6[15], All or almost all respondents construed that the protection structure offered by patents and trade secrets are relevant (100%) and play cooperative roles (93%). 50% of the respondents perceive trade secret protection as an alternative to non-patentable innovation, and 35% perceive the patent system as the protection *option* for mature innovation.

h. Per answers to Q7, 85% of respondents anticipate that patents will become or remain more relevant than trade secrets for ongoing research and development projects.

i. Per answers to Q8, all respondents stressed the relevance of education and training to ensure IP awareness and partnerships with mature innovators to improve the interplay between patents and trade secrets at their institutions. 85% of the respondents highlighted the need for more precise definitions or guidelines on choosing between patents and trade secrets.

j. Per answers to Q9, 93% of the respondents signed a non-disclosure agreement regarding their relationship with their respective innovation centers.

IV.3. Interpretation of the results and practical areas of improvement

45. Albeit quantitively limited, the responses to the questionnaire demonstrated that the respondents were generally familiar with their respective research center's approach toward IP protection. The following summary considered their objective responses and seven (7) follow-up interviews:

a. The respondents indicated that their research centers would benefit from specific educational and training sessions, which could advance their "beyond basic" IP knowledge and drive stewardship-like initiatives, where trained in-house individuals promote and disseminate less academic and more practical IP-oriented information and support.

b. Within the Sector, training programs could consider formats such as round tables, problem-solving, and cases-based information sessions attended by Sector-dedicated IP representatives from the private and public sectors, including medical and research centers, representatives of the relevant

15 When translated into English, the questionnaire may have failed to reflect the caption of the boxes precisely. The results are presented "as is," while the context mirrors that of the correct and original form.

patent and trademark office, security information officers, personal patent, and trade secret practitioners. Nationwide initiatives could result from such sessions, continuously educating Sector IP experts.

c. IP-related decisions and procedures would gain from institutional instructions and general guidelines, facilitating and driving IP-related discussions and decision-making processes. *Toolkit*-like initiatives could help innovation and research centers by compiling and identifying definitions and suggesting communication workflow between IP individuals, e.g., research team, technology officers, patent professionals, and board of directors.

d. Respondents are associated with publicly funded research centers, which either have little financial or operational resources to develop customized policies or may have to observe convoluted bidding processes to select outside consultants or vendors, which may hinder their ability to effectively contract the drafting of or training on such guidelines and policies. A public and readily available guide could support such research centers, kick-start broader institutional IP awareness, and support Sector innovators in strengthening their internal IP decision-making processes. The WIPO E-Learning initiative may consider Sector-focused programs.

e. The fast track (and associated expedited review process) highlighted the relevance of the patent system and added to decision-making processes. A fast-track system offers expedited processing of patent applications, allowing applicants to receive a quicker decision on their patent requests than the standard examination timeline. The design provided several benefits to the patent system, applicants, and the overall innovation ecosystem, including offering a faster route to obtaining patent protection, which spurs innovation, likely accelerating the commercialization of innovative medical devices and technology, improving the efficiency of the patent system, and encouraging inventors to disclose inventions.

f. Creating mechanisms or frameworks that facilitate cooperation and the exchange of knowledge without jeopardizing trade secrets (or confidential information) could enhance innovation and accelerate the development of medical technologies. The key is establishing clear guidelines and utilizing legal agreements and technological solutions to collaborate while safeguarding sensitive information. Stakeholders should consider efficient and available tools to drive more productive sharing initiatives, such as segmenting collaborations, limiting disclosure, better defining project scope, and implementing scouting and secure collaboration platforms, which facilitate collaboration between inventors, researchers, and companies while maintaining controlled access to sensitive information; implementing data sharing protocols, sponsoring consortium and alliances alike, setting up ethical walls, and “must know basis”-type access systems. Sector-focused research centers flagged their need for cooperation with other stakeholders, including private enterprises.

g. Cooperation between industry stakeholders, research institutions, and regulatory bodies can facilitate best practices and knowledge exchange. Establishing standards and guidelines for protecting trade secrets and utilizing patents in collaborative research efforts could enhance innovation and streamline commercialization processes. Cooperation between industry stakeholders, research institutions, and regulatory bodies in the medical device industry requires a commitment to shared goals and open communication. Through these collaborations, innovation can thrive while ensuring patient safety, regulatory compliance, and the overall advancement of medical technology.

h. Public and private interests should explore partnerships to foster innovation and increase access to medical technologies. Such partnerships can help navigate the complexities of trade secrets and patents, ensuring that the benefits of research and innovation are accessible to the broader population.

i. Private and public parties can align their shared goals and priorities regarding medical technology innovation and access via training and education. These could include improving healthcare outcomes, addressing locally unmet medical needs, advancing research, and clearly defining each partner's roles and responsibilities within the partnership. Public-private initiatives may drive optimized results by exploring funding mechanisms and capacity-building exercises. Public-private partnerships for the Sector may organically result from capacity-building practices based on educational supporting rationale rather than purely commercially oriented.

V. Conclusion

46. The COVID-19 pandemic has profoundly impacted how innovators in the Sector research centers approach intellectual property (IP) protection, leading them to carefully consider the interplay between patents and trade secrets. The pandemic-induced changes in IP strategies have prompted a reevaluation of existing IP structures and decision-making processes, offering opportunities for improving internal IP guidelines, policies, training, and collaborations with other stakeholders.

47. The INPI's fast-track program during the pandemic significantly accelerated the patent prosecution process in Brazil, encouraging inventors to rethink their IP protection strategies and promoting a culture of disclosure among Brazilian research centers. This shift in the IP landscape may have permanently altered how Sector innovators in Brazil view and approach IP protection. As innovators and research centers adapt to these changes, the future of IP protection in the Brazilian Sector ecosystem appears promising and ripe for continued growth and development.

48. Sector innovators recognize patents and trade secrets as complementary and mutually supportive elements of IP protection, with many previously confidential innovations eventually becoming patent applications. Yet, there is space for enhanced systems use, and real-life-based training programs can further advance research agendas and capacity-building within Sector research centers.

49. Collaboration between private and public sectors can lead to transformative programs, including developing high-quality Sector-focused IP guidelines and decision-making workflows and establishing public-private partnerships for locally relevant medical technology. Educational programs emphasizing Sector-focused content, procedures, and policies can enhance the IP literacy of crucial individuals within Sector innovators and the associated research centers.

50. Questionnaires, interview-based assessments, and real-life experiences generally serve different purposes in research and evaluation. The choice between them depends on the research objectives, sample size, available resources, and the need for structured or contextual data. Combining both methods may have provided a comprehensive and aligned understanding of the interplay of patents and trade secrets and the improvement areas and activities “real-life” Sector innovators see as relevant.

SCHEDULE I

The INPI makes available an online tool that generates Portuguese-written data and figures relating to patent applications. For the questionnaire and associated interviews, I have programmed the tool only to identify patent applications (a) filed with and initially reviewed by the INPI between April 3, 2020, and December 31, 2022, i.e., the initial and final dates of the first phase of INPI's COVID-19-dedicated fast track; and (b) that claimed patent prosecution under the INPI's COVID-19-dedicated fast track. The image generated by the INPI tool follows below.

While one hundred (100) patent applications were identified, the contact data of fifty-seven (57) applicants, inventors, or co-inventors was readily available. Fourteen (14) applicants, inventors, or co-inventors: (a) responded timely to the questionnaire; (b) were associated with, contracted, or employed by Brazilian research institutions (and their innovation centers); and (c) confirmed that they were (i) familiar with the concepts of patents and trade secrets and (ii) directly involved in the decision to file the relevant patent application.