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Original Article

An empirical study of large, human biobanks: intellectual property policies and financial conditions for access

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ABSTRACT

Biobanks are repositories that collect, store and distribute large quantities of biological samples and associated data (collectively called biobank 'material'). Although biobanks have different modes of operation, all face a variety of similar challenges. Some of these challenges, such as donor consent and privacy, have been rigorously debated, but comparatively less attention has been paid to biobanks' intellectual property (IP) practices. IP rights (particularly patents) are integral to the translation of research into clinically relevant outcomes and, therefore, are key features in the business models of many biobanks. As a foundation for such research, commentators have identified five IP clauses of interest: (i) non-obstruction clauses; (ii) march-in clauses; (iii) grant-back clauses; (iv) return-of-results clauses and (v) reach-through clauses (also commonly called 'reach-through rights'). In the limited literature that discusses the five clauses, commentators have largely debated their advantages and disadvantages in the abstract. The IP terms that biobanks *actually* use have not been empirically examined, apart from some small case studies. In particular, no industry-wide evidence exists on three points of biobanks' IP practice: (i) if and how biobanks implement

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these five types of IP clauses, (ii) whether any norms or standards have emerged, and (iii) whether the norms and standards align with commentators' recommendations for using the five IP clauses. To address these three gaps, the authors conducted a systematic, global survey of the IP clauses used by large, human biobanks. The results indicate that biobanks draft bespoke policies to meet their own needs, and probably do so without knowledge of the gamut of IP terms available. This study also revealed that, in general, biobanks are using IP terms differently from the advice of the commentators. On reviewing the differences, we encourage the use of march-in and grant-back clauses, discourage biobanks from using redundant non-obstruction clauses, and call for more research on return-of-results clauses. We also encourage the use of reach-through clauses to claim royalties (not IP), but only in limited circumstances; for example, where user access fees do not cover a biobanks' operational costs.

KEYWORDS: biobanks, intellectual property, grant-back, licensing, march-in, reach-through

I. INTRODUCTION

Biobanks are repositories that collect, store, and distribute large quantities of biological samples and associated data (collectively called biobank 'material').[1] By allowing third parties to use their contents, biobanks play an important role in facilitating innovation. They help scientists researching basic biological questions, as well as those translating breakthroughs into new products.[2] Often established with public seed funding,[3] biobanks have proliferated across the world with a wide variety of technical arrangements, access policies, disease foci, and populations.[4]

Although biobanks have different modes of operation, all face a variety of similar challenges. Some of these challenges, such as donor consent[5] and privacy,[6] have been rigorously debated, but comparatively less attention has been paid to biobanks' intellectual property (IP) practices.[7] IP rights (particularly patents) are integral to the translation of research into clinically relevant outcomes and, therefore, are key features

1 Yvonne G. De Souza & John S. Greenspan, *Biobanking Past, Present and Future: Responsibilities and Benefits*, 27 AIDS 303 (2013).

2 Johnathon E. Liddicoat & Kathleen Liddell, *Open Innovation with Large Bioresources: Goals, Challenges and Proposals*, University of Cambridge Faculty of Law Research Paper No. 6/2017, 1, 4 (2017); W Nicholson Price II, *Biobanks as Innovation Infrastructure for Translational Medicine*, in Global Genes, Local Concerns: Legal, Ethical and Scientific Challenges in Biobanking 42 (Timo Minssen, Janne R. Hermann & Jens Schovso eds., 2019).

3 Don Chalmers et al., *Has the Biobank Bubble Burst? Withstanding the Challenges for Sustainable Biobanking in the Digital Era*, 17 BMC Med Ethics 39, 1, 2 (2016).

4 Ma'n H. Zawati & Michael Lang, *Biobank Donors and the Concept of Benefit: Time for Reciprocity*, 4 Journal of Law and the Biosciences 371, 372 (2017).

5 E. A. Whitley, N. Kanellopoulou & J. Kaye, *Consent and Research Governance in Biobanks: Evidence from Focus Groups with Medical Researchers*, 15 PHG 232–242 (2012).

6 Mark A. Rothstein, Bartha Maria Knoppers & Heather L. Harrell, *Comparative Approaches to Biobanks and Privacy*, 44 J Law Med Ethics 161–172 (2016).

7 Kathleen Liddell, Johnathon Liddicoat & Matthew Jordan, *IP Policies for Large Bioresources: the Fiction, Fantasy and Future of Openness, in* Global Genes, Local Concerns: Legal, Ethical and Scientific Challenges in Biobanking 257–260 (Timo Minssen, Janne R Hermann & Jens Schovso eds., 2019).

in the business models of many biobanks.[8] As one commentator put it, IP is the 'last piece of the biobank governance puzzle' calling out for detailed research.[9]

As a foundation for such research, commentators have identified five IP clauses of interest. These clauses have the potential to prevent socially undesirable innovation, enrich biobanks' collections, or improve biobanks' financial positions. Each clause is limited to downstream IP generated using biobank material. This study refers to these clauses as: (i) non-obstruction clauses; (ii) march-in clauses; (iii) grant-back clauses; (iv) return-of-results clauses; and (v) reach-through clauses (also commonly called 'reach-through rights').[10] Briefly, non-obstruction clauses encourage biobank users (hereafter, 'users') to follow certain principles when licensing their IP. March-in clauses state that the user of a biobank must hand over user-owned IP to the biobank after a triggering event. The triggering event could be other parties' health-related research being unreasonably restricted by the user, for example. Grant-back clauses oblige the user to grant the biobank a license to their IP as a matter of course (without a triggering event). Return-of-results clauses oblige users to give the biobank copies or samples of their research results (generated from biobank material). Reach-through clauses give the biobank certain rights over users' innovations, for example, the clauses could give the biobank joint-ownership of users' IP.

Of the five clauses, commentators have mostly focused on reach-through clauses. They attract special attention because, on their face, they could be lucrative and help biobanks address one of their biggest challenges: financial sustainability.[11] At least 10 biobanks have filed for bankruptcy or been acquired by other entities in recent years.[12] Another reason reach-through clauses garner attention is that they are seen as being too favorable to biobanks: biobanks provide biobank users with data and tissue, but not the creativity that is typically essential for IP.

In the limited literature that discusses the five clauses, commentators have largely debated their advantages and disadvantages in the abstract. The IP terms that biobanks *actually* use have not been empirically examined, apart from some small case studies.[13] In particular, no industry-wide evidence exists on three points of biobanks' IP practice: (i) if and how biobanks implement these five types of IP clauses, (ii) whether any

8 Hermann Garden, Naomi Hawkins & David Winickoff, *Building and Sustaining Collaborative Platforms in Genomics and Biobanks for Health Innovation*, OECD Science, Technology and Industry Policy Papers, No. 102, 5 (2021).

9 Yann Joly, Panel Discussion at *Precision Medicine: Legal and Ethical Challenges* (Apr. 8, 2016, University of Hong Kong, Hong Kong).

10 Kathleen Liddell, *Realising Genomic Medicine: Intellectual Property Issues*, Centre for Law, Medicine and Life Sciences & Centre for Science and Policy Workshop Report 1, 12 (2015).

11 A US survey found that 37 per cent of biobank personnel cited funding as their biobank's greatest challenge: R. Jean Cadigan et al., *Neglected Ethical Issues in Biobank Management: Results from a U.S. Study*, 9 Life Sci Soc Policy 1, 5 (2013).

12 Jimmie Vaught et al., *Biobankonomics: Developing a Sustainable Business Model Approach for the Formation of a Human Tissue Biobank*, 2011 J Natl Cancer Inst Monogr 24 (2011); Timothy Caulfield et al., *A Review of the Key Issues Associated with the Commercialization of Biobanks*, 1 J Law Biosci 94, 106 (2014).

13 S. Fortin et al., *'Access Arrangements' for Biobanks: A Fine Line between Facilitating and Hindering Collaboration*, 14 PHG 104–114 (2011); Aisling McMahon, *Patents, Human Biobanks and Access to Health Benefits: Bridging the Public–Private Divide*, in Intellectual Property and Access to Im/material Goods 196–199 (Jessica Lai and Antoinette Maget Dominicé eds., 2016).

norms or standards have emerged, and (iii) whether the norms and standards align with commentators' recommendations for using the five IP clauses.

To address these three gaps, the authors conducted a systematic, global survey of the IP clauses used by large, human biobanks. This study analyses the use of all five IP clauses of interest, paying particular attention to reach-through clauses. Commentators have discouraged biobanks from using reach-through clauses,[14] yet if biobanks exclude such terms, the only other way for biobanks to generate income when users access their materials is to charge access fees (unless the user pays the biobank to conduct additional analyses).[15] This means the use or avoidance of reach-through clauses can affect biobanks' financial sustainability. Consequently, this study contextualizes the results on reach-through clauses by analyzing biobanks' financial access conditions.

This paper is structured as follows. The first part provides an introduction and context for the paper. The second part provides background information on each of the five IP clauses, summarizing their operation and commentators' opinions about their desirability. The third part describes the survey method. The fourth part details the results, and shows that none of the five clauses are used by more than 19 per cent of the surveyed biobanks. Though norms of use have arisen for each clause, standards (in the sense of similar drafting) have not.

The fifth part of the article discusses these findings. The results indicate that biobanks draft bespoke policies to meet their own needs, and probably do so without knowledge of the gamut of IP terms available. This study also revealed that, in general, biobanks are using IP terms differently from the advice of the commentators. On reviewing the differences, we encourage the use of march-in and grant-back clauses, discourage biobanks from using redundant non-obstruction clauses, and call for more research on return-of-results clauses. We also encourage the use of reach-through clauses to claim royalties (not IP), but only in limited circumstances; for example, where user access fees do *not* cover a biobanks' operational costs.

II. BACKGROUND

This part provides background information on the five IP clauses, describing their operation and summarizing commentators' opinions. Box 1, located at the end of this part, provides a summary of the five IP clauses, and Table 11, located at the beginning of Part IV, summarizes and compares commentators' opinions with biobanks' actual practice.

The limited literature in this area leaves room to contest or refine commentators' opinions. However, this Background does not aim to provide a substantive critique of these opinions. Instead, this study analyses these opinions in light of the study's results when discussing policy implications in Part IV.

II.A. Non-Obstruction Clauses

Non-obstruction clauses seek to influence the way users exploit their IP, and have two characteristic features. First, non-obstruction clauses 'encourage' licensing that

14 Saminda Pathmasiri et al., *Intellectual Property Rights in Publicly Funded Biobanks: Much Ado about Nothing?*, 29 Nat Biotechnol 319 320–321 (2011); Jim Vaught & Nicole C. Lockhart, *The Evolution of Biobanking Best Practices*, 413 Clinica Chimica Acta 1569, 1573 (2012); Marika Doucet et al., *Biobank Sustainability: Current Status and Future Prospects*, 5 BSAM 1, 4 (2017); McMahon, *supra* note 13 at 186–187.

15 Pathmasiri et al., *supra* note 14 at 321.

does not interfere with follow-on research, without expressly forbidding any specific licensing practices. Second, since the terms only 'encourage' certain practices, if a user ignores the encouragement, the biobank cannot seek a remedy against the user. As a result, non-obstruction clauses can be aptly considered as guidance.

Pathmasiri et al. are the only commentators to recommend non-obstruction clauses (under the name of 'non-restrictive licensing'),[16] however, they have not been the subject of criticism. Pathmasiri et al.'s commentary draws heavily on two high-profile policy documents: the Organization for Economic Co-operation and Development's (OECD) 'Guidelines for the Licensing of Genetic Inventions'[17] and the US National Institute of Health's (NIH) 'Best Practices for the Licensing of Genomic Inventions'.[18] An overarching idea in these documents is that DNA-related patents should be licensed in a way that fosters further innovation and dissemination of scientific knowledge, and provides a reasonable financial return.

Pathmasiri et al. discuss several aspects of non-obstructive licensing practices, but focus on one issue in particular: non-exclusive licensing.[19] In short, they argue that non-exclusive licensing practices protect the public from patent owners and exclusive licensees cornering the market and imposing supra-normal prices.[20] However, the commentators acknowledge that exclusive licenses might be necessary for commercial success in some circumstances.[21] Consequently, Pathmasiri et al. recommend biobanks 'strongly encourage' users to adopt non-obstructive practices.

II.B. March-In Clauses

March-in clauses stipulate that certain user-owned IP must be given to the biobank after a triggering event. What constitutes a triggering event is determined by the biobank, and the triggers typically reflect types of user behavior the biobank wants to avoid.

March-in clauses rose in prominence after one was adopted by UK Biobank, a high-profile longitudinal biobank in the UK.[22] This term grants UK Biobank a royalty-free license to a user's IP if the user exercises their IP to 'restrict health-related research and/or access to health-care unreasonably'.[23] UK Biobank included this term after

16 Pathmasiri et al., *supra* note 14 at 321–322.

17 OECD, *Guidelines for the Licensing of Genetic Inventions*, http://www.oecd.org/sti/emerging-tech/36198812.pdf (accessed Oct. 20, 2020).

18 Department of Health and Human Services, *National Institutes of Health Best Practices for the Licensing of Genomic Inventions*, https://www.govinfo.gov/content/pkg/FR-2004-11-19/pdf/04-25671.pdf (accessed Oct. 20, 2020).

19 *Id* at 21.

20 *Id.*

21 Julien Pénin & Jean-Pierre Wack, *Research Tool Patents and Free-Libre Biotechnology: A Suggested Unified Framework*, 37 Research Policy 1909, 1919 (2008); Pathmasiri et al., *supra* note 14 at 322; Donna M. Gitter, *The Challenges of Achieving Open Source Sharing of Biobank Data*, in Comparative Issues in the Governance of Research Biobanks 165–189 (Giovanni Pascuzzi, Umberto Izzo & Matteo Macilotti eds., 2013); Michiel Verlinden, Timo Minssen & Isabelle Huys, *IPRs in Biobanking—Risks and Opportunities for Translational Research*, 2 I.P.Q. 106, 107 (2015).

22 David E. Winickoff, *Partnership in U.K. Biobank: A Third Way for Genomic Property?*, 35 J Law Med Ethics 440, 441 (2007).

23 UK Biobank, *Access Procedures: Application and Review Procedures for Access to the UK Biobank Resource* (2011), https://www.ukbiobank.ac.uk/wp-content/uploads/2011/11/Access_Procedures_Nov_2011.pdf (accessed Oct. 20, 2020).

consultation with the UK patent and biobank communities, as well as with the broader public.[24]

March-in clauses have support in the biobank industry, as evidenced by UK Biobank's adoption of such a clause after consultation with industry and the public. However, no settled academic consensus on their use has emerged. Commentary about march-in clauses in biobank policies is limited. It points out that another high-profile UK biobank, the 100,000 Genomes project, chose to omit a march-in clause,[25] and that biobanks might have difficulty retrieving data which has been deidentified, incorporated into other datasets, and spread across multiple research projects.[26]

There is considerably more commentary about march-in clauses in the pharmaceutical and biotechnology sectors. Commentators have tended to discuss this under the name 'march-in rights'.[27] This name references a provision in US law that enables a public sector funding agency (eg the National Institutes of Health) to insist, after one of four triggering events, that the patentee funded by the government grant an additional patent license to the government or another party.[28] 'March-in rights' is an established term, but this study adopts the terminology of 'march-in *clauses*' as a broader category which captures a range of powers and consequences, which, for example, include biobanks taking full ownership of users' IP.

II.C. Grant-Back Clauses

Grant-back clauses oblige users to license their IP to the biobank.[29] Pathmasiri et al. describe grant-back clauses as automatically conveying biobanks a sub-licensable, non-exclusive license to users' IP, but only for non-commercial purposes.[30] The aim of these clauses is similar to non-obstruction clauses, in the sense that both are designed to avoid the negative effects of users exploiting their IP unreasonably. However, the two operate differently: non-obstruction clauses 'encourage' users to license IP in ways that do not hinder follow-on research; while grant-back clauses safeguard follow-on research by granting biobanks a license to the users' IP.

Both Pathmasiri et al. and Verlinden et al. recommend biobanks use grant-back clauses. Both also envisage grant-back clauses being sub-licensable, but Verlinden et al. go further and describe the idea of limiting to whom the license can be extended. They suggest that the licenses could limit authorization to use by academics, or internal use

24 Winickoff, *supra* note 22; UK Biobank, *Public Consultation,* https://www.ukbiobank.ac.uk/public-consultation/ (accessed Oct. 20, 2020).

25 Liddell, *supra* note 10 at 7–8.

26 Jane Kaye et al., *Dynamic Consent: A Patient Interface for Twenty-First Century Research Networks*, 23 Eur J Hum Genet 141, 144 (2015).

27 See e.g. Carolyn L. Treasure, Jerry Avorn & Aaron S. Kesselheim, *Do March-In Rights Ensure Access to Medical Products Arising From Federally Funded Research? A Qualitative Study*, 93 The Milbank Quarterly 761, 763 (2015). For a list of petitions to use march-in rights under the US law, see https://www.keionline.org/cl/march-in-royalty-free (last accessed Dec. 4, 2020).

28 35 USC §203 (commonly referred to as the Bayh Dole Act).

29 A grant-back clause obligates the licensee to grant the rights on future advances or improvements in the licensed technology to the licensor (Carl Shapiro, *Patent Licensing and R&D Rivalry*, 75(2) American Economic Review 25–30 (1985).

30 Pathmasiri et al., *supra* note 14 at 322.

by the biobank only.[31] Verlinden et al. do not prefer any specific type of grant-back. Rather, they describe these different types of licenses as possibilities.[32]

II.D. Return-of-Results Clauses

Return-of-results clauses oblige users to return research results (generated with biobank material) to the biobank. These results can include biological samples, but generally commentators focus on users returning data. Verlinden et al. recommend grant-back terms because new data from the user enriches the biobank collection.[33] Pathmasiri et al. agree, adding that returned results maximize the utility of biobanks, reduce reliance on finite physical samples, and promote the efficient use of research funds.[34]

Several commentators have raised concerns about return-of-results clauses interfering with users' ability to publish. Many researchers consider their data confidential until they choose to publish it.[35] The commentators argue that researchers might be deterred from using a biobank that obliges users to return their results, because the researchers might fear others will publish their results first.[36] However, this issue can be allayed by several means, including granting users an exclusivity period to publish their work or requiring the return of results only after publication.[37] With the proviso of creating a period of exclusivity for researchers to publish their results, commentators recommend biobanks adopt return-of-results clauses.[38]

II.E. Reach-Through Clauses

Reach-through clauses grant biobanks certain rights over users' innovations, or as this study defines them, they grant biobanks rights to users' innovations where the biobank has *not* made an inventive contribution. The scope of reach-through clauses varies and can include full or partial ownership of users' inventions and rights to royalties (or revenues) from commercialized products.[39]

Several justifications for reach-through clauses exist. Pathmasiri et al. suggest that biobanks might see reach-through clauses as an opportunity to generate income (eg from licensing), and that biobanks might feel entitled to rights over users' inventions because the research would not have been possible without the biobank's material.[40] McMahon offers a further possible motivation for biobanks to seek reach-through terms over downstream IP: by retaining a share in users' IP, biobanks have more

31 Verlinden, Minssen & Huys, *supra* note 21 at 123.
32 *Id.*
33 Verlinden, Minssen & Huys, *supra* note 21 at 125.
34 Pathmasiri et al., *supra* note 14 at 322.
35 Liddicoat & Liddell, *supra* note 2 at 29.
36 Gitter, *supra* note 21 at 171; Roberto Caso & Rossana Ducato, *Opening Research Biobanks: An Overview*, *in* Comparative Issues in the Governance of Research Biobanks 226 (Giovanni Pascuzzi, Umberto Izzo, & Matteo Macilotti eds., 2013).
37 Gitter, *supra* note 21 at 170.
38 Caso and Ducato, *supra* note 36; Verlinden, Minssen & Huys, *supra* note 21 at 125.
39 Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698, 699 (1998); Jane Nielsen, *Reach-Through Rights in Biomedical Patent Licensing: A Comparative Analysis of Their Anticompetitive Reach*, 32 Federal Law Review 169, 171 (2004).
40 Pathmasiri et al., *supra* note 14 at 320.

control over the products that reach the market, and this control could be justified as a commitment to protecting the public interest.[41]

Despite these motivations for reach-through clauses, commentators generally advise against them for two reasons. The first argument is that the terms are unjustifiable because biobanks do not generally help users invent new products and processes. Several commentators highlight that biobanks typically do not participate in users' research projects. These commentators argue that it would therefore be unfair for biobanks to reach-through to users' IP when they do not meet the requirements of inventorship under patent law.[42]

The second argument concerns increased transaction costs. Agreeing IP terms and the apportionment of revenue-sharing are often the central objectives of licensing deals. Due diligence exercises often focus on IP entitlements and royalty rights, raising red flags when too many parties have legal interests that complicate negotiations and dilute returns.[43] Commentators argue that biobanks should avoid reach-through clauses because they overly complicate licensing deals, and IP-savvy researchers might then view biobanks that forego reach-through rights as more attractive.[44] Beyond the biobanking literature, some commentators also warn against the use of reach-through rights because these and other claims to royalties can lead to 'royalty stacking'. Researchers are likely to avoid biobanks and partnerships which involve multiple downstream royalty payments.[45] Consequently, biobanks that insist on reach-through clauses risk being under-utilized.

Reach-through clauses have been the topic of various critiques in biobanking literature and biomedical law more widely, and the different fields have raised a variety of different issues. One difference is that the biomedical law literature has discussed reach-through terms to royalties *decoupled* from IP[46] (ie a reach-through term to royalties without a concomitant claim to IP rights). This study did not identify any reach-through clauses to IP, but did identify clauses reaching-through to other subject matter, particularly royalties. Part IV of this paper addresses the difference between these types of reach-through clauses and their implications for biobanks' IP practices.

Reach-through clauses are similar to grant-back clauses, in the sense that biobanks obtain rights over users' inventions. However, whereas grant-back terms provide biobanks with non-commercial, non-exclusive *licenses*, reach-through terms convey ownership or royalties.[47] Reach-through clauses can also be considered similar to march-in clauses in that the latter *can* convey ownership, but march-in clauses are only triggered by predetermined behaviors, whereas reach-through rights occur as a matter of course.

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41 McMahon, *supra* note 13 at 187.

42 Pathmasiri et al., *supra* note 14 at 320; Vaught and Lockhart, *supra* note 14 at 1573; Verlinden, Minssen, & Huys, *supra* note 21 at 127.

43 Pathmasiri et al., *supra* note 14 at 321; John Liddicoat, Jeffrey M. Skopek & Kathleen Liddell, *Precision Medicine: Legal and Ethical Challenges,* University of Cambridge Faculty of Law Research Paper No. 64/2017, 1, 6 (2017).

44 Pathmasiri et al., *supra* note 14 at 321.

45 Heller & Eisenberg, *supra* note 39 at 698–700; see also Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, in Innovation Policy and the Economy 119 (Adam B. Jaffe et al. eds., 2001).

46 Heller and Eisenberg, *supra* note 39 at 698–701; Nielsen, *supra* note 39 at 169–204.

47 Heller and Eisenberg, *supra* note 39; Nielsen, *supra* note 39.

Box 1. Core characteristics of the five IP clauses

Non-obstruction clauses encourage users to license their IP on non-exclusive and reasonable terms. The clauses do not forbid any specific licensing practices, nor do they stipulate remedies for ignoring the encouragement.
March-in clauses are characterized by having a triggering condition/s. When a user engages in behavior which constitutes a triggering event, the user must give the biobank rights over their IP, for example, ownership or rights under license.
Grant-back clauses stipulate that biobanks are granted, as a matter of course, a non-exclusive license to users' IP for research purposes. These licenses may be sub-licensable to all biobank users, or limited to specific groups. There is no triggering event.
Return-of-results clauses oblige users to return the results of their research to the biobank for incorporation into the collection. The clauses typically focus on data, but results may also include biological samples.
Reach-through clauses grant biobanks certain rights over users' IP, which the biobank has not invented. Biobank commentators describe the clauses reaching through to IP, but the clauses can also reach through to other subject matter (such as royalties).

III. SURVEY METHOD, IP DOCUMENTS & BIOBANK DEMOGRAPHICS

This study's primary aim was to identify and compare the IP terms and financial access conditions used by biobanks. Accordingly, it focusses on large, human biobanks because they are the most likely to be involved in translational research and, therefore, have policies on IP.

III.A. Biobank Identification & Survey Distribution

An initial 'long list' of candidate biobanks was prepared, drawing on information from online searches, specialized websites, and publications.[48] This long list was reviewed to exclude organizations that: (i) were still being established; (ii) were no longer operational; (iii) were generally inaccessible to the public (such as private collections held by commercial diagnostic companies); and (iv) promoted best practices for biobanks but did not hold any samples or data. Once these organizations were excluded, 504 biobanks remained.

This study determined which of the 504 biobanks were 'large' via two proxies. The first proxy was size, measured either in terms of the number of samples held or the number of participants. Any biobanks with over 1,000,000 samples or 30,000 participants were considered large. The second proxy was whether the biobank was publicized as a 'national' resource. This second proxy supplements size by including biobanks that are likely to be the largest or most developed in countries with smaller

48 E. Zika et al., *A European Survey on Biobanks: Trends and Issues*, 14 Public Health Genomics 96–103 (2011); Holger Langhof et al., *Access Policies in Biobank Research: What Criteria Do They Include and How Publicly Available Are They? A Cross-Sectional Study*, 25 Eur J Hum Genet 293–300 (2017); Erika Kleiderman et al., *The Author Who Wasn't There? Fairness and Attribution in Publications Following Access to Population Biobanks*, 13 PLoS ONE e0194997 (2018).

populations. The number of biobanks that qualified as 'large' or a 'national' resource was 150.

All 150 biobanks were contacted by email between July 2018 and April 2019. The email explained the project and asked for copies of relevant documents, including: (i) access policies for researchers; (ii) conditions of access; (iii) material transfer agreements (or similar); (iv) policies for entering into agreements with commercial partners; and (v) policies on inventions and the ownership of IP created in collaborations. Fifty-four biobanks responded to the emails with relevant documents, a response rate of 36 per cent.

Biobanks were not offered an inducement to respond to the email. Anonymity was offered to the biobanks to encourage document sharing. One biobank requested that its documents were not reproduced verbatim, and two biobanks requested that their participation remain anonymous. Anonymity of these two biobanks has been protected by refraining from naming these biobanks and by omitting information that could be used to deduce or infer their identity. In some instances, this paper has replaced information on these biobanks with 'anonymous'.

III.B. IP Documents & Biobank Demographics

The 54 respondent biobanks provided 184 documents. Ninety-seven documents included details of IP terms or financial access conditions, leaving 87 that did not. The 97 documents represented 18 broad document types (eg agreements and forms), which fell into one of two categories: (i) sixty-one contained binding terms (eg contracts); and (ii) thirty-six did *not* contain binding terms (eg policies). Table A in the Supplementary Material breaks down these documents by title and whether they contain binding terms.

The 61 documents with binding terms came from 44 biobanks, meaning 10 biobanks did not provide a document with binding terms. However, these biobanks did provide documents that detailed their approaches to IP and access conditions. As a result, all 54 biobanks provided information on the topics under study.

Whether the biobanks' documents were available *gratis* (publicly available and free-of-charge) online affects whether other biobanks can access them. This accessibility, in turn, affects whether norms and standards can arise. Thirty-eight biobanks (70%) supplied documents that were available online, while 16 (30%) did not.

Fifty-one of the 54 biobanks were located in 23 countries. The other three biobanks were based in multiple countries or were international in character (Table 1). The three countries with the most biobanks were the UK, Australia and the USA, which together constituted 39 per cent of the sample. Fourteen countries had one biobank, including countries such as Latvia, Malta, Norway, and Taiwan (Table 1). Overall, the results give a global perspective, albeit one orientated towards English-speaking nations.

Table 1 shows that four of the five most common respondent jurisdictions were English-speaking, common law nations: the UK, Australia, USA, and Canada. Due to shared legal and cultural histories, it is possible that biobanks from these nations employed similar drafting techniques and stances on IP. This study investigated this possibility by analyzing whether any of the terms under study arose more frequently in these four common law nations compared with the rest of the world (Table E,

Table 1. Locations of the respondent biobanks

Country	# Biobanks (% of total per country)
UK	9 (17%)
Australia	7 (13%)
USA	5 (9%)
Canada and Sweden	4 (7%)
International/multi-country	3 (6%)
Denmark; India; Israel; and Spain	2 (4%)
Argentina; Austria; Anonymous; China/UK; Cyprus; Finland; France; Japan; Latvia; Malta; The Netherlands; Norway; and Taiwan; and Zambia	1 (2%)

Table 2. Research foci of the respondent biobanks

Research focus	# Biobanks (% of total)
Numerous disease foci/general purpose	24 (44%)
Cancer (in general)	16 (30%)
Neurobiological diseases	3 (6%)
Cancer and rare diseases	2 (4%)
Chronic diseases	2 (4%)
Infectious diseases	2 (4%)
Cancer, heart disease and osteoporotic fractures in post-menopausal women	1 (2%)
Diabetes, digestive health, and kidney diseases	1 (2%)
Health and nutrition	1 (2%)
Impacts of exposure to terrestrial trunked radio on health	1 (2%)
Phenylketonuria	1 (2%)

Supplementary Material). The numbers are all quite small (10 or less), and no patterns that significantly diverge from the results below were observed.

The biobanks had 11 different research foci. Two foci were particularly common: 24 biobanks (44%) were designed for general use or had numerous research foci, and another 16 (30%) focused on cancer (in general). The remaining biobanks focused on nine areas (Table 2).

Seven different organizational structures managed the biobanks (Table 3). The most common types of managing organizations were universities or research institutes (17, 31%), followed by not-for-profit organizations (12, 22%). Only one biobank (2%) was managed by a for-profit company.

Table 3. Managing organizations of the respondent biobanks

Biobanks' managing organizations	# Biobanks (% of total)
University/Research Institute (includes university hospitals and university networks with central access points)	17 (31%)
Not-for-profit organizations (includes domestic and international consortia with central access points and independent organizations established largely with government funding)	12 (22%)
State/Government (includes government-owned companies)	11 (20%)
University/Research Institute + Hospital	5 (9%)
State/Government + Hospital + University/Research Institute	2 (4%)
State/Government + Hospital	1 (2%)
For-profit company	1 (2%)

III.C. Non-Responder Bias

This study examined non-responder bias by comparing the demographics of biobanks that did respond to this survey (54) with the biobanks that did not (96). Non-responder bias was examined for: (i) the locations of the biobanks; (ii) the research foci; and (iii) biobanks' managing organizations. The full breakdowns are recorded in Tables B–D in the Supplementary Material. The numbers are too small to permit in-depth statistical analysis, but the following three findings stand out.

First, the survey received fewer responses than might be expected from biobanks located in the USA. Biobanks from the USA constituted 31 (21%) of the 150 biobanks that were invited to participate in this survey, yet only five biobanks responded, which comprises 9 per cent of the respondent cohort. It is unclear how this result affects this study; especially as common law jurisdictions are well-represented in the respondent cohort. Second, the proportion of UK biobanks that responded to the survey was higher than expected. UK Biobanks constituted 11 per cent (17/150) of the biobanks emailed to participate in this study yet made up 17 per cent of the respondent biobanks. This higher-than-expected response is likely due to the location of the study authors. Third, 30 per cent (16/54) of respondent biobanks focused on cancer research yet only constituted 21 per cent of the 150 invited to participate in the study. Cancer research often aims at translating findings into clinical practice, and, since IP is often necessary for translation, the high response from cancer biobanks might reflect their interest in IP. There were no significant differences between respondent and non-respondent biobanks with regard to managing organizations.

III.D. Coding and a Typology of Biobanks' Financial Access Conditions

The documents supplied were coded using the software package Nvivo 12. The documents were coded for: (i) the presence and content of the five IP terms; and (ii)

financial access conditions. In addition, the documents were coded for (iii) definitions of IP; and (iv) ownership of background IP. The definitions of IP affect how the five IP terms operate, and the ownership of background IP allowed an evaluation of whether biobanks made claims to users' IP generated *before* the users accessed biobanks' materials.

A three-model typology was devised to describe biobanks' financial access conditions. Table 10 (in Part III) describes these models and records each biobank's financial access conditions.

III.E. Limitations

This study has two limitations. The first is that the study sample cannot claim to be comprehensive or represent every possible approach towards IP and financial access conditions. However, with a 36 per cent response rate from large biobanks and at least one document from each addressing IP practices and access conditions, this study does provide a useful picture of contemporary IP practices in biobanking.

The second limitation is that one biobank (2%) provided documents in a language the investigators could not read, so they were analyzed using Google Translate. The accuracy of this software is questionable, but the translations were intelligible.

IV. RESULTS

This part first describes how biobanks define IP and allocate the ownership of background IP, then examines how biobanks use the five IP clauses. This part also identifies some differences between actual practice and commentators' views of the five IP clauses.

IV.A. Definitions of IP and Ownership of Background IP

Forty-four biobanks (81%) did not define the term 'intellectual property'. The 10 biobanks (19%) that did define IP used 11 definitions, with one biobank supplying two definitions (extractions of the definitions are recorded in the Supplementary Material, Table F). All the definitions included copyright, design rights, know-how, and patents or inventions, but were worded differently. For example, the definitions listed 67 different subject matters in total (eg brand names, ideas, and circuit layouts), of which 44 were unique to one definition (see Supplementary Material, Table G).

Although all the definitions of IP were different, 10 of the 11 definitions included a phrase that acted as a substantive catch-all. Two examples of these phrases are 'including but not limited to' and 'all other forms of intellectual property rights having similar or equivalent effect'. These phrases extend the definitions of IP to cover subject matter that was not explicitly mentioned. These phrases show an intention by the biobanks to capture all substantive forms of IP. Consequently, although all the definitions of IP were different, they could have similar interpretations. On the other hand, all remain somewhat vague as there is no settled, uniform definition of 'intellectual property law' or 'intellectual property rights'.

Forty-seven biobanks (87%) addressed the ownership of background IP. Roughly stated, 'Background IP' is the IP that a biobank and user respectively owned *before* the user accessed the biobank. No biobank included a term that transferred ownership of background IP from the biobank to the user (or vice versa). The various clauses the biobanks used to described background IP are summarized in Supplementary Material, Table H.

IV.B. Non-Obstruction Clauses

Four biobanks (7%) included a non-obstruction clause to patents or inventions, leaving 50 biobanks (93%) that did not. The relatively low uptake of non-obstructive licensing terms differs from the view of commentators, who tended to advocate their use. Table 4 summarizes the content of the four terms. All four had different wording, though two mentioned compliance with the NIH's policy document. Supplementary Material, Table I reproduces the full wording of each of the four clauses.

Table 4. Summaries of non-obstruction clauses

Biobanks' non-obstruction clauses	# Biobanks (% of total)	Sub-total (% of total)
Users agree to implement licensing policies that do not obstruct future research.	1 (2%)	4 (7%)
Users agree to implement licensing policies that do not obstruct future research, following the OECD's Guidelines.	1 (2%)	
Users agree to implement licensing policies consistent with the NIH's Best Practices for the Licensing of Genomic Inventions.	2 (4%)	

IV.C. March-In Clauses

Five biobanks (9%) included a march-in clause whilst the remaining 49 (91%) did not, showing that these clauses are uncommon in practice. There is no consensus on the use of march-in clauses in biobanking literature. This means it is not possible to evaluate whether theory accords with practice.

Table 5 summarizes the content of the five march-in clauses, explaining the four distinct sets of triggers and consequences. The triggers can be classified into two groups: (i) breaches of research standards (ie 'prohibited use' or when the access agreement is violated), and (ii) harms to innovation (ie IP licensed 'unreasonably' or users not actively developing inventions). Only the clauses concerning harms to innovation directly concerned IP-related issues. Consequently, the number of biobanks that used a march-in clause for IP-related reasons is only two (4%).

Two of the 49 biobanks that did not include a march-in clause used a 'pseudo' march-in term (not described in Table 5). These terms specified that users were only permitted IP over inventions created in the course of authorized uses of biobank material. The terms did not specify what action would be taken if users obtained IP in the course of 'unauthorized' uses.

This study did not classify these terms as march-in clauses because their purpose was to prevent users from obtaining IP rights, rather than reallocating IP. These terms were not classified as non-obstruction clauses either, because the terms prevented users from obtaining IP, rather than suggesting ways IP should be exercised.

IV.D. Grant-Back Clauses

Nine biobanks (17%) included a grant-back clause to data, patents or inventions, leaving 45 (83%) that did not (Table 6). All grant-back clauses generated licenses which were royalty-free, non-exclusive, and limited to non-commercial purposes.

Table 5. Summary of biobanks' march-in clauses

Trigger	Consequence	# Biobanks
Users put the borrowed material to a 'prohibited use' (eg the biobank material is used in a research project other than the one authorized by the biobank).	Ownership of all information, research results, inventions and the like arising from the prohibited use is transferred to the biobank.	2
Users violate the terms of their agreement with the biobank	The biobank may request immediate termination of the user's study, may deny future access to data, and may recapture any data in the possession of the user.	1
Users put their IP to an 'unreasonable use' (eg the recipient licenses their innovation in an unreasonably restrictive way)	A sub-licensable license is granted to the biobank so that other researchers who are granted access to the biobank can exercise rights to the extent necessary to conduct their research project.	1
Users do not maintain or develop inventions	The biobank is entitled to have the patents or patent applications assigned to them at no cost.	1

Table 6. Summary of biobanks' stances on grant-bank clauses

Stances on grant-back clauses	# Biobanks (% of total)
Omitted	45 (83%)
Included	9 (17%)

Pathmasiri et al. supported grant-back clauses on the basis that the clauses were sub-licensable (ie the license could be extended to other users), but only two biobanks (4%) used a term that operated this way. The other seven biobanks (13%) drafted terms that limited the license to internal biobank purposes, which meant these biobanks could *not* license other users. Verlinden et al. support the idea of non-sublicensable grant-back clauses on the basis the biobanks could use the technology. Putting to one side the nuance in operation, both Pathmasiri et al. and Verlinden et al recommend the use of grant-back clauses, yet the results show relatively few biobanks are embracing them.[49]

49 Pathmasiri et al., *supra* note 14; Verlinden, Minssen & Huys, *supra* note 21.

IV.E. Return-of-Results Clauses

Nine biobanks (17%) included a return-of-results clause, leaving 45 (83%) that did not (Table 7). The characteristics of return-of-results differed on two points: (i) when the results should be returned, and (ii) the purposes to which the results could be put (Table 8). No biobank obliged users to return the results before they had published them as a matter of course. The most common time to return results was on request, but such requests can only be made when the biobank is aware the results exist, indicating that return is most likely after publication. The second most common time to return results was on completion of the research project, which would typically be signaled by the publication of results. Therefore, commentators' concerns that return-of-results clauses would interfere with users' abilities to publish are unlikely to be relevant in practice.

The majority of return-of results-clauses identified in this study (56%) limited biobanks to using returned results for internal purposes only. Commentators recommend return-of-results clauses on the basis that other users could use the returned results.[50] This means that only four biobanks (44%) used return-of-results terms that were consistent with the commentators' recommendations.

This study also identified a type of pseudo-return-of-results clause not recorded in Tables 7 or 8. The biobank that used this term was government-owned, and the term authorized the government healthcare provider to use the results to treat patients. The term provided the government healthcare provider with 'fair and reasonable' access to any results the user produced from biobank materials. This study did not count this term as a full return-of results clause because the 'fair and reasonable access' can be in the form of preferential financial terms. This clause was not classified as a grant-back clause either, because the rights do not arise as a matter of course, they have to be negotiated.

Table 7. Summary of biobanks' stances on return of results terms

Stances on return-of-results terms	# Biobanks (% of total)
Included	9 (17%)
Omitted	45 (83%)

Table 8. Characteristics of return-of-result terms

When should the results be returned?	# Biobanks (% of total)
On request	5 (55%)
On completion of the research project	3 (33%)
Prior to first sale of a commercial product	1 (11%)
Internal biobank use only	5 (56%)
For merging with the biobank's contents (internal research purposes and sharing)	4 (44%)

50 Pathmasiri et al., *supra* note 14; Verlinden, Minssen & Huys, *supra* note 21.

IV.F. Reach-Through Clauses

This section first discusses clauses that reach-through to IP before addressing three other types of reach-through terms.

1. Reach-Through Clauses to IP

No biobank used a reach-through clause to IP (Table 9). As mentioned above, biobank literature has focused on reach-through clauses to IP, with biobank commentators discouraging biobanks from using them. Accordingly, biobank practice aligns with the commentators' opinions on this topic.

Although no biobank used a reach-through clause to IP, 11 biobanks adopted approaches to the ownership of foreground IP in which ownership was not predetermined. These 11 approaches fell into one of three categories: (i) on a case-by-case basis; (ii) relative contributions; and (iii) a relatively complicated set of predefined scenarios. These clauses raised the *possibility* that biobanks obtained IP they did not create. However, these clauses were generally orientated towards joint research or covered situations when a biobank provided material approximating an inventive

Table 9. Summary of biobanks' reach-through terms

Stances on reach-through clauses to foreground IP	# Biobanks (% of total)	Sub-total (% of total)
No reach-through term included	44 (81%)	44 (81%)
Reach-through to tangible property		
Biobank materials and 'any substances that incorporate any part of the biobank materials' will remain the property of the biobank.	1 (2%)	
Biobank material and any 'modifications' shall remain the sole property of the biobank.	1 (2%)	3 (6%)
The biobank is the sole owner of the biological samples and all their derivatives.	1 (2%)	
Reach-through to royalties		
Royalty-sharing determined on a case-by-case basis	3 (6%)	
The biobank (together with other collaborating parties) is entitled to 75% of net revenues; the user retains 25%	1 (2%)	4 (8%)
Reach-through to royalties for the benefit of donors		
Commercial royalties are payable to the donor who provided the relevant material	2 (4%)	2 (4%)
Other		
Biobank operator is entitled to 'favorable' conditions on users' products and services	1 (2%)	1 (2%)

contribution. Consequently, these clauses were *not* classified as reach-through terms to IP. Supplementary Material, Table J summarizes these clauses and the remaining stances biobanks took on the ownership of foreground IP.

2. Reach-Through Clauses to Tangible Property, Royalties & 'Favorable' Conditions

The three other types of reach-through clauses identified in this study have not been analyzed by commentators. This section, therefore, offers some reasons why biobanks may have chosen to implement them.

The first type is reach-through clauses to 'tangible' property. This study found three biobanks (6%) used these terms, but none of the biobanks *explained* why. One of four possible explanations is that the biobanks want to protect donor privacy, and biobanks do this by asserting property over things that incorporate users' samples. A second reason is that the biobanks might want to improve their resources by obtaining new derivatives of their materials, and the biobank might see this as a fair exchange for the material provided in the first instance. A third reason is that biological samples are a finite resource and that the biobanks want a property right to prevent material going to waste. These second and third reasons are plausible, but they require the biobanks to monitor users' research and organize return of the samples. These are time intensive processes, thus, less compelling explanations than the first.

A fourth explanation is based on the possibility that a user's commercial product incorporates biobank material. If this occurs, then a reach-through clause to tangible property would mean the biobank would have the power to deal with the commercial product and could potentially stop the user's commercial activities or ask for a royalty on product sales. However, this reason is unlikely, due to the difference between ownership of IP and ownership of tangible property. Although the biobank might be able to request the material is returned, the user would likely own the IP in the material and, therefore, could avoid the royalty by creating the material from another source. Consequently, biobanks that did include a reach-through term to tangible property probably did so for the first suggested explanation, namely the protection of donors' privacy.

The second type of reach-through clause found in this study was to royalties *decoupled* from IP rights. This study found that four biobanks (8%) used one of these clauses for the benefit of the biobank (or its partners), and two biobanks (4%) used one for the benefit of biobank donors. None of these six biobanks was a for-profit company.

The operation of the reach-through clauses to royalties varied significantly. The most common approach to determining royalties was assessment on a case-by-case basis, but the three biobanks that adopted this approach differed on when the determination occurred. One biobank, which was managed by a university, determined the royalty when the invention was made (regardless of whether the invention was patented) and stated that the university would obtain a 'reasonable share' of the revenue. The second, which was also managed by a university, determined the royalty when the user accessed the biobank, and the third, which was managed by a government, determined the royalty before the first sale of the user's product. No other information on determining the royalties was provided.

The biobank that stated users retain 25 per cent of their net revenue was managed by a government and university. The remaining 75 per cent was distributed in equal portions to the government health service, the biobank, and the managing university.

This was the only biobank that specified a royalty rate in the clause, but no information was provided explaining how the biobank arrived at this rate beyond the implicit distribution of net royalties between the four parties (ie user, biobank, university, and government health service).

Two biobanks used reach-through clauses to royalties for the benefit of 'donors'. The first of these biobanks was managed by a government, and the term was required by law. The biobank's access policy required that users outline the details of a revenue-sharing scheme in their research proposal. The second biobank that included a reach-through royalty for donors was managed by a not-for-profit company that was closely aligned with government objectives. The reach-through term required that individual donors receive commercial royalties but provided little other information.

This study classified the final reach-through clause used by a biobank as 'other'. This biobank was managed by a state health department, and the term entitled the national health provider to 'favorable' conditions on users' services and products (based on the biobank material). This approach was deemed to fall under the umbrella of reach-through clauses because it conveys a financial benefit to the biobank and would apply to market products the biobank did not invent. The biobank's terms stated that the 'favorable' conditions would reflect the contributions the health service made in the development of the product, but no other details were provided.

One conspicuous lack of detail concerned how 'favorable' should be interpreted. One interpretation of the word 'favorable' is that the user would have to sell their product to the health provider at a lower price than normal, otherwise the clause would fail to convey an advantage. This study classified this term as a reach-through because this interpretation is plausible and would therefore likely entitle the government to a discount on users' products.

Overall, this study found that 10 biobanks (19%) used a reach-through clause of some description. However, this study does not emphasize this finding because the four types of clauses this study did find (tangible property, royalties for biobanks, royalties for donors, and 'favorable' terms) operate differently. These differences mean that grouping these clauses together would likely lead to misunderstandings, especially because analyses of reach-through clauses in biobank literature predominantly have addressed reach-through to patent rights.

IV.G. Financial Conditions for Access

A three-model typology was devised to describe biobanks' financial access conditions. Table 10 describes the three models and records each biobank's conditions against these models. With all models, users *may* also have to pay administrative and ancillary costs, covering expenses like sample preparation, postage, and application processing.

Table 10 shows that 52 of the 54 biobanks were roughly split between those that charge access fees (28 biobanks, 52%) and those that do not (24, 44%). The remaining two biobanks had 'miscellaneous' conditions. The most common fee-paying model was 'variable' (17, 31%), which describes a fee structure that varies according to certain criteria, rather than being fixed. There were differences between each of the variable models adopted by biobanks, but some of the criteria included: whether the user was profit-making, whether the user was part of the biobank's network or consortium, and the type of data and samples requested. Another typical way to vary the access fee was

Table 10. Biobanks' financial access conditions

Financial access model	Description of model	# Biobanks, % of total (# Biobanks also used a reach-through to royalties)
Model 1—no fee	Biobanks either described free access or the documents did not describe an access fee.	24, 44% (2)
Model 2.1—flat, unspecified fee	Biobanks charge a one-off, flat fee of an unspecified amount for access.	6, 11% (0)
Model 2.2—flat specified fee	Biobanks charge a one-off, flat fee of a specified amount.	4, 7% (0)
Model 3—variable access fee	Biobanks charge an upfront, variable fee for access.	18, 33% (2)
Miscellaneous	Financial access conditions not fitting into the above models.	2, 4% (0)

to provide users with lists of different types of materials at different prices. Eight of the 17 biobanks (47%) provided a price list. These 'price lists' allowed users to decide on the type and amount of materials they wanted and could afford.

Table 10 also shows how biobanks financial access conditions overlap with reach-through clauses to royalties that benefit biobanks (hence the two reach-through clauses to royalties that benefit 'donors' are excluded). Table 10 shows that an equal number of reach-through terms to royalties were associated with fee-based access models (2) as no-fee access models (2). These numbers are small, but indicate that biobanks that charge fees are similarly inclined to draft reach-through terms to royalties as those that do not charge access fees. Furthermore, Table 10 shows that if the reach-through terms to royalties are considered a type of fee for access, then 22 biobanks (41%) did not charge any type of fee.

Two 'miscellaneous' stances did not fit neatly into the models in the typology. One biobank's access terms included the possibility of models 1, 2, and 3. Thus, this model could be more accurately described as multi-model. The second biobank supplied documents with conflicting statements on fees. One document stated that it did not charge a fee, and another stated that it charged a flat fee. Consequently, this model could not be accurately categorized.

V. SYNTHESIS OF RESULTS AND POLICY IMPLICATIONS

This part of the paper is divided into two sections. The first section considers the norms and standards in the results and what these mean for the drafting of IP policies. The second section analyses the divergences and alignments between commentators'

opinions and the norms identified in this study. For each of the five IP clauses, this study offers advice on whether biobanks should reconsider their use.

V.A. Drafting IP Policies: Norms and Standards

Table 11 summarizes the commentators' opinions and the results of this study. The term 'norm' is used to describe the most common approaches employed by biobanks, and 'standard' is used to describe specific wording used by biobanks.

Table 11 shows that an overall biobank norm was to omit all five IP clauses. This finding aligns with commentators' recommendations on reach-through clauses to IP, indicating that biobanks and commentators have shared views. However, this finding diverges from commentators' recommendations for non-obstruction clauses, grant-back clauses and return-of-results clauses. Further, no standard language was found when biobanks did use one of the five terms. These findings have two implications for the drafting of IP policies.

The first implication is based on the absence of standards. This indicates that when biobanks draft IP terms, they are *not* copying terms used by other biobanks or templates produced by NGOs.[51] The second implication concerns whether biobanks are aware of the gamut of IP terms available when drafting their documents. On the one hand, biobanks *could* be aware of the full range of IP terms, informed by external advice or in-house knowledge and research, especially since the majority of biobank access arrangements in this survey were accessible *gratis* online (38/54, 69%), as were several NGO's templates.

On the other hand, a variety of factors weigh in favor of biobanks being 'unaware' of the gamut of IP clauses. First, even if biobanks obtain other biobanks' access agreements, relatively few access documents incorporate an IP term, limiting any IP knowledge biobanks can gain. Second, biobanks must grapple with a myriad of other issues, which probably limit their abilities to explore IP options. For instance, biobanks have to deal with an overwhelming number of governance issues, such as donor privacy and confidentiality, donor consent, complicated access requests, updates to technology, external research projects, external funding, technical aspects of collection and storage of samples, hiring sufficient expertise, and returning results to donors.[52] Moreover, managing organizations such as universities and hospitals often employ staff that dedicate only part of their time to the biobanks. The rest of their time is dedicated to other tasks such as teaching, research, and clinical practice. Consequently, attention to IP terms is likely forgone in favor of simpler, functional arrangements. Indeed, whilst conducting this study, eight biobanks have requested a copy of the results and two biobanks have informally asked the authors for results because they are largely unaware of what terms most biobanks use.

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51 See for example the P3G Generic Access Agreement: Bartha Maria Knoppers et al., *A P3G Generic Access Agreement for Population Genomic Studies*, 31 Nat Biotechnol 384–385 (2013).

52 Stefan Eriksson & Gert Helgesson, *Potential Harms, Anonymization, and the Right to Withdraw Consent to Biobank Research*, 13 European Journal of Human Genetics 1071–1076 (2005); Caulfield et al., *supra* note 12 at 94–110; Dianne Nicol et al., *Precision Medicine: Drowning in a Regulatory Soup?*, 3 J Law Biosci 281–303 (2016); Catherine Heeney & Shona M. Kerr, *Balancing the Local and the Universal in Maintaining Ethical Access to a Genomics Biobank*, 18 (80) BMC Medical Ethics 1–11 (2017).

Table 11. Summary of commentators' opinions and survey results

Topic	Summary of opinion(s)	Survey results
Non-obstruction clauses	Pathmasiri et al. **recommend** biobanks should use non-obstruction clauses to encourage users to license non-exclusively.	Norm to omit non-obstructive licensing clauses: 4/54 biobanks used a non-obstruction clause (7%). No standards were evident.
March-in clauses	**No opinion in biobank literature.**	Norm to omit march-in terms: 5/54 biobanks used a march-in clause (9%) and only 2 (4%) concerned IP-related issues. No standards were evident.
Grant-back clauses	Commentators **recommend** biobanks draft terms that require users to license their IP back to biobanks for non-commercial purposes. These clauses might also be limited to certain users or internal biobank.	Norm to omit grant-back terms: 9/54 biobanks used a grant-back clause (17%). No standards were evident.
Return-of-results clauses	Commentators **recommend** biobanks draft terms that require users to return their results to the biobank so other users may obtain them.	Norm to omit return-of-results clauses: 9/54 biobanks used a return-of-results clause (17%). No standards were evident.
Reach-through clauses	Commentators **advise against** biobanks drafting reach-through terms to IP. Biobank commentators have not analyzed reach-through terms to tangible property or royalties 'decoupled' from IP.	No biobank used a reach-through term to IP, but three (6%) used a reach-through to tangible property, six (11%) used a reach-through to royalties 'decoupled' from IP, and one used a reach-through to secure access to innovations on 'favorable' terms (2%). Overall, norm to omit reach-through terms, 10/54 (19%) included one. No standards were evident.

On balance, the argument that biobanks are operating with imperfect knowledge when drafting their IP policies is the more convincing. The sheer number and complexity of competing governance considerations limits the amount of time and resources biobanks can allocate to developing their IP practices. Where dedicated legal expertise is unavailable, biobanks are likely to be unaware of the gamut of IP terms available to them. Similarly, the need to prioritise other aspects of governance means biobanks have limited capacity to refine the terms they do draft.

Bearing these implications in mind, the discussion in the next two sections draws on wider legal commentary and IP practice to refine and encourage the use of some terms and discourage the use of others.

V.B. Theory vs. Practice

This section reviews the areas of divergence and one area of alignment between the IP clauses that biobanks use and commentators' opinions. The discussion of terms proceeds thematically, first addressing march-in clauses, then non-obstruction clauses, grant-back clauses, return-of-results clauses, and lastly reach-through clauses and financial access conditions.

1. March-In Clauses: A Fire Extinguisher?

March-in clauses are neither recommended nor advised against in the biobanking literature, and this survey found that five biobanks (9%) use one, each with one of four triggering behaviors. The results show that these triggers fall into two categories: (i) breaches of research standards and (ii) harms to innovation. Only two biobanks (4%) used a march-in clause that concerned IP-related issues.

Two reasons potentially explain why relatively few biobanks use march-in clauses. The first is that biobanks are not aware of them. This reason is quite compelling for march-in clauses because biobank commentators have barely mentioned them. Another reason is that breaches of research standards and harms to innovation occur infrequently. However, excluding clauses because issues arise infrequently is not a compelling justification. Even if a triggering event occurs only once every 10 years, biobanks would likely want to avoid it. This is especially true for breaches of research standards. For example, if a donor's privacy is breached, then trust in the general idea of biobanks is harmed, and people will be discouraged from donating in the future. The biobank managers involved in this breach would prefer to avoid the negative publicity and the possibility of an investigation into its operations. The offending user would also rub salt into the wound if they retained IP connected to the breach.[53]

The effects of breaching research standards are slightly different from harms to innovation. Breaches of research standards are often decided by disciplinary bodies, leaving no questions about whether a breach occurred. In comparison, harms to innovation are typically not decided by a body of experts, and the terms are quite vague as to what behavior triggers them. For example, one of the terms in this study empowered the biobank to obtain users' IP if a user fails to develop an invention. However, the user might have good reasons for not developing an invention; for example, funding,

53 Aisling M. McMahon, *Biotechnology, Health and Patents as Private Governance Tools: the Good, the Bad and the Potential for Ugly?*, 3 I.P.Q. 161, 172 (2020).

technical difficulty, or the user might have a vision for the technology that depends on the development of another technology first. Consequently, parties might have different views on when a harm to innovation has occurred.

A report following an expert workshop discussed march-in clauses that are designed to prevent users licensing their IP on unreasonably restrictive terms. Focusing on the march-in clause used by UK Biobank, the report notes that experts present at the workshop queried whether such clauses were 'genuinely enforceable', but did not resolve the issue.[54] The passage under discussion stated that the biobank obtains a license '[if the user's IP] is used to restrict health-related research or access to healthcare unreasonably'.[55] When there are competing views about whether health research has been restricted (or access to healthcare unreasonably restricted), it could be difficult to decide if the march-in condition has been triggered. In contract law, a contract may be unenforceable for 'uncertainty' if the term has 'no clear objective meaning'.[56] This—or practical difficulties of enforcement—may explain why participants at the Expert Workshop questioned whether the UK Biobank's march-in clause was genuinely enforceable. That said, courts rarely void terms for uncertainty,[57] and several strategies exist to redress contractual uncertainty and give the parties more clarity on what the terms mean.

The first strategy is that a biobank could provide examples of what types of behavior it wants to avoid. For example, a biobank may wish to avoid issues that have attracted significant criticism in the past, such as licensing of diagnostic tests that exclude second opinions,[58] prices for drugs in countries in which most people cannot afford them,[59] and preventing universities from conducting non-commercial research.[60] 'History does not repeat itself, but it rhymes',[61] and examples would provide more clarity on what types of behavior should be avoided.

Second, contractual terms can be given more certain meaning with a third-party arbiter.[62] For example, in a contract between two oil companies, the parties agreed that disputes would be decided by an international arbitrator, whose powers included deciding which country's system of law they would apply in their decision.[63] The contract was alleged to be unenforceable because it failed to specify the governing law,

54 Liddell, *supra* note 10 at 4.

55 *Id.*

56 Sir Kim Lewison, *Chapter 8: Ambiguity and Uncertainty* in Interpretation of Contracts 6TH Edition (K. Leweson ed., 2015).

57 *Openwork Ltd. v Forte* [2018] EWCA Civ 783.

58 Department for Health and Human Services USA, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests: Report of the Secretary's Advisory Committee on Genetics, Health, and Society.* Available at https://osp.od.nih.gov/sacghsdocs/gene-patents-and-licensing-practices-and-their-impact-on-patient-access-to-genetic-tests-report-of-the-secretarys-advisory-committee-on-genetics-health-and-society/ (accessed Oct. 22, 2020).

59 Regina Deverio, *Activist for AIDS sufferers*. Available at https://www.princeton.edu/~paw/archive_new/PAW01-02/11-0313/classnotes.html#ClassNotes3 (accessed Oct. 22, 2020).

60 Tania Bubela, Saurabh Vishnubhakat & Robert Cook-Deegan, *The Mouse That Trolled: the Long and Tortuous History of a Gene Mutation Patent That Became an Expensive Impediment to Alzheimer's Research*, 2 J Law Biosci 213, 238–252 (2015).

61 An expression of unknown origin but often attributed to Mark Twain.

62 Lewison, *supra* note 56.

63 *Deutsche Schachtbau-Und Tiefbhorgesellschaft m.b.H. v R'as al-Khaimah National Oil Co.* [1987] 3 WLR 1023 at 1023.

but Donaldson MR found the terms were sufficiently certain for the simple reason that the parties specifically left the decision-making power to the arbitrator.[64] In the context of biobanking and deciding whether a march-in clause has been triggered, suitable arbitrators might include: members from IP licensing societies, university ethics bodies, and biobank ethics bodies.

Biobanks have good reasons to avoid breaches of research standards and harms to innovation, and march-in clauses could provide suitable mechanisms to address these concerns. The possibility of having a third party decide when harms to innovation arise not only solves the issue of contractual uncertainty and arguments about what constitutes harm, but also means the issue can be dealt with swiftly compared with seeking a court decision. In this way, march-in clauses can be considered akin to a fire extinguisher: generally lying dormant but able to counteract undesirable situations when needed. This study, therefore, encourages biobanks to consider (or reconsider) march-in clauses for breaches of research standards and harms to innovation and society.

2. Non-Obstruction Clauses: A Paper Tiger?

This study found only four biobanks (7%) used non-obstruction clauses, which contrasts with Pathmasiri et al.'s recommendation to use them. Several reasons potentially explain why these clauses have been infrequently adopted. First, the non-binding nature of the clauses (these clauses only 'encourage' users to adopt certain licensing behaviors) means they cannot be enforced. Accordingly, non-obstruction clauses may have been perceived as 'toothless' and serving no legal purpose. In contrast, the small number of biobanks that did adopt these clauses may have done so because they 'signal' to users the type of behavior the biobanks desire.

Second, Supplementary Material Table I shows that biobanks that implement non-obstruction clauses often adopt phrases similar to 'the [user] agrees not to obstruct future research'. However, what is 'obstructive' is open to different interpretations. The mere fact a license fee is charged will likely obstruct *some* research, and users could justify relatively high fees on the basis of financial investment, risk, the quality of the product, or the company's ongoing commercial viability. Few licensors are likely to think their license terms are unreasonable. Consequently, biobanks have good reasons to think that non-obstruction clauses will *not* alter any users' behavior.

A third issue is the overlap between march-in clauses preventing harms to innovation and non-obstruction clauses. Both are broadly aimed at preventing the same issue, meaning that march-in clauses, perhaps with slight drafting modifications, could fulfil the role of non-exclusive licensing terms, and probably perform better because they can be enforced. Indeed, even if biobanks have no intention of enforcing march-in clauses, they are still preferable. Users may not be aware that march-in clauses are not enforced, or that compliance is not monitored. In any event, a user might comply simply because they are written in obligatory terms. Consequently, this study recommends that biobanks omit non-obstruction clauses because they are toothless, too open-textured, and redundant in light of march-in clauses.

64 *Id.* at 1035.

3. Grant-Back Clauses: A 'Quid Pro Quo'?

This study found nine biobanks used grant-back clauses (17%), a finding at odds with commentators' recommendations that biobanks should embrace the clauses. This study also found that two of these clauses were sub-licensable, in the sense that the license could be extended to other biobank users. The other seven clauses were *not* sub-licensable, only allowing biobanks to use the IP internally. The different scopes of these licenses have implications for how biobanks and users are likely to see the terms.

Grant-back clauses that are not sub-licensable allow a biobank to handle users' IP for the biobank's own internal purposes. For instance, the IP might cover methods of analyzing data or biological samples. The biobank could license this IP from the user in a separate agreement. However, the biobank might consider a grant-back clause for internal use a reasonable 'quid pro quo' for providing the material. Although commercial users may argue that these types of licenses undermine the value of their IP because they lose a license fee, this is a relatively unconvincing argument, as the biobank would constitute only one licensee in a national or global licensing strategy. Thus, biobanks have justifiable grounds to use grant-back clauses for internal uses.

The situation, however, is different for *sub-licensable* grant-back clauses. Pathmasiri et al. advocated the use of such clauses to guard against users licensing on unreasonable terms, thereby harming follow-on innovation. Sub-licensable grant-backs act as a remedy to this situation, by allowing biobanks to extend the license to other users. Yet, one problem with sub-licensable grant-back clauses is that sub-licenses could authorize hundreds or thousands of users. Mass licensing would raise the risk of grant-back licenses undermining the value of the IP. For example, if a user developed a new way of analyzing samples and the biobank automatically licensed all other users, then the user could be deprived of a substantial proportion of its potential licensees. This example also raises the question of whether the uses would be commercial (in which the user should pay a license fee) or whether the uses would be non-commercial (in which a user would not have to pay). However, it is not always clear whether uses of inventions are commercial or non-commercial, and policing this line would likely be expensive and time consuming. Consequently, users have good grounds to avoid sub-licensable grant-back clauses, and biobanks therefore have a good reason to omit them.

If biobanks did not have a mechanism to ensure that users license their IP on reasonable terms, then perhaps this conclusion on sub-licensable grant-back licenses would be different. However, this study found that march-in clauses can be drafted to provide appropriate responses to unreasonable licensing practices, which effectively leaves sub-licensable grant-back clauses redundant.

4. Return-of-Results Clauses: Pyrite or Gold?

Commentators recommended biobanks use return-of-results clauses on the grounds that the results would be shared with other users. Yet, this study found only nine biobanks (17%) included a return-of-results clause and that only four of these biobanks included a clause that allowed the results to be shared with other users. The discussion below explores why biobanks may have omitted return-of-result clauses and concludes that it is prudent to collect more evidence on the benefits of these clauses before encouraging or discouraging biobanks from using them.

Biobanks take great care in developing and curating their data and might consider any returned data to be unworthy of reintegration for several reasons. One reason is that biobanks might be concerned about the quality and reproducibility of the data, a situation commonly known as the 'reproducibility crisis'.[65] Another reason concerns interoperability and file formats. Scientists frequently transfer data to each other in different formats and, hence, biobanks might be concerned about interoperability issues. It takes time and effort to reformat the data to make it compatible and to avoid errors the reformatting may introduce.[66] A third reason is that, even if the data is in the correct format, biobank staff might find the data incomprehensible or have to spend too much time trying to interpret it. Moreover, these issues are multiplied by the number of biobank users, possibly making the management of the returned data overwhelming.

The arguments opposing the use of return-of-project-results terms are compelling, but so is the prospect of the clauses enriching biobanks' collections. Consequently, further empirical research on this topic is required, with particular emphasis on identifying if biobanks view the adoption of such clauses as beneficial. This research should also distinguish between situations where biobanks use users' results for internal purposes and situations where the biobank shares the results with other biobank users. Until this research has been conducted, it remains difficult to comment definitively on whether biobanks should embrace or avoid return-of-results clauses.

5. Reach-Through Clauses: A Lottery?

No biobank in this study used a reach-through clause to claim IP rights. Therefore, biobank practice on these terms aligns with the opinions of commentators, who discouraged the use of reach-through clauses because biobanks typically do not contribute to inventions and claims to IP can increase transaction costs. However, this study also found four other types of reach-through clauses: (i) tangible property; (ii) royalties for donors; (iii) 'favorable' terms; and (iv) royalties for biobanks. Each of these clauses will be discussed in turn.

Previous studies on IP clauses focused on how the clauses could prevent undesirable innovation, enrich biobanks' collections, or improve biobanks' financial positions.[67] This study was designed to focus on the same issues, especially financial sustainability. However, the first three types of reach-through clauses found in this study do not address these issues: reach-through to tangible property likely protect donor privacy; royalties for donors are connected to benefit sharing and donor recruitment;[68] and 'favorable' terms typically benefit the higher-level government or healthcare institutions (by allowing them to buy less expensive products), not the biobank. Since these three clauses raise issues beyond the scope of this study, this paper reports these findings but leaves them for other studies to analyze.

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65 Paul Glasziou et al., *Reducing Waste from Incomplete or Unusable Reports of Biomedical Research*, 383 Lancet 267–276 (2014); John P. A. Ioannidis, *Why Most Clinical Research Is Not Useful*, 13 PLoS Med (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915619/ (accessed Oct. 21, 2020).

66 Moritz Lehne et al., *Why Digital Medicine Depends on Interoperability*, 2 NPJ Digit Med (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6702215/ (accessed Oct. 21, 2020).

67 Pathmasiri et al., *supra* note 14.

68 Dianne Nicol & Christine Critchley, *Benefit Sharing and Biobanking in Australia*, 21 Public Underst Sci 534–555 (2012).

6. Reach-Through Royalties & Financial Access Conditions: Securing Sustainability?

Reach-through clauses to royalties (for the benefit of biobanks) can generate extra income, and were used by four biobanks (7%). Reach-through clauses to royalties secure a return for the biobank while navigating commentators' concerns about biobanks obtaining rights over downstream IP without making an inventive contribution. However, the apportionment of royalties dilutes returns for users, who receive less income from sales or licensing. The issue of diluted returns is a key part of weighing whether biobanks should embrace reach-through clauses to royalties. Before that issue is addressed, though, it is instructive to review this study's findings on financial access conditions and other studies' conclusions on the financial sustainability of biobanks. These findings indicate that some biobanks likely need to use reach-through clauses to royalties to remain financially viable. Consequently, this study supports reach-through claims to royalties when biobanks need them to stay solvent but also suggests these terms should be constrained by several other competing interests.

If biobanks omit reach-through terms to royalties and IP, then the only option for them to generate income when users access their materials is to charge a fee (assuming users do not pay for additional analyses). This study found that 22 biobanks (41%) do not charge access fees or include a reach-through clause to royalties. This finding means nearly half of the biobanks in this study fund their activities from other sources. These 22 biobanks are in a good position to maximize the utility of their materials as public infrastructure, as no researchers will be deterred from seeking access because of up-front costs or diluted returns.

The financial position of biobanks that need to charge access fees is different. Albert et al. studied the financial positions of three cancer biobanks in Canada.[69] Their study assessed what different types of users are prepared to pay to obtain biobank materials as well as the costs to collect and maintain the materials. Albert et al. found that academic researchers were able to pay only 10–25% of the costs to collect and maintain the samples,[70] yet they also found that industry researchers were able to pay the full cost of samples and could even afford an additional margin to offset the costs that academics could not cover.[71]

This study found that 32 biobanks (59%), including the one biobank which offered conflicting statements, charged an access fee or included a reach-through term to royalties for the biobanks' benefit. This study also found that 18 of these biobanks adopted a variable charging model, but only one altered their fees if a user was from industry. The biobanks in this study are likely to have a variety of funding sources (eg government, external grants, cross-subsidies from other operations), and they are also likely to have a firm idea about their revenue and expenditure. Nonetheless, Albert et al. showed that the costs of maintaining samples increase over time rather than decrease as many might expect. They also argue that biobanks have inflated expectations of their ability to recover costs,[72] and their results suggest biobanks should look to variable

69 Monique Albert et al., *Biobank Bootstrapping: Is Biobank Sustainability Possible Through Cost Recovery?*, 12 Biopreservation and Biobanking 374–380 (2014).

70 *Id.* at 377.

71 *Id.* at 379.

72 *Id.*

charging models with higher rates for industry users if they are facing or expect financial challenges.[73]

Variable charging models with higher fees for users from the commercial sector may be appropriate for biobanks that need extra income, yet many biobanks will not know ex ante what level of fees will deter industry users. Biobanks are also usually keen to attract as many users as possible because it is the primary reason the biobanks are built. This puts some biobanks between a rock and a hard place: raise fees for industry users too high and risk losing the industry users, or lower the fees and risk insolvency. This is where reach-through rights to royalties can fit in. If biobanks think that they have raised fees as high as possible without deterring users, then royalties might be their only other option to generate additional income.

This justification for reach-through terms to royalties is relatively cogent because insolvent biobanks cannot serve their purpose of enabling scientific research. However, this discussion is incomplete until the issue of whether diluted commercial returns will deter users is addressed.

7. Do Reach-Through Clauses to Royalties Deter Users?

No evidence exists on whether reach-through clauses to royalties deter users. Nevertheless, it is still useful to consider this issue from first principles with some insights from related research. To begin with, the issue can be split into two questions (i) whether a reach-through royalty will deter users regardless of the rate and (ii) whether only certain 'higher' royalty rates will deter users.

Future studies should try to answer these questions. In the meantime, two studies that consulted the public on this topic offer some insight on the first question. These studies found support for royalties, especially when the biobank made a material contribution to the user's product.[74] Consequently, if the extra funds from the royalties help biobanks remain solvent and the public thinks that it can be appropriate for biobanks to have a share of the royalties, users will have difficulty arguing that royalty clauses are unjustified in principle. Instead, a more important issue is to identify the rates at which users are likely to be deterred.

One biobank in this study had a fixed rate of 75 per cent of revenue returned to the biobank (and its associated partners). This biobank might serve as a good case study to examine the deterrence effects of royalty rates. The other three biobanks determined their royalties on case-by-case bases. This approach has the bonus of fitting the royalty to the contribution the biobank makes, with one biobank going one step further by stating that it was entitled to a 'reasonable share'.

The word 'reasonable' connotes ideas of 'sound judgement', 'fairness', and 'moderation'.[75] Users would likely find it difficult to argue that biobanks are not entitled to a 'fair'

73 Recent ideas on 'infrastructure theory' also support this approach. See Brett M. Frischmann, *An Economic Theory of Infrastructure and Commons Management*, 89 Minn. L. Rev. 917–1030 (2004); W Nicholson Price II, *supra* note 2.

74 Dianne Nicol et al., *Understanding Public Reactions to Commercialization of Biobanks and Use of Biobank Resources*, 162 Social Science & Medicine 79, 85 (2016); UK Biobank, *Access to the UK Biobank Resource: Advising on the Public Interest and Public Good*, https://egcukbiobank.org.uk/meetingsandreports.html (accessed Oct. 20, 2020).

75 Oxford English Dictionary.

or 'moderate' share if the biobank made a material contribution to the product, even if this contribution falls below the threshold of inventiveness for a patent. However, users might still have concerns about how the biobank's share will be calculated. In particular, users will generally be the party risking resources on the commercial product, and hence it is possible that they might be concerned if the royalty calculations exclude or downplay this risk and other commercial realities.

Perhaps the best way for biobanks to alleviate users' concerns about how a royalty will be calculated is to specify that, in the absence of agreement between the parties, the rate will be determined by a third party with suitable qualifications. The World Intellectual Property Office (WIPO) offers arbitration and 'expert determination' services,[76] as do several other groups.[77] WIPO even supplies clauses to be inserted into contracts mentioning these dispute resolution mechanisms.[78] Thus, mechanisms exist for biobanks to implement reach-through terms to licenses that will likely alleviate users concerns about royalty calculations.

8. Roles for Reach-Through Clauses to Royalties

The discussion in this section has so far concentrated on whether reach-through clauses to royalties can be justified and, if so, how royalty rates can be set and calculated so as not to deter users. However, two further issues arise with royalties and biobank finances. The first issue is that royalty income is unpredictable, as no one knows when a user will produce a commercial product. This unpredictability is compounded by the relatively low success rates of biomedical commercialization.[79] The second issue is that the amounts that biobanks stand to receive are variable, depending on the royalty rate and the commercial success of the product.

These two issues do not mean the clauses will fail to benefit biobanks, but they do suggest biobanks should think of royalties in different ways to access fees (and other funding). Biobanks could see royalties as an opportunity to fill unforeseen financial gaps that will almost inevitably open up (eg the increasing cost of maintaining samples, as foreseen by Albert et al.).[80] Another way is to see them as opportunities to fund improvements over time to the biobank or, if the royalties are large enough, to relieve governments (or other funders) of funding commitments in future years.

In short, reach-through terms can be viewed as an unusual lottery: it is unwise for any organization to base its finances on winning a lottery, but if lottery tickets are free (or low cost) and the proceeds can alleviate fiscal difficulties, then organizations that have access to these unusual lotteries should consider taking out tickets.

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76 World Intellectual Property Organization, *Alternative Dispute Resolution*, https://www.wipo.int/amc/en/ (accessed Oct. 21, 2020).

77 See for example the UK IPO's mediation service: https://www.gov.uk/guidance/intellectual-property-mediation#the-ipos-mediation-service (accessed Oct. 20, 2020).

78 World Intellectual Property Organization, *WIPO Clause Generator*, https://www.wipo.int/amc-apps/clause-generator/ (accessed Oct. 21, 2020).

79 J. A. DiMasi et al., *Trends in Risks Associated With New Drug Development: Success Rates for Investigational Drugs*, 87 Clinical Pharmacology & Therapeutics 272, 274–276 (2010); Michael Hay et al., *Clinical Development Success Rates for Investigational Drugs*, 32 Nat Biotechnol 40–50 (2014).

80 Albert et al., *supra* note 69 at 375.

VI. CONCLUSION

This survey sought to provide an empirical review of the IP practices and financial access conditions employed by large, human biobanks. Earlier studies identified five IP clauses that had the potential to prevent socially undesirable innovation, enrich biobanks' collections, and improve biobanks' financial positions: (i) non-obstruction clauses; (ii) march-in clauses; (iii) grant-back clauses; (iv) return-of-results clauses; and (v) reach-through clauses. This study analyzed whether and how biobanks used these clauses, and paid particular attention to reach-through clauses because they have the potential to help biobanks' financial sustainability.

This study found a low uptake of all five IP clauses and, where the clauses were used, no standards have emerged in the form of similar wording. The low uptake of reach-through clauses is consistent with commentators' opinions. On the other hand, the low uptake of the four remaining IP terms differs from commentators' recommendations. Two overlapping reasons potentially explain this divergence: (i) biobanks are not aware of the gamut of IP terms available; and (ii) IP is not a critical concern in practice, and biobanks instead focus on more pressing aspects of biobank governance. Regardless of the reason, this study suggests that biobanks should take renewed interest in their IP policies, as several of the underused clauses could offer significant benefits.

This study reviewed the competing arguments for the five clauses. In conclusion, it encourages the use of march-in clauses, finding that, with some tweaks, the clauses could be useful tools for rectifying breaches of research standards and preventing unreasonable licensing practices. Contrastingly, this study discourages non-obstruction clauses because they are toothless, too open to different interpretations, and redundant (in light of march-in clauses). This study also discourages the use of grant-back clauses that are sub-licensable to other IP users because the clauses could undermine the value of users' IP, and thus deter users. On the other hand, this study encourages a subtler use of grant-back clauses that licenses biobanks to handle users' IP for internal purposes. These clauses can be justified as a 'quid pro quo' for the material and data supplied by the biobanks.

The arguments for and against return-of-results clauses are relatively balanced, and it is unclear whether they are beneficial in practice. Therefore, this study neither encourages nor discourages their adoption. Instead, this study calls for further empirical research.

All biobank commentators that discussed reach-through clauses focused on the idea of biobanks claiming users' IP rights. This study found no examples of biobanks that used a reach-through clause to IP. However, this study did find several other reach-through clauses to different subject matter, of which the most common was royalties. This study recommends that biobanks use reach-through terms to royalties, but only in limited circumstances.

This study recommends that access fees with higher charges for commercial industry should the primary way biobanks remain solvent. However, if access fees prove insufficient, then reach-through terms to royalties might provide vital additional funds. In these circumstances, biobanks should consider: (i) limiting the royalties to circumstances when the biobank made a 'material contribution' to the product; (ii) ensuring royalties rates are 'reasonable' or 'fair'; and (iii) using a third party with experience in commercial negotiations to settle royalties when they cannot be settled between the parties.

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SUPPLEMENTARY DATA

Supplementary data are available at *JLBIOS* online.