Intellectual Property and Bioprinting: the battle royale between BICO and Organovo

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Do you know how far these people will go to protect their intellectual property?

Westworld [1]

1. INTRODUCTION

3D printing – additive manufacturing – has a long history of evolution and development.[2] In its amicus brief to the Supreme Court of the United States in the *Apple* v. *Samsung* litigation, Public Knowledge provides a useful summary and outline of the field of 3D printing: 'Generally speaking, 3D printing is a set of technologies for using computer-controlled machinery to manufacture parts or devices.'[3] Public Knowledge highlighted the medical applications of 3D printing: 'Personalized medical implants and prosthetics can be custom-made to fit individual patients'. [4] An important subsector of 3D printing has been the health applications – including medical 3D printing, bioprinting, and dental 3D printing.

In a 2014 survey, C. Lee Ventola provides a useful classification of medical 3D printing: 'Medical uses for 3D printing, both actual and potential, can be organized into several broad categories, including: tissue and organ fabrication; creation of customized prosthetics, implants, and anatomical models; and pharmaceutical research regarding drug dosage forms, delivery, and discovery'.[5] The researcher considers the future of the technology: '3D printing has become a useful and potentially transformative tool in a number of different fields, including medicine.'[6] Ventola predicted further growth in the field: '3D printing is expected to play an important role in the trend toward personalized medicine, through its use in customizing nutritional products, organs, and drugs.'[7]

As the technology has matured, it has become apparent that 3D printing has a number of health applications in respect of medicine, biotechnology, pharmacology, and dentistry. Richard d'Aveni observes that 'a significant amount of [additive manufacturing] development has come from the medical industry'.[8] He observes: 'Bioprinting is already being used to create tissues for use in drug testing and pathology experiments, skin cells for use in grafts and repairs, and living materials for other applications.'[9] Lucas Osborn has commented that 'the medical community was an early adopter of 3D printing technology', and 'established products like customized hearing aid shells, dental products, and prosthetics have been 3D printed for years'.[10]

There is a growing literature in respect of intellectual property, regulation, and 3D printing. Such work touches upon the sub-fields of medical 3D printing, bioprinting, and dental 3D printing. In his book on the Maker Movement, *Makers*, Chris Anderson considers the evolution of 3D printing, and has a short chapter at the end, deal-

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1 HBO, *Westworld*, https://www.hbo.com/westworld https://www.imdb.com/title/tt0475784/characters/nm0628601

2 Dinusha Mendis, '3D Printer' in Claudy Op Den Kamp and Dan Hunter (ed.), *A History of Intellectual Property in 50 Objects*, Cambridge: Cambridge University Press, 2019, 353-359.

3 Brief of Public Knowledge, the Electronic Frontier Foundation and Engine Advocacy as Amici Curiae in Support of Petition for Writ of Certiorari in *Samsung Electronics Co.* v. *Apple Inc.,* April 2017, https://www.scotusblog.com/wp-content/uploads/2017/04/16-1102-cert-amicus-Public-Knowledge.pdf

4 Ibid.

5 C. Lee Ventola, 'Medical Applications for 3D Printing: Current and Projected Uses' (2014) 39 (10) *Pharmacy and Therapeutics* 704-711.

6 Ibid.

7 Ibid.

8 Richard D'Aveni, *How New Manufacturing Titans Will Transform the World*, Boston and New York: Houghton Mifflin Harcourt, 2018.

9 Ibid., 24.

10 Lucas Osborn, *3D Printing and Intellectual Property*, Cambridge: Cambridge University Press, 2019, 12.

ing with the emergence of DIY Biology.[11] He speculated: 'What happens when the tools get powerful enough to extend to biology and genetics?'.[12] Mark Lemley draws comparisons between 3D printing and other generative technologies such as synthetic biology.[13] He envisages: 'Combine these four developments—the Internet, 3D printing, robotics, and synthetic biology— and it is entirely plausible to envision a not-too-distant world in which most things that people want can be downloaded and created on site for very little money—essentially the cost of raw materials.'[14] In his book *The Zero Marginal Cost Society*, Jeremy Rifkin considers 3D printing, and patient-centred care.[15] He envisages a revolution in the provision of healthcare. Angela Daly compares and contrasts the regulatory regimes for the EU and United States in respect of medical 3D printing.[16] Jasper Tran has directly addressed some of the regulatory dilemmas in respect of bioprinting.[17] Nicole Syzdek suggests that there will be a progressive accommodation of 3D printing within patent law.[18] James Griffin and his collaborators have considered the emergence of 4D printing and its implications for healthcare, amongst other sectors.[19]

As part of a larger project focused on intellectual property and 3D printing,[20] this paper will consider the intersection of intellectual property and bioprinting. It builds upon previous work of the author – looking at copyright law and 3D printing;[21] trade mark law and 3D printing;[22] open design and 3D printing;[23] patent law and dental 3D printing; [24] patent law and metal 3D printing;[25] education and 3D printing; [26] and the regulation of 3D printing construction. [27] In terms of its methodology, this work conducts corporate case studies of key players in the field

11 Chris Anderson, *Makers: The New Industrial Revolution*, New York: Random House LLC, 2012.

12 Ibid., 233.

13 Mark Lemley, 'IP in a World Without Scarcity', (2015) 90 *New York University Law Review* 460-515.

14 Ibid., 462.

15 Jeremy Rifkin, *The Zero Marginal Cost Society: The Internet of Things, the Collaborative Commons, and the Eclipse of Capitalism*, New York: St Martin's Press, 2014.

16 Angela Daly, *Socio-Legal Aspects of the 3D Printing Revolution*, London: Palgrave Pivot, 2016. See also: Thomas Birtchnell, Angela Daly, Thierry Rayna, and Ludmila Striukova, *3D Printing and Intellectual Property Futures*, Newport (UK): United Kingdom Intellectual Property Office, 2018, https://ro.uow.edu.au/cgi/viewcontent.cgi?article=5885&context=sspapers

17 Jasper Tran, 'To Bioprint or Not to Bioprint', (2015) 17 *North Carolina Journal of Law and Technology* 123-178.

18 Nicole Syzdek, 'Five Stages of Patent Grief to Achieve 3D Printing Acceptance' (2015) 49 *University of San Francisco Law Review* 335-360.

19 James Griffin, *The State of Creativity: The Future of 3D Printing, 4D Printing and Augmented Reality*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, 2019; and Hing Kai Chan, Hui Leng Choo, Onyeka Osuji and James Griffin (ed.), *Intellectual Property Rights And Emerging Technology: 3D Printing in China*, London and New York: Routledge, 2019.

20 The author and his collaborators sought to map the field of intellectual property, 3D printing, and regulation. See Dinusha Mendis, Mark Lemley, and Matthew Rimmer (ed.), *3D Printing and Beyond: Intellectual Property and Regulation*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, 2019.

21 Matthew Rimmer, 'The Maker Movement: Copyright Law, Remix Culture, and 3D Printing', (2017) 41 (2) *The University of Western Australia Law Review* 51-84; and Matthew Rimmer, 'Makers Empire: Australian Copyright Law, 3D Printing, and the 'Ideas Boom'', in Dinusha Mendis, Mark Lemley, and Matthew Rimmer (ed.), *3D Printing and Beyond: Intellectual Property and Regulation*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, 2019, 253-293

22 Matthew Rimmer, 'Save Left Shark: Katy Perry, Intellectual Property, and 3D Printing', (2016) 29 (1) *Australian Intellectual Property Law Bulletin* 15-21.

23 Matthew Rimmer, 'Lady Ada: Limor Fried, Adafruit Industries, Intellectual Property, and Open Source Hardware' (2021) 16 (10) *Journal of Intellectual Property Law and Practice* 1047-1061

24 Matthew Rimmer, 'ClearCorrect: Intellectual Property, 3D Printing and the Future of Trade', (2019) 23 (1) *Gonzaga Journal of International Law* 154-194.

25 Matthew Rimmer, 'Metal 3D Printing: Patent Law, Trade Secrets, And Additive Manufacturing', (2022) 7 *Frontiers in Research Metrics and Analytics*, Article number: 958761, https://www.frontiersin.org/articles/10.3389/frma.2022.958761/full

26 Matthew Rimmer, 'Make and Share: Intellectual Property, Higher Education, Technology Transfer, and 3D Printing in a Global Context', in Jacob Rooksby (ed.), *Research Handbook on Intellectual Property and Technology Transfer*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, 2020, 447-479.

27 Brydon Timothy Wang and Matthew Rimmer, '3D Printing and Housing: Intellectual Property and Construction Law' in Brydon Timothy Wang and Chien Ming Wang (ed). *Automating Cities: Design, Construction, Operation and Future Impact*, Singapore: Springer, 2021, 113-140; and Matthew Rimmer, 'Automating Fab Cities: 3D Printing and Urban Renewal', in Brydon Timothy Wang and Chien Ming Wang (ed). *Automating Cities: Design, Construction, Operation and Future Impact*, Singapore: Springer, 2021, 255-272.

of bioprinting – most notably, Organovo and Cellink. It examines the intellectual property portfolios of these companies, and the licensing arrangements in respect of their technology, as well as litigation. This article follows a similar approach to that of Sally Smith Hughes – who conducted a case study of Genentech.[28] It is a scientific history in the manner of Paul Rabinow.[29] It engages an in-depth case study of patent litigation in respect of bioprinting – following the example of Jorge Contreras who provided an in-depth case study of gene patent litigation involving Myriad Genetics.[30] This study is an extension of past research on landmark intellectual property cases.[31] This work is part of a large genre of legal writing – which engages in storytelling of narratives about watershed litigation.[32]

This article has several parts. Part 2 will chart the landscape for patents in respect of bioprinting. This data analysis will look at the databases of the World Intellectual Property Organization (WIPO), IP Australia, the United States Patent and Trademark Office (USPTO), the United Kingdom Intellectual Property Office (UKIPO), the European Patent Office (EPO), and the Japanese Patent Office (JPO). The study will seek to illuminate patent trends in the field. Moreover, it will seek to analyse patent thickets and white spaces in the field of bioprinting. This will be of considerable importance in determining the freedom to operate for researchers and scientists working in the field. Part 3 considers questions of patent infringement and enforcement. In particular, it analyses the conflict between United States company Organovo and Swedish company Cellink (now part of the BICO corporate group) over bioprinting patents. 3D printing and bioprinting also raises larger questions about the nature of patent infringement, and the role and scope of patent exceptions. Part 4 looks at patent defences, exceptions, and limitations – such as the defence of experimental use – and their application in the context of 3D printing and bioprinting. There has been interest in public licensing, research exchanges, patent pools, in respect of bioprinting. There has also been discussion of compulsory licensing, Crown Use, and government acquisition. The conclusion considers the issues raised under patent law by bioprinting. It also notes secondary forms of intellectual property protection – such as trade marks, trade secrets, and copyright protection. The conclusion considers the inter-relationship between intellectual property and regulation in the context of bioprinting.

It should be noted that scope of this article is limited to patent law and bioprinting. A number of topics are beyond the circumference of this article due to space considerations – given the expanding literature in the field. The topic of patentable subject matter in the context of 3D printing and bioprinting deserves separate consideration (especially given the growing policy debate around the topic). The author hopes to consider how other forms of intellectual property (such as copyright law, trade mark law, and database protection) impinge upon the bioprinting in the future. There is scope for further work in the future on open source bioprinting projects; the regulation of bioprinting; and product liability in the fields of medical 3D printing and bioprinting.

2. BIOPRINTING PATENT LANDSCAPES

To begin with, this article charts the patent landscapes in respect of 3D printing generally, and bioprinting in particular. In particular, it will focus upon the patent landscapes of 3D printing and bioprinting, which have been mapped by the World Intellectual Property Organization (WIPO), the United States Patent and Trademark Office (USPTO), the United Kingdom Intellectual Property Office (UKIPO), the European Patent Office (EPO), and IP Australia. The study will seek to illuminate patent trends in the field. Moreover, it will seek to analyse patent thickets and white spaces in the field of bioprinting. This will be of considerable importance in determining the freedom to operate for researchers and scientists working in the field.

As Peter Drahos has observed, it is useful to analyse the workings of patent offices, and how they deal with the governance of new technologies and forms of knowledge.[33] Historically, patent offices have struggled to adapt to the examination of new technology fields – such as information technology, business methods, biotechnology, and nanotechnology in the past.[34] As a result, patent officers have sought to recruit specialised examiners, and have established cross-disciplinary patent examination teams to deal with new fields of technology. Patent offices have also invested heavily in information technology and Big Data to better map new fields of knowledge. WIPO and key patent offices around the world have sought to proactively engage with some of the new developments in respect of 3D printing and additive manufacturing –

28 Sally Smith Hughes, *Genentech: The Beginnings of Biotech,* Chicago: University of Chicago Press, 2011.

29 Paul Rabinow, *Making PCR: A Story of Biotechnology*, Chicago: The University of Chicago Press, 1996; and Paul Rabinow, *French DNA: Trouble in Purgatory*, Chicago: The University of Chicago Press, 1999.

30 Jorge Contreras, *The Genome Defense: Inside the Epic Legal Battle to Determine Who Owns Your DNA,* Chapel Hill (North Carolina): Algonquin Books, 2021.

31 Seth Shulman, *Owning the Future*, Boston: Houghton Mifflin, 1999; Jane Ginsburg, and Rochelle Cooper Dreyfuss, *Intellectual Property Stories*. New York: Thomson/West, 2006, and Andrew Kenyon, Megan Richardson, and Sam Ricketson (eds). *Landmarks in Australian Intellectual Property Law.* Cambridge: Cambridge University Press, 2009.

32 See for instance – the Law Stories Series of West Academic, https://www.westacademic.com/series/Law-Stories; Richard J. Lazarus, *The Rule of Five: Making Climate History at the Supreme Court*, Cambridge (Ma.) and London: The Belknap Press of Harvard University Press, 2020.

33 Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients*, Cambridge: Cambridge University, 2010.

34 Alison McLennan and Matthew Rimmer, 'Cosmo, Cosmolino: Patent Law and Nanotechnology' in Matthew Rimmer and Alison McLennan (ed.), *Intellectual Property and Emerging Technologies: The New Biology*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, 2012, 255-290.

and key subsectors, such as medical bioprinting and bioprinting.

A. World Intellectual Property Organization

In 2013, the then Director-General of WIPO, Francis Gurry, highlighted the transformative power of new developments in the life sciences: 'The next developments in the life sciences, for instance, could transform our lives.'[35] He predicted: 'Information technology, molecular biology, regenerative medicine, and even technologies such as 3D printing are coming together in and around the life sciences to generate extraordinary potential.'[36]

WIPO has been undertaking data analytical work in respect of emerging technologies – including 3D printing.[37] The WIPO undertook patent analysis in respect of innovations with future breakthrough potential – including 3D printing. WIPO highlights that 3D printing raised significant issues in respect of enforcement: 'The personal 3D printing market segment raises new challenges to the IP system, especially with regard to how to enforce existing IP rights.'[38] The main focus of this report was on personal 3D printing. There was also a strong accent upon industrial 3D printing. There was not a strong focus on medical 3D printing or bioprinting in this report.

B. United States Patent and Trademark Office (USPTO)

The United States Patent and Trademark Office (USPTO) has sought to engage with 3D printing and bioprinting. Much like it did with the hybrid field of nanotechnology,[39] the USPTO established an inter-disciplinary team of patent examiners to focus on the examination of patent applications in the fields of 3D printing and additive manufacturing. There was also activity by public interest groups who would crowdsource prior art data in order to challenge the validity of patents, and the breadth and scope of their claims.

Obama administration USPTO Director Michelle K. Lee gave a presentation at the Microsoft Tech Lab, highlighting the relationship between intellectual property and 3D printing.[40] She maintained that 3D printing, or additive manufacturing as we call it at the USPTO, [is] a rising industry directly correlated with the role of patents driving innovation.'[41] Lee paid tribute to the pioneers of 3D printing – such as Charles Hull. She was particularly interested in the future applications of 3D printing – particularly in the field of medicine and health: 'There are life-changing products being quickly and easily produced to the exact specifications needed, such as revolutionary prosthetics'.[42] She highlighted the Marvel Star presenting a prosthetic arm made by a college student to a child: 'Some of you may have seen the viral video of Robert Downey, Jr., presenting a seven-year-old boy with a prosthetic arm that looked just like a piece of his armored suit in the Iron Man and Avengers movies.'[43] Lee highlighted the role of 3D printing and additive manufacturing in boosting innovation and 'changing lives'. She observed: 'To give you an idea of that potential, the USPTO has received about 1,700 applications per year over the last five years in the field of additive material technologies; and in hundreds of different patent classification areas, due to the varying types of end products that can be manufactured with this technology.'[44] Lee concluded: 'So additive manufacturing, fueled by the promise of intellectual property protection, is taking off, and as we've seen it's having a positive impact on people's lives and the economy.'[45]

The USPTO has participated as an exhibitor in events, such as the World Maker Faire in New York in 2014, and other Maker Faires around the United States.[46] The USPTO stressed: 'These are opportunities to provide IP education to exhibitors and attendees who are creating, inventing, and innovating every day but who may not know if what they are creating can be protected.'[47]

The USPTO conducted an Additive Manufacturing Partnership meeting in 2016 to seek opinions from various stakeholders and participants.[48]

The USPTO hosted a public conference on intellectual property and 3D printing in 2016 at its headquarters at Alexandria, Virginia.[49] The USPTO noted: '3D printing is used in the fields of jewelry, footwear, architecture, engineering and construction, automotive, aerospace, dental and medical industries, education, geographic information systems, civil engineering, and many others.'[50]

35 Francis Gurry, 'Creativity – The Next Generation', World Intellectual Property Day, 26 April 2013, https://www.wipo.int/ip-outreach/en/ipday/2013/dg_message.html

36 Ibid.

37 World Intellectual Property Organization, *World IP Report: Breakthrough Innovation and Economic Growth*, Geneva: World Intellectual Property Organization, 2015 https://www.wipo.int/publications/en/details.jsp?id=3995

38 Ibid.

39 Alison McLennan and Matthew Rimmer, 'Cosmo, Cosmolino: Patent Law and Nanotechnology' in Matthew Rimmer and Alison McLennan (ed.), *Intellectual Property and Emerging Technologies: The New Biology*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, 2012, 255-290.

40 Michelle K. Lee, 'Remarks at Microsoft Tech Lab', United States Patent and Trademark Office, Washington DC, 30 September 2015, https://www.uspto.gov/about-us/news-updates/remarks-director-michelle-k-lee-microsoft-tech-lab

41 Ibid.

42 Ibid.

43 Ibid.

44 Ibid.

45 Ibid.

46 Elizabeth Dougherty, 'Making Innovation Fun and Faire', Inventors Eye, United States Patent and Trademark Office, https://www.uspto.gov/learning-and-resources/newsletter/inventors-eye/making-innovation-fun-and-faire

47 Ibid.

48 United States Patent and Trademark Office, 'USPTO Additive Manufacturing Partnership Meeting', 18 May 2016, https://www.uspto.gov/about-us/events/uspto-additive-manufacturing-partnership-meeting

49 United States Patent and Trademark Office, 'Legal and Policy Considerations of IP in 3D Printing', Conference, Arlington, Virginia, 28 July 2016, https://www.uspto.gov/learning-and-resources/ip-policy/uspto-ip-and-3d–printing-conference

50 Ibid.

Reflecting on the event, Shira Perlmutter discussed the legal challenges of intellectual property and 3D printing.[51] She observed that 'the USPTO is well aware of the growth of the 3D printing industry: in 2015, there were 23 times more patent applications filed for 3D printing technologies than in 2010.'[52] Perlmutter also noted that 'Similar growth was seen on the trademarks side, with filings having grown by more than 300 percent over the same period.'[53] Indeed, in '2016 alone, there have been 425 new trademark applications filed for 3D printing-related goods and services'.[54]

Perlmutter highlighted concerns about intellectual property infringement: 'Participants discussed how the explosion of 3D printing technologies may eventually place intellectual property rights at a greater risk of infringement from a widening base of infringers'.[55] She commented: 'Improvements in additive manufacturing technologies suggest that, in the not-too-distant future, copies of protected products may be easier than ever for anyone to make.'[56] Perlmutter observed: 'The best way to respond to rapid technological change is to collaborate—not just with colleagues, but with those working across disciplines.'[57] She concluded that the gathering was intended to encourage collaborative thought and action.

In 2017, the USPTO highlighted the growth of 3D printing in intellectual property filings.[58] The institution observed: 'The (USPTO) received over 8,000 patent applications last year alone in the field of additive material technologies.'[59] The USPTO noted: 'These represent a range of products – from household items to prosthetics – that are being manufactured with 3D printing and are having a positive impact on people's lives and the economy'.[60] The USPTO specifically highlighted the subarea of bioprinting: 'Exciting advances are being made with 3D bioprinting, a method of using 3D printing to create new tissues and organs.'[61] The USPTO noted that the National Inventors Hall of Fame showcased the next generation of 3D printing innovation, including the work of Dave Kolesky for 3D bioprinting of vascularized human tissue. The USPTO maintained that it 'plays an important role in supporting American businesses in new and growing industries to get new products and technologies to the marketplace faster', which 'ultimately drives innovation and creates new jobs for American workers, benefitting consumers and manufacturers alike.'[62] The USPTO noted that 'to stay ahead of the curve in new areas, the agency partners with private industry in other areas such as cyber security and bioscience, all while providing the most up-to-date technical training to patent examiners who examine these new technologies every day.'[63]

There have been a series of patent landscapes conducted in respect of 3D printing, drawing upon the data of the USPTO.

In 2016, Robert Esmond and Deborah Sterling have also sought to chart the intellectual property landscape in respect of bioprinting.[64] They sought to provide a summary of the landscape of utility patents in respect of three key stages of bioprinting – first, bioimaging, CAD, and blueprint patents; second, bioink, biopaper and bioprinter patents; and third, maturogens, biomonitoring and bioreactor patents. Esmond and Sterling maintained that there was still scope for further patent applications in respect of bioprinting: 'While it may seem that it is too late to start filing patent applications on bioprinting innovations, there remains room for further patentable improvements.'[65]

There has been some interesting work on emerging patent landscapes in respect of 3D bioprinting. The lawyers John Hornick and Kai Rajan have provided some interesting data analysis of United States and overseas patent filings.[66] They observed that there have been a diverse array of patent applications from around the world, and from countries big and small. The attorneys identified a number of key players in the marketplace. The leading 3D bioprinting patent assignees in 2015-216 were, in order, Organovo Inc., Koninklijke Philips, Wake Forest University, the Hewlett-Packard Company, the University of Texas System, Medprin Regenerative Medical Technologies Co Ltd, and Corning Incorporated.

In addition to the United States, there has also been interest in the implications of 3D printing for intellectual property in the neighboring state of Canada.[67]

51 Shira Perlmutter, 'Intellectual Property and the Challenge of 3D Printing', United States Patent and Trademark Office, 2016, https://www.uspto.gov/subscription-center/2016/intellectual-property-and-challenge-3d–printing

52 Ibid.

53 Ibid.

54 Ibid.

55 Ibid.

56 Ibid.

57 Ibid.

58 United States Patent and Trademark Office, '3D Printing – A New Industry Made in America', 2017, https://www.uspto.gov/subscription-center/2017/3d–printing-new-industry-made-america

59 Ibid.

60 Ibid.

61 Ibid.

62 Ibid.

63 Ibid.

64 Robert Esmond and Deborah Sterling, 'Bioprinting: The Intellectual Property Landscape' in Aleksandr Ovsianikov, James Yoo and Vladimir Mironov (eds.), *3D Printing and Biofabrication, Reference Series in Biomedical Engineering*, Cham (Switzerland): Springer, 2016, 485-512.

65 Ibid., 510.

66 John Hornick and Kai Rajan, 'The 3D Bioprinting Patent Landscape Takes Shape as IP Leaders Emerge', *3D Printing Industry*, 7 July 2016, https://3dprintingindustry.com/news/3d–bioprinting-patent-landscape-takes-shape-ip-leaders-emerge-84541/

67 Tesh Dagne, 'Overview of Implications of 3D Printing upon Canadian Intellectual Property Law' (2015) 31 *Canadian Intellectual Property Review*; Tesh Dagne and Gosia Piasecka, 'The Right to Repair Doctrine and the Use of 3D Printing Technology in Canadian Patent Law' (2016) 14 (2) *Canadian Journal of Law and Technology* 263-287; and Tesh Dagne, 'Governance of Health-related 3D Printing Applications in Canada and the United States: Between Regulated and Unregulated Innovation' (2020) 22 *Columbia Science and Technology Law Review* 281-328.

C. United Kingdom Intellectual Property Office

The United Kingdom Intellectual Property Office (UKIPO) has been engaged in commissioning empirical work in the field of 3D printing.

Dinusha Mendis and her collaborators produced a series of research papers on intellectual property and 3D Printing for the UKIPO.[68]

Dinusha Mendis has further explored the history of 3D printing.[69] Dinusha Mendis and Ana Santos Rutschman have sketched out some of the emerging challenges for bioprinting in a piece for *The Conversation*.[70] They observed that there was debate over how the patent system would deal with bioprinting – citing past controversies such as the effort to patent cloning sheep: 'In Europe and the U.S., scholars and commentators have questioned whether bioprinted materials should enjoy patent protection because of the moral issues they raise'.[71] Mendis and Rutschman suggested that 'if, at some point in the future, bioprinters or indeed cloneprinters can be used to replicate not simply organs but also human beings using cloning technologies, a patent application of this nature could potentially fail, based on the current law.'[72]

In their report to the UKIPO, Thomas Birtchnell, Angela Daly, Thierry Rayna, and Ludmila Striukova discuss in passing some of the intellectual property issues arising in respect of bioprinting.[73] The report discusses the work of Minssen and Mimler.[74] Birtchnell and co observed: 'Minssen and Mimler have identified different patent claims which may occur at different stages in bioprinting research: design patents (and design rights in Europe) for machines, methods and techniques used in bioimaging and CAD at the preprocessing phase; patents for bioinks at the production phase; and a postproduction maturation phase in which 'additional patent prospects might emerge in advanced organ production'.[75] The report also cites the work of Phoebe Li and Jasper Tran on intellectual property and bioprinting.[76] In addition to conducting a literature review, this study also held stakeholder forums in various jurisdictions. At the Paris forum, the participants highlighted 'the usage of 3D printing in the medical sector, with a growing importance from now to 2050, with in 2050 the ability existing to print all sorts of organs (or even to bioprint directly into the body) and, thereby, to extend human life significantly.'[77]

In 2020, Edison Bicudo and collaborators undertook quantitative analysis of bioprinting patents filed from 2001 to 2019 and found on The Lens and Google Patents.[78] The research team also conducted fieldwork was conducted in three countries (the UK, Brazil, and Italy), involving interviews with academics and entrepreneurs exploring bioprinting.

D. European Patent Office

In 2020, the European Patent Office (EPO) has conducted large-scale investigations into patent law and 3D printing, publishing data analysis, and hosting a conference.[79] The report provides a case study on bioprinting.[80] The report observes: '3D printing for medical purposes such as the manufacture of custom implants and prosthetics usually involved plastics, metals and ceramics materials.'[81] The report notes: 'The field of cell-based bioprinting did not emerge until 2003, when Thomas Boland used a modified inkjet printer to print cells.'[82] The report comments: 'Subsequent developments led to it being used to create more complex tissues and organs.'[83]

The EPO discusses the development of biomaterials: 'The generic term "biomaterials" is used for a class of materials which have one thing in common: they are designed to interact with a patient's biological system.'[84] The EPO observes: 'The use of cells in combination with

68 Dinusha Mendis, Davide Secchi, and Phil Reeves, *A Legal and Empirical Study into the Intellectual Property Implications of 3D Printing. Executive summary*. London: UK Intellectual Property Office, 2015 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/421222/A_Legal_and_Empirical_Study_into_the_Intellectual_Property_Implications_of_3D_Printing_-_Exec_Summary_-_Web.pdf. Dinusha Mendis and Davide Secchi, *A Legal and Empirical Study of 3D Printing Online Platforms and an Analysis of User Behaviour,* London: UK Intellectual Property Office, 2015, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/421546/A_Legal_and_Empirical_Study_of_3D_Printing_Online_Platforms_and_an_Analysis_of_User_Behaviour_-_Study_I.pdf and Phil Reeves, and Dinusha Mendis, *The Current Status and Impact of 3D Printing Within the Industrial Sector: An Analysis of Six Case Studies*, London: UK Intellectual Property Office (UKIPO), 2015, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/413673/The_Current_Status_and_Impact_of_3D_Printing_Within_the_Industrial_Sector_-_Study_II.pdf

69 Dinusha Mendis, '3D Printer' in Claudy Op Den Kamp and Dan Hunter (ed.), *A History of Intellectual Property in 50 Objects*, Cambridge: Cambridge University Press, 2019, 353-359.

70 Dinusha Mendis and Ana Santos Rutschman, '3D Printing of Body Parts is Coming Fast – But Regulations are not Ready', *The Conversation*, 11 January 2020, https://theconversation.com/3d-printing-of-body-parts-is-coming-fast-but-regulations-are-not-ready-128691

71 Ibid.

72 Ibid.

73 Thomas Birtchnell, Angela Daly, Thierry Rayna, and Ludmila Striukova, *3D Printing and Intellectual Property Futures*, Newport (UK): United Kingdom Intellectual Property Office, 2018, https://ro.uow.edu.au/cgi/viewcontent.cgi?article=5885&context=sspapers

74 Ibid., 26.

75 Ibid., 25. Timo Minssen and Marc Mimler, 'Patenting Bioprinting-Technologies in the US and Europe: The Fifth Element in the Third Dimension' in Rosa Ballardini, Marcus Norrgard and Jouni Partanen (ed.), *3D Printing, Intellectual Property and Innovation: Insights from Law and Technology*, Alphen aan den Rijn: Wolters Kluwer, 2017, 117-148.

76 Ibid., 26. Phoebe Li, '3D Bioprinting Technologies: Patents, Innovation, and Access.' (2014) 6 (2) *Law, Innovation and Technology* 282-304; and Jasper Tran, 'Patenting Bioprinting', *Harvard Journal of Law and Technology*, 7 May 2015 https://ssrn.com/abstract=2603693 and https://jolt.law.harvard.edu/digest/patenting-bioprinting

77 Ibid., 55.

78 Edison Bicudo, Alex Faulkner, and Phoebe Li, 'Patents and the Experimental Space: Social, Legal and Geographical Dimensions of 3D Bioprinting' (2020) 35 (1) *International Review of Law, Computers and Technology* 2-23.

79 European Patent Office, *Patents and Additive Manufacturing: Trends in 3D Printing Technologies*, Munich: European Patent Office, 2020, http://documents.epo.org/projects/babylon/eponet.nsf/0/C2F08712126718 51C125859F0040BCCA/$FILE/additive_manufacturing_study_en.pdf (accessed 1 August 2021).

80 Ibid., 28-31

81 Ibid., 29.

82 Ibid., 29.

83 Ibid., 29.

84 Ibid., 29.

additive manufacturing techniques offers the chance to fabricate biomedical parts that maximally imitate natural tissue characteristics.'[85] The European Patent Office stresses: 'This "3D bioprinting" uses bio-inks, which comprise cells and other cell-supporting materials, to create tissue-like structures for use in medical and tissue engineering fields.'[86]

The EPO discusses the state of the art in respect of bioprinting, and the challenges in the field:

> With additive manufacturing, constructs with the required shape, size, porosity and mechanical properties can be made from a variety of materials. However, when printing said constructs together with cells, certain temperatures, solvents and other cytotoxic materials and conditions such as shear stress, viscosity and humidity, which can adversely affect living cells, need to be avoided or controlled. This limits the choice of AM printing techniques that can be used and requires solutions to allow for a more diverse and precise 3D bioprinting process.[87]

The EPO also comments: 'Along with in vitro (i.e. outside the body) bioprinting, in vivo bioprinting, i.e. bioprinting directly onto the body, is also being developed.'[88]

The EPO acknowledges that there remain a number of innovation challenges in respect of bioprinting: 'Although all these advantages of 3D bioprinting of cell-seeded tissues or organs are promising, and have already been successfully implemented on a small scale, further developments need to be made in the additive manufacturing processes, as well as in controlling the stimulation and differentiation of cells after formation of the structure, to allow for the formation of 3D printed tissues or organs of a clinically relevant size.'[89] The EPO cautioned: 'The formation of a sufficiently large and branched vascular network for delivering the required oxygen and nutrients to the cells remains particularly challenging' [90] The EPO also stressed that 'improving the resolution and accuracy of printers to allow for more detailed structures and controlled single cell deposition to closely mimic human organs would be useful.'[91] The EPO also noted: 'Biomedical devices often need to have dynamic properties, i.e. changes in shape, functionality and property.' [92] The EPO suggests: 'When these challenges have been overcome, 3D bioprinting will be a promising tool for making personalised tissues and organs.'[93] The EPO also flags the rise of 4D Printing: 'Another important development is 4D printing, a technology which describes additive manufacturing technologies adding another dimension to the device.'[94] The EPO notes that 4D printing could have significant implications for medicine and healthcare.

Previously, the EPO has had to grapple with an array of bioethical issues in respect of biotechnological inventions – in relation to plants, animals, human genes and stem cells.[95] In light of this history of conflict, the EPO also cautions that bioprinting has also presents a number of other bioethical challenges.[96] Phoebe Li has detailed how a number of the European precedents on biotechnological inventions may be relevant to adjudications in respect of bioprinting patents.[97]

The EPO is impressed by the potential commercial value of the field of bioprinting: 'According to recent market research, the global market for 3D bioprinters and biomaterials amounted to USD 651 million in 2019, and is expected to grow rapidly over the next few years, with annual growth rates exceeding 20%.'[98] The EPO has heady predictions of the future growth of the field of bioprinting: 'By 2024, it is expected to pass the USD 1.5 billion mark, with applications in the pharmaceutical and cosmetology industries.'[99]

Taking a more circumspect and wary approach to the growth of the bioprinting field, European scholars Minssen and Minier have highlighted the potential for a tragedy of the anti-commons: 'The great variety of patents and patent applications where few market-leaders with enormous patent portfolios, such as Organovo Inc., hold many overlapping patents covering key technologies could lead to patent thickets and other potential anti-commons scenarios.'[100]

The European Commission has published a commissioned report on the intellectual property implications of the development of industrial 3D printing in 2020.[101] This report considers questions around the patentability of 3D printing and bioprinting under European law. The

85 Ibid., 29.

86 Ibid., 29.

87 Ibid., 30.

88 Ibid., 30.

89 Ibid., 30.

90 Ibid., 30.

91 Ibid., 30.

92 Ibid., 30.

93 Ibid., 30.

94 Ibid., 30.

95 See Shobita Parthasarathy, *Patent Politics: Life Forms, Markets, and the Public Interest in the United States and Europe*, Chicago: The University of Chicago Press, 2017.

96 European Patent Office, *Patents and Additive Manufacturing: Trends in 3D Printing Technologies*, Munich: European Patent Office, 2020, http://documents.epo.org/projects/babylon/eponet.nsf/0/C2F0871212671851C125859F0040BCCA/$FILE/additive_manufacturing_study_en.pdf (accessed 1 August 2021).

97 Phoebe Li, '3D Bioprinting Technologies: Patents, Innovation, and Access.' (2014) 6 (2) *Law, Innovation and Technology* 282-304

98 European Patent Office, *Patents and Additive Manufacturing: Trends in 3D Printing Technologies*, Munich: European Patent Office, 2020, 29, http://documents.epo.org/projects/babylon/eponet.nsf/0/C2F0871212671851C125859F0040BCCA/$FILE/additive_manufacturing_study_en.pdf (accessed 1 August 2021).

99 Ibid., 29.

100 Timo Minssen and Marc Mimier, 'Patenting Bioprinting-Technologies in the US and Europe: The Fifth Element in the Third Dimension' in Rosa Ballardini, Marcus Norrgard and Jouni Partanen (ed.), *3D Printing, Intellectual Property and Innovation: Insights from Law and Technology*, Alphen aan den Rijn: Wolters Kluwer, 2017, 117-148 at 147.

101 Dinusha Mendis et al., *The Intellectual Property Implications of the Development of Industrial 3D Printing*. Brussels: European Commission, 2020, http://eprints.bournemouth.ac.uk/33718/

report observes: 'Considering that possibilities for relying on patent protection might have a great impact on where the greatest investments and Research & Development (R&D) efforts in this technology will be made, the question whether certain types of bioprinting technologies should be barred from patenting is crucial.'[102]

E. IP Australia

For its part, IP Australia has been interested in patent statistics around advanced manufacturing (of which perhaps 3D printing is a subset and a performance).

Sam Tavassoli and his RMIT colleagues have conducted a number of studies of the adoption and diffusion of medical 3D printing in Australia.[103] The group have produced a white paper on opportunity areas, stakeholder mapping and road mapping.[104] The researchers have also compiled a white paper on business models, barriers and resolutions.[105] The research team have presented their findings,[106] and published a summary of the work.[107]

An important dimension of this work has been the question of intellectual management and commercialisation in respect of medical 3D printing and bioprinting. In the second white paper, the team discuss concerns of small-to-medium enterprises about the time and money involved in seeking intellectual property protection. They observed: 'For medical device manufacturers in Australia, this process can cost an SME approximately $50k for a new device and it takes months to years to be processed.'[108] The researchers commented: 'The barrier raised is those companies, especially SMEs, have been the theft of IP, which not only threatens an SME's standing in a market but also negates the substantial amounts of money they put into patenting their medical devices.' [109] Tavassoli and his team reflected that 'Due to the experiences the SMEs had, some are no longer willing to patent their medical devices in Australia' and 'Instead, they file their patents only in larger and more competitive markets, such as North America, Europe, and China.'[110] Tavassoli and his research team concluded: 'The benefit does not outweigh the risk and the cost to patent a device in Australia is not deemed worth by the SMEs.'[111] Nonetheless, there was a concern about the consequences of lack of intellectual property protection and enforcement in the field of medical 3D printing and bioprinting. One of the respondents observed that 'we just don't have the money to fight the big companies.'[112]

Summary

The patent data statistics have highlighted a rise in patent applications and registrations in the field of 3D printing in key intellectual property offices around the world. There has been a particular concentration in patent applications and registrations in respect of the sub-fields of 3D printing and health – including in respect of bioprinting. Given the rise of patent thickets, there is the potential for conflict and disputation over patent validity and patent infringement in respect of bioprinting – particularly as the commercial value of the technology rises.

3. BIOPRINTING PATENT LITIGATION

There has previously been significant patent litigation in the field of biotechnology – with biological inventions posing difficult questions for the doctrines of patent infringement.[113]

In the field of patent law, there has been much controversy in respect of the prospect of patent infringement involving 3D printing. In a speech to a judicial conference, the Obama administration USPTO Director Michelle Lee observed: 'Some of these new technologies are right now on the cusp of moving from early stages of development to becoming more commercialized and widely accessible—for example, 3D-printing and personalized medicine'.[114] She noted: 'We can already anticipate that these developments, both of which hold so much promise for improving the quality of life not just here but worldwide, are also likely to require us to reimagine the contours of the patent landscape.'[115] Lee highlighted: 'With 3D-print-

102 Ibid., 41.

103 Sam Tavassoli, *Adoption and Diffusion of Disruptive Technologies: The Case of 3D Printing in the Medical Device Industry*, ECP Opportunity Fund (EOF) GBI Projects, RMIT, 2017-2020, https://www.rmit.edu.au/research/our-research/enabling-capability-platforms/global-business-innovation/ecp-opportunity-fund-gbi-projects

104 Sam Tavassoli et al., 'Adoption and Diffusion of Disruptive Technologies: The Case of 3D Printing in the Medical Device Industry – White Paper I: Opportunity Areas, Stakeholder Mapping and Road Mapping', Melbourne: RMIT, November 2018, https://www.rmit.edu.au/content/dam/rmit/au/en/research/ecps/gbi/Medtech-3D-Report-2018.pdf

105 Sam Tavassoli et al., 'Adoption and Diffusion of Disruptive Technologies: The Case of 3D Printing in the Medical Device Industry – White Paper II: Business Models, Barriers, and Solutions', Melbourne: RMIT, November 2019, https://www.rmit.edu.au/content/dam/rmit/au/en/research/ecps/gbi/Medtech-3D-Report-2019.pdf

106 Sam Tavassoli, 'Adoption and Diffusion of Disruptive Technologies: The Case of Additive Manufacturing in MedTech Industry in Australia', Symposium on *3D Printing: Intellectual Property and Innovation,* QUT Faculty of Law, 25 October 2018, https://www.youtube.com/watch?v=V3JqQ61fvg0

107 Sam Tavassoli et al. (2020). 'Adoption and Diffusion of Disruptive Technologies: The Case of Additive Manufacturing in Medical Technology Industry in Australia' (2020) 43 *Procedia Manufacturing* 18-24.

108 Sam Tavassoli et al., 'Adoption and Diffusion of Disruptive Technologies: The Case of 3D Printing in the Medical Device Industry – White Paper II: Business Models, Barriers, and Solutions', Melbourne: RMIT, November 2019, 18, https://www.rmit.edu.au/content/dam/rmit/au/en/research/ecps/gbi/Medtech-3D-Report-2019.pdf

109 Ibid.

110 Ibid.

111 Ibid.

112 Ibid.

113 See Brad Sherman, 'Biological Inventions and the Problem of Passive Infringement' (2002) *Australian Intellectual Property Journal* 146-154; and the Supreme Court of Canada in *Monsanto Canada Inc.* v. *Schmeiser* [2004] 1 S.C.R. 902, 2004 SCC 34.

114 Michelle K. Lee, 'Remarks at Federal Circuit Judicial Conference', Washington DC, 11 April 2016, https://www.uspto.gov/about-us/news-updates/remarks-director-michelle-k-lee-federal-circuit-judicial-conference

115 Ibid.

ing—we can foresee a future where individuals will have a factory at their fingertips—it will be commonplace to be able to manufacture products in your home or office, to customize a design downloaded from the internet to your particular needs.'[116] She wondered how the patent system would deal with questions of patent infringement in both theory and practice: 'But from the perspective of patent law—what will this do to the doctrines of patent infringement?'[117] She highlighted that the technology of 3D printing would pose challenges for the doctrines of patent infringement interpreted by the judiciary.

Michael Weinberg – now a Professor at New York University – observes that 3D printing could be used to create objects, which infringe patents: 'There is no exception for independent creation in patent law'.[118] As such, Weinberg is concerned that both the developers of 3D printers and the users of the 3D printers will need to exercise caution and restraint, so as not to infringe upon patents, particularly in respect of inventions in the field of manufacturing.

There has been concern that 3D printing has the potential to be a new frontier of intellectual property infringements – a 'Napster'-like of mass infringement of patents for manufacturing.[119] Ben Depoorter and Bregt Raus have interrogated this mythology: 'Described as the Napster of patents, illegal 3D printing is foretold to disrupt manufacturing in the same manner as digital piracy unsettled the music industry.'[120] They argue that such a negative forecast is overstated. Depoorter and Raus maintained that aggressive enforcement action would impede innovation and the development of 3D printing technologies.

Kyle Trout and Justin Mullen have considered how medical device patents may be impacted by 3D printing.[121] They observed: 'It is a distinct possibility that medical device manufacturers may turn to 3D printing technology as a new distribution channel.'[122] They predicted: 'Traditional device manufacture may give way to the sale of digital device models to hospitals for in-house, on-demand production.'[123] Trout and Muller considered the complexities of patent enforcement in such scenarios, where 'the designer and manufacturer are decoupled': 'Identifying, approaching, negotiating with and potentially litigating against each infringer becomes a much larger and more costly endeavour'.[124] The attorneys consider the options of action for direct patent infringement and indirect patent infringement (including contributory infringement and induced infringement).

University of Tasmania researchers have also been investigating 3D printing and patent infringement.[125] The researchers wonder whether there will be a need to revise Australia's laws with respect to patent infringement: 'Should authorisation and supply infringement under Australian patent law become impractical mechanisms to enforce patent rights to the point where the economic incentive provided by patents is eroded, then legislative action may be required to balance interests'.[126] The researchers wonder whether Australia's laws with respect to patent infringement are overbroad.

In his 2019 book, Lucas Osborn considers the operation of patent law in respect of 3D printing – looking at both direct patent infringement and indirect patent infringement.[127] He observed in respect of direct patent infringement: 'In a 3D Printing world, one of the most problematic infringement scenarios will involve patented goods with many end users.'[128] He suggested that indirect infringement is generally helpful to capture centralized actors who assist others who are directly infringing.'[129] Osborn notes that the law requires culpability on the part of the indirect infringer: 'For technologies, like 3D printers, which have clear non-infringing uses, the law does not want to hamper technological development by imposing liability on manufacturers for uses over which they have no control'.[130] As a matter of law reform, Osborn wonders whether patent law should have safe harbours for 3D print shops and other intermediaries.[131]

There have been a number of preliminary pieces of patent infringement litigation in respect of 3D printing. There was the ClearCorrect litigation over 3D printing dental appliances.[132] There was also rather inconclusive metal 3D printing patent conflicts between Desktop Metal and Markforged.[133] There has been major conflict over

116 Ibid.

117 Ibid.

118 Michael Weinberg, *It Will Be Awesome If They Don't Screw It Up: 3D Printing, Intellectual Property, and the Fight Over the Next Great Disruptive Technology*, Washington DC: Public Knowledge, 2010, https://www.publicknowledge.org/news-blog/blogs/it-will-be-awesome-if-they-dont-screw-it-up-3d-printing

119 Deven Desai and Gerard Magliocca, 'Patents, Meet Napster: 3D Printing and the Digitization of Things' (2014) 102 *Georgetown Law Journal* 1691-1720.

120 Ben Depoorter and Bregt Raus, 'Who's Afraid of 3D Printing?' (2019) 25 *Boston University Journal of Science and Technology Law* 60-99 at 60.

121 Kyle Trout and Justin Mullen, 'Preserving the Value of Medical Device Patents During the Rise of 3D Printing', *KramerAmado*, 29 January 2014, http://www.krameramado.com/blog/preserving-value-medical-device-patents-during-rise-three-dimensional-printing

122 Ibid.

123 Ibid.

124 Ibid.

125 Jane Nielsen and John Liddicoat, 'The Multiple Dimensions of Intellectual Property Infringement in the 3D Printing Era', (2017) 27 *Australian Intellectual Property Journal* 184-208; and John Liddicoat, Jane Nielsen and Dianne Nicol, 'Three Dimensions of Patent Infringement: Liability for Creation and Distribution of CAD Files', (2016) 26 *Australian Intellectual Property Journal* 165-178.

126 John Liddicoat, Jane Nielsen and Dianne Nicol, 'Three Dimensions of Patent Infringement: Liability for Creation and Distribution of CAD Files', (2016) 26 *Australian Intellectual Property Journal* 165-178.

127 Lucas Osborn, *3D Printing and Intellectual Property*, Cambridge: Cambridge University Press, 2019.

128 Ibid., 82.

129 Ibid., 104.

130 Ibid., 104.

131 Ibid., 88.

132 *ClearCorrect Operating, LLC* v. *International Trade Commission* 810 F.3d 1283 at 1304 (November 10, 2015). For commentary, see Matthew Rimmer, 'ClearCorrect: Intellectual Property, 3D Printing and the Future of Trade', (2019) 23 (1) *Gonzaga Journal of International Law* 154-194.

133 *Desktop Metal, Inc.* v. *Markforged, Inc. et al* D.Mass. Mar. 19, 2018. Docket 1:18-CV-10524. See Matthew Rimmer, 'Metal 3D Printing: Patent Law, Trade Secrets, And Additive Manufacturing', (2022) 7 *Frontiers in*

bioprinting patents between Cellink (now part of BICO) and Organovo in 2021-2022 (which will be the focus of the article here). This case study will provide insights into the operation of patent law in practice in the field of bioprinting. This in-depth analysis of the bioprinting patent litigation follows in the tradition of the writing of Sally Smith Hughes, Paul Rabinow, and Jorge Contreras.[134]

A. Cellink v. Organovo Inc. – Cellink's Complaint

i. Cellink

The Swedish company Cellink was founded in 2016 and pursued an IPO in November 2016. The company has been seen as a rising star in 3D bioprinting.[135] In its self-description of legal documents, Cellink says that it is 'the world leading bioconvergence company providing innovative and cutting-edge technologies, products, and services for our customers to create, understand and master biology'.[136] The company elaborates that it is 'the forerunner in the evolving life science universe where it together with its customers develop game-changing solutions by combining biology and technology to create the future of medicine.'[137] Cellink has a number of companies within its corporate group. Cellink AB is a publicly listed stock company; Cellink LLC is a Virginia limited liability company based in the United States; MarkTek Corporation is a Massachusetts corporation based in the United States; and Visikol Inc. is a Delaware corporation, which is based in New Jersey in the United States.

In its 2018-2019 Annual report, Cellink discusses the importance of intellectual property: 'Cellink is highly dependent on intellectual property protection to be able to pursue development, marketing and sales without obstructing competition'. [138] Cellink noted the commercial value of its intellectual property portfolio: 'At the end of the 2018/19 financial year, the group's capitalized development costs corresponded to 46 MSEK and other intangible fixed assets amounted to 60 MSEK, which constitutes approximately 10 percent of the group's total balance sheet total.'[139] Cellink was concerned about the risks of patent prosecution – with the possibility of patent applications being rejected or narrowed: 'As Cellink and its portfolio are in an expansive and early phase, there is a risk that some existing patent applications, which have not yet been granted or registered, will not be approved or the approved scope of protection for some patents will be narrowed.'[140] The company stressed: 'Protection of intellectual property and other proprietary rights is therefore an essential issue for Cellink's business and the opportunity to develop new products.'[141] Cellink highlights a patent it was granted in South Korea for a technique, which enables bioprinting in a clean environment.[142]

ii. Cellink's Claims of Patent Infringement

In June 2021, Organovo's U.S. Patent Nos. 9,855,369 and 9,149,952, which relate to its bioprinter technology, became the subject of Inter Partes Review proceedings filed by Cellink AB and its subsidiaries, MatTek Incorporated and Visikol, Inc.[143] Organovo filed a preliminary response to Cellink AB's IPR petition in September 2021, and the Patent Trial and Appeal Board denied institution of the proceedings in December 2021.[144] In June 2021, Cellink sought a declaration that they did not infringe any of the patent claims in U.S. Patent Nos. 9,149,952, 9,855,369, 8,931,880, 9,227,339 and 9,315,043 (all assigned to Organovo, Inc.) and U.S. Patent Nos. 7,051,654 and 9,752,116 (licensed exclusively to Organovo, Inc.) in the United States District Court for the District of Delaware.[145]

On the 3rd June 2021, Cellink made a legal complaint in the Delaware District Court about Organovo Inc.[146] Cellink argued that Organovo's patents infringe upon its own, as well as those of its acquired subsidiaries. Cellink had sought leave to file the complaint in this action under seal. Cellink emphasized that the litigation involved confidential information and trade secrets between the parties: 'Cellink's Complaint contains information protected by a non-disclosure agreement ("NDA") entered into between Cellink and Organovo, Inc. ("Organovo").'[147] The company elaborated: 'The underlying information is confidential, contains sensitive business information, and the NDA expressly prohibits unrestricted public disclosure of the underlying information. Cellink's Complaint not only discusses the subject matter covered by the NDA, but it also quotes from communications covered by the NDA.'[148] Cellink's attorneys argued: 'Moreover, publicly

Research Metrics and Analytics, Article number: 958761, https://www.frontiersin.org/articles/10.3389/frma.2022.958761/full

134 Sally Smith Hughes, *Genentech: The Beginnings of Biotech,* Chicago: University of Chicago Press, 2011; Paul Rabinow, *Making PCR: A Story of Biotechnology*, Chicago: The University of Chicago Press, 1996; Paul Rabinow, *French DNA: Trouble in Purgatory*, Chicago: The University of Chicago Press, 1999; Jorge Contreras, *The Genome Defense: Inside the Epic Legal Battle to Determine Who Owns Your DNA,* Chapel Hill (North Carolina): Algonquin Books, 2021.

135 Nanalyse, 'A 3D Bioprinting Stock That's Not Organovo – Cellink', 1 April 2019, https://www.nanalyze.com/2019/04/3d–bioprinting-stock/

136 Original Complaint for Patent Infringement in *Organovo Inc.* v *Cellink AB* (2021) 6:21-cv-769-ADA

137 Original Complaint for Patent Infringement in *Organovo Inc.* v *Cellink AB* (2021) 6:21-cv-769-ADA

138 Cellink, *Annual Report*, 2018-2019, 26, https://cellink.com/investors/wp-content/uploads/sites/3/2019/11/Cellink-annual-report-2019-ENG-V4.pdf

139 Ibid., 26.

140 Ibid., 26.

141 Ibid., 26.

142 Ibid., 13.

143 Organovo, 'Form 8-K', 28 February 2022, https://sec.report/Document/0001564590-22-007614/

144 Organovo, 'Form 8-K', 28 February 2022, https://sec.report/Document/0001564590-22-007614/

145 Organovo, 'Form 8-K', 28 February 2022, https://sec.report/Document/0001564590-22-007614/

146 *Cellink AB* et al. v. *Organovo, Inc* 1:21-cv-00832, https://portal.unifiedpatents.com/litigation/Delaware%20District%20Court/case/1:21-cv-00832

147 'Plaintiff's Motion for Leave to File Complaint Under Seal' in *Cellink AB* et al. v. *Organovo, Inc* 1:21-cv-00832, 7 June 2021.

148 'Plaintiff's Motion for Leave to File Complaint Under Seal' in *Cellink AB* et al. v. *Organovo, Inc* 1:21-cv-00832, 7 June 2021.

disclosing this information would result in serious harm to both parties by causing public disclosure of confidential information covered by the NDA.'[149]

According to media reports, Cellink alleged that Organovo's US9149952B2, US9855369B2, US8931880B2, US9227339B2, US9315043B2 bioprinting patents were in breach of its own patents.[150] The patents have broad claims – involving 'bioprinters comprising one or more printer heads,' including the 'devices, systems and methods' of fabricating tissues. Cellink also claims that Clemson University's US7051654B2 patent regarding the 'inkjet printing of viable cells,' and University of Missouri's US9752116B2 on 'self assembling cell aggregates' encroach on its patents. It is worth noting that Organovo holds exclusive licenses in respect of Clemson University and University of Missouri patents in relation to bioprinting.

Cellink's complaint also refers to its MatTek Corporation and Visikol Inc subsidiaries, both of which have substantial biotechnology patent portfolios.

Cellink has also filed a petition before the USPTO Patent Trial and Appeal Board (PTAB) to institute proceedings against claims 1-11 of U.S. Patent No. 9,149,952 and claims 1-15 of U.S. Patent No. 9,855,369 on June 7, 2021 (IPR2021-01049 and IPR2021-01050).[151]

In September 2021, Cellink AB filed two additional proceedings against Organovo's U.S. Patent. Nos. 9,315,043 and 9,752,116, which related to its bioprinter technology.

iii. Cellink's Expansion and Rebranding

In 2021, the parent company of the 3D bioprinting company Cellink has rebranded itself as BICO or 'BIoCOnvergence'.[152] Erik Gatenholm, CEO and President of BICO, explained that the company had diversified, with new acquisitions: 'We continue to invest for future growth, which can be seen in acquisition-related costs, costs related to the name change, group-wide systems and innovative product development'.[153]

The Cellink bioprinting division will continue to trade under its existing brand, 'Cellink'. Cellink will operate as one of eleven subsidiaries under the 'BICO' umbrella. As part of its expansion, BICO has engaged in the acquisition of a number of biomedical companies. The company has made a number of acquisitions in recent years – including MatTek Corporation; Nanoscribe; Discover Echo; and Visikol; and Scienion. The company BICO will operate three business segments – including Bioprinting; Biosciences; and Bioautomation.

B. Organovo Inc. v Cellink – Organovo's Complaint

Organovo is a leading bioprinting company based in San Diego in the United States, established in 2007. The company grew out of research by Gabor Forgacs, the George H. Vineyard Professors of Physics at the University of Missouri Columbia.[154]

i. Intellectual Property Portfolio

In terms of its corporate filings, Organovo emphasizes that it has built a portfolio of intellectual property in respect of bioprinting – primarily relying upon patent protection. The company boasts: 'Our unique bioprinting platform is based on proprietary technologies for preparing bioinks, bioprinting functional 3D human tissues and maintaining the viability and functionality of the tissues for an extended period of time.'[155] Organovo's origin story goes back to public sector research: 'Our foundational proprietary technology, grounded in over a decade of peer-reviewed scientific publications, derives from research led by Dr. Gabor Forgacs, the former George H. Vineyard Professor of Biological Physics at the University of Missouri-Columbia'.[156] The company explains its intellectual property portfolio: 'We have a broad portfolio of intellectual property rights covering the principles, enabling instrumentation, applications, and methods of cell-based printing, including exclusive licenses to certain patented and patent pending technologies from the University of Missouri-Columbia and Clemson University.'[157] The company notes: 'We have continued to develop our technology and grow our intellectual property portfolio.[158]

Organovo summarizes its portfolio: 'In addition to our in-licensed patents, we own outright more than 90 additional patents and pending patent applications around the world.'[159] The company was confident about the strength and power of this regime: 'We believe that our broad and exclusive commercial rights to patented and patent-pending 3D bioprinting technology, 3D tissues and applications provides us with a strong and defensible market position for the successful commercialization of 3D bioprinted human tissues serving a broad array of unmet preclinical and clinical needs'.[160]

Organovo has highlighted the importance of its patent protection: 'Our success depends in large part on our ability to establish and protect our proprietary bioprinting technologies and our engineered tissue products and services.'[161] The company also relies on other species of intellectual property as well: 'We rely on a combination of pat-

149 Ibid.

150 Maxval, 'Cellink Files Patent Infringement Suit Against Organovo', 15 June 2021, https://www.maxval.com/blog/cellink-files-patent-infringement-suit-against-organovo/

151 Ibid.

152 Paul Hanaphy, 'CELLINK Parent Firm Rebranded BICO, Reports Over 600% Acquisition-Led Grwoth in H1 2021', *3D Printing Industry,* 19 August 2021, https://3dprintingindustry.com/news/cellink-parent-firm-rebranded-bico-reports-over-600-acquisition-led-growth-in-h1-2021-194740/

153 Ibid.

154 'Clinical Trial Research: MU Research Team Makes Progress Toward "Printing" Organs', *Health & Medicine Week*, 19 November 2019, 3463.

155 Organovo Holdings Inc., *Annual Report*, 2017, 2 https://ir.organovo.com/node/10031/html

156 Ibid., 2.

157 Ibid., 2.

158 Ibid., 2.

159 Ibid., 7.

160 Ibid., 7.

161 Ibid., 7.

ents, trademarks, trade secrets, confidential know-how, copyrights and a variety of contractual mechanisms such as confidentiality, material transfer, licenses, research collaboration, limited technology access, and invention assignment agreements, to protect our intellectual property'. [162]

The company noted: 'We solely own or hold exclusive licenses to 16 issued U.S. patents and 32 issued international patent applications.'[163] The company also observed: 'We solely or jointly own, or hold exclusive licenses to more than 20 pending U.S. patent applications and over 100 pending international applications'.[164] The company stressed: 'These patent families relate to our bioprinting technology and our engineered tissue products and services, including its various uses in areas of tissue creation, in vitro testing, utilization in drug discovery, and in vivo therapeutics.'[165]

In its report on intellectual property, Organovo observes that the company was formed in part through the licensing of public research intellectual property: 'Our intellectual property portfolio for our core technology was initially built through licenses from the University of Missouri-Columbia ("MU") and the Medical University of South Carolina'.[166] The company elaborates that it has 'world-wide exclusive licenses to intellectual property owned by MU and the Medical University of South Carolina, which now includes 6 issued U.S. patents, 6 pending U.S. applications, 15 issued international patents and 5 pending international applications'.[167] Organovo explains: 'Dr. Gabor Forgacs, one of our founders and a former George H. Vineyard Professor of Biophysics at MU, was one of the co-inventors of all of these works (collectively, the "Forgacs Intellectual Property")'.[168] The company observes: 'The Forgacs Intellectual Property provides us with intellectual property rights relating to cellular aggregates, the use of cellular aggregates to create engineered tissues, and the use of cellular aggregates to create engineered tissue with no scaffold present.'[169] Organovo notes: 'The intellectual property rights derived from the Forgacs Intellectual Property also enables us to utilize our NovoGen MMX Bioprinter to create engineered tissues.[170]

Organovo emphasized: 'We have subsequently expanded our intellectual property portfolio by filing patent and trademark applications worldwide and negotiating additional licenses and purchases.'[171]

The company has also licensed other key intellectual property. In 2011, Organovo obtained an exclusive license to a U.S. patent (U.S. Pat. No. 7,051,654) owned by the Clemson University Research Foundation which relates to methods of using ink-jet printer technology to dispense cells, and relating to the creation of matrices of bioprinted cells on gel materials. In 2015, Organovo obtained worldwide exclusive licenses to intellectual property owned by The University of Queensland (collectively, "UniQuest Intellectual Property") relating to technologies for producing kidney cells and kidney organoids from induced pluripotent stem cells (iPSCs). Organovo observed: 'The patent rights we obtained through these exclusive licenses are not only foundational within the field of 3D Bioprinting, but provide us with favorable priority dates.'[172] The company noted: 'We are required to make ongoing royalty payments under these exclusive licenses based on net sales of products and services that rely on the intellectual property we in-licensed.'[173]

In addition to the in-licensed intellectual property, Organovo has also obtained patents in respect of its NovoGen MMX Bioprinter and methods of bioprinting; and 3D bioprinted tissues and methods of fabricating such tissues (such as the ExVive™ Human Liver Tissue and the ExVive™ Human Kidney Tissue). Additionally, in 2013, Organovo purchased the exclusive rights to "Perfusion Bioreactors for Culturing Cells" (U.S. Patent No. 7,767,446, Japan Patent No. 4,914,835, and Australia Patent No. 2,005,287,162) from Becton Dickinson and Company.

In terms of its philosophy of intellectual property management, Organovo has vowed to take an aggressive approach to the protection and enforcement of its intellectual property: 'We believe that protection of the proprietary nature of our bioprinting technologies and products and services is essential to our business.'[174] The company promised to engage in an active protection and enforcement of its intellectual property: 'Accordingly, we have adopted and will continue a vigorous program to secure and maintain protection of our intellectual property'.[175]

As a supplement, Organovo would also seek protection under trade secrets and confidential information: 'We also will continue to rely upon trade secret and confidential know-how protection of our methods and technology, including our proprietary in-house manufacturing methods and in vitro testing methods.'[176] There has been an increasing attraction to biotechnology companies of reliance on the use of trade secrets and confidential information in the wake of the Supreme Court of the United States decision on gene patents in the *Myriad* case.[177]

162 Ibid., 7.
163 Ibid., 7.
164 Ibid., 7.
165 Ibid., 7.
166 Ibid., 7.
167 Ibid., 7.
168 Ibid., 7.
169 Ibid., 7.
170 Ibid., 7.
171 Ibid., 7.
172 Ibid., 7.
173 Ibid., 7.
174 Ibid., 8.
175 Ibid., 8.
176 Ibid., 8.
177 Robert Cook-Deegan, John Conley, James Evans and Daniel Vorhaus, 'The Next Controversy in Genetic Testing: Clinical Data as Trade Secrets?' (2013) 21 *European Journal of Human Genetics* 585-588; Chris

There has also been growing litigation over trade secrets and confidential information in the field of 3D printing.[178]

The company boasted: 'We have developed a proprietary instrument platform, our NovoGen Bioprinters®, which enables us to create a wide array of tissue compositions and architectures, using purely cellular 'bio-ink' (building blocks comprised of only living cells), biocompatible hydrogels, or combinations of the two.'[179] Organovo observed: 'A key distinguishing feature of our bioprinting platform is the ability to generate complex 3D tissues that have all or some of their components comprised entirely of cells'.[180]

ii. Legal action

In response to the accusations of Cellink, bioprinting company Organovo filed a legal action in a Federal Court in Waco, Texas, accusing Cellink of infringing its bioprinting patents.[181] The Patent Complaint alleged that Cellink AB has infringed U.S. Patent Nos. 9,149,952, 9,855,369 and 9,315,043 (all assigned to Organovo, Inc.) and U.S. Patent No. 9,752,116 (licensed exclusively to Organovo, Inc.).[182] The Company later amended the complaint to add U.S. Patent No. 8,852,932 in the Patent Complaint. Organovo sought an injunction against continuing infringement of the patents by Cellink AB and monetary damages. The Patent Complaint was transferred to the District of Delaware in December 2021 to be consolidated with Cellink's Declaratory Judgment Complaint.

The complaint notes that Organovo is the patent holder of three patents, and it is the exclusive licensee of another owned by the University of Missouri. Organovo contends that Cellink's Bio X has infringed three patents and Bio X6 has infringed another patent. Organovo is reportedly seeking royalties after alleging that Cellink sold technologies relating to the '3D printing of tissues and drug development,' which relied upon its intellectual property. Organovo has sought compensation for a patent infringement and a court order blocking further unauthorised use of inventions. The dispute attracted some broader media attention – including that of Bloomberg.[183]

In a later complaint for declaratory judgment, Cellink outlines the timeline of the dispute between the parties.[184] Organovo had a sent a letter in 2019, asserting that a number of its patents 'cover the sale and use of the bioprinting technology Cellink is currently marketing, including the Bio X bioprinter'.[185] The parties engaged in discussions about the issue in 2019. While Organovo asserted that its patents cover the accused products, Cellink disputed this charge. Organovo withdrew from discussions in 2020 after a change in management. Cellink sought to reinitiate negotiations with Organovo in 2021. Cellink observed that it has 'steadfastly maintained that it does not infringe any claim of the Patents-in-Suit'.[186] As a result, Cellink observed that it sought 'a declaratory judgment that Cellink does not infringe the claims of the Patents-in-Suit.'[187]

For its part, Cellink has questioned the accusations that it contravened the patents of fellow 3D bioprinting firm Organovo.[188] Cellink has argued that the patent claims of Organovo are invalid. Cellink has cautioned that 'while it respects valid IP, Organovo's patent claims are invalid.' and if its lawsuit is successful, this 'could lead to the cancellation of the challenged claims in Organovo's patents.'[189] Moreover, Cellink has maintained that it has not infringed upon the patents or other intellectual property of its rival, Organovo. Notwithstanding the legal conflict, Cellink has insisted that it remains 'committed to evolving the future of medicine.'[190]

iii. Organovo's Restructuring

Journalist Paul Hanaphy observed that the intellectual property conflict came at a time of crisis for Organovo.[191] In August 2019, Organovo announced that it would

Palmer, 'The Myriad Decision: A Move Toward Trade Secrets?' (2014) 22 (2) *The Catalyst* https://irp.nih.gov/catalyst/22/2/the-myriad-decision-a-move-toward-trade-secrets; and Jorge Contreras, *The Genome Defense: Inside the Epic Legal Battle to Determine Who Owns Your DNA*, Chapel Hill (North Carolina): Algonquin Books, 2021.

178 *Desktop Metal, Inc.* v. *Markforged, Inc. et al* D.Mass. Mar. 19, 2018. Docket 1:18-CV-10524; *Jabil, Inc.* v. *Essentium, Inc. et al* Case Number: 8:19-cv-01567 Court: Florida Middle; Beau Jackson, 'Jabil Files Suit Against Essentium For Alleged Theft of HSE 3D Printer IP', 3D Printing Industry, 17 July 2018, https://3dprintingindustry.com/news/jabil-files-suit-against-essentium-for-alleged-theft-of-hse-3d–printer-ip-158688/; and Beau Jackson, 'Essentium Moves to Dismiss Jabil lawsuit For HSE 3D Printing', *3D Printing Industry*, 21 August 2019, https://3dprintingindustry.com/news/essentium-moves-to-dismiss-jabil-lawsuit-for-hse-3d–printing-160630/; and *Soarus LLC* v. *Bolson Materials International Corporation* 2018 US App. LEXIS 27802 (7th Cir., 1 October 2018). For commentary, see Matthew Rimmer, 'Metal 3D Printing: Patent Law, Trade Secrets, And Additive Manufacturing', (2022) 7 *Frontiers in Research Metrics and Analytics*, Article number: 958761, https://www.frontiersin.org/articles/10.3389/frma.2022.958761/full

179 Organovo Holdings Inc., *Annual Report*, 2017, 2 https://ir.organovo.com/node/10031/html

180 Ibid., 2.

181 Paul Hanaphy, 'Cellink Brands Organovo's 3D Bioprinting Patent Lawsuit "Invalid"', *3D Printing Industry*, 9 August 2021, https://3dprintingindustry.com/news/cellink-brands-organovos-3d–bioprinting-patent-lawsuit-invalid-194179/

182 Organovo, 'Form 8-K', 28 February 2022, https://sec.report/Document/0001564590-22-007614/

183 Christopher Yasiejko, 'Organovo Sues Rival Cellink for Bio-Printing Patent Royalties', *Bloomberg*, 21 July 2021, https://news.bloomberglaw.com/pharma-and-life-sciences/organovo-sues-rival-cellink-for-bio-printing-patent-royalties

184 Complaint for Declaratory Judgment in *Cellink* v. *Organovo Inc.* (2021) 1:21-cv-00832-MN, 5.

185 Complaint for Declaratory Judgment in *Cellink* v. *Organovo Inc.* (2021) 1:21-cv-00832-MN, 5.

186 Complaint for Declaratory Judgment in *Cellink* v. *Organovo Inc.* (2021) 1:21-cv-00832-MN, 7.

187 Complaint for Declaratory Judgment in *Cellink* v. *Organovo Inc.* (2021) 1:21-cv-00832-MN, 7.

188 Paul Hanaphy, 'Cellink Brands Organovo's 3D Bioprinting Patent Lawsuit "Invalid"', *3D Printing Industry*, 9 August 2021, https://3dprintingindustry.com/news/cellink-brands-organovos-3d–bioprinting-patent-lawsuit-invalid-194179/

189 Ibid.

190 Ibid.

191 Paul Hanaphy, 'Cellink Brands Organovo's 3D Bioprinting Patent Lawsuit "Invalid"', *3D Printing Industry*, 9 August 2021, https://3dprintingindustry.com/news/cellink-brands-organovos-3d–bioprinting-patent-lawsuit-invalid-194179/

explore strategic and implement a restructuring plan after 'concluding that the Company had not generated decisive scientific data supporting the prolonged functionality and therapeutic benefit of its lead therapeutic liver tissue candidate.'[192] Taylor Crouch, the CEO of Organovo commented: 'After a rigorous assessment of our liver therapeutic tissue program, we've concluded that the variability of biological performance and related duration of potential benefits presents development challenges and lengthy timelines that no longer support an attractive opportunity given our resources.'[193] He observed: 'We're also taking restructuring steps to manage our resources and extend our cash runway as we evaluate a range of ways to generate value from our technology platform and intellectual property, our commercial and development capabilities, and our financial assets.'[194]

In December 2019, Organovo and Tarveda Therapeutics announced a merger agreement.[195] Taylor J. Crouch, President and Chief Executive Officer of Organovo, commented: 'After completing an extensive and thorough review of strategic alternatives, we are extremely pleased to announce this transaction with Tarveda, which we believe is in the best interest for our stockholders'.[196] The company's ex-CEO Keith Murphy published a letter, criticising the board's record, and encouraging stockholders not to vote for the plan.[197] He argued that the company should instead refocus on organic growth via bioprinting. In April 2020, Organovo announced that it had terminated the merger agreement with Tarveda Therapeutics because 'Organovo's stockholders did not approve the merger related proposal.'[198]

Organovo has been struggling to retain its listing on the NASDAQ stock exchange.[199] It should also be noted that Organovo has faced a class action led by Henry Rianhard, alleging false and misleading disclosures by Organovo and its Board of Directors in respect of a reverse stock split of the company's common stock.[200] Previously, Organovo brought a libel case against investor Georgi Dimitrov, alleging libel, libel per se, and tortious interference with prospective economic advantage.[201]

In September 2022, founder and former CEO, Keith Murphy, returned as the Executive chairman of the Board, and became chief executive again.[202] Murphy has sought to recover Organovo's previous leading position in the field of bioprinting and medical 3D printing.

iv. Counterclaims

In January 2022, Organovo filed counterclaims in the patent lawsuit brought against the company by Cellink in the United States District Court for Delaware.[203] The company argued: Organovo believes that Cellink, as a newer company with limited patent filings, has moved forward without regard to its patents and now is at risk of owing significant license fees and royalties to Organovo.'[204] The company emphasized that ' Organovo is accusing Cellink of infringing several of Organovo's patents, and thus Organovo filed counterclaims to the Delaware suit on Friday, January 7, 2022, and asserted an additional patent against Cellink.'[205] Organovo also alleged wilful infringement of its patents by Cellink – and sought a triple damages award. Organovo Executive Chairman Keith Murphy commented on the legal proceedings: 'Organovo has a powerful foundational patent portfolio in the 3D bioprinting space'.[206] Murphy reflected: 'Cellink launched itself and grew to $1.5B market capitalization on the basis of bioprinting revenue streams Organovo now contends were achieved through unauthorized use of Organovo's intellectual property.'[207] Murphy insisted that the company was confident of victory: 'We look forward to the legal process to award Organovo its due share of the revenue that Cellink has only achieved due to such patent infringement.'[208] Murphy commented: 'We believe that this revenue, and IP licensing revenue more broadly in the bioprinting space, will properly reward our investors for the early investment in intellectual property.'[209] A trial was set for April 2022.

192 Organovo, 'Organovo to Explore Strategic Alternatives and Implement Restructuring Plan', Press Release, 7 August 2019, https://ir.organovo.com/news-releases/news-release-details/organovo-explore-strategic-alternatives-and-implement

193 Ibid,

194 Ibid.

195 Organovo, 'Organovo and Tarveda Therapeutics Announce Definitive Merger Agreement'. Press Release, 16 December 2019, https://ir.organovo.com/news-releases/news-release-details/organovo-and-tarveda-therapeutics-announce-definitive-merger

196 Ibid.

197 Keith Murphy, 'Organovo Holdings Founder Issues Letter Regarding Alternative Paths to Illogical Merger With Tarveda Therapeutics to Stockholders', Press Release, 23 March 2020, https://www.globenewswire.com/en/news-release/2020/03/23/2005028/0/en/Organovo-Holdings-Founder-Issues-Letter-Regarding-Alternative-Paths-to-Illogical-Merger-With-Tarveda-Therapeutics-to-Stockholders.html

198 Organovo, 'Organovo Announces Termination of Merger Agreement with Tarveda Therapeutics', Press Release, 7 April 2020, https://ir.organovo.com/news-releases/news-release-details/organovo-announces-termination-merger-agreement-tarveda

199 Organovo, 'Organovo Regains Compliance with Nasdaq Minimum Bid Price Requirement', Press Release, 3 September 2020, https://ir.organovo.com/news-releases/news-release-details/organovo-regains-compliance-nasdaq-minimum-bid-price-requirement

200 Class Action Complaint in *Rianhard* v. *Crouch* et al. (2019) Case 1:19-cv-01922-MN.

201 *Organovo Holdings, Inc*. v. *Georgi Dimitrov*, C.A. No. 10536-VCL (Del. Ch. June 5, 2017).

202 Vanessa Listek, 'Organovo's Keith Murphy Back as Executive Chairman', 3DPrint.com, 24 September 2020, https://3dprint.com/273310/organovos-keith-murphy-back-as-executive-chairman/

203 Organovo Holdings Inc., 'Organovo Files Counterclaims In Patent Lawsuit Brought Against It by CellInk', Press Release, 10 January 2022, https://ir.organovo.com/news-releases/news-release-details/organovo-files-counterclaims-patent-lawsuit-brought-against-it

204 Ibid.

205 Ibid.

206 Ibid.

207 Ibid.

208 Ibid.

209 Ibid.

C. Settlement

In March 2022, it was announced that there was a settlement of the dispute, with BICO agreeing to license Organovo's 3D Bioprinting patents. The press release declared: 'Organovo Holdings, Inc. announced they have reached agreement on a broad license for BICO and its affiliate companies to Organovo's foundational patent portfolio in 3D bioprinting.'[210] The press release emphasized the primacy of the research of Organovo: 'Organovo exclusively licensed early bioprinting work by Gabor Forgacs, its scientific founder, and Thomas Boland of Clemson, both bioprinting pioneers.'[211] The press release also highlighted the range of foundational patents in its portfolio: 'After its founding, the company did early innovation in the 3D bioprinter space and obtained a further broad set of patents that provide foundational claims in the bioprinting space.'[212] The press release stressed that Organovo was willing to engage in patent licensing: 'In order to broaden the impact of the technology and serve the needs of a broad array of researchers and other users of bioprinting, the company seeks to make these patents available for license to first rate bioprinter developers.'[213] Organovo Executive Chairman Keith Murphy commented on the settlement: 'Organovo celebrates the success of Cellink's bioprinting product lines in opening up the horizons of 3D bioprinting to customers.'[214] Murphy added: 'We are proud to be a part of enabling Cellink and BICO to grow these products and we look forward with excitement to their next generation of bioprinters.'[215]

The settlement resolves the various legal disputes between Organovo and BICO regarding the patents. The press release notes: 'Under the new agreement, all civil actions regarding potential infringement and IPRs concerning validity of Organovo's patents are dismissed and/or terminated'.[216] The press release observes: 'Both BICO and Organovo have released each other from all previous claims, demands liabilities and costs in favor of the beneficial and sustainable solution created through this patent license agreement.'[217]

In accordance with SEC requirements, Organovo included in its 8K filing a description of all material terms of the settlement agreement.[218] The notice observed: 'On February 22, 2022, the Company and BICO Group AB, the parent Company of Cellink AB ("BICO"), entered into a settlement and patent license agreement (the "Settlement Agreement").'[219] The notice commented: 'Pursuant to the Settlement Agreement, (i) the parties settled and agreed to file to dismiss each of the Actions, (ii) the Company agreed to grant BICO a worldwide, non-exclusive, non-sub-licensable, non-transferable perpetual, irrevocable, license under the Company's patents that were the subject of the Actions (collectively, the "Licensed Patents") with respect to products based on the Licensed Patents (the "Licensed Products") in all fields of use under any BICO brand, OEM customer's private label or in association, (iii) BICO agreed to make an upfront payment of $1.5 million to the Company, and (iv) BICO agreed to pay the Company ongoing royalties at rates in the range of low to high single digit percentages of net sales of the Licensed Products.'[220] The notice stressed: 'The license contained in the Settlement Agreement continues until the expiration of the last surviving Licensed Patent.' The notice also acknowledged: 'The Settlement Agreement also contains customary termination, confidentiality and other provisions.'[221]

Paul Hanaphy has commented that the settlement will help bolster the reputation of Organovo: 'With its BICO settlement, however, the company has finally established a fresh source of income.'[222] He commented: 'Although this comes as a small percentage of the BICO Group's overall revenue, it represents a share in the spoils of one of the industry's leading 3D bioprinting firms.'[223]

For its part, bioconvergence company BICO has expressed relief at the end of the long-running legal dispute. BICO's CEO Erik Gatenholm observed: 'This [settlement] will further enable an even more innovative and ground-breaking commercial agenda, speed up development for our customers, and enhance our market position; resulting in improved profitability in the long run.'[224] Gatenholm noted: 'Onwards we will focus on strategic sales efforts to gain market share as well as our ambitious agenda for launching new instruments.'[225] Paul Hanaphy reported: 'In exchange for access [to Organovo's bioprinting patents], the firm [BICO] will have to pay around 1-2% of its total revenue for 2022, and while it has deemed this figure to be "non-material for the group," the capital could prove vital to Organovo.'[226]

It would be fair to say that this patent litigation has been settled on terms favourable to Organovo. This settlement could be counterpointed with the outcome of other disputes. Organovo seemed to have prevailed in its objectives with this settlement by its competitor. By contrast,

210 Organovo Holdings Inc., 'Update: Organovo and BICO (CELLINK) Reach Licensing Agreement on Bioprinting Patents', Press Release, 1 March 2022, https://ir.organovo.com/news-releases/news-release-details/update-organovo-and-bico-cellink-reach-licensing-agreement

211 Ibid.

212 Ibid.

213 Ibid.

214 Ibid.

215 Ibid.

216 Ibid.

217 Ibid.

218 Organovo, 'Form 8-K', 28 February 2022, https://sec.report/Document/0001564590-22-007614/

219 Ibid.

220 Ibid.

221 Ibid.

222 Paul Hanaphy, 'BICO licenses Organovo's 3D Bioprinting Technology to end Legal Dispute', *3D Printing Industry*, 7 March 2022, https://3dprintingindustry.com/news/bico-licenses-organovos-3d-bioprinting-technology-to-end-legal-dispute-205571/

223 Ibid.

224 Ibid.

225 Ibid.

226 Ibid.

the 3D printing patent settlement between MarkForged and Desktop Metal seemed to be much more of a stalemate – with neither side gaining advantage in either the litigation or the settlement.[227]

Summary

This case study of the bioprinting patent conflict between Cellink (BICO) and Organovo provides a useful insight into the operation of patent law and practice in this field. Michael Molitch-Hou commented that 'lawsuits are part and parcel with any industry and have played an important part of 3D printing history.'[228] Paul Hanaphy has predicted that there could be further patent disputes in the field of bioprinting, given the commercial potential of the field, and the proliferation of patent filings in the area: 'As is the case in many emerging fields, 3D bioprinting is awash with novel methodologies, and given their commercial potential, researchers are increasingly moving to patent their work in order to prevent it from being marketed elsewhere.'[229]

4. BIOPRINTING PATENT EXCEPTIONS

In the context of patent litigation over 3D printing and bioprinting, it is worthwhile considering the array of patent flexibilities, defences, and exceptions which are available to promote research, health-care, and competition.

The UN Secretary-General's High Level Panel on Access to Medicines has considered the operation of various intellectual property flexibilities to advance public health.[230] Justice Michael Kirby – who chaired the expert advisory group – has discussed intellectual property and public health technologies.[231] He discussed a number of possible options to encourage access to key inventions – including TRIPS flexibilities, publicly funded research, open access, alternative forms of research and development, and better governance and transparency. There is a need to learn lessons from the past conflicts over intellectual property and public health in respect of methods of human treatment, pharmaceutical drugs, access to medicines, gene patents, and some of the emerging areas of the life sciences such as stem cell research, synthetic biology, nanotechnology, and CRISPR gene-editing technology.[232] The COVID-19 crisis has highlighted issues in respect of intellectual property flexibilities during times of public health emergency.

A number of TRIPS flexibilities have been employed in respect of intellectual property and public health in the past. In particular, it is worthwhile considering the options of the defence of experimental use; compulsory licensing; crown use; public sector licensing; and patent pools. Such mechanisms could have application in the context of 3D printing, generally – but bioprinting in particular.

A. Defence of Experimental Use

3D printing also raises larger questions about the role and scope of patent exceptions – such as the defence of experimental use.[233]

In the United States, the defence of experimental use is narrowly confined, as illustrated by the case of *Madey* v. *Duke University*.[234] In this important precedent, Judge Gajarsa upheld the appeal by Madey against Duke University.[235] He commented: 'In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.'[236]

The judge held that the district court attached too great a weight to the non-profit, educational status of Duke, 'effectively suppressing the fact that Duke's acts appeared to be in accordance with any reasonable interpretation of Duke's legitimate business objectives.'[237] He stressed that 'Duke... like other major research institutions of higher learning is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream.'[238] The judge directed that on remand the district court would have to revise and limit its conception of the experimental use defense: 'The correct focus should not be on the non-profit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.'[239]

227 Matthew Rimmer, 'Metal 3D Printing: Patent Law, Trade Secrets, And Additive Manufacturing', (2022) 7 *Frontiers in Research Metrics and Analytics*, Article number: 958761, https://www.frontiersin.org/articles/10.3389/frma.2022.958761/full

228 Michael Molitch-Hou, 'Bioprinting Battle Ends: BICO and Organovo Come to Licensing Agreement', *3DPrint.com*, 4 March 2022, https://3dprint.com/289414/bioprinting-battle-ends-bico-and-organovo-come-to-licensing-agreement/

229 Paul Hanaphy, 'BICO licenses Organovo's 3D Bioprinting Technology to end Legal Dispute', *3D Printing Industry*, 7 March 2022, https://3dprintingindustry.com/news/bico-licenses-organovos-3d–bioprinting-technology-to-end-legal-dispute-205571/

230 Ruth Dreifuss et al., *Report of the United Nations Secretary-General's High Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies*, 2016, http://www.unsgaccessmeds.org/final-report/ http://www.unsgaccessmeds.org/

231 United Nations Human Rights – Office of the High Commissioner, 'Access to Essential Medicines is a Fundamental Element of the Right to Health', 24 March 2017, https://www.ohchr.org/en/stories/2017/03/access-essential-medicines-fundamental-element-right-health

232 Matthew Rimmer and Alison McLennan (ed.), *Intellectual Property and Emerging Technologies: The New Biology*, Cheltenham and Northampton (Ma.): Edward Elgar, 2012.

233 Matthew Rimmer, 'The Freedom To Tinker: Patent Law and Experimental Use' (2005) 15 (2) *Expert Opinion on Therapeutic Patents* 167-200.

234 *Madey* v. *Duke University*, 307 F.3d 1351 (Fed. Cir. 2002).

235 *Madey* v. *Duke University* 307 F.3d 1351 (2002).

236 *Madey* v. *Duke University* 307 F.3d 1351 at 1362 (2002).

237 *Madey* v. *Duke University* 307 F.3d 1351 at 1362 (2002).

238 *Madey* v. *Duke University* 307 F.3d 1351 at 1362-1363 (2002).

239 *Madey* v. *Duke University* 307 F.3d 1351 at 1363 (2002).

As a result of action under Bill Clinton's Administration, there has been recognition of a defence for medical practitioners and their sponsors from facing patent infringement action. There has been inconclusive debate as to whether this defence should be extended in respect of genetic testing. This regime does not look well prepared for medical 3D printing and bioprinting. David S. Forman has highlighted that there could be patent difficulties for 3D printed medical implants.[240]

Australia introduced a statutory defence of experimental use under patent law with the *Intellectual Property Laws Amendment (Raising the Bar) Act* 2012 (Cth). This defence would be of particular relevance to inventors, makers, and designers involved in 3D printing. The European Union has taken a broader approach to the defence of experimental use, allowing for both non-commercial and commercial uses of patented inventions.

In the context of the European Union, Rosa Maria Ballardini and Nari Lee have considered the private and non-commercial use defence in the context of 3D printing technologies.[241] They argue that the 'consumer use of 3DP technology highlights the importance of the private and non-commercial use exception to patent rights'.[242] Ballardini and Lee consider a number of possible scenarios, in which the private and non-commercial use could apply. They examine home 3D printing; printing at a 3D service bureau; and design file sharing. Ballardini and Lee comment that the private use exception in European patent law deserves more attention with the 3D printing revolution: 'With the advent of 3DP, however, this private working of an invention is expected to dramatically increase due to cost cutting developments in 3DP technology that enable home manufacturing.'[243] They recommend that 'more clarity may be required in applying the private use exception to this conduct.'[244] In terms of their future scenario planning, Ballardini and Lee contend that, 'even though home 3DP falls under the private and non-commercial use exception in most circumstances, printing infringing objects from services such as service bureaus and other public spaces may not be exempted under a strict interpretation of the 'private' requirement.'[245]

There has also been a consideration of the development of standards in respect of 3D printing and additive manufacturing. Zhang, Ituarte, and Ballardini have considered the interaction between essential patents and technical standards in additive manufacturing.[246]

B. Public Sector Licensing

In addition to the commercial activity in respect of 3D printing, there has also been significant portion of patent activity by universities and public sector research institutions. The WIPO Study provides a useful portrait of activity in respect of the public sector in respect of 3D printing patents.[247] Universities, higher education institutions,

240 David S. Forman, 'Patent Difficulties for 3-D Printed Medical Implants', *Law360*, 1 June 2016, https://oshaliang.com/wp-content/uploads/2016/06/Patent-Difficulties-For-3-D-Printed-Medical-Implants.pdf

241 Rosa Maria Ballardini and Nari Lee, 'The Private and Non-Commercial Use Defence Revisited: The Case of 3D Printing Technologies', in Rosa Maria Ballardini, Marcus Norrgård, and Jouni Partanen (ed.), *3D Printing, Intellectual Property and Innovation: Insights from Law and Technology*, Kluwer Law International, 2017, 169-188.

242 Ibid., 179.

243 Ibid., 179.

244 Ibid., 187.

245 Ibid., 188.

246 Liguo Zhang, Inigo Flores Itarte and Rosa Maria Ballardini, 'Essential Patents and Technical Standards in Additive Manufacturing' in Rosa Maria Ballardini, Marcus Norrgård, and Jouni Partanen (ed.), *3D Printing, Intellectual Property and Innovation: Insights from Law and Technology*, Kluwer Law International, 2017, 189-218.

247 World Intellectual Property Organization, *World IP Report: Breakthrough Innovation and Economic Growth*, Geneva: World Intellectual Property Organization, 2015 https://www.wipo.int/publications/en/details.jsp?id=3995

and research organisations have invested in makerspaces in a range of fields.[248]

Tel Aviv University researchers have printed a tiny 3D heart using a patient's own cells.[249] In respect of this research, Prof. Tal Dvir of Tel Aviv University claimed: 'This is the first time anyone anywhere has successfully engineered and printed an entire heart replete with cells, blood vessels, ventricles and chambers.'[250] He observed: 'This heart is made from human cells and patient-specific biological materials.'[251] Dvir commented: 'In our process these materials serve as the bioinks, substances made of sugars and proteins that can be used for 3D printing of complex tissue models.'[252] Prof. Dvir maintained: 'Our results demonstrate the potential of our approach for engineering personalized tissue and organ replacement in the future.' [253] The researcher speculates: 'Maybe, in ten years, there will be organ printers in the finest hospitals around the world, and these procedures will be conducted routinely.'[254] The press release for the announcement noted that Tel Aviv University had a high filing rate of United States patents.

The dispute between Organovo and Cellink amongst other things involves publicly licensed patents.

There has been discussion about the need for public sector licensing in respect of 3D printing.[255]

In the 2011 *Advanced Manufacturing Report,* the President's Council of Advisors on Technology and Science called for new commitment by the administration to advanced manufacturing. [256] In the field of 3D Printing, the Obama administration had some success with America Makes, the National Additive Manufacturing Innovation Institute – which was designed to generate cross-collaboration between universities, industry, and government on additive manufacturing.[257] William Bonvillian and Peter Singer have evaluated this innovation model as a means of revitalizing America's declining manufacturing sector by encouraging advanced manufacturing.[258] America Makes has been in operation for a number of years.

The administration has sought to emulate its success with a specific new hub for bioprinting. In 2016, President Barack Obama helped establish an Advanced Tissue Biofabrication Manufacturing Innovation Institute (which is known now as ARMI/ BioFabUSA).[259] The Obama administration had high hopes for this Institute: 'In collaboration with the Department of Defense, the Institute will pioneer next-generation manufacturing techniques for repairing and replacing cells and tissues, which may one day lead to the ability to manufacture new skin for soldiers scarred from combat or to produce life-saving organs for the too many Americans stuck on transplant waiting lists today.'[260] The Obama administration maintained: 'The Institute will focus on solving the cross-cutting manufacturing challenges that stand in the way of producing new synthetic tissues and organs – such as improving the availability, reproducibility, accessibility, and standardization of manufacturing materials, technologies, and processes to create tissue and organ products'.[261] The Obama administration wanted to encourage co-operation and collaboration between the private sector and the public sector: 'We expect collaborations across multiple disciplines; from 3D bio-printing, cell science, and process design, automated pharmaceutical screening methods to the supply chain expertise needed to rapidly produce and transport these live-saving materials.'[262]

The Advanced Regenerative Manufacturing Institute (ARMI) is focused on advancing the bioeconomy of the United States.[263] BioFabUSA is a program of ARMI. BioFabUSA is now a public-private partnership with more than 170 members, including companies, academic institutions and not-for profit organizations. BioFabUSA seeks to translate research into industry: 'The mission of BioFabUSA is to bring together the fundamental tenets of good manufacturing processes and the science of regenerative medicine to create regenerative manufacturing and the trained and ready workforce necessary for that manufacturing.'[264]

248 Matthew Rimmer, 'Make and Share: Intellectual Property, Higher Education, Technology Transfer, and 3D Printing in a Global Context', in Jacob Rooksby (ed.), *Research Handbook on Intellectual Property and Technology Transfer*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, 2020, 447-479.

249 Michael Arnold, 'Israeli Researchers Print 3D Heart Using Patient's Own Cells', *Bloomberg*, 15 April 2019, https://www.bloomberg.com/news/articles/2019-04-15/israeli-researchers-print-3d-heart-using-patient-s-own-cells?fbclid=IwAR0Njl9W3P9DsddJvoC_PWoCOrFwHjrWW-n9ogMG9vW_EpM4bwPDkXB-UAs

250 American Friends of Tel Aviv University, 'Tel Aviv University Scientists Print First 3D Heart Using Patient's Biological Materials', EurekAlert!, 15 April 2019, https://www.eurekalert.org/pub_releases/2019-04/afot-tau041519.php

251 Ibid.

252 Ibid.

253 Ibid.

254 Ibid.

255 Matthew Rimmer, 'Make and Share: Intellectual Property, Higher Education, Technology Transfer, and 3D Printing in a Global Context', in Jacob Rooksby (ed.), *Research Handbook on Intellectual Property and Technology Transfer*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, 2020, 447-479.

256 President's Council of Advisors on Science and Technology, *Report to the President on Ensuring American Leadership in Advanced Manufacturing*, June 2011, at https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/pcast-advanced-manufacturing-june2011.pdf

257 America Makes, https://www.americamakes.us/

258 William Bonvillian and Peter Singer, *Advanced Manufacturing: The New American Innovation Policies*, Cambridge (MA) and London, MIT Press, 2018.

259 Advanced Tissue Biofabrication Manufacturing Innovation Institute (ARMI/ BioFabUSA), https://www.manufacturingusa.com/institutes/biofabusa

260 White House, 'Fact Sheet: President Obama Announces Winner of Smart Manufacturing Innovation Institute and New Manufacturing Hub Competitions', 2016 WL 3383256, 20 June 2016.

261 Ibid.

262 Ibid.

263 Advanced Regenerative Manufacturing Institute, https://www.armiusa.org/

264 Ibid.

C. The NIH 3D Print Exchange

The National Institutes of Health (NIH) has been historically concerned about access to research tools (which may be subject to patent protection).[265] This was a particularly prominent concern in the fields of access to medicines and biotechnology.[266] In 2016, the Director of the NIH, Francis Collins, was enthusiastic about the potential of bioprinting in the short-term and the long-term (especially in terms of dealing with the need for transplants):

> In the near term, tissues and organs grown on such scaffolds might also find use as sophisticated, 3D tissue 'chips' with potential for use in studies to predict whether drugs will be safe in humans. In the long term, this technology may allow production of replacement organs from those needing them. [267]

Collins had high hopes for the technology: 'Ultimately, with the aid of bioprinting advances like this one, perhaps one day we'll have a ready supply of perfectly matched and fully functional organs.'[268]

The NIH 3D Print Exchange could be seen as an effort to encourage co-operative and collaborative behaviour amongst public sector researchers.[269] Meghan Coakley and her colleagues explained the impetus for the project: '3D printing technology is advancing rapidly, with the expectation that within the next decade, 3D-printed human tissues and organs will regularly be used in medical treatment.' [270] They observed: 'The Exchange is thus a well-positioned resource for supporting this significant medical development, and puts the NIH and the U.S. Department of Health and Human Services ahead of this emerging technology, which aligns with their interests to promote research leading to new and improved treatments for patient care'. [271] Moreover, 'the Exchange supports government initiatives in the Maker Movement and STEM education.'[272]

Coakley and her colleagues conclude: 'Ultimately, we hope that the NIH 3D Print Exchange will help to bolster the use of 3D printing in medical and bioscientific research, education, and communication.'[273]

The NIH 3D Print Exchange explains its objectives in these terms: '3D printing technology is advancing at a rapid pace, but it is difficult to find or create 3D-printable models that are scientifically accurate or medically applicable.' [274] The organization explains that 'The NIH 3D Print Exchange provides models in formats that are readily compatible with 3D printers, and offers a unique set of tools to create and share 3D-printable models related to biomedical science.'[275] The NIH 3D Print Exchange is designed to address a gap in the literature: 'Few scientific 3D-printable models are available online, and the expertise required to generate and validate such models remains a barrier.'[276] The program has the following objective: 'The NIH 3D Print Exchange eliminates this gap with an open, comprehensive, and interactive website for searching, browsing, downloading, and sharing biomedical 3D print files, modeling tutorials, and educational material.'[277]

The NIH 3D Print Exchange is the product of a collaboration by the National Institute of Allergy and Infectious Diseases in collaboration with the Eunice Kennedy Shriver National Institute for Child Health and Human Development and the National Library of Medicine. The program is intended to encourage scientific discovery, STEM education, and medical learning. The project is designed to promote patient and practitioner education: 'One goal of the NIH 3D Print Exchange is to provide an outlet for creating and sharing medical models to facilitate visualization and learning'.[278]

The project is also designed to foster the further development of 3D printing in health and medicine: 'From surgical implants and prosthetics, 3D printing technology is transforming the field of medicine, allowing doctors to create customized, patient-specific implants.'[279] The project comments: '3D-printed medical devices range from highly specialized prosthetics to DIY robotics parts that you can print at home.'[280]

The NIH 3D Print Exchange is a community-driven model. There is a policy in respect of licensing.[281] Creative Commons licenses can be applied to models submitted to the database. There is also scope for public domain dedications; GNU General Public Licences; and Open Source Licences. The database includes medical and anatomical models; custom labware; small molecules and chemicals; proteins, macromolecules, and viruses; and bacteria, organelles, and cells. There is also a disclaimer: 'The NIH 3D Print Exchange is not responsible for misuse of models hosted on our site, and users are required to adhere to

265 Ibid.

266 Robert Cook-Deegan, *The Gene Wars: Science, Politics, and the Human Genome*, WW Norton & Company, 1996; and Matthew Rimmer, 'The New Conquistadors: Patent Law and Expressed Sequence Tags' (2007) 16 *Journal of Law, Information, and Science* 10-50.

267 Francis Collins, 'Progress Toward 3D Printed Human Organs', *NIH Director's Blog*, 20 July 2019, https://directorsblog.nih.gov/tag/bioprinting/

268 Ibid.

269 Meghan Coakley et al., 'The NIH 3D Print Exchange: A Public Resource for Bioscientific and Biomedical 3D Prints' (2014) 1 (3) *3D Printing and Additive Manufacturing* 137-140.

270 Ibid., 139.

271 Ibid., 139.

272 Ibid., 139.

273 Ibid., 139.

274 NIH 3D Print Exchange, https://3dprint.nih.gov/

275 Ibid.

276 Ibid.

277 Ibid.

278 NIH 3D Print Exchange, '3D Prints in Medicine', https://3dprint.nih.gov/about/medicine

279 Ibid.

280 Ibid.

281 NIH 3D Print Exchange, Licensing, https://3dprint.nih.gov/about/site-policies/licensing

our Terms and Conditions.'[282] The terms of use include terms and conditions in respect of general information, user accounts, intellectual property, liability, and "NIH Verified" Content.[283]

D. Patent Pools

Historically, there has been a use of patent pools as a means of providing access to a common set of technologies. In the area of access to essential medicines, the Medicines Patent Pool was established to help provide for the licensing of medicines – particularly to deal with the HIV/AIDS crisis.[284] In the field of biotechnology, there has been a discussion of whether patent pools would be helpful to provide access to gene patents.[285] There has also been an investigation of the use of patent pools to facilitate diagnostic testing.[286] In the midst of the coronavirus crisis, Costa Rica and the World Health Organization (WHO) helped establish the WHO COVID-19 Technology Access Pool.[287] However, major intellectual property holders have been unwilling to participate in the venture thus far.[288] The public policy option of patent pools has been mooted in the context of clean technologies and climate change.[289]

Intellectual property lawyer John Hornick has considered the prospect of a patent pool in the 3D printing technology field:

> 3D printing machine innovations will force incumbent 3D printing companies to travel down R&D paths they may not otherwise have trod, which will be necessary to compete, but will also generate patent wars absent a savior, such as a patent pool. A patent pool could free the industry to develop (radio developed under a patent pool that became known as RCA), largely unhindered by patent litigation. But the industry probably will not accept a pool, so patent wars are likely.[290]

He has remained sceptical as to whether the 3D printing industry would agree to the imposition of a patent pool.

There has been a push, though, towards the development of standards in respect of 3D printing – particularly through the auspices of America Makes.

E. Compulsory Licensing, Crown Use, and Government Acquisition

There has also been an interest in the use of compulsory licensing and Crown use provisions to provide access to patented inventions in the context of public health. In the field of access to essential medicines, there has been numerous cases of compulsory licensing provisions being invoked to gain access to HIV/AIDS medicines.[291] There has been a deployment of compulsory licensing to provide access to cancer medicines.[292] The public policy option of compulsory licensing was also discussed in the context of gene patents and diagnostic testing.[293] The device of compulsory licensing has also been discussed in new emerging fields of the life sciences – such as stem cell research,[294] and nanotechnology.[295] The topic of compulsory licensing also emerged as a critical issue during the COVID-19 crisis – with calls for a TRIPS Waiver.[296]

In the context of 3D printing, Phoebe Li expressed concerns about 'the possible chilling effects of forced sharing by resorting to compulsory licensing.'[297] She nonetheless acknowledges that bioprinting companies should be wary of engaging in restrictive licensing – citing the backlash

282 NIH 3D Print Exchange, '3D Prints in Medicine', https://3dprint.nih.gov/about/medicine

283 NIH 3D Print Exchange, 'Terms and Conditions', https://3dprint.nih.gov/about/site-policies/terms-and-conditions#medicine

284 Medicines Patent Pool, https://medicinespatentpool.org/ See Jorge Bermudez and Ellen 't Hoen, 'The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good' (2010) 4 *Open AIDS Journal* 37-40; and Sandeep Juneja, Aastha Gupta, Seurie Moon, and Stephen Resch, 'Projected Savings Through Public Health Voluntary Licences of HIV Drugs Negotiated by the Medicines Patent Pool (MPP)' (2017) *Public Library of Science One* https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0177770

285 Geertrui van Overwalle (ed.) *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes*, Cambridge: Cambridge University Press, 2009.

286 Birgit Verbeure, Esther van Zimmeren, Gert Matthijs, and Geertrui van Overwalle, 'Patent Pools and Diagnostic Testing' (2006) 24 (3) *Trends in Biotechnology* 115-120.

287 WHO COVID-19 Technology Access Pool, https://www.who.int/initiatives/covid-19-technology-access-pool

288 Matthew Rimmer, 'The People's Vaccine: Intellectual Property, Access to Essential Medicines, and COVID-19' (2022) 5 (1) *Journal of Intellectual Property Studies* 1-71.

289 Matthew Rimmer, *Intellectual Property and Climate Change: Inventing Clean Technologies*, Cheltenham (UK) and Northampton (Mass.): Edward Elgar, September 2011.

290 John Hornick, '3D Printing – The Next Five Years', *3D Printing Industry*, 25 April 2017, https://3dprintingindustry.com/news/3d–printing-next-five-years-john-hornick-partner-finnegan-111501/

291 Anna S.Y. Wong, Clarke B. Cole, and Jillian C. Kohler, 'TRIPS Flexibilities and Access to Medicines: An Evaluation of Barriers to Employing Compulsory Licenses for Patented Pharmaceuticals at the WTO', South Centre, Research Paper 168, 28 October 2022, https://www.southcentre.int/research-paper-168-28-october-2022/

292 Cinthia Leite Frizzera Borges Bognar, Brittany L. Bychkovsky, and Gilberto de Lima Lopes Jr, 'Compulsory Licenses for Cancer Drugs: Does Circumventing Patent Rights Improve Access to Oncology Medications?' (2016) 2 (5) *Journal of Global Oncology* 292-301.

293 Geertrui Van Overwalle, Esther van Zimmeren, Birgit Verbeure and Gert Matthijs, 'Models for Facilitating Access to Patents on Genetic Inventions', (2005) 7 *Nature Reviews Genetics* 143-148; and Geertrui Van Overwalle (ed.), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models, and Liability Regimes*, Cambridge: Cambridge University Press, 2010; and Devdatta Malshe, *Patent Pools, Competition Law, and Biotechnology*, Routledge, 2020.

294 Aurora Plomer and Paul Torremans, *Embryonic Stem Cell Patents: European Law and Ethics*, Oxford: Oxford University Press, 2009.

295 Amber Rose Stiles, 'Hacking through the Thicket: A Proposed Patent Pooling Solution to the Nanotechnology "Building Block" Patent Thicket Problem', (2011) 4 (2) *Drexel Law Review* 555-592.

296 Hilary Wong, 'The Case for Compulsory Licensing During COVID-19', (2020) 10 (1) *Journal of Global Health*, 010358; and Matthew Rimmer, 'The People's Vaccine: Intellectual Property, Access to Essential Medicines, and COVID-19' (2022) 5 (1) *Journal of Intellectual Property Studies* 1-71.

297 Phoebe Li, '3D Bioprinting Technologies: Patents, Innovation, and Access.' (2014) 6 (2) *Law, Innovation and Technology* 282-304 at 302.

against the aggressive enforcement of patents by Myriad Genetics. Phoebe Li comments: '3D bioprinting companies must balance the need to consolidate their market dominance and their corporate social responsibilities in disseminating the technology in order to minimise the disparities in access to health.'[298] She observed: 'Rights are associated with corresponding responsibilities in a healthy, dynamic and sustainable IP system.'[299] Phoebe Li reflected: 'A patent holder's exclusive right to practise an invention must be balanced against the public's expectation that the invention should be disseminated.'[300]

Summary

In the field of bioprinting, there have been emerging patent conflicts and disputes over key technology. There are a range of mechanisms within the patent system which may help provide access to key foundational technologies. The research exemption, the defence of experimental use, and the private and non-commercial use defence may provide protection for users of patented technology. Public sector licensing schemes, the NIH Print Exchange, and patent pools may encourage the sharing of key intellectual property in the field of 3D printing and health. There is also scope for the use of compulsory licensing, Crown Use, and government acquisition – if the patent thickets in the field of bioprinting prove to be impenetrable, and creating adverse impacts in terms of research, public health, and competition.

5. CONCLUSION

There has been considerable activity in respect of intellectual property and bioprinting. This study has examined a number of dimensions of the topic. In the field of patent law, it has looked at a number of challenges for bioprinting – including the definition of patentable subject matter; the patent landscapes; and exceptions and defences under patent law. In particular, the patent dispute between Organovo and Cellink/ BICO has been discussed as a case study. Jeremy Thomas Harbaugh has observed: 'Bioprinting will continue to develop at its dizzying pace, and the law must be nimble enough to evolve with it.'[301]

Journalist Paul Hanaphy has observed that, in spite of such legal conflict, bioprinting remains a promising scientific and commercial field of endeavour: 'While bioprinting entire organs still remains some way away, the technology is increasingly showing end-use potential, thus its future applications and probable profitability has begun to attract the attention of the industry's biggest firms.'[302] He observed that there had been progress in the field by a number of companies – including 3D Systems, with its Print to Perfusion regenerative medicine program; Desktop Metal with Desktop Health programme; and attempts to 3D print a living model of the human pancreas.[303]

In addition to patent protection, bioprinting companies have relied upon a variety of other forms of intellectual property protection – including trade mark law, copyright law and database protection, and trade secrets protection and confidential information. There have already been early conflicts over trade marks relating to bioprinting.[304] Both Organovo and Cellink rely heavily upon trade mark registration to protect an array of brans. Copyright law has increasingly been invoked in matters of 3D printing.[305] There have on occasion been difficulties applying copyright law to the field of biotechnology.[306] Trade secrets protection and confidential information has often been used as an alternative – or a supplement – to patent protection, particularly where there are complications in obtaining database protection. There has been a flurry of trade secrets litigation in respect of 3D printing in recent years.[307]

In addition to raising questions about intellectual property, bioprinting also raises larger questions about the regulation of new technologies. There have been challenges in adapting health systems for the regulation of bioprinting.[308] The United States Food and Drug Administration

298 Ibid., 303.

299 Ibid., 303.

300 Ibid., 303.

301 Jeremy Thomas Harbaugh, 'Do You Own Your 3D Printed Body? Analyzing Property Issues at the Intersection of Digital Information and Biology' (2015) 41 *American Journal of Law and Medicine* 167-189 at 189.

302 Paul Hanaphy, 'Cellink Brands Organovo's 3D Bioprinting Patent Lawsuit "Invalid"', *3D Printing Industry*, 9 August 2021, https://3dprintingindustry.com/news/cellink-brands-organovos-3d-bioprinting-patent-lawsuit-invalid-194179/

303 Ibid.

304 *Advanced Solutions Life Sciences, LLC* v. *BioBiots Inc.* 15 May 2017, 2017 WL2114969.

305 Dinusha Mendis, Jane Nielsen, Diane Nicol, and Phoebe Li, 'The Co-existence of Copyright and Patent Laws to Protect Innovation — A Case Study of 3D Printing in UK and Australian law' in Roger Brownsword, Eloise Scotford, and Karen Yeung (eds.) *The Oxford Handbook of Law, Regulation, and Technology*. Oxford: Oxford University Press, 2017, 451-476.

306 Christopher Holman, Claes Gustafsson and Andrew Torrance, 'Are Engineered Genetic Sequences Copyrightable? The US Copyright Office Addresses a Matter of First Impression' (2016) 35 *Biotechnology Law Report* 103-111; and John Hornick and Kai Rajan, 'Intellectual Property in 3D Printing and Nanotechnology' in Lijie Graze Zhang, John P. Fisher, and Kam Leong (ed.), *3D Bioprinting and Nanotechnology in Tissue Engineering and Regenerative Medicine*, Elsevier Science & Technology, 2015, 349-364 at 360.

307 *Desktop Metal, Inc.* v. *Markforged, Inc. et al* D.Mass. Mar. 19, 2018. Docket 1:18-CV-10524; *Jabil, Inc.* v. *Essentium, Inc. et al* Case Number: 8:19-cv-01567 Court: Florida Middle; Beau Jackson, 'Jabil Files Suit Against Essentium For Alleged Theft of HSE 3D Printer IP', *3D Printing Industry*, 17 July 2018, https://3dprintingindustry.com/news/jabil-files-suit-against-essentium-for-alleged-theft-of-hse-3d-printer-ip-158688/; and Beau Jackson, 'Essentium Moves to Dismiss Jabil lawsuit For HSE 3D Printing', *3D Printing Industry*, 21 August 2019, https://3dprintingindustry.com/news/essentium-moves-to-dismiss-jabil-lawsuit-for-hse-3d-printing-160630/; and *Soarus LLC* v. *Bolson Materials International Corporation* 2018 US App. LEXIS 27802 (7th Cir., 1 October 2018). For commentary, see Matthew Rimmer, 'Metal 3D Printing: Patent Law, Trade Secrets, And Additive Manufacturing', (2022) 7 *Frontiers in Research Metrics and Analytics*, Article number: 958761, https://www.frontiersin.org/articles/10.3389/frma.2022.958761/full

308 Jasper Tran, 'To Bioprint or Not to Bioprint' (2015) 17 *North Carolina Journal of Law and Technology* 123–178.

has revised its guidelines in relation to the regulation of medical 3D Printing and bioprinting. The Therapeutic Goods Administration in Australia has also engaged in a process of law reform in the area of the regulation of medical 3D printing and bioprinting.[309] The European Union has also sought to engage in a holistic regulation with 3D printing – with a more specific set of reforms targeting medical 3D printing.[310] There have been concerns about governments taking a light-handed approach to the regulation of bioprinting.[311] In addition to matters of regulatory approval, there are also important issues in respect of product liability in respect of 3D printing in health contexts.[312] There are also significant issues in respect of liability for software problems in respect of bioprinting as well.[313]

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309 Therapeutic Goods Administration, 'Personalised Medical Devices (including 3D-printed devices)', Australian Government, 25 August 2022, https://www.tga.gov.au/resources/resource/guidance/personalised-medical-devices-including-3d-printed-devices For a summary, see Tony Shaw, Tommy Chen, and Jess McKenna, '3D Printing – New Rules for Personalised Medical Device', *Allens*, 28 June 2021, https://www.allens.com.au/insights-news/insights/2021/06/3d-printing-new-rules-for-personalised-medical-devices/

310 Phoebe Li and Alex Faulkner, '3D Bioprinting Regulations: a UK/EU Perspective' (2017) 8 (2) *European Journal of Risk Regulation* 441-447; and Phoebe Li, Alex Faulkner, and Nicholas Medcalf, '3D Bioprinting in a 2D Regulatory Landscape: Gaps, Uncertainties, and Problems' (2020) 11 (1) *Law, Innovation and Technology* 1-29.

311 Richard Matthews, 'Proposed New Regulations for 3D Printed Medical Devices Must Go Further', *The Conversation*, 9 February 2018, https://theconversation.com/proposed-new-regulations-for-3d-printed-medical-devices-must-go-further-90314

312 Nora Freeman Engstrom, '3D Printing and Product Liability: Identifying the Obstacles' (2013) 162(35) *University of Pennsylvania Law Review* 35–41; Angela Daly, *Socio-Legal Aspects of the 3D Printing Revolution*, Palgrave Pivot, 2016; and James Beck and Matthew Jacobson, '3D Printing: What Could Happen to Products Liability When Users (And Everyone Else in Between) Become Manufacturers' (2017) 16 *Minnesota Journal of Law, Science and Technology* 143–205.

313 Edison Bicudo, Alex Faulkner and Phoebe Li, 'Software, Risks, and Liabilities: Ongoing and Emergent Issues in 3D Printing' (2020) *Journal of Risk Research*, DOI: 10.1080/13669877.2020.1848904