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Editorial Issue 1 2023

The spring of 2023 has been an eventful one for the future of the IP system. The presentation of the pharmaceutical legislation package and of the patent package, as well as the entry into force of the unitary patent package triggers new developments in the field of patent law the effects of which are still difficult to overview.

EU pharmaceutical legislation (Directive 2001/83 and Regulation 726/2004) constituted a major breakthrough in creating a system providing for the authorisation of safe, effective and high-quality medicinal products. After four years of deliberation, the EU Commission submitted its proposals for new legislation on 26th April 2023. The proposed revision EU pharmaceutical legislation is the first momentous review of the pharmaceutical legislation since 2004. The reform has a double aim, to enhance innovation and ensure timely and equitable access to medicines. Another objective of the reform is to enhance security of supply and address shortages through specific measures. The overarching objective is of course to support the European pharmaceutical industry's innovative power and competitiveness. In order to achieve that, the right balance needs to be struck between giving incentives for innovation and taking measures towards more equitable access and affordability.The proposed revision of the pharmaceutical legislation will consist of two legislative proposals: a new Directive, repealing and replacing Directive 2001/83/EC and Directive 2009/35/EC of the European Parliament and of the Council and incorporating relevant parts of the Paediatric Regulation (Regulation (EC) No 1901/2006) and a new Regulation, repealing and replacing Regulation (EC) No 726/2004, repealing and replacing the EU Regulation No. 141/2000 on "orphan" medicinal products and repealing and incorporating relevant parts of the Paediatric Regulation (Regulation (EC) No 1901/2006).

The day after, the 27th of April 2023 the Commission presented yet one more legislative revision this time with the Patent Package. This reform package impacts on the pharmaceutical industry, as it contains proposals on **Supplementary Protection Certificates**(SPCs) and compulsory licensing (CL) in crisis situations. It also includes a new Regulation on **Standard Essential Patents**(SEPs). The proposed reform, which is part of the EU Industrial Strategy, will now undergo the scrutiny of the European Parliament and Council. It aims to **improve European competitiveness, innovation and technological sovereignity**, with a special attention to the role played by SMEs. The proposal is based on comments received during the consultation on the Action Plan on Intellectual Property issued in November 2020. The IP legislative framework comes as a complement to the **Unitary Patent system**, that entered into force on 1 June 2023.

The Unitary Patent system provides a one-stop-shop for the registration and enforcement of patents in Europe It allows companies and other innovators to receive a single "unitary" patent for their inventions, valid across all the participating Member States. This replaces the need for patent holders to navigate a complex mosaic of national patent laws and procedures and sets aside the national validation requirements applicable to European patents.

In addition, a new Unified Patent Court (UPC), with jurisdiction over Unitary Patents and existing European Patents, will allow companies to enforce their patent rights more effectively. The UPC is expected to provide a more consistent legal framework for patent disputes and reduce the risk of inconsistent rulings.

Having these recent developments as a background one can only expect an IP rich 2023.

This issue of the Stockholm IP Law Review is characteristic of the geographic diversity not only of the issues analyzed and of our readers but also of our authors, from Canada to Australia, Italy and UK.We hope you enjoy reading this issue of the SIPLR that discusses timely IP issues. Darinka Tomic discusses the particularities of the Canadian system for the protection of geographical indications while in her article, Leila Magnini presents the new Regulation on Geographical Indication protection for craft and industrial products. In his contribution, Justin Lambert analyzes the use of plausibility as a concept under EPC and UK case-law respectively, while Matthew Rimmer introduces as to the very interesting interface of bioprinting and intellectual property rights.

Frantzeska Papadopoulou Skarp

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Incorporating Cultural Heritage in the Proposal for a Regulation on Geographical Indications protection for Craft and Industrial products

By Leila Magnini, LL.M.

ABSTRACT

The European Commission finally unveiled, in early April 2022, its Proposal for a Regulation on Geographical Indication protection for craft and industrial products. The new Regulation aims to fill the legislative gap that concerns this section of the Single Market. The adoption of the new Regulation will extend the current agricultural products *sui generis* Geographical Indication framework also to non-agricultural products.

This piece of legislation has been several years in the making, and during this time several references have been made to Geographical Indications as an instrument to be used for the protection of European Cultural Heritage and traditions.

This article, after giving a brief overview of the Proposal and its backdrop, tackles the need for defining what is to be regarded as European Cultural Heritage, before suggesting possible approaches to be followed in order to incorporate cultural heritage into the European Geographical Indications scheme.

INTRODUCTION

The European Union's (EU's) Geographical Indication (GI) scheme, which is developed in several legislative instruments, provides the EU agri-food sector with protection and recognition of a *sui generis* intellectual property right. The GI system currently allows producers to protect those agricultural products that have a close and established link to a particular European region, through the registration of the GI name that identifies qualities and origin of the agri-food products.

GIs provide consumers with valuable controlled information regarding both the quality and the essential characteristics of the products they are purchasing. A direct reference to the place of origin is often present in the name of the product itself, forming an integral part of the sign, as it is the case, for example, for Prosciutto di Parma or Savon de Marseille. Whilst the first of the two products mentioned is recognized and safeguarded as a registered Protected Designation of Origin (PDO) for 'meat-based products' under EU law, the latter, for soap, although internationally renowned, cannot currently enjoy GI protection, unlike its foodstuff counterpart.[1] This disparity of treatment is set to be changed by the ongoing legislative process at EU level[2].

The Quality Schemes Regulation[3], the Spirits Regulation[4], Wines Regulation[5] and Aromatized Wines Regulation[6] are now to be joined by the proposed Regulation on geographical indication protection for craft and industrial

1 Commission Regulation (EC) No 1107/96 of 12 June 1996 on the registration of geographical indications and designations of origin under the procedure laid down in Article 17 of Council Regulation (EEC) No 2081/92 [1996] OJ L148/1, annexs A.

2 This article is based on the European Commission's original Proposal and does not take into account the latest developments which have followed from the Trialogues held in 2023, nor the amendments proposed to the original text by the European Parliament.

3 Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [2012] OJ L343/1.

4 Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 [2008] OJ L039/16.

5 Commission Delegated Regulation (EU) 2019/33 of 17 October 2018 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, restrictions of use, amendments to product specifications, cancellation of protection, and labelling and presentation [2018] OJ L009/2.

6 Regulation (EU) No 251/2014 of the European Parliament and of the Council of 26 February 2014 on the definition, description, presentation and labelling of aromatised wine products and repealing Council Regulation (EEC) No 1601/91 [2014] OJ L84/14.

(C&I) products[7], which will be concerned with the "registration, protection, control and enforcement of certain names that identify handicraft and industrial goods with given quality, reputation or other characteristics linked to their geographical origin".[8] The proposed Regulation will encompass a large variety of craft and industrial products, such as natural stones, woodwork, jewellery, textiles, lace, cutlery, glass, porcelain, as well as hides and skins and raw cotton.

This expansion in scope of the GI system will allow C&I producers to obtain the means to valorise, through recognition, as well as to protect, the name under which their products are marketed. Quality Schemes, as they have been designed and implemented by the EU legislation on GIs, are "essentially communication tools" that perform functions of both a private and public nature.[9] It is from this public side especially that the connection to Cultural Heritage (CH) has risen. In the years that the European agricultural GI system has been in place, several references have been made in the literature to Quality Schemes as an instrument to be used to protect European Cultural Heritage and traditions.[10] It could be argued that, in the same way in which locally specific *savoir faire* became increasingly relevant to agricultural GIs, the same could be applied now to the production techniques and to the human factors that play a fundamental role for the realisation of traditional handicrafts and industrial local goods. Manufacturing geographically linked products is, indeed, often based on local know-how and follows production methods that are rooted in the cultural and social heritage of the home region of such goods, where they are passed down from generation to generation. Adopting a piece of legislation to bring these elements under a *sui generis* GI framework would be in line with the EU's desire to support the tutelage and promotion of cultural heritage, which clearly emerged from a joint Decision from the European Parliament and the Council.[11] This Decision, declaring 2018 the "European Year of Cultural Heritage", highlighted how cultural heritage is "of great value to European society from a cultural, environmental, social and economic point of view", making its sustainable management "a strategic choice" in pursuing the common policies of the Union.[12]

To achieve the objectives laid out in Recitals (7) and (8) of the Proposal, one must overcome the argument of the core incompatibility between these two sets of rights and interests, which would see Geographical Indications and Cultural Heritage as fundamentally different concepts. To this end, one must move past a few objections, the two main ones relating to the definition of CH and to the suitability of an IP framework, such as the GI one, to an immaterial right embodied by a traditional C&I product.

1. THE PROTECTION OF CULTURAL HERITAGE AS A MOTIVATING FACTOR FOR THE NEW GI REGULATION

The Commission was not wrong in proposing GIs as the instrument which could help convey aspects of the cultural identity of a specific region. Because of the nature of GIs, applying this *sui generis* protection to a traditional product, with the product in question being the result of the skills and know-how of local people employed in manufacturing these goods in the specific geographical region, can help communicate its underlying cultural value.[13]

Indeed, by reading the Proposal for a Regulation on craft and industrial GI products ('Proposal'), it can be seen how the cultural and social heritage elements have been presented as reasons behind the adoption of this new instrument, specifically in Recitals (7), where it is said that geographical indication protection "is acknowledged so as to safeguard and develop cultural heritage both in the agricultural and the craft and industrial areas" and (8), where it is added that it is therefore necessary to "safeguard and develop cultural heritage and traditional know-how", something that the GI system for craft and industrial products should ensure. The Explanatory Memorandum accompanying the Proposal details how improving the visibility of authentic C&I products on the markets can benefit both consumers, producers, and the regions these operate in.[14] More specifically, by establishing a directly applicable GI protection for C&I products at Union level, the Proposal aims at improving the ability of producers to protect their goods from counterfeiting, incentivizing them to invest into their trade. This will in return, the Commission asserts, also positively affect consumers, by improving the availability and visibility of authentic C&I products.

7 European Commission, 'Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on geographical indication protection for craft and industrial products and amending Regulations (EU) 2017/1001 and (EU) 2019/1753 of the European Parliament and of the Council and Council Decision (EU) 2019/1754 COM(2022) 174 final (hereafter 'Commission Proposal for Regulation on GI for CI').

8 Ibid, Art 1(a).

9 Matteo Gragnani, 'The EU Regulation 1151/2012 on Quality Schemes for Agricultural Products and Foodstuffs' (2013) 8 Eur Food & Feed L Rev 376, 377.

10 Dev S. Gangjee, 'Geographical Indications and Cultural Rights: The Intangible Cultural Heritage Connection?' in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar Publishing 2015) 546.

11 Decision (EU) 2017/864 of the European Parliament and of the Council of 17 May 2017 on a European Year of Cultural Heritage (2018) OJ L 131, 20.5.2017, p. 1–9.

12 Ibid, whereas (5).

13 Delphine Marie-Vivien and Estelle Biénabe, 'The Multifaceted Role of the State in the Protection of Geographical Indications: A Worldwide Review' (2017) 98 World Development 1, 2.

14 Explanatory Memorandum accompanying the European Commission Proposal for a Regulation Of The European Parliament And Of The CouncilCounci on geographical indication protection for craft and industrial products European CommissionI COM(2022) 174 final 2022/0115 (COD) on European Union geographical indications for wine, spirit drinks and agricultural products, and quality schemes for agricultural products, amending Regulations (EU) No 1308/2013, (EU) 2017/1001 and (EU) 2019/787 and repealing Regulation (EU) No 1151/2012. 1-2.

Consequently, these circumstances ought to help safeguard the Cultural Heritage of the regions that GI C&Is originate from, drawing in tourism and contributing to the profitability and attractiveness of the traditional craft professions, thus ensuring that the know-how is handed down to the next generation.[15] Overall, the Commission asserts that the introduction of an efficient intellectual property protection for craft and industrial products would help fuel the economy[16] of the, especially rural, regions where traditional C&Is are manufactured, providing a driving force for sustainable growth[17], as it is already the case for agri-tourism.[18]

Moreover, in the Commission Staff Working Document, published alongside the Proposal, one of the arguments given in support of an EU legislative intervention on craft and industrial GIs is the fact that a lack of unitary C&I GI protection negatively affects the preservation of cultural heritage, as, more often than not, the products that embody it suffer for lack of recognition or counterfeiting.[19] Without adequate tutelage, C&I geographically linked products and the traditions they are derived from, tend to disappear. This fact is made evident by comparing the lists of potential GI C&I products compiled by two studies, the first conducted in 2013[20] and the second in 2020[21], from which several items identified in the previous study had already gone missing in less than a decade. Moreover, a legislative intervention aimed at addressing this issue is in line with what is set out in Article 167 of the Treaty on the Function of the European Union, where by the Union has a duty to contribute to "the flowering of the cultures of the Member States"[22] and keeping the attention to cultural heritage alive. At present, a few EU member states have adopted[23] forms of protection and recognition for craft and industrial traditional territorially linked products that are seen as expressions of their regional culture, but, as already stated, no uniform instrument exists to provide for such non-agricultural products' protection at Union level.[24] It is worth looking at some examples of such provisions, starting with the French Consumer Law of March 17, 2014, which enacted its own protection for non-agricultural GIs, adopting nationally the scheme provided in EU legislation for agricultural PGIs.[25]

Another example can be found by looking at Italy.[26] This Member State has adopted sectoral laws that offer some form of GI C&I protection, including laws covering specific products deemed worthy of recognition. One of these instruments is *Law n. 188/1990 for the Protection of Artistic and Traditional Ceramics and of Quality Ceramics*[27], which gives protection to two categories of ceramics: the first on the basis of them being the expression of cultural heritage for those areas where working ceramics is a solid tradition, the second category is instead awarded protection when the production of the ceramics is completed following specific guidelines, leaving it open to all who choose to adhere to it.[28] Although laws like this one are not considered to be covered by the IP umbrella, some elements of the GI instrument are clearly visible: there is mention of a specific region of production, which is the source of a product that is expression of peculiar human element pertaining specifically to the area in question, as well as the referencing to an approved and registered discipline on how to conduct production in order to obtain the mark of recognition, that is then synonymous with quality. Italian Law n. 188/1990 also created special registries for the producers of the two categories of ceramics covered by this bill, as well as a national Ceramics Counsel, tasked with protecting and promoting the traditional

15 The above considerations can be found transposed in Recitals (7) and (8) of the Proposal, where specific GI protection is chosen as an instrument to, amongst other objectives, provide for the safeguarding and developing of Cultural Heritage and traditional know-how.

16 Cecilia Navarra and others, *'Geographical Indications for Non-Agricultural Products: Cost of Non-Europe Report'*. (2019). The Cost of Non-Europe (CoNE) report conducted by the European Parliamentary Research Service (2019) shows that the introduction of EU GI protection for non-agricultural products would have a positive effect on employment and rural development.

17 Pilar Montero, 'Towards a Core Unitary Legal Regime for Geographical Indications in the European Union Digital Market' (2021) 16 Journal of Intellectual Property Law & Practice 427.

18 Marianna Bicskei and others, 'Reform Proposals on the Geographical Indications of the European Union for the Protection of Traditional Knowledge' (2012) 3 The WIPO Journal 222.

19 Commission Staff Working Document Accompanying the document Proposal for a Regulation of The European Parliament and of The Council on geographical indication protection for craft and industrial products and amending Regulations (EU) 2017/1001 and (EU) 2019/1753 of the European Parliament and of the Council and Council Decision (EU) 2019/1754 (n 108) 3.

20 Insight Consulting and others, 'Study on Geographical Indications Protection for Non-Agricultural Products in the Internal Market: Final Report'. Prepared on behalf of the European Commission (Insight Consulting 2013).

21 Navarra and others (n 12) 11.

22 Article 167 of the Consolidated version of the Treaty on the Functioning of the European Union (TFEU) OJ C 202 7.6.2016, p. 47–390.

23 Currently, the protection of non-agricultural products under the hat of GIs is provided by over a dozen Member States, using various legal schemes, varying from national to regional regulations on crafts, specific legislation on a single product or national laws that institute a GI regulatory system. A fact that is bound to change when the new self-standing Regulation will be adopted, if we are to consider that what happened in regard to the agricultural sector of GIs is bound to be mirrored. For the relevant analysis see: Nicola Coppola, 'The CJEU Confirms the Exclusive Character of EU Competence in PDO/PGI Schemes' (2014) 9 Journal of Intellectual Property Law & Practice 717, 718.

24 For an analysis on why this is the case: Hanna Schreiber, 'Intangible Cultural Heritage, Europe, and the EU: Dangerous Liaisons?' in Andrzej Jakubowski and others (eds), Cultural Heritage in the European Union A critical Inquiry into Law and Policy, vol 9 (Studies in Intercultural Human Rights, Brill | Nijhoff 2019) 338.

25 Article L721-2 of the French IP Code, modified according to Article 73 of the Law n. 2014-344 of 17 March 2014 on consumption together with Decree n. 2015-595 of 2 June 2015 concerning provisions on geographical indications protecting industrial products and handicrafts.

26 Italy has a long standing tradition when it comes to protecting products originating within its borders, starting from the creation of the Denominazione di Origine Controllata (DOC) label, introduced by the law Decreto-legge del 12 luglio 1963, n. 930, and currently incorporated by the European PDO. Italy has also introduced a law specifically for the protection of the "Made in Italy" mark, Legge 20 novembre 2009, n. 166 "Conversione in legge, con modificazioni, del decreto-legge 25 settembre 2009, n. 135, recante disposizioni urgenti per l'attuazione di obblighi comunitari e per l'esecuzione di sentenze della Corte di giustizia delle Comunità europee. (09G0180)" and is the European country with the most registered agricultural GIs, landing at a whopping 876 registered quality schemes.

27 Repubblica Italiana Legge 9 luglio 1990, n.188 – "Tutela della ceramica artistica e tradizionale e della ceramica di qualità".

28 Ibid, Art. 2.

and historical cultural heritage linked to ceramics production, and with monitoring the compliance with this law throughout national bounds.

Such legislative instruments are nothing more than a diluted version of a Geographical Indication. These norms already show how the elements of tradition and cultural heritage are integrated in the legislative texts that deal with the same C&I products that the Proposal would ultimately cover. The legislation of MS plays a significant role in recognizing expressions of cultural heritage in geographically linked C&I products, thereby highlighting the need to ensure their protection through a unitary scheme.

2. THE OVERLAP BETWEEN GEOGRAPHICAL INDICATIONS AND CULTURAL HERITAGE

Despite the cited cases in MS laws, a question remains regarding the compatibility between the two frameworks of IP and Cultural Heritage.[29]. The idea of using GIs specifically as a means to protect Cultural Heritage is not a completely novel one[30]. Historically, this link between GIs and culture has been elaborated thanks to the French legislation, through the development of its system of *Appellation d'Origine Contrôlée*, which built on the meaning of *terroir*. This concept, representing the link that exists between a quality, reputation or other characteristic of the good in question, and which is essentially attributable to its geographical origin, was thus expanded to also include C&Is.[31]

However, it must be noted that some authors have shared less than enthusiastic opinions regarding the impact of a GI registration on a traditional product from an artisanal industry, meaning the association between GIs and CH has not always been welcomed.[32] The objections raised are not entirely without merit.[33] For instance, one of the arguments against this association was that applying the intellectual property rights regime to cultural heritage would result in its commodification, acquainting its commercialization with unfair exploitation.[34] This would, some say, turn something that is, in its essence, collective heritage, into a privately controlled asset.[35]

Nonetheless, it has also been found in the literature that a successful GI is the result of the intergenerational transmission of the know-how and traditions of several generations of people over an extended period, which gives the GI itself a communal heritage dimension[36], highlighting also the fact that "the subject matter of intellectual property law may sometimes overlap with that of cultural heritage".[37] This goes to show how the view that GIs could provide a positive contribution to Cultural Heritage has also gathered supporters amongst scholars.[38] To summarise, it cannot be denied that Geographical Indications "are constructed not just as a tool to protect and promote quality products, but also as a pillar which should contribute to defining the identity of a place, as well as the identities of the group(s) operating within that place".[39]

3. WHERE TO LOOK FOR A DEFINITION FOR CULTURAL HERITAGE

Despite repeated references to "European Culture", EU legislative texts lack a precise definition for it. Even if we can find mention of common European culture all the way back into the fundamental Treaties of the European Union, it is important to acknowledge that these terms have come to bear true meaning in the actions of the Union only far more recently.[40] The EU has limited powers when it comes to direct intervention on the subject of cultural heritage, as most of the competence has been

29 For a recently published analysis of this topic see: Fiona Macmillan, 'Intellectual Property and Cultural Heritage: Towards Interdisciplinarity' in Irene Calboli and Maria Lillà Montagnani (eds), *Handbook of Intellectual Property Research: Lenses, Methods, and Perspectives* (1 st edn, Oxford University Press 2021) 331.

30 To provide an example of the literature on the subject of the connection made between IP and traditional knowledge connected with GIs: Teshager Dagne, 'Law and Policy on Intellectual Property, Traditional Knowledge and Development: Legally Protecting Creativity and Collective Rights in Traditional Based Agricultural Products through Geographical Indications' (2010) 11 The Estey Centre Journal of International Law and Trade Policy 68.

31 The concept of *terroir* was not created as a legal category, but as a technical concept developed by the French experience of GIs. For an in depth account of the birth and application of the concept of terroir: Marie-Vivien Delphine, 'Le Droit Des Indications Géographiques En Inde. Un Pays De L'ancien Monde Face Aux Droits Français, Communautaire Et International' (Doctoral Thesis en Droit et Sciences Sociales, Ecole des Hautes Etudes en Sciences Sociales 7 September 2010) 169–78. See also: Dev S Gangjee, '(Re)Locating Geographical Indications: A Response to Bronwyn Parry' in Lionel Bently and others (eds), Trade Marks and Brands: An Interdisciplinary Critique (Cambridge University Press 2008).

32 Amit Basole, 'Authenticity, Innovation, and the Geographical Indication in an Artisanal Industry: The Case of the Banarasi Sari: Authenticity, Innovation, and the Geographical Indication in an Artisanal Industry' (2015) 18 The Journal of World Intellectual Property 127.

33 Dennis S Karjala and Robert K Paterson, 'The Case Against Property Rights in Old Intangible Indigenous Cultural Property' (2017) 15 Nw J Tech & Intell Prop, 3.

34 Paolo Davide Farah and Riccardo Tremolada, 'Diritti Di Proprietà Intellettuale, Diritti Umani e Patrimonio Culturale Immateriale' (2014) I Rivista di Diritto Industriale 21.

35 Macmillan (n 29) 331.

36 FAO Regional Office for Asia and the Pacific, *Quality Linked to Geographical Origin and Geographical Indications: Lessons Learned from Six Case Studies in Asia* (RAP publication 2010/04, Amélie Lecoent and others eds, Food and Agriculture Organization of the United Nations, Regional Office for Asia and the Pacific 2010) 181.

37 Macmillan (n 29) 336.

38 Steven Van Uytsel, 'When Geographical Indications Meet Intangible Cultural Heritage: The New Japanese Act on Geographical Indications' in Irene Calboli and Wee Loon Ng-Loy (eds), *Geographical Indications at the Crossroads of Trade, Development, and Culture* (Cambridge University Press 2017) 510.

39 Matteo Ferrari, 'The Narratives of Geographical Indications' (2014) 10 International Journal of Law in Context 222, 223.

40 For an overview of the timeline of the EU's acts see Krzysztof Pomian, 'European Heritage and the Future of Europe' in Andrzej Jakubowski and others (eds), *Cultural Heritage in the European Union A Critical Inquiry into Law and Policy*, vol 9 (Studies in intercultural human rights, Brill | Nijhoff 2019).

retained by the Member States.[41] Nevertheless, the EU has, under Article 3(3) of the TFEU, a duty to ensure the safeguarding and promotion of European cultural heritage. This is usually achieved by providing financial support to MS and cultural institutes, via various funds and programmes, through the promotion of cultural tourism, and by encouraging intra-EU cooperation, as per Article 167 TFEU.[42]

But what is then, in the eye of the EU legislator, cultural heritage? For a definition we need to go no further than to the Council Conclusions of 21 May 2014 on *cultural heritage as a strategic resource for a sustainable Europe*.[43] In this document, the Council lists what it believes cultural heritage to be, namely "the resources inherited from the past in all forms and aspects – tangible, intangible and digital (born digital and digitised), including monuments, sites, landscapes, skills, practices, knowledge and expressions of human creativity, as well as collections conserved and managed by public and private bodies such as museums, libraries and archives".[44]

Lacking more stringent regulatory references, this one can be taken as applicable to the present reasoning, in good faith. In such a broad definition, goods resulting from traditional craftsmanship would fit right in, as an expression of the interaction between people and places through time: a localised manifestation of collective human creativity.

4. LOOKING AT UNESCO FOR FURTHER GUIDANCE

The notion of cultural heritage provided by the Council did not come to existence in a void. The United Nations Educational, Scientific and Cultural Organization (UNESCO) introduced the concept of Cultural Heritage as heritage of humanity into international law as early as 1954, in the Convention for the protection of Cultural Property during armed conflicts.[45] The same year, the Council of Europe had also taken action by drafting the European Cultural Convention.[46] Adopted in Paris, this Convention has the purpose of developing a mutual understanding and appreciation of both the similarities and diversities in European culture, recognizing that it is founded on the same fundamental values. By comparison, the EU's intervention on the subject came at a much later date.[47]

Apart from the aforementioned Conventions, other pieces of international legislation contribute to defining what constitutes cultural heritage, and can support the argument that it includes C&Is with specific geographical links. The most prominent and promising example is undoubtedly offered by UNESCO. Its rich catalogue provides a broad definition for cultural heritage, that is not limited to physical artefacts, i.e., material heritage, but also comprises living expressions inherited from our ancestors, such as oral traditions, performing arts, and, for what most pertains to the present topic, knowledge and techniques linked to traditional crafts. All of these elements fall in the category of intangible cultural heritage[48], which includes traditional craftsmanship.[49] The Preamble to the UNESCO Universal Declaration on Cultural Diversity reads that "culture should be regarded as the set of distinctive spiritual, material, intellectual and emotional features of society or a social group" and that culture encompasses, in addition to art and literature, also "lifestyles, ways of living together, value systems, traditions and beliefs".[50]

With the above legal framework as a reference, the most interesting legal instrument to highlight the connection between craft and industrial GIs and cultural heritage in European products is the 2003 UNESCO Convention for the Safeguarding of the Intangible Cultural Heritage. This Convention instituted a registry under which States signatories can inscribe practices, expressions, knowledge, skills, instruments and objects or artefacts associated with cultural heritage and human creativity. On this registry we can find several elements registered by EU Member States that have all the credentials to meet the requirements set for obtaining a registered GI under the Proposal for a Regulation on C&Is. Amongst the elements inscribed, we find the manufacturing process to make: Louça preta de Bisalhães[51], traditional black pottery that is known with the name of the Portuguese town where it is produced; Aubusson tapestry[52], a form of upholstery obtained by weaving an image using processes practised in the town of Aubusson and a few other limited localities in the Creuse region of France; Pag needle-point lace[53], a type of lace that is peculiar to the Croatian coastal

41 Magdalena Pasikowkska-Schnass, 'Cultural Heritage in EU Policies' in (Cultural Heritage in Europe: Linking Past and Future, Brussels, European Parliamentary Research Service June 2018) 1.

42 To find more on the topic one can directly visit the European Commission's dedicated webpage: <https://culture.ec.europa.eu/cultural-heritage/cultural-heritage-in-eu-policies>. Last accessed 3rd of January 2023.

43 Council conclusions of 21 May 2014 on cultural heritage as a strategic resource for a sustainable Europe 2014/C 183/08 OJ C 183, 14.6.2014, p. 36–38.

44 Ibid, paragraph 2.

45 UNESCO, 'Convention for the Protection of Cultural Property in the Event of Armed Conflict with Regulations for the Execution of the Convention' (14 May 1954), Preamble.

46 Council of Europe, 'European Cultural Convention' (5 May 1955). See in particular Article 5.

47 Pomian (n 40) IX.

48 UNESCO Convention for the Safeguarding of the Intangible Cultural Heritage adopted 17 October 2003.

49 Ibid, Article 2(2)(f).

50 General Conference of the United Nations Educational, Scientific and Cultural Organization, 31 st session, 'Universal Declaration on Cultural Diversity' (first published 2002, 2001).

51 <https://ich.unesco.org/en/USL/bisalhes-black-pottery-manufacturing-process-01199> accessed 3rd of January 2023.

52 Inscribed by France in 2009 (4.COM 13.39) on the Representative List of the Intangible Cultural Heritage of Humanity. Nomination file No. 00250 <https://ich.unesco.org/en/RL/aubusson-tapestry-00250> accessed 3rd of January 2023.

53 Inscribed by Croatia in 2009 (4.COM 13.32) on the Representative List of the Intangible Cultural Heritage of Humanity. Nomination file No. 00245

town of Pag; Organ craftsmanship, a form of instrument-making that has been shaped in Germany for centuries[54] Blaudruck/Modrotisk[55], a kind of cloth that is dyed blue and printed with a special technique that is shared by artisans from Austria, Czechia, Germany, Hungary and Slovakia[56].

The existence of this Lists of Intangible Cultural Heritage, under the guild of UNESCO, but populated by goods from EU's Member States, can offer a strong launch pad to support the argument in favour of including cultural heritage in the upcoming legislation on C&I Geographical Indications in a more pervasive way. The listed elements represent but a small fraction of traditional handicrafts and industrial products that are historically connected or anchored to specific areas in Europe. These inscribed goods represent a wealth that the Regulation could tap into, also considering that "items inscribed under [the Convention] may carry commercial and financial value".[57] Such economic value may pre-exist, or it might arise thanks to "the commodification that comes with legal protection".[58] Therefore, it could not be denied that registering a product expression of Intangible Cultural Heritage as a GI would benefit the producers of such goods. This could do more for the preservation and transmission of the craftsmanship that lies behind them, than what the UNESCO Convention ever could, because it would help put local traditional C&I products literally back on the market's map and available to a wider platform of consumers.The public would therefore be able to engage with the products, and therefore sustain the producers, further ensuring that the traditional C&I products' production is perpetuated and the underlying cultural elements preserved.

According to this line of reasoning, the proposed Regulation on craft and industrial GIs would finally provide a protective legal framework to the Intangible Cultural Heritage that informs many of the European C&I goods. Indeed, this could be accomplished through the registration of the name identifying such goods as a Geographical Indication.

5. HOW AND WHERE TO FIT CULTURAL HERITAGE IN THE GI FRAMEWORK

Having highlighted this connecting thread between GIs and CH, the issue at stake is how to effectively include a substantial protection for an intangible element, pertaining to cultural heritage law, which is mostly expressed via a process, into an IP instrument that is structured instead around the protected use of a registered name. Cultural heritage could be incorporated in the text of the Proposal for a Regulation on GI protection for craft and industrial products either directly, in a specific provision, or indirectly through interpretation.

To accomplish this objective, the rationale behind the protection of GIs is arguably the first aspect to consider. When it comes to GIs, the law protects the registered sign against use by an unauthorised party. This is done in order to prevent third parties from appropriating the qualities of those products, making consumers believe that the goods arrive from the same particular places of production as the genuine GI product, when instead this is not the case. The right awarded allows the GI consortium of owners to build and keep their reputation for quality and, at the same time, to assist consumers in more easily finding goods which quality and authenticity they can trust in.

Secondly, one must consider the framework in which this right is built. The protected element is a registered name, which acts as an indicator of geographical origin, rather than of a specific undertaking. The products placed on the Single Market under the sign, accompanied by the corresponding Quality Schemes labels, are not subject to protection *per se*, but only tangentially, because of the strict relation between the name and a given quality, reputation, or another essential characteristic of it. These are all part of the requirements that a name must comply with in order to obtain GI protection ex Article 5(b) of the Proposal for a Regulation.[59]

Only in reference to these essential elements, needed to register a GI, the additional information that a GI name is instilled with becomes relevant. The know-how and traditions that are behind the uniqueness of the final product can contribute to informing its reputation or an essential quality or characteristic. This kind of information represents a type of property that is intangible, that is impossible to trace back to a single author and, most relevantly, that has been in the public domain far beyond any term normally supplied by the traditional information protection regimes with regard to the duration of IP rights.

It is evident that the very nature of the object for which protection is sought here makes most of the more traditional IP rights unsuitable to provide any kind of recognition to the traditional knowledge aspects[60] behind a

<https://ich.unesco.org/en/RL/lacemaking-in-croatia-00245> accessed 3rd of January 2023.

54 Inscribed by Germany in 2017 (12.COM 11.b.10) on the Representative List of the Intangible Cultural Heritage of Humanity. Nomination file No. 01277 <https://ich.unesco.org/en/RL/organ-craftsmanship-and-music-01277> accessed 3rd of January 2023.

55 Inscribed by Austria, Czechia, Germany, Hungary and Slovakia in 2018 (13.COM) on the Representative List of the Intangible Cultural Heritage of Humanity. Nomination file No. 01365 <Blaudruck/Modrotisk/Kékfestés/Modrotlač, resist block printing and indigo dyeing in Europe – intangible heritage – Culture Sector – UNESCO> accessed 3rd of January 2023.

56 This last example of an inscription would also serve to exemplify a possible GI product whose area of origin is not defined by national borders, an eventuality that is taken into account by the Proposal for a Regulation on craft and industrial GIs in Article 6(4), and that would serve even the ulterior purpose of promoting cooperation between MSs.

57 Tomer Broude, 'Mapping the Potential Interactions between UNESCO's Intangible Cultural Heritage Regime and World Trade Law' (2018) 25 International Journal of Cultural Property 419, 422.

58 Ibid.

59 Article 5 of the Proposal is concerned specifically with establishing the requirements for the terroir link, the connection to be established between C&I product and the geographical area of source.

60 Dennis S Karjala and Robert K Paterson, 'The Case Against Property Rights in Old Intangible Indigenous Cultural Property' (2017) 15 Nw J Tech & Intell Prop, 8.

Geographical Indication. Even so, the Cultural Heritage element contributes to making the C&I product what it is, hence it plays a fundamental role in filling the requirements for GI registration, as they are posed.

A. How case law from the CJEU could help safeguard CH

Regardless of the challenges posed by the incorporation of the Cultural Heritage element into this future Regulation on C&I GIS, as the recitals explicitly state the protection of CH among the pursued objectives, during the practical application of the future Regulation the scope of protection that it awards to a craft or industrial product will need to be interpreted accordingly.

This has already been the case in the jurisprudence developed for agricultural GIs. More specifically, this reasoning was recently presented in the Opinion given by Advocate General Pitruzzella in the *Morbier* case.[61]

While discussing the object of protection under the Quality Scheme Regulation, especially the issue whether it is only the registered name to be protected or whether the protection is to be extended to the product covered by that name, the Advocate General underlined how the core objective of the legislation on PDOs and PGIs is to protect traditional products with specific characteristics linked to geographical origin. Henceforth, the scope of protection granted to GIs must be interpreted in the light of this objective.[62] AG Pitruzzella had also advanced this concept in a previous Opinion he had given in case *Queso Mancheso.*[63] In paragraph 20 of his Opinion, AG Pitruzzella had stated that the protection of designations of origin "forms part of the objective of safeguarding European cultural heritage, as referred to in Article 3(3), fourth subparagraph of the EU Treaty".

These Opinions could not be more welcomed to the questions here discussed, as one of the more complex issues to overcome when trying to apply GIs to Intangible Cultural Heritage is the fact that GIs do not offer protection strictly to an expression of tradition, such as a cultural practice, or to its resulting product. What GIs do, is to offer protection against the misuse and misappropriation of a geographical name, as linked to a good. This means that, as of now, a GI cannot, in theory, be used to protect the technique behind blowing Murano glass, or the process for vitrifying Limoges porcelain, but only the name and the sign under which these highly traditional and notorious products are commercialised. This aspect though seems to have been abandoned by the CJEU, which embraced the Advocate General's Opinion and found that Article 13(1) of Regulation No 1151/2012 does not prohibit solely the use by a third party of the registered name. This is the result of the fact that geographical indications, in the *Morbier* case, a PDO, designate a product that has certain qualities or characteristics. As a consequence, the geographical sign and the product covered by it are closely linked.[64]

Building on what the Advocate General stated in the *Morbier* and *Queso Mancheso* cases, the argument that could be brought forward is that GIs could still provide an indirect form of tutelage to a cultural practice or a traditional craftsmanship process, because their end result, i.e. the final product, is in fact protected not as an isolated item, but rather as the product of tradition, and ultimately as one of the objectives pursued by GIs: the protection of common cultural heritage[65].

With this result in mind, the expectation is that future cases dealing with the application of what is currently Article 35 of the Proposal will not be able to disregard the result of this jurisprudential interpretation of the scope of protection of a GI.

Having set the basis for this reasoning, the question then becomes how to further integrate this element in the existing framework of a GI and, more specifically, of a craft or industrial GI.

B. Drafting the Product specifications for GIs under Article 7 of the Proposal

Another element that could help advance the argument that GIs can be a vector for protecting expression of Intangible Cultural Heritage can be found within what is required to apply for GI registration in the EU legislation. Article 8 of the Quality Scheme Regulation, for example, prescribes that the registration application requires the applicant to file several elements, including the 'product specification', which can be found in Article 7 of the same provision and in Article 7 of the Proposal. The product specification is the document containing all the details relevant to identifying the geographically linked product.

Looking more closely at article 7 of the Proposal, we see that the product specification, also known as *cahier des charges*, includes not only the product's name, description, definition of the geographical area, raw materials, labelling and inspection rules, link between area of production and quality/reputation, but also, and most importantly here, under letter (e), the need to provide a description of the method used to obtain the product and "when appropriate" the additional information concerning "the traditional methods and specific practices

61 Case C-490/19 *Syndicat interprofessionnel de défense du fromage Morbier v. Société Fromagère du Livradois SAS* (*Morbier*), Opinion Of Advocate General Pitruzzella delivered on 17 September 2020 EU:C:2020:730.

62 Ibid, paragraphs [26] and [27]. The CJEU, in its final decision in the *Morbier* Case recalls this passage from the Advocate General's Opinion in paragraph [37], restating that 'the PDO and the product covered by it are closely linked'.

63 Case C-614/17 Opinion of Advocate General Pitruzzella delivered on 10 January 2019 in case *Fundación Consejo Regulador de la Denominacio´n de Origen Protegida Queso Manchego* v *Industrial Quesera Cuquerella SL e Juan Ramón Cuquerella Montagud* (*Queso Manchego*) EU:C:2019:344.

64 Case C-490/19 *Syndicat interprofessionnel de défense du fromage Morbier v. Société Fromagère du Livradois SAS* (*Morbier*), EU:C:2020:1043.

65 Case C-490/19 *Syndicat interprofessionnel de défense du fromage Morbier v. Société Fromagère du Livradois SAS* (*Morbier*), Opinion of Advocate General Pitruzzella delivered on 17 September 2020 paragraph [29] EU:C:2020:730.

used"[66]. By the looks of it, it could then be said that "a product becomes eligible for a GI not only by virtue of where it is produced, but [also] how"[67].

It is in the product specifications that the cultural heritage dimension lying behind the product could be identified and valorised, giving a legal framework to practices that are both origin-linked and collectively shared.[68] This argument is supported by the fact that it has been found in the relevant literature that "GIs are seen as potential bulwarks against commoditization because they do not merely designate what the product is (its appearance or physical and organoleptic qualities) but also where, by whom and how – very specifically – it was made".[69]

This hypothesis is not without weak spots, as they have been pointed out in the literature on agricultural GIs, that is here once again borrowed. Because the quoted section of Article 7(e), based on the text of Article 7(e) of the QSR, is preceded by the location "when appropriate", it has been raised as an objection that the inclusion of an historical overview or other references to traditional methods connected with intangible cultural heritage elements is not an actual requirement[70] under Article 7. When it comes to agricultural Geographical Indications, it is left to the applicant to add these elements into the product specification. This might be modified when it comes to registering craft and industrial products under the proposed self-standing system, if such a requirement is introduced.

Notably, when considering how to discipline the protection of GIs for craft and industrial products, the Commission introduced a slight reform in this respect of the Quality Scheme Regulation, possibly with the intention to move away from the objections raised in the foregoing paragraph.

Under the proposed formulation of Article 7 of the Regulation for C&Is, the requirement to provide a description of the production method is now standing alone under letter (e), which originally read "the authentic and unvarying local methods", but has then become "the traditional methods and specific practices used". We find here an explicit mention of the term 'traditional' as related to a C&I Geographical Indication in an actual Article of the proposal .

The Commission did not abandon the approach of giving the applicant the possibility of opting out from providing this information where it is not appropriate. Since there is no frame of reference given as to when this condition of appropriateness is satisfied, this seems to be left once again to the arbitrary volition of the applicant.

Nonetheless, it would be auspicious, in the opinion of the author, that the Proposal take a stronger stance towards protecting, even if indirectly, traditional knowledge and therefore the intangible cultural heritage connected with handicrafts and industrial products and their place of provenance. This could be realised in Article 7(e) by simply removing the expression "where appropriate" and including, as an actual requirement for registration, the description of the traditional methods and specific practices in the application.

In the eventuality that none of the proposed approaches is found convincing, an alternate or even additional solution could be implemented, namely that of hybrid quality scheme.

6. THE (REVISED) TSG: TRADITIONAL GEOGRAPHICAL PRODUCT

This alternative approach, currently not considered by the Proposal for a Regulation on the protection of C&Is, revolves around the inclusion of a quality scheme other than PGI, which is the only label from the Quality Schemes that is reprised in the Proposal. Title III of the Quality Scheme Regulation lists, after PGI and PDO, the Traditional Specialities Guaranteed. The objective of this provision, as detailed under Article 17 Regulation 1151/2012, is to safeguard traditional methods of production and recipes, by providing support to consumers in the effort to communicate to the public which value-adding attributes their products possess.

Differently from PDOs and PGIs, TSGs do not list amongst their qualifying criteria a link to a specific place of origin, but rather focus the attention on a different element: tradition. The term "traditional" is defined in article 3(3) of Regulation 1151/2012 as indicating that there has been "proven usage on the domestic market for a period that allows transmission between generations", adding then that "this period is to be at least 30 years".

The emphasis posed on the methods of production and on the use perpetuated through time make this quality scheme interesting for the discipline of GIs on craft and industrial products, as they bring the human factors to the forefront[71]. This is because C&Is are generally relying more on such factors to establish the connection with the area of origin. Consequently, the *terroir* link is based on an historical reputation, or by reference to localised technical know-how that is mostly an endowment of "authentic products that are a part of the EU's cultural heritage".[72]

66 Proposal for a Regulation, Article 7(e), mirroring Regulation 1151/2012 Article 7(e) which prescribes to include "the authentic and unvarying local methods".

67 Amit Basole, 'Authenticity, Innovation, and the Geographical Indication in an Artisanal Industry: The Case of the Banarasi Sari: Authenticity, Innovation, and the Geographical Indication in an Artisanal Industry' (2015) 18 The Journal of World Intellectual Property 130.

68 Gangjee (n 9) 549.

69 Dev S. Gangjee, 'Introduction: timeless signs or signs of the times?' in Dev S. Gangjee (ed.) *Research Handbook on Intellectual Property and Geographical Indications* (Edward Elgar Publishing 2016) 3.

70 Gangjee (n 9) 551.

71 Andrea Zappalaglio and others, 'Sui Generis Geographical Indications for the Protection of Non-Agricultural Products in the EU: Can the Quality Schemes Fulfil the Task?' (2020) 51 IIC – International Review of Intellectual Property and Competition Law 38.

72 Thanasis Kizos, 'Consumers' and Producers' Expectations and Gains from Geographical Indications' in *Comprehensive Analytical Chemistry* (Elsevier 2013) vol 60, 34.

If the inclusion of the traditional cultural elements in the PGI scheme were to prove too cumbersome, revising something akin to the TSG could allow for the incorporation of Intangible Cultural Heritage in a more direct and clear way. To this end, the Commission could have included in the Proposal a new quality scheme based strictly on human factors and the historical connection of a specific C&I product to the geographical area of origin.

This quality scheme could, hypothetically, be called the Traditional Geographical Product[73]. In this TGP, the element of tradition would then become central, relating to the method used, as it is now for TSG, but with the added element of the strictly defined geographical area as a requirement for registration. The human element would take centre stage in a solution which, uniting CH and IP, would make of the GI sign "something which is, at the same time, external and internal to the fabric of a place, as well as of the community living in that place"[74].

Such a solution would allow to merge the scheme of the TSG, still based on the use of a protected geographical name, with the additional character of traditional methods and cultural heritage therein, even when the source material comes from an area different than the one defined. This combination would then result in a sign capable of transmitting the relevant information to consumers: namely, that the product bearing the logo is the result of a traditional practice or method, that it has been manufactured in the designated geographical area, and that the raw materials employed are those traditionally used.

While basing the structure for a TGP generally in what now is the one defined in the Quality Scheme Regulation for TSG, the objectives of this quality scheme could be defined as a means to safeguard traditional methods of production and products representing cultural heritage expressions, "by helping producers of traditional product in marketing and communicating the value-adding attributes of their traditional [methods] and products to consumers".[75]

As to what the qualifying criteria to register the name as a TGP are concerned, these would need to be spelled out as describing a product:

a) That originates in a specific place, region or, exceptionally, country;
b) That is the result of a method of production, processing or composition corresponding to traditional practices;
c) That is produced from raw materials that are the ones traditionally used.

By making a direct reference to the traditional character of the methods of production, a TGP would be then a sign capable of representing "a form of geographically embedded creativity".[76]

This scheme would allow to introduce the elements expressing Intangible Cultural Heritage directly into the criteria that need to be met for the name connected to it to be protected, without needing the legal devices otherwise employed basing the reasoning on the Opinions of AG Pitruzzella in the cited *Morbier* and *Queso Mancheso* cases.

What becomes essential, to be able to implement such an alternative solution, is defining what is to be intended as 'traditional'.

This element, as connected with agricultural and gastronomical products, is already present in the Quality Scheme Regulation, but despite being already available to use, has not been totally embraced by the Proposal for a Regulation on C&Is.[77]

Under Article 3(f) of the Regulation Proposal, a definition of the words 'traditional' and 'tradition' are given, in association with a product originating in a geographical area, as meaning that there has been a proven historical usage in a community for a period that "allows transmission between generations". It appears that, again, as it was the case before the Quality Scheme Regulation was reformed to establish a minimum period of at least 30 years.[78] There is a gap in the definition that is to be applied, leaving the interpretation somewhat open to what is to be considered as settled in a culture as traditional.

It would bode well if the final text of the Proposed Regulation included a time frame to mark a product as being an expression of traditional knowledge, considering that, as it is now, it is not sufficiently clear. The European legislator should intervene and provide a clear-cut time frame that would be applicable across the Single Market, to eliminate any possibility of inconsistent interpretation. This is relevant also if a reference is made to the fact that some European countries have adopted their own definitions on what constitutes 'tradition', that include different time frames, as is the case for example for Austria. The Republic of Austria has created a register for Traditional Austrian Specialties[79], where the time limit imposed for a product to be listed in it is 75 years or over three generations[80].

Lastly, to incorporate Intangible Cultural Heritage into this proposed quality scheme, the product specifications should be structured to include:

73 Some inspiration for the idea behind the scheme proposed in this paragraph descends from reading: Kilian Bizer and others, 'Sui Generis Rights for the Protection of Traditional Cultural Expressions: Policy Implications' (2011) 2 J Intell Prop Info Tech & Elec Com L 114.

74 Ferrari (n 39), 223.

75 Article 17 of Regulation 1151/2012.

76 Ferrari (n 39) ibid.

77 Article 3(3) Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs OJ L 343, 14.12.2012, p. 1–29.

78 Down from the 50 years originally presented in the Proposal for what was to become, and now is, Regulation No 1151/2012.

79 The registry can be consulted at: <https://info.bmlrt.gv.at/themen/lebensmittel/trad-lebensmittel.html> accessed 3rd of January 2023.

80 Roman Sandgruber, *Traditional Craftsmanship as Intangible Cultural Heritage and an Economic Factor in Austria* (Facultas 2019) 18.

a) a document providing the relevant information pertaining to the history behind the manufacturing methods employed and the historical connections between the place, region, or country;
b) details establishing the link between the reputation or other characteristics of the product and the geographical origin.

These documents, as an essential component of the application for registration, would serve to show a strong *terroir* link, based on human factors rather than biological or chemical ones. Thus, it would go to show how this connection can be based also on the development of knowledge, technological advances as expressions of traditions and skills developed over time, in a specific place.

Applying such a solution would provide for an actual framework to accommodate cultural heritage protection into the Regulation on geographical indication protection for C&Is, therefore achieving through a binding instrument the public policy objective listed in Recitals (7) and (8) of the Proposal.

7. CONCLUDING REMARKS

What emerges finally from the presented analysis is that Cultural Heritage, when it comes to craft and industrial geographically linked products, is an element that is hard to keep away from.

Its inclusion in Recitals (7) and (8) of the Proposal for a Regulation on C&I Geographical Indications has solid bases and should not be limited there, but rather be incorporated also in a legally binding operative provision.

In that respect, it has been shown that the legislator could pick various degrees of inclusion to implement this reform of the Geographical Indications system. CH could be increasingly relevant for the registration of a GI because it affects the ability of the product to meet the requirements set by Article 5(b) of the Proposal. Namely, the know-how and traditions that make the final product what it is are also the source of its reputation or of an essential quality or characteristic, which is linked to the underlying CH elements. Another relevant provision would be the one concerned with the drafting of product specifications, in which CH could include the traditional methods and specific practices behind the production of the C&I GI goods.

Even if neither option would be enacted, GIs could still provide an indirect form of tutelage to a cultural practice or a traditional craftsmanship process. When the final product has been granted protection according to the most recent case law on the topic, the scope of it would need to take into consideration the objectives that this IP right pursues, namely the protection of common cultural heritage.

Taking it one step further, an additional solution could be to introduce a new Quality Scheme with the express purpose of explicitly making CH one of the requirements, alongside the indication of a determined geographical area.

Unless additional attention is drawn to this topic, it is still unlikely that the final version of the Proposal will include any further action towards implementing the protection of European regional CH through craft and industrial GIs.

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

Matthew Rimmer*

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

Reputation as Expressed in the Canadian Law of Geographical Indications

by Darinka Tomic

ABSTRACT

Reputation is a core concept in geographical indications. It has been a substantive element in defining geographical indications since their international recognition in the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In addition to TRIPS, which required member states, including Canada, to only regulate geographical indications for wine and spirits, the trade agreements which Canada signed, such as the 2014 Canada-Korea Free Trade Agreement and 2016 Canada-European Union Comprehensive Economic and Trade Agreement (CETA), required Canada to amend its Trademarks Act to include geographical indications for various food and agricultural products. However, none of these agreements required Canada to change the definition of geographical indications. The main argument in this article is that there is no geographical indication without satisfying the evidence of reputation. In Canada, a request to register geographical indication must be submitted directly to the Canadian Intellectual Property Office (CIPO), which then rigorously examines the application. Even though there has not been much litigation involving geographical indications in Canada, it is clear from the legislation that an applicant can provide evidence of reputation during the application process sufficient to support the awarding of geographical indication protection as declared in the Canadian statute. The decision in Canadian 2021 *Champagne v Sugarfina, Inc*. shows that the evidence of reputation was vital in protecting the Champagne geographical indication.

A. THE ARRIVAL OF GEOGRAPHICAL INDICATIONS IN INTERNATIONAL LAW

(a) The origin of the term

Article 10(1) of the original 1883 Paris Convention notes

> The provisions of the preceding Article shall apply to any goods which falsely bear as an **indication of source** the name of a **specified locality**, when such indication is joined to a trade name of a fictious character or used with fraudulent intention.[1]

However, despite inclusion of "indications of source" and "specified locality" to any goods of industrial property, the 1883 Paris Convention did not include any provisions related to their governance.

The concepts of indications of source and appellations of origin had been emerging in Europe (and, particularly, in France) since the eighteenth century.[2] Particularly in the case of the initial French preoccupation with protecting "Champagne" through legislation in the nineteenth century, Dev Gangjee has noted that "[r]eputation and quality were not central to the enquiry"[3]—"the initial emphasis [was] on physical geography in wine regulation systems."[4]

The name Champagne (a wine region in France) and wines produced from the specific type of grapes grown in the Champagne region have been legally protected in the European countries since the 1891 Madrid Treaty.[5] Article

1 Paris Convention for the Protection of Industrial Property 20 March 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and as amended on September 28, 1979, 828 UNTS 305 [Paris Convention] https://www.wipo.int/wipolex/en/text/288514 accessed 10 September 2023 (emphasis added).

2 Dev Gangjee, 'The Appellation of Origin in France' in *Relocating the Law of Geographical Indications* (Cambridge University Press 2012).

3 Dev Gangjee, *Relocating the Law of Geographical Indications* (Cambridge University Press 2012) 97.

4 ibid, 125.

5 Madrid Agreement for the Repression of False or Deceptive Indications of Source of Goods 14 April 1891 (Act revised at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, and at Lisbon on October 31, 1958) [Madrid Agreement] https://wipolex.wipo.int/en/text/286776 accessed 10 September 2023. The 1891 Madrid Agreement came only eight years after the Paris Convention. Since the inception of the Madrid Agreement, the term "indication of source" has

1 of the Madrid Treaty provides that "[a]ll goods bearing a false or deceptive **indication** by which one of the countries to which this Agreement applies, or a place situated therein, is directly or indirectly indicated as being **the country or place of origin** shall be seized on importation into any of the said countries."[6] Standards defining the quality of wine production and marking the zone of the Champagne region were further regulated by French laws in the twentieth century, which led to the establishment of the principle of Appellation d'Origine Contrôlée (AOC) and the establishment of the Institut national de l'origine et de la qualité (INAO) which regulates and controls the origin and quality of the Champagne wine to this day.

The opening paragraph of a case brought before the Trademarks Opposition Board of the Canadian Intellectual Property Office (CIPO)[7] notes that

> [t]he *Institut national de l'origine et de la qualité* (INAO) is a French government agency that has for responsibility, ... to define the controlled designations of origin (*appellation d'origine contrôlée (AOC)*) ... [while] the *Comité interprofessionnel du vin de Champagne* (CIVC) is a French organization ... of the Champagne winemaking region in France and has for mission ... to insure the **recognition and the protection around the world of the Champagne controlled designation of origin** ... including the requirements that these wines meet ... their **geographical origin and conditions of production.**[8]

In addition to geography, Gangjee notes a "gradual recognition of human factors"[9] including recognition that "historic ties serve as an anchor [but] ... the emphasis on human intervention and methods of production implies that tools and techniques can migrate, perhaps with perfect fidelity."[10]

The legal protection of the "appellation of origin" that began in France led eventually to the internationally recognized protection of "geographical indications" at the end of the twentieth century under the TRIPS Agreement.[11]

Part II of the TRIPS Agreement (Standards Concerning the Availability, Scope and Use of Intellectual Property Rights) contains a discrete section, Section 3 (comprised of articles 22, 23 and 24) dealing with geographical indications.[12]

Article 22 provides the first definition of "geographical indications" in any multilateral international instrument. It reads as follows:

> Geographical indications are, for the purposes of this Agreement, indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, **reputation** or other characteristic of the good is essentially attributable to its geographical origin.[13]

This definition does not impose any legal obligation upon member states. It is Article 23 that requires TRIPS member states to legally regulate protection of geographical indications – and only geographical indications specific to wines and spirits:

> [e]ach Member shall provide the legal means ... to prevent use of a geographical indication identifying wines for wines not originating in the place indicated by the geographical indication in question ... even where the true origin of the goods is indicated or the geographical indication is used in translation

appeared in Article 10 of the Paris Convention and has remained almost unchanged into the latest 1967 Stockholm revision of the Paris Convention, which reads as follows:

Article 10 [False Indications: Seizure, on Importation, etc., of Goods Bearing False Indications as to their Source or the Identity of the Producer]:

(1) The provisions of the preceding Article shall apply in cases of direct or indirect use of a false **indication of the source** of the goods or the identity of the producer, manufacturer, or merchant.

(2) Any producer, manufacturer, or merchant, whether a natural person or a legal entity, engaged in the production or manufacture of or trade in such goods and established either in the locality falsely indicated as the source, or in the region where such locality is situated, or in the country falsely indicated, or in the country where the false **indication of source** is used, shall in any case be deemed an interested part (emphasis added).

It was through in the 1925 Hague revision of the Paris Convention that, in Article 1(1)(2), the phrase "indications of source or appellations of origin" appeared for the first time. In the latest 1967 Stockholm Revision of the Paris Convention, it reads as follows:

Article 1(1)(2) The protection of industrial property has as its object patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition.

6 Madrid Agreement, art 1(1). Full text of Article 1 reads:

(1) All goods bearing a false or deceptive indication by which one of the countries to which this Agreement applies, or a place situated therein, is directly or indirectly indicated as being the country or place of origin shall be seized on importation into any of the said countries.

(2) Seizure shall also be effected in the country where the false or deceptive **indication of source** has been applied, or into which the goods bearing the false or deceptive indication have been imported.

(3) If the laws of a country do not permit seizure upon importation, such seizure shall be replaced by prohibition of importation.

(4) If the laws of a country permit neither seizure upon importation nor prohibition of importation nor seizure within the country, then, until such time as the laws are modified accordingly, those measures shall be replaced by the actions and remedies available in such cases to nationals under the laws of such country.

(5) In the absence of any special sanctions ensuring the repression of false or deceptive **indications of source**, the sanctions provided by the corresponding provisions of the laws relating to marks or trade names shall be applicable (emphasis added).

7 *Institut national de l'origine et de la qualité and Comité interprofessionnel du vin de Champagne v Sugarfina, Inc.*, 2021 TMOB [Trademarks Opposition Board] 238 [*Champagne v Sugarfina, Inc.*].

8 *Champagne v Sugarfina, Inc.*, [2021], para 1 (emphasis added).

9 Dev Gangjee, *Relocating the Law of Geographical Indications* (Cambridge University Press 2012) 125.

10 ibid.

11 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299; 33 ILM 1197 (entered into force 1 January 1995) [TRIPS Agreement].

12 TRIPS Agreement, arts 22-24.

13 ibid, art 22(1) (emphasis added).

> or accompanied by expressions such as "kind", "type", "style", "imitation" or the like.[14]

Irene Calboli has noted, however, that

> TRIPs' inclusion of the word "reputation" in the definition of art. 22(1) clearly validated not only the trend of products not entirely made in the GI-denominated regions, but also the **possibility of securing a monopoly on the exploitation of the value of the reputation associated** with GIs on a commercial scale. Not surprisingly, in an increasingly competitive (and less subsidised) marketplace for both agricultural and non-agricultural products, the value of GIs as signifiers of quality, tradition, and, in turn, reputation, can be paramount to securing a large market share against competing products.[15]

The subsequent and final article dealing with geographical indications (Article 24) is titled "International Negotiations: Exceptions". Its first paragraph states "[m]embers agree to enter into negotiations to increase the protection of individual geographical indications under Article 23".[16]

(b) Beyond wines and spirits

The question of expansion of geographical indications beyond wines and spirits led to one of the longest international negotiations that took place during the formation of the World Trade Organization, a round of negotiations known as the Doha Round.[17] These negotiations over the expansion of geographical indications were described as an "Old World – New World" contest between the "Old World" countries of Europe, with centuries' long traditions (especially in wine making), and the "New World" countries relatively new to wine making, such as Canada, the United States, and Australia but also New Zealand, Argentina, Chile and South Africa.[18]

Some countries, particularly an enthusiastic group of "Old World" countries, insisted any expansion of geographical indications be also regulated to a 'higher level of protection' than was already the case with wines and spirits.[19]

The Doha Round[20] did advance the agenda on geographical indications to exploring possibilities for creating an internationally acceptable common approach to regulating various "foodstuff"[21] (in addition to the already established protection for selected wines and spirits, predominantly from wine regions across Europe).

Eventually, negotiations that focused on creating a multilateral register for the geographical indications for wines and spirits (already protected in the TRIPS Agreement, Article 23) were separated from the negotiations with respect to extending the TRIPS Agreement of geographical indications beyond wines and spirits to encompassing food and agricultural products.[22]

The initiative to add a required geographical indication protection for food and agricultural products into the TRIPS Agreement came from Europe, the birthplace of "appellation of origin."[23] The concept of appellation of origin is analogous in some ways to the concept of geographical indication: international protection of appellations of origin predates protection of geographical indications: the Lisbon Agreement for the Protection of Appellations of Origin and Their International Registration, agreed in 1958 but only entered into force, for its members, in 1983.[24] Canada has never been, and is still not, a member.

14 ibid, art 23.1.

15 Irene Calboli, 'In Territorio Veritas? Bringing Geographical Coherence into the Ambiguous Definition of Geographical Indications Origin' (2014) 6(1) WIPO Journal 57, 67 (emphasis added). She goes on to note that "This status quo, however, runs directly against the rationale for GI protection—providing accurate information to consumers about the geographical origin of the products, while offering incentives to local communities to invest in local production."(emphasis added).

16 TRIPS Agreement, art 24.1.

17 *The Doha Round Texts and Related Documents* (WTO 2009) https://www.wto.org/english/res_e/booksp_e/doha_round_texts_e.pdf accessed 10 September 2023.

18 In this article, the "Old World" term generally refers to Europe. It is used in conversation about the "Old World – New World" contest relevant in making decisions about granting the geographical indications protection domestically and in international negotiations. For example, Europe is a natural adopter of geographical indications because of its long history, while, on the other hand, "New World" countries are relatively new to wine making that has been known for centuries in the countries of the "Old World". The discussion about "Old World – New World" has been treated in Sara Zborovski & Patrick Duke, 'Shining a Light on the Protection of Geographic Indications in Canada: The Battle Between GIs and Generic Terms' (2013) 29(2) CIPR 201; and in Michele Ballagh, 'Geographical Indications Versus Trade-Marks: Collective Versus Private Rights?' (2009) 25(1) CIPR 137, 143.

19 World Trade Organization, TRIPS: Geographical Indications: Background: Extending the "Higher Level of Protection" Beyond Wines and Spirits (2008) https://www.wto.org/english/tratop_e/trips_e/gi_background_e.htm accessed 10 September 2023.

20 The Doha Ministerial Declaration adopted 14 November 2001, WT/MIN(01)/DEC/1 in *The Doha Round Texts and Related Documents* (WTO, 2009), para 18.
Paragraph 18 reads as follows:
18. With a view to completing the work started in the Council for Trade-Related Aspects of Intellectual Property Rights (Council for TRIPS) on the implementation of Article 23.4, we agree to negotiate the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits by the Fifth Session of the Ministerial Conference. We note that issues related to the extension of the protection of geographical indications provided for in Article 23 to **products other than wines and spirits** will be addressed in the Council for TRIPS pursuant to paragraph 12 of this Declaration https://www.wto.org/english/res_e/booksp_e/doha_round_texts_e.pdf accessed 10 September 2023 (emphasis added).

21 The term "foodstuff" appears in documents of EU institutions. See Council Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L031, c 1, art 2.

22 World Trade Organization, TRIPS: Geographical Indications: Background: Multilateral register for wines and spirits. ("The work began in 1997 under Article 23.4 of the TRIPS Agreement and now also comes under the Doha Agenda (the Doha Declaration's paragraph 18)") https://www.wto.org/english/tratop_e/trips_e/gi_background_e.htm accessed 10 September 2023.

23 A term defined in the 1958 Lisbon Agreement for the Protection of Appellations of Origin and Their International Registration (31 October 1958, amended 28 September 1979, entered into force 4 November 1983, last revised 1 January 1994) [Lisbon Agreement]. There are currently thirty member countries.

24 Although Canada is not signatory to the Lisbon Agreement, certain regulatory regimes analogous to the type of protection granted under

The enthusiasm from European countries (but also other countries worldwide) in the Doha Round to include in the TRIPS Agreement protection of geographical indications beyond wines and spirits (i.e., for various agricultural products and food) was understandable considering the production of handicrafts and various food and agricultural products where their centuries-long renommé was directly associated with the quality or reputation built upon the terroir of their origin. The idea of adding appellations of origin to TRIPS was also supported by several developing and least developed countries.[25] These countries viewed the expansion of geographical indications as an opportunity, especially for their small food and agricultural producers, to seize a valuable niche in the global market. These countries recognized that expanding the protection of geographical indications beyond wines and spirits (especially in those countries where wine making was not part of traditional culture) could become a powerful instrument in securing a better position in international trade (through acceptable and recognizable identification of their unique agricultural and food products), therefore creating a broader social and political space for them on the world map. In most cases, least developed countries already have traditional, predominantly agricultural products having a "quality, reputation or other characteristic" attributable to the territory of their origin. On the other hand, many of these least developed countries lacked adequate domestic regulatory instruments to protect those products even within their own national boundaries. The lack of domestic legal instruments for protecting geographical indications creates a considerable obstacle in preparing these products for competitive global markets.[26]

(c) "Old World" versus "New World"

At a time when the least developed countries were recognizing possibilities to access global markets through an accessible, standardized geographical indications registry, WTO member states with advanced economies, such as Canada, had a different view on expanding geographical indications.[27] Regardless of their advanced economies, in terms of geographical indications, the countries of the "New World" could not respond to the "Old World" with reciprocity in terms of a number of products capable of being promoted for geographical indication protection.

Canada-European Union Comprehensive Economic and Trade Agreement (CETA)[28] provides an example of the disparity between a "New World" nation, Canada, and the European Union's 28 "Old World" countries[29]: in Annex 20-A to CETA, the 2017 trade agreement between Canada and the European Union, Part A contains a list of 171 products originating in the European Union, while part B, Geographical Indications Identifying a Product Originating in Canada lists no products at all.[30]

WTO members like Canada, Australia and New Zealand opposed the proposal for broader inclusion of products for inclusion as geographical indications in a revised TRIPS Agreement that are already covered in the original TRIPS Agreement: these countries saw the expansion of geographical indications protection beyond wines and spirits as an administrative burden as well as a limitation on free production, export, and trade.[31]

In the production of goods aspiring to geographical indications protection, the balance between human input and a "quality, reputation or other characteristic" originating in the specific geographic region (i.e., strictly tied to the nature-related features of the locality) was another issue for the 'New World' countries. Knowledge of production processes has been transferred from the 'Old World' and recreated in 'New World' territories – but geographical indications will not protect (indeed, will be a barrier to) these products when emanating from the 'New World'.[32]

While protection of geographical indications for wines and spirits was relatively smoothly accepted worldwide through the TRIPS Agreement, global expansion of geo-

the Lisbon Agreement have been introduced by Canadian provinces. Protection of 'appellations' for wines have been introduced by Ontario under its Vintners Quality Alliance Act, 1999, SO 1999, c 3 (VQA Ontario Appellations of Origin, https://vqaontario.ca/ontario-appellations/_ accessed 10 September 2023) and by British Columbia under its Wines of Marked Quality Regulation, BC Reg 168/2018, pursuant to the Food and Agricultural Products Classification Act, SBC 2016, c.1. In April 2022, Nova Scotia passed the Nova Scotia Wine Authority Act, SNS 2022, c 6. In Québec, on the other hand, an appellation of origin for Québec wines has been secured by obtaining the geographical indication "Vin du Québec", listed in the Canadian government's CIPO database (and thus enforceable) as of 1 June 2022.

25 The WTO recognizes as least developed countries (LDCs) those countries which have been designated as such by the United Nations. There are currently 49 least developed countries on the UN list, 30 of which to date have become WTO members https://www.wto.org/english/thewto_e/minist_e/min01_e/brief_e/brief03_e.htm accessed 10 September 2023.

26 Envisioning the importance of the expansion of geographical indications for economic growth, cultural development, and a way to reduce poverty, Uganda, for example, adopted The Geographical Indications Act No 8 of 2013, a *sui generis* system for the protection and registration of geographical indications.

27 Michelle Agdomar, 'Removing the Greek from Feta and Adding Korbel to Champagne: The Paradox of Geographical Indications in International Law' (2008) 18(2) Fordham Intell Prop Media & Ent LJ 54, 543.

28 Canada-European Union Comprehensive Economic and Trade Agreement (CETA), 30 October 2016 (entered into force 21 September 2017), arts 20.16-20.23 [CETA].

29 The number of EU member countries is down to 27 since the United Kingdom left the EU in 2020.

30 CETA, Annex 20-A, Part A-- Geographical Indications Identifying a Product Originating in the European Union; Part B -- Geographical Indications Identifying a Product Originating in Canada https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/20-A.aspx?lang=eng#a accessed 10 September 2023. This data reflects the number of products as they were at the time the agreement was signed (in 2017): it is expected that these numbers will change as new products are added to the two lists over time.

31 *'Extending the "Higher Level of Protection" Beyond Wines and Spirits'* ("They caution that providing enhanced protection would be a burden and would disrupt existing legitimate marketing practices. They also reject the "usurping" accusation, particularly when migrants have taken the methods of making the products and the names with them to their new homes and have been using them in good faith"). https://www.wto.org/english/tratop_e/trips_e/gi_background_e.htm#protection accessed 10 September 2023.

32 Irene Calboli, 'In Territorio Veritas? Bringing Geographical Coherence into the Ambiguous Definition of Geographical Indications Origin' (2014) 6(1) WIPO Journal 57, 65-66.

graphical indication protection beyond wines and spirits has faltered. The lengthy Doha Round of negotiations failed to secure widespread multilateral international agreement on expanded geographical indications. International expansion of categories of protection through geographical indications, at this point, has been limited to bilateral and smaller multilateral free trade agreements between countries.[33]

Daniel Gervais noted, after geographical indications entered the TRIPS Agreement but in light of the failure of a further attempt to enhance multilateral geographical indication protection during negotiations for the Lisbon Agreement, that

> Reputation could be considered at first glance as a soft, subjective criterion. However, it can be measured. Reputation is the result of years of work in association with a product that has created a mental link between that product and its geographical origin, but reputation is also a cause that can be measured by its effects. For example, consumer surveys, price differentials attributable to the perceived advantage of the product because of its origin, etc. The other criteria mentioned in TRIPS Article 22.1 are "harder" and perhaps easier to prove, namely the quality and (other) characteristics of the product itself. But even "quality" may be defined in a number of ways according to a consumer's priorities. In the same vein, at least the selection of which (other) characteristics are relevant may be subject to the same criticism. In other words, while all the criteria mentioned in Article 22 are potentially partially "subjective," they can be considered by way of rational demonstration and comparative analysis. Presumably, if potential buyers of a product want it because of a quality or characteristic associated with it stem from its geographical origin (whether the cause is human or natural factors or a combination of both), then that product could be said to have a given reputation. The difference in treatment of reputation between Lisbon and TRIPS would then not be *functionally* different.[34]

B. REPUTATION IN GEOGRAPHICAL INDICATIONS IN CANADIAN LAW

(a) In the Trademarks Act [35]

In the light of its obligations arising from the TRIPS Agreement, Canada, in 1996, amended its Trade-marks Act definition section (Section 2), to include, for the first time, a definition of "geographical indications". That definition read as follows:

> **geographical indication** means, **in respect of a wine or spirit**, an indication that
>
> **(a)** identifies the wine or spirit as originating in the territory of a WTO Member, or a region or locality of that territory, where a **quality, reputation or other characteristic** of the wine or spirit is essentially attributable to its geographical origin, and
>
> **(b)** except in the case of an indication identifying a wine or spirit originating in Canada, is protected by the laws applicable to that WTO Member[36]

In the same amendment, the term "reputation" was added as part of new section 11.12(3)(e) of the Trade-marks Act:

> (3) For the purpose of subsection (2), the statement by the Minister must set out all of the following information in respect of an indication:
>
> ---(e) the quality, **reputation** or other characteristic of the wine or spirit that, in the opinion of the Minister, qualifies that indication as a geographical indication;[37]

While global multilateral international negotiations have failed since the TRIPS Agreement to extend standards respecting geographical indications beyond those for wines and spirits, the failure of those negotiations has not prevented WTO members from entering into bilateral and multilateral agreements in which geographical indications respecting food and other agricultural products have been agreed. The first step in this direction for Canada was the 2014 Canada-Korea FTA, followed by the 2016 CETA.

In the Canada-Korea FTA, the term "reputation" appears only in the definition of geographical indications (the text of that definition is almost identical to the definition of geographical indications in the TRIPS Agreement).[38] Article 16.10 of the Canada-Korea FTA articulates further legal obligations regarding geographical indications for the parties.[39]

As a result of the Canada-Korea FTA and CETA, Canada amended its Trade-marks Act provisions respecting

33 See the Canada-Korea Free Trade Agreement, 22 September 2014 (entered into force 1 January 2015), art 16.10 [Canada-Korea FTA].

34 Daniel Gervais, 'The Lisbon Agreement's Misunderstood Potential' (2009) 22(1) IPJ 57, 61 (emphasis in original).

35 Canada made significant changes to the trademarks statute in 2019. These changes included eliminating the hyphenated term "trade-marks" and replacing it with "trademarks." Therefore, in this article, all citations from the statute before 2019 refer to the Trade-marks Act as the name of the statute then was.

36 Trade-marks Act, RSC 1985, c T-13, s 2 [1996-2012] (emphasis added).

37 ibid, s 11.12(3)(e) (emphasis added).

38 Canada-Korea FTA, art 16.10, footnote 3:
Geographical indications are, for the purposes of this Article, indications which identify a good as originating in the territory of a Party, or a region or locality in that territory, where a given quality, **reputation** or other characteristic of the good is essentially attributable to its geographical origin (emphasis added)

39 Canada-Korea FTA, art 16.10 (footnotes omitted).
1. Canada shall, with respect to the geographical indications of "GoryeoHongsam", "GoryeoBaeksam", "GoryeoSusam", and "IcheonSsal" and their translations, respectively, "Korean Red Ginseng", "Korean White Ginseng", "Korean Fresh Ginseng" and "Icheon Rice", provide the legal means for interested parties to prevent

geographical indications. The definition of 'geographical indication' was changed to the current definition:

> **geographical indication** means an indication that identifies a wine or spirit, **or an agricultural product or food of a category set out in the schedule**, as originating in the territory of a WTO Member, or a region or locality of that territory, if a quality, reputation or other characteristic of the wine or spirit **or the agricultural product or food** is essentially attributable to its geographical origin[40]

This definition incorporates any "agricultural product or food of a category set out in the schedule."[41] The schedule currently consists of a list of 24 categories of food and agricultural products.[42]

Section 11.12(3)(e) of the Trade-marks Act, quoted above as containing the term "reputation", was amended, in light of the Canada-Korea FTA, to reflect the inclusion of agricultural products and food. It now reads as follows:

> (3) For the purpose of subsection (2), the statement by the Minister must set out all of the following information:
>
> ---
>
> (e) the quality, reputation or other characteristic of the wine or spirit **or the agricultural product or food** that, in the Minister's opinion, qualifies that indication as a geographical indication[43]

As set out in the Canada-Korea FTA, Canada was required to protect a number of Korean food products: a list was added in 2017 to the Trade-marks Act at s 11.23.[44]

After Canada signed the Comprehensive Economic Agreement between the European Union and Canada in 2016 (an agreement which entered into force in 2017),[45] in addition to the list of 24 agricultural products and food categories already added to its trademark statute (following an earlier Canada-Korea Free Trade Agreement), Canada added 172 specific geographical indications identifying various categories of agricultural products and food originating in the countries of the European Union.[46] It though was noted that "[i]n the Canada-EU CETA deal, Canada accepted GIs for many European-based foods, although it won an exception for existing Canadian feta cheese makers."[47]

The provision of the Canadian Trademarks Act (s 11.22) now states, however, that the list of wines, spirits, agricultural products or foods from Korea whose geographical indications are to be protected in Canada can be "amended from time to time."[48]

In CETA Chapter 20 Intellectual Property, Sub-section C – Geographical Indications, Article 20.16 – Definitions, it is provided that

> For the purposes of this Sub-section:
> geographical indication means an indication which identifies an agricultural product or foodstuff as originating in the territory of a Party, or a region or locality in that territory, where a given quality, **reputation** or other characteristic of the product is essentially attributable to its geographical origin; and product class means a product class listed in Annex 20-C [49]

When Canada became a member of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), which came into effect 30 December 2018 and now comprises Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam, it took on, amongst many other things, an obligation relating to geographical indications that, again, expressly links geographical indications to reputation:

> Chapter 18 – Intellectual Property
> Section A: General Provisions
> ...

(a) the use of any means in the designation or originates in a geographical area other than the true place of origin in a manner that misleads the public as to the geographical origin of the good;
(b) and (c) omitted
2. Korea shall, with respect to the geographical indications of "Canadian Whisky" and "Canadian Rye Whisky", provide the legal means for interested parties to prevent
(a) the use of any means in the designation or originates in a geographical area other than the true place of origin in a manner that misleads the public as to the geographical origin of the good;.
(b) and (c) omitted

40 Trademarks Act, RSC 1985, c T-13, s 2 (emphasis added).

41 ibid.

42 Trademarks Act, RSC 1985, c T-13, sch.

43 Trademarks Act, RSC 1985, c T-13, s 11.12(3)(e) (emphasis added)

44 Trade-marks Act, RSC 1985, c T-13, s 11.23 (added by SC 2017, c 6, s 67):
Canada — Korea indications
Paragraphs 11.18(2)(a) and (c) and section 11.21 do not apply with respect to an indication that is a protected geographical indication and that is included in the following list:
(a) GoryeoHongsam;
(b) GoryeoBaeksam;
(c) GoryeoSusam;
(d) IcheonSsal;
(e) ginseng rouge de Corée;
(f) ginseng blanc de Corée;
(g) ginseng frais de Corée;
(h) riz Icheon;
(i) Korean Red Ginseng;
(j) Korean White Ginseng;
(k) Korean Fresh Ginseng;
(l) Icheon Rice.

45 See again CETA, Annex 20-A, Part A- Geographical Indications Identifying a Product Originating in the European Union; Part B – Geographical Indications Identifying a Product Originating in Canada, https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/20-A.aspx?lang=eng#a accessed 10 September 2023.

46 See Trade-marks Act, RSC 1985, c T-13, sch 6.

47 Ed White,''Geographical indications' can have mixed results' (2021) The Western Producer https://www.producer.com/markets/geographical-indications-can-have-mixed-results/ accessed 10 September 2023.

48 Trademarks Act, RSC 1985, c T-13, s 11.22.

49 CETA, Chapter 20: Intellectual property, Sub-section C -Geographical Indications, art 20.16 (emphasis added).

> Article 18.1: Definitions
> ...
> **geographical indication** means an indication that identifies a good as originating in the territory of a Party, or a region or locality in that territory, where a given quality, **reputation** or other characteristic of the good is essentially attributable to its geographical origin;[50]

Canada, Mexico and the United States have entered into agreement known by its acronym CUSMA,[51] which includes "TRIPS-Plus"[52] provisions for geographical indications, including, in Section A: General Provisions:

> Article 20.1 Definitions
> 1. For the purposes of this Chapter: **geographical indication** means an indication that identifies a good as originating in the territory of a Party, or a region or locality in that territory, where a given quality, **reputation**, or other characteristic of the good is essentially attributable to its geographical origin;[53]

When the United Kingdom left the European Union at the start of 2020, Canada and the UK agreed by December 2020 to the Canada-United Kingdom Trade Continuity Agreement, which entered into force on 1 April 2021.[54] This Canada-UK agreement incorporated the text of CETA and did not make any substantive changes to the provisions already instantiated in the CETA.

None of these trade agreements to which Canada has become signatory since TRIPS[55] have required Canada to make any changes to its Trademarks Act that have had any impact regarding the concept of reputation as already expressed in Canada's geographical indications law.

(b) Protection of geographical indications

Canada protects geographical indications by applying numerous provisions of its Trademarks Act. For example, section 11.12 empowers the Registrar to supervise the list of geographical indications. It reads as follows:

> 11.12 (1) There shall be kept under the supervision of the Registrar a list of geographical indications and, in the case of geographical indications identifying an agricultural product or food, translations of those indications.[56]

The prohibition against adopting geographical indications for wine and spirits "in connection with a business, as a trademark or otherwise" is set out in section 11.14, and the prohibition against adopting geographical indications for agricultural products and food as trademarks is in section 11.15 of the *Trademarks Act*.[57]

The Canadian Intellectual Property Office (CIPO) is the government body that processes a request[58] that a geographical indication be entered on Canada's list of geographical indications.[59] Tesh Dagne indicated in 2016 that

> [i]n Canada, there [had] not been significant initiative to use GIs as instruments of marketing regional identity in agricultural production. In recent years, however, the province of Québec has become a leader in the use of GIs after it launched the *produits du terroir* initiative.[60]

On the CIPO website, a current search of the Canadian Trademarks Database for the category "geographical indications" retrieved 878 entries (data current as of 1 November 2023). Geographical indications for wines and spirits and agricultural and food products were amongst those retrieved. Four entries were found to have "removed" status notifications and three were in the process of "advertising". The full list of geographical indications on Canada's list of recognized geographical indications has 184 entries on it.[61]

(c) Geographical indications in Canadian case law

Considering that geographical indications entered the Canadian intellectual property legal environment relatively recently (first only for wines and spirits (following the 1994 TRIPS Agreement), and even more recently following the 2014 *Canada-Korea Free Trade Agreement* and the 2017 *Comprehensive Economic and Trade Agree-*

50 Consolidated TPP Text -- Chapter 18-Intellectual Property https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/tpp-ptp/text-texte/18.aspx?lang=eng accessed 10 September 2023.

51 Canada – United States – Mexico Agreement (CUSMA) entered into force 1 July 2020.

52 "TRIPS-Plus" is an informal term for protection of intellectual property rights that goes beyond the requirements in the TRIPS Agreement.

53 CUSMA, Chapter 20 – Intellectual Property Rights – Section A: General Provisions, art 20.1: Definitions (emphasis added).

54 Canada-UK Trade Continuity Agreement, entered into force 2021 (Canada-UK TCA) https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cuktca-acccru/agreement_trade_continuity-accord_continuite_commerciale.aspx?lang=eng accessed 10 September 2023.

55 In addition to the Canada-Korea FTA, and CETA, Canada has also entered into CUSMA and CPTPP – all discussed above.

56 Trademarks Act, RSC 1985, c T-13, s 11.12.

57 Trademarks Act, RSC 1985, c T-13, ss 11.14, 11.15.

58 Process to register a geographical indication in Canada is found on the CIPO website https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04244.html accessed 05 November 2023.

59 CIPO provides a searchable trademarks database with geographical indications as additional search option https://ised-isde.canada.ca/cipo/trademark-search/srch accessed 05 November 2023.

60 Tesh W Dagne, 'The Narrowing Transatlantic Divide: Geographical Indications in Canada's Trade Agreements' (2016) 10 European Review of Intellectual Property Law 598, 609.

61 The complete list of geographical indications recognized in Canada - with the option to select the list of Canada's geographical indications - is available through the CIPO trademarks database https://ised-isde.canada.ca/cipo/trademark-search/srch accessed 05 November 2023.

ment between Canada and the European Union), it may be understandable that litigated disputes involving geographical indications appear to be scarce.

Although geographical indications fall under Canada's federal statute (Trademarks Act), Renata Watkin proffers an interesting constitutional argument based on the concept of "reputation" that is inherent in the protection of geographical indications. She argues that "[t]he assessment of the "essentially attributable characteristics" of origin-specific products seems to fall under provincial jurisdiction."[62] She continues that "[a]ssessing reputation would arguably involve concurrent or overlapping federal-provincial jurisdiction as both federal trademark law and common law tort of passing off protect reputation."[63] Watkin summarizes that "[w]here a product's renown is linked to a production method, the determination as to whether the method itself is distinctive is a matter of exclusive provincial jurisdiction."[64]

To register a geographical indication in Canada requires a "responsible authority" to apply for registration directly to the Canadian Intellectual Property Office, which then rigorously examines the application. It is not known how many details contained in those applications are evidence of "reputation," mainly because the definition in the Trademarks Act reads "if a **quality, reputation or other characteristic** of the wine or spirit or the agricultural product or food is essentially attributable to its geographical origin".[65] Because the requirement for registration is not simply for "reputation" but is for "reputation or other characteristic", it is not possible to isolate those applications which dealt with reputation from those that dealt with other characteristics.

Considering relatively recently established legal obligations for the protection of geographical indications, there appears to be little litigation concerning the prohibitions for the use of geographical indications legislated in Canada's Trademarks Act (sections 11.14 and 11.15).

There are, however, cases in which Canadian Trademarks Opposition Board of the Canadian Intellectual Property Organization (established under Canadian Trademarks Act)[66] have denied trademark registration to an applicant because the applicant was attempting to register (as a trademark, not a geographical indication), a mark that included a protected geographical indication. The case regarding the use of the term "Champagne", *Institut national de l'origine et de la qualité and Comité interprofessionnel du vin de Champagne v Sugarfina, Inc.*, as mentioned at the very beginning of this article, is such a case. During the hearing, the Trademarks Opposition Board established that "the Opponent [Institut national de l'origine et de la qualité and Comité interprofessionnel du vin de Champagne] essentially argues that:

> • Champagne wine has a considerable, if not legendary, **reputation** which extends to comestible products and so even when the word CHAMPAGNE is used in the context of such products including those covered by the application for the Mark, Canadian consumers would be aware that it is indicative of a specific wine, with specific features, from a specific geographical area, produced according to specific standards;
>
> And that ---
>
> • The Applicant's [Sugarfina, Inc.,] goods used in association with the Mark are in fact bear-shaped candies ("gummy bears") having Champagne wine as one of their ingredients.[67]
>
> ...

Iana Alexova, of Trademarks Opposition Board, who conducted the hearing refused application of the Sugerfina, Inc., pursuant to section 38(12) of the Trademarks Act. She was "satisfied that a fair review of the whole of the Opponent's evidence establishes that the average Canadian consumer would be familiar with the word "champagne" being used in respect of wine and would likely associate it to a sparkling wine from the wine-making region of Champagne in France."[68] She was, on the other hand, "far from convinced that whatever **reputation** the Opponent has established for Champagne wine in any way extends to food products".[69]

C. CONCLUSION

This article demonstrates that reputation is a core concept of geographical indications, the evidence of which has been given in the Canadian law of geographical indications. The term 'geographical indication' has a statutory definition, which Canada added to its trademarks legislation following the requirement established in the TRIPS Agreement. The definition of geographical indication includes "reputation," which has become a prominent requirement for geographical indications protection in Canada. A geographical indication must have a strict connection with a specific locality. This link separates the concept of geographical indication from the concept of trademark, though, as demonstrated in this article, geographical indications are associated with Canada's trademark law. In addition, for a geographical indication to be registered in Canada, the application must include evidence of reputation before a geographical indication can

62 Renata Watkin, 'Placing Canadian Geographical Indications on the Map' (2018) 30(2) IPJ 271, 284.

63 ibid.

64 ibid.

65 Trademarks Act, RSC 1985, c T-13, s 2, "geographical indication" (emphasis added).

66 Trademarks Act, RSC 1985, c T-13, s 63(3).

67 *Champagne v Sugarfina, Inc.*, [2021], para 22.

68 *Champagne v Sugarfina, Inc.*, [2021], para 33.

69 *Champagne v Sugarfina, Inc.*, [2021], para 34 (emphasis added).

be accepted for registration. In contrast, a trademark can be first registered and then acquire reputation.

Furthermore, this article has demonstrated that international trade agreements Canada signed after the TRIPS (such as the Canada-Korea FTA and CETA) used the definition of geographical indications, which always include reputation.

On a general note, this article compared the international dimension of geographical indications with the unique Canadian perspective. The article highlights reputation as the critical component in determining geographical indications protection. Though the case law on geographical indications in Canada is scarce, the concept of reputation associated with geographical indications is omnipresent. The *Champagne v Sugarfina Inc*. example showed that reputation was a crucial argument in the Trademarks Opposition Board of the Canadian Intellectual Property Organization's decision not to allow a trademark registration to Sugarfina Inc. because it conflicted with an already established reputation of Champagne as geographical indication. The case was also an example of a uniquely Canadian approach to regulating geographical indications. The federal statute regulates geographical indications in Canada, which gives the Trademarks Opposition Board of the Canadian Intellectual Property Organization power in matters concerning geographical indications disputes.

Darinka Tomic

Darinka Tomic obtained her PhD from Western Law (Canada) in 2022. Her doctoral thesis concerns reputation, rather than intellectual property designation, as an underlying aggregating link amongst moral rights, prohibited marks, and geographical indications. Her master's thesis, also defended at Western Law in 2017, concerns the right to food and intellectual property in the United Nations, including international human rights and international trade. She is the author of the chapter "Challenging Intellectual Property: Intellectual Property and the Right to Food" in the Nouveaux paradigmes dans la protection des inventions, données et signes – New Paradigms in the Protection of Inventiveness, Data and Signs (Éditions Yvon Blais 2019). Her research interests further the right to food and intellectual property in space law. Before coming to Western Law, Darinka served in the Legislative Assembly of Ontario for fifteen years. She is currently a professor at the School of Legal, Public and Office Administration at Seneca Polytechnic College at York University.

Must Assertions made in European Patents be Plausible, or is Invention a Question of Faith instead of Fact?

by Justin Lambert

ABSTRACT

The concept of "plausibility" is used to test the quality of information that a patent application must contain to support valid claims. A significant divergence between the way the UK courts apply the concept, and the way the European Patent Office and Courts in other European jurisdictions may apply the concept, is looming on the horizon following the Enlarged Board of Appeal's opinion in G 2/21 (Sumitomo). The opinion opens the way for patentees to rely on information that is not contained in the patent application, nor the state of the art, to support assertions made in the application. Allowing patentees to rely on such additional information, equivalent to "added matter", is likely to negatively impact the credibility of the European Patent System.

Recent patent litigation in Europe about Bayer's multi-billion dollar anticoagulant drug, Apixaban (sold as ELIQUIS), has highlighted how important the concept of "plausibility" is to the European patent system.

Prior to the Apixaban litigation, a common perception was that plausibility was only important in "second medical use" cases for policy reasons. It was thought that second medical uses deserved special treatment because, on the one hand, it is desirable to encourage research into new uses of known drugs, but, on the other hand, clinical trials for testing whether the drug has an effective second use are very expensive and difficult to keep confidential until after a patent is filed.

However, in the Apixaban litigation, Bayer's patent was for the drug molecule *per se*. By the time of the trial there was no dispute that the molecule worked, the patent identified it clearly, and the skilled person would have no difficulty following the patentee's instructions on how to make it. Nevertheless, the UK trial judge concluded:

> "European Patent (UK) 1 427 415 B1, is invalid by reason of lack of plausibility."[1]

A comparison between the reasoning of the UK courts, such as that in the Apixaban litigation, and a recent opinion of the Enlarged Board of Appeal of the European Patent Office (**EBA**) foreshadows divergence between how the UK courts, the EPO, and courts in other European countries understand and deploy the concept of "plausibility". This is of particular concern, given its importance.

In the UK, "post published information" [2] cannot be used in an analysis of the technical information that a skilled person can derive from a patent application in support of an assertion that a claimed invention delivers an asserted benefit or technical effect. There is no debate. However, in the EPO there has been debate about when it is permissible to rely on post-published information in such an analysis. According to the EBA, post-published information can be relied upon to support an assertion of technical effect if the technical effect is "encompassed by the teaching" of the original application.

This article will explore the consequences of the divergence. It will start with a discussion of second medical use claims, so as to refresh readers' understanding of what they are, and their role in the development of plausibility.

Secondly, it will work through some cases and statements of principle selected from different areas of patent law, all relating to the quality of information that must be contained in a patent application in order to justify a claimed monopoly. These include cases relating to industrial applicability, added matter, priority, inventive step, and insufficiency. Readers that are familiar with all of these subjects may skip (or skim read) these sections.

1 Sandoz Ltd v Bristol-Myers Squibb [2022] EWHC 822 (Pat) (07 April 2022) at [257.1].

2 Information that was not available to a skilled person at the filing or priority date of a patent application, either because the information did not yet exist or was secret.

Thirdly, the article explores the proposition that patents are not religious texts. Courts and patent offices should not assume that the notional skilled person will read patent applications with faith in all, or any, assertions made therein. While the notional skilled person is not inventive, he or she is rational.

Fourthly, it explores plausibility in more detail, by reference to three relatively recent and important cases, namely Pregabalin[3], Sumitomo[4], and Apixaban[5]. Pregabalin is a judgment of the UK Supreme Court. Since the Supreme Court is the UK's highest court, the judgment sets out the position that all UK trial and Court of Appeal judges must follow. The decision is also important because it features in the reasoning of the Technical Board of Appeal (**TBA**) and the reasoning of the EBA in Sumitomo. Finally, both Pregabalin and Sumitomo were considered and compared by the UK Patents Court and Court of Appeal in Apixaban.

The article will end with some discussion and conclusions. In summary, in the author's opinion, the approach of the UK courts is logical. On the other hand, the approach that seems to be that advocated by the EBA is not logical, and could lead to abuse and degradation of the European patent system, including for the reasons given by Richard Arnold QC[6] (and accepted by the Court of Appeal) in relation to "added matter" in Vector Corp v Glatt Air Technologies[7]:

> "The applicant or patentee could gain an unwarranted advantage in two ways if subject-matter could be added: first, he could circumvent the "first-to-file" rule, namely that the first person to apply to patent an invention is entitled to the resulting patent; and secondly, he could gain a different monopoly to that which the originally filed subject-matter justified.

SECOND MEDICAL USE CLAIMS

The effects that a compound will have on a human body, and therefore its potential medical uses, are an inherent property of the compound. If an active pharmaceutical ingredient (**API**) is administered to a patient for the purpose of treating one medical condition, it may inherently treat another, without either the patient or the doctor intending or being aware of the second benefit. In that case the use of the API is uninformative, in the sense that it does not disclose information about its second use to the public.

If methods of medical treatment *per se* could be patented under the European Patent Convention (**EPC**), a second medical use patent might claim:

> A method of treating medical condition Y by administering compound X.

However, the EPC forbids the grant of patents claiming methods of treatment. Accordingly, "EPC 2000 form"[8] claims are used instead, and up until 2011 "Swiss form" claims[9] were used[10]. However, it is helpful to remember that these types of claims are a substitute for method of treatment claims. Both EPC 2000 and Swiss from claims require that the compound exhibits some degree of efficacy. Further, and importantly, the process of administering a compound to a patient for the purpose of **treating** a specific medical condition may be contrasted with simply administering a compound to a patient without any **intention** to improve the relevant condition. Accordingly, these claims are limited by (a) efficacy of the compound, and (b) a mental element on the part of the person using the compound. This mental element distinguishes the claimed method from prior, uninformative, uses of the compound that might have improved a patient's condition because of the compound's inherent properties.[11]

The issue of plausibility arises when prior art proposes or announces a clinical trial of the drug to treat a new condition, but no results of the trial have been published. Since a proposal does not disclose the efficacy of the drug, which is a technical feature of such claims, it will not anticipate them.[12]

Birss J explained the issue very clearly in Hospira[13]:

> The effect of these points is that such claims are generally regarded as novel over a mere proposal to administer the drug to patients in the manner claimed. That is because the mere proposal does not disclose that the treatment is indeed efficacious. If it was obvious that the treatment would be efficacious, or at least it was obvious to conduct a trial of the treatment which would involve treating patients, then the claim is likely to lack inventive step but that is another matter.
>
> One might say therefore that the patent specification must contain the results of a clinical trial in

3 Warner Lambert v Generics [2018] UKSC 56 (14 November 2018).

4 T 0116/18 and G 2/21.

5 Sandoz Ltd v Bristol-Myers Squibb [2022] EWHC 822 (Pat) (07 April 2022) and Sandoz Ltd v Bristol-Myers Squibb [2023] EWCA Civ 472 (04 May 2023).

6 As he then was, because he is now a Lord Justice of the Court of Appeal.

7 [2007] EWCA Civ 805, at [6].

8 "Compound X for use in treating medical condition Y".

9 Having the form "Use of compound X in the manufacture of a medicament for treating medical condition Y".

10 The EBA decided in G 2/08 that patent applications filed after 28 January 2011 could no longer contain Swiss form claims. Since EPC 2000 claims were introduced in 2007, both forms of claims existed in parallel during this period, and patents in force contain both types.

11 See for example the reasoning of Floyd LJ in *Warner-Lambert v Actavis* [2105] EWCA Civ 556 at [121].

12 Likewise, since the results of clinical trials cannot be predicted, an announcement will not always make a claim obvious.

13 Hospira UK Ltd v Genentech Inc [2014] EWHC 1094 (Pat) (10 April 2014) at [59] to [64].

> order to prove efficacy, since the claims contain this element as a feature. But to require that at least in all circumstances may cause another problem. Finding new treatments for disease is highly desirable. Clinical trials are a necessary but very expensive and complex part of that process. The existence of a patent (or application) may facilitate investment in the clinical trial which might not otherwise take place but that means that the patent has to be applied for before the results are known. So a rule which demanded clinical results could cause real difficulties.
>
> On the other hand, if all the patent contains is a mere proposal, then it has not made a contribution to the art in this example. One has now come full circle. A mere proposal is not a disclosure of the claim, properly construed. But the patentee can hardly argue, and the Court or Patent Office is unlikely to accept, that a mere prior proposal is not enough to invalidate the claim if all that is present in the specification of the patent is a mere proposal followed by a use claim.
>
> Moreover, it would be a recipe for abuse if all that was required in order to obtain a patent in this field was a proposal, without any basis, to use drug A to treat disease B.
>
> Patent law seeks to address these factors balancing the requirements for sufficiency of disclosure against the rules of novelty and inventive step**. But the conventional sufficiency test of asking whether the claimed invention works, does not help. The treatment does work but what if the patent does not say so**? [emphasis added]
>
> For these reasons the idea of "plausibility" as part of the law of sufficiency of disclosure has been developed both in the EPO (T609/02 Salk Institute) and the UK (Regeneron). The term "plausibility" has been coined to characterise what it is that a patent specification must provide in order to be sufficient, short of full clinical proof of efficacy.

The highlighted sentence, asserting that the conventional sufficiency test doesn't work in such scenarios, deserves further explanation. The Judge was considering a "Swiss form" claim. These types of claims cover any process for manufacturing a relevant medicament (i.e. one containing the API and which is suitable and intended for use to treat the relevant disease). In most cases, the skilled person won't have any difficulty with the manufacturing process. Indeed, the patent is likely to say that well known formulation techniques may be used. So, an argument to the effect that the claim is insufficient because the skilled person would face undue burden working out how to formulate the product could not succeed.

In Pregabalin, Lord Sumption explained the same point in the following terms:[14]

> Section 14 of the Patents Act and the corresponding provisions of the EPC assume that an invention will be sufficiently disclosed if the specification enables it to be "performed". In the case of a patent for a new product or process, that assumption is almost always correct. The skilled person will discover that it works by replicating it in accordance with the specification. But the assumption is not correct in the case of a second use patent. The invention is not the compound or the process of its manufacture. The skilled person already knows how to make the product from the prior art disclosed in the original patent. The invention consists in the new purpose for which the product is to be manufactured. If sections 14(3) and 72(1)(c) are read literally and as an exhaustive statement of the requirement of sufficiency, **all that needs to be disclosed is the new purpose, which is enough to enable it to be administered to a patient suffering from the relevant condition**. The skilled person does not need to know how or why the invention works in order to replicate it. The result would be that the knowledge which made the identification of the new purpose inventive need not be disclosed at all. [emphasis added]
>
> The main problem about this result is that it would enable a patent to be obtained on a wholly speculative basis. Without some disclosure of how or why the known product can be expected to work in the new application, it would be possible to patent the manufacture of known compounds for the purpose of treating every conceivably relevant condition without having invented anything at all, in the hope that trial and error might in due course show that the product was efficacious in treating at least some of them.

If the sufficiency of such claims is considered in this way, it is easy to sympathise with an argument that a requirement that the patent also make it plausible that the API can be used to treat the disease is an impermissible addition to the statutory test, which has led to arguments about the role of plausibility in patent law.

However, in the author's view, there is another way to look at things. As mentioned above, in these cases the invention comprises new information about the drug's utility. Accordingly, the invention is not put into the skilled person's possession until he or she is provided with information that allows him or her to consider, on an objective basis, that administration of the drug will result in some form of treatment. Without such information, no rational skilled person could form the intention to treat the relevant disease by administering a medicament containing the relevant API. Since a mere assertion won't provide the skilled person with such information, such claims are not made sufficient by mere assertions. Considered in this way, the requirement that the patent contain sufficient information to make a treatment effect plausible is **not** an addition to the statutory test.

14 At [19] and [20].

INDUSTRIAL APPLICABILITY

An idea for something that is useful, but which is not enabled, is not an invention.

In Biogen Inc v. Medeva[15] Lord Hoffmann, explained:

> The idea of making HBV antigens by recombinant DNA technology was shared by everyone at the Geneva meeting of Biogen in February 1978 and no doubt by others working in the field, just as the idea of flying in an heavier-than-air machine had existed for centuries before the Wright brothers. The problem which required invention was to find a way of doing it.

The flip side of the above statement is just as important. That is, something that is enabled, but which is not useful, is not an invention either. This idea may be considered in the context of Article 57 of the EPC, which requires that a claimed invention be susceptible of industrial application.

The way in which this requirement applies to a patent for biological material was considered by the UK Supreme Court in HGS v Lilly[16]. Lord Neuberger considered that the following general principles could be distilled from TBA cases:

> (i) The patent must disclose "a practical application" and "some profitable use" for the claimed substance, so that the ensuing monopoly "can be expected [to lead to] some ... commercial benefit" (T 0870/04, para 4, T 0898/05, paras 2 and 4);
>
> (ii) A "concrete benefit", namely the invention's "use ... in industrial practice" must be "derivable directly from the description", coupled with common general knowledge (T 0898/05, para 6, T 0604/04, para 15);
>
> (iii) A merely "speculative" use will not suffice, so "a vague and speculative indication of possible objectives that might or might not be achievable" will not do (T 0870/04, para 21 and T 0898/05, paras 6 and 21);
>
> (iv) The patent and common general knowledge must enable the skilled person "to reproduce" or "exploit" the claimed invention without "undue burden", or having to carry out "a research programme" (T 0604/04, para 22, T 0898/05, para 6).

The overlap between issues that must be considered under this heading, and issues that must be considered under inventive step or sufficiency, is immediately apparent. Indeed, Eli Lilly conceded that, on the facts before the Court, the issue of industrial applicability and inventive step, more specifically "Agrevo obviousness", stood or fell together. It is therefore appropriate to say something further about Agrevo obviousness, and the problem-solution test that the EPO applies when determining inventive step, under this heading.

The EPO's "problem-solution" test involves the following stages:

> (a) determine the closest prior art;
>
> (b) compare the subject matter of the claim at issue with the disclosure of the closest prior art and identify the differences between them;
>
> (c) determine the technical effect or result achieved by and linked to these differences;
>
> (d) define the objective technical problem solved by the invention as achieving these effects or results; and
>
> (e) consider whether or not the skilled person would have suggested the differences in order to obtain the effect or result.[17]

The patent under consideration in Agrevo[18] claimed a class of compounds described by a Markush formula. The claims were to the compounds *per se* and not limited by any use, but the specification asserted that they were useful as herbicides. The Examining Division found that the skilled reader would not expect all the claimed compounds would have herbicidal activity. In relation to inventive step, the TBA explained:[19]

> [T]he appellant submitted that ... even on the basis of known starting compounds and known synthetic methods, a practically unlimited number of chemical compounds would have had to be considered, and that a particular selection from this unlimited number of possibilities should be regarded as inventive, even if it was arbitrary, unless there was a direct pointer to the preparation of just these very compounds in the state of the art.
>
> This argument must, however, fail, since in the Board's judgment the answer to the question as to what a person skilled in the art would have done, depends on the result he wished to obtain ...
>
> If this result is only to be seen in obtaining further chemical compounds, then all known chemical compounds are equally suitable as the starting point for structural modification, and no inventive skill needs to be exercised in selecting [some of them]. ... In other words, the selection of such compounds, in order to be patentable, must not be arbitrary but must be justified by a hitherto unknown technical effect which is caused by those structural features which distinguish the claimed compounds from the numerous other compounds.
>
> ... [T]he technical problem which the present patent application asserts to solve is the provision of fur-

15 [1996] UKHL 18 (31 October 1996) at [49].

16 [2011] UKSC 51.

17 See G2/21 at [24].

18 T 939/92.

19 At 2.5.2 and 2.5.3.

> ther (alternative) chemical compounds with **herbicidal activity**.
>
> However, ... this technical problem could only be taken into account if it could be accepted as having been solved, that is, if, in deciding the issue under Article 56 EPC, it would be credible that substantially all claimed compounds possessed this activity.

The key reasoning is that, in relation to compounds that did not provide a new technical effect, the only technical contribution was providing "other compounds", which was not inventive. In other words, if the claim is for an arbitrary selection, it cannot be said to be inventive.

In this context, a new technical effect may be understood as a new concrete benefit, new use in industrial practice, or some improvement or advantage over the closest prior art. For the purposes of convenience, "utility" will be used as a catchall description.

Returning to the problem-solution approach, while steps (a) and (b) are easy to understand, steps (c) to (e) are not intuitive, because they involve looking for a solution before knowing the problem. They involve, respectively (c) searching the patent for a reason why the invention is delivers "utility" over the closest prior art, (d) if some utility can be found, defining the problem solved as how to deliver that utility, and (e) asking whether it would have been obvious to the skilled person to adapt the prior art in the way claimed in the patent in order to deliver it. The "utility" identified in step (c) defines the problem in step (d). If no utility can be found, there is no need to proceed to steps (d) and (e), for reasons given by the TBA in *Agrevo*.

ADDED MATTER

Article 123(2) of the EPC provides:

> A European patent application or a European patent may not be amended in such a way that it contains subject matter which extends beyond the content of the application as filed.

In G 1/93, the EBA explained that the underlying idea for the rule was "that an applicant shall not be allowed to improve his position by adding subject matter not disclosed in the application as filed, which would give him an unwarranted advantage and could be damaging to the legal security of third parties relying upon the content of the original application."

Whether or not an amendment "adds matter", is determined by the Court or patent office adopting the mantle of the skilled person reading and comparing the original and amended documents to see if any subject matter relevant to the invention has been added. Subject matter will be added unless it is "clearly and unambiguously disclosed" in the original application. New subject matter might be added by amendment to the claims, or amendment to the description.

In G 2/10, the EBA explained:

> [A]ny amendment to the parts of a European patent application or of a European patent relating to the disclosure (the description, claims and drawings) is subject to the mandatory prohibition on extension laid down in Article 123(2) EPC and can therefore, irrespective of the context of the amendment made, only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of these documents as filed.
>
> ...
>
> Therefore, as is the case for any other amendment, the test for an amendment to a claim by disclaiming subject-matter disclosed as part of the invention in the application as filed must be that **after the amendment the skilled person may not be presented with new technical information**. Hence, disclaiming subject matter disclosed in the application as filed can also infringe Article 123(2) EPC if it results in the skilled person being presented with technical information which he would not derive directly and unambiguously, using common general knowledge, from the application as filed. [Emphasis added].

Accordingly, if the claims of a patent application have a defect relating to lack of inventive step, or insufficiency, the applicant cannot fix that defect by an amendment (whether to the claims or to the description), which would result in the addition of technical information that a skilled person could not derive directly and unambiguously from the application as filed.

In Gilead v Nucana[20], Meade J considered a series of TBA and EBA added matter cases, in some detail, in the context of a patent for nucleoside analogues described by a Markush formula. The proposed amendments would have resulted in a significant narrowing of the Markush formula in the description and the claims. In this context Meade J explained:

> I do not see anything inconsistent in G2/10 with the notion that when asking whether an amendment adds matter, which is the fundamental question, it will be relevant to ask whether it presents a different invention, and that part of that inquiry may be whether it provides a new technical contribution. One is not inquiring whether there is a new technical contribution instead of asking whether there is added

20 [2023] EWHC 611 (21 March 2023).

> matter, but simply recognising it as a likely symptom of there being added matter.
>
> ...
>
> Given my reasoning above, the effect of an amendment, such as to allow a new argument on inventive step (as distinct from the motive for it) may also be relevant to added matter.

The Judge found that the effects of the proposed amendments was to define a new class of compounds, which was not disclosed in the original application. The purpose of the amendments was to restrict the claimed class to compounds that were active, which could be made, and which were not made obvious by prior art. The Judge observed that while there was nothing wrong with these motives, they were symptoms of an invention being put forward in the proposed amended patent that was different to the invention disclosed in the original application.

In summary, it is not permissible to amend a patent in order to bolster an inventive step or sufficiency case in a way that adds technical information that a skilled person could not derive directly and unambiguously from the original application.

PRIORITY

More than 30 years ago, the UK House of Lords in Asahi[21] decided that for matter in an application to be capable of supporting an invention it must contain an enabling disclosure.

In Unilin v Berry[22], the UK Court of Appeal explained:

> The approach is not formulaic: priority is a question about technical disclosure, explicit or implicit. Is there enough in the priority document to give the skilled man essentially the same information as forms the subject of the claim and enables him to work the invention in accordance with that claim?

In G 2/98, the EBA expressed the test for priority in the following way:

> The requirement for claiming priority of 'the same invention', referred to in Article 87(1) EPC, means that priority of a previous application in respect of a claim in a European patent application in accordance with Article 88 EPC is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole.

In Gemvax[23], one of the appellants submitted to the TBA that even though the wording of the claims could be derived from the priority document, the claims did not relate to the same invention since the priority document lacked any experimental data which made it plausible that the claimed invention worked. The TBA was nevertheless convinced that the claimed subject matter was "directly and unambiguously derivable from the priority document in the sense of opinion G 2/98":

> Since the enablement of the disclosure of the priority document has not been explicitly challenged by [the appellant], the Board does not consider it appropriate to doubt that the priority document discloses the invention in an enabling way. Beyond the issue of enablement, the Board sees no legal basis for imposing additional criteria such as the presence of experimental data in the priority document which make plausible the invention will work. The Board is furthermore convinced that the experimental data which are present in the patent and not in the priority document do not change the nature of the invention disclosed.
>
> [The appellant] submitted that in view of decision T 1329/04 of 28 June 2005, it would be necessary that the priority document contained experimental data which made plausible that the invention now claimed worked. However, said decision is concerned with the question of inventive step and is therefore not relevant for the present issue of entitlement to priority.

Gemvax was considered in Hospira. After explaining the role of plausibility in relation to second medical use claims (see above) the Judge extended his reasoning to priority:[24]

> Genentech submitted that the requirement for plausibility which is part of the law of sufficiency was not relevant in the context of priority and referred to [Gemvax] in which the Technical Board of Appeal rejected the suggestion that to be entitled to priority it was necessary for the priority document to contain data which made it plausible that the claimed invention worked (paragraph 11).
>
> ...
>
> Although I am reluctant to do so I disagree with the statement in Gemvax. The requirement for priority is that the earlier application must be in respect of the same invention as the patent. The establishment of priority includes a requirement for an enabling disclosure (Biogen v Medeva [1997] RPC at 48–49). In order to make an enabling disclosure of an invention it must be possible to make a reasonable prediction

21 Asahi Kasei Kogyo KK's Application [1991] R.P.C. 485.

22 [2004] EWCA Civ 1021.

23 T 093/05 (30 August 2007).

24 Hospira UK Ltd v Genentech Inc [2014] EWHC 1094 (Pat) (10 April 2014), at [147] and [149].

> that the invention will work (Regeneron v Genentech [2013] EWCA Civ 93, paragraph 100). In the context of an invention which includes the achievement of a therapeutic effect as one of its features, absolute proof is not required but the patentee must show that the therapeutic effect is plausible (Regeneron paragraph 103). It seems to me that this logic applies just as much to priority as it does to sufficiency of disclosure (see also Biogen on the relationship between priority and sufficiency). The alternative would be a recipe for abuse. A patentee could file a speculative priority application and obtain an earlier priority date, thereby stealing a march on the competition. I find that in law the test for priority includes the requirement for plausibility in a case like this one.

The above logic is compelling.

INVENTIVE STEP OR INSUFFICIENCY?

Article 83 of the EPC provides:

> The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

The test for insufficiency in the UK was summarised in Regeneron v Kymab Ltd:[25]

> It is a general requirement of patent law both in this country and under the European Patent Convention that, in order to patent an inventive product, the patentee must be able to demonstrate (if challenged) that a skilled person can make the product by the use of the teaching disclosed in the patent coupled with the common general knowledge which is already available at the time of the priority date, without having to undertake an undue experimental burden or apply any inventiveness of their own.

If there is nothing in the patent specification that would give the skilled person a basis on which to identify which products or processes are likely to "work", he or she may have to carry out their own research in order to find that out, which might involve an undue burden.

In the EPO, whether an attack based on the paucity of information in the patent is considered under inventive step or insufficiency depends on whether or not the claim in issue includes a utility requirement as a limitation.

In G 1/03, the EBA said:

> If … there is lack of reproducibility of the claimed invention, this may become relevant under the requirements of inventive step or sufficiency of disclosure. If an effect is expressed in a claim, there is lack of sufficient disclosure. Otherwise, i.e. if the effect is not expressed in a claim but is part of the problem to be solved, there is a problem of inventive step.

Agrevo has been discussed above. The claim was to a large Markush class of compound which the patent asserted had herbicidal activity. If the patentee had inserted a limitation into the claim, so that the claims only covered compounds of the Markush formula that had the relevant herbicidal activity, then the skilled person would have to do her own experiments to determine which compounds were within the claim, which would have involved an undue burden, and the claims would have been found insufficient.

In the UK, the quality of disclosure necessary to support an assertion of utility remains the same, whether it is considered under insufficiency or inventive step, so it doesn't matter under which heading "plausibility" is considered. This makes sense. If the test for inventive step were easier to satisfy than the test for sufficiency, the patentee would gain an artificial advantage by leaving any limitation to useful subject matter out of the claim, and the consequently broader claim would be harder to challenge than the narrow one.

FAITH

In the author's opinion, patents ought not be treated as religious texts, and what they teach the notional skilled person ought not be a question of faith in assertions contained therein. This is a fundamental point of this article and is consistent with everything said above. The notional skilled person (more accurately, a court or patent office adopting the mantle of the notional skilled person) has many roles, and is expected to apply a combination of common general knowledge and rational thinking when fulfilling them. This includes when bringing to bear his or her common general knowledge in order to: interpret words or phrases used in claims; consider the disclosure in the original application and whether any amendments to that disclosure result in the addition of new technical information; figure out how to implement a claimed invention in a sensible way; consider the teaching of prior art and how he might adapt the prior art to solve a technical problem, and so on.

For example, in relation to inventive step, the structured approach that is used in the UK to assess inventive

25 [2020] UKSC 27 at [2].

step (as originally set out in Windsurfing[26] and refined in Pozzoli[27]) involves the following steps:

> 1. Identify the notional "person skilled in the art" and the relevant common general knowledge of that person;
> 2. Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
> 3. Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
> 4. Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

The patent in Pozzoli was for a case to hold two or more compact discs, with centres off-set, in a stepped arrangement. The patentee argued that the skilled person would be prejudiced against overlapping, by a fear that the CDs would be at risk from damage to their playing surfaces upon removal or replacement.

The Court of Appeal agreed that prejudice, if established, was relevant:

> Patentability is justified because the prior idea which was thought not to work must, as a piece of prior art, be taken as it would be understood by the person skilled in the art. He will read it with the prejudice of such a person.

In some cases, the closest prior art will be a patent. The recent UK case Mirabegron[28] is an example. In this case, the patent was for use of mirabegron to treat overactive bladder. At the priority date, the idea of using β3 adrenoreceptor agonists (**Agonists**) to treat overactive bladder had momentum. Some Agonists had been tested in clinical trials, but without success, and the reasons for failure were not clear.

The prior art patent (**288**) described a large number of compounds asserted to be Agonists, including six "best modes for conducting the invention". One of the six was mirabegron. However, 288 only contained limited test data for a single compound, which was not mirabegron. The trial judge explained:

> My overall conclusion is that the skilled addressee would think that no safe conclusion could be reached over what testing had been done other than the one data point for Example 6. That does not mean that they would think that the teaching could not usefully be progressed; they would have the hope that if they tested the six examples they might get some positive results, but they would have no expectation for any particular compound, other than perhaps Example 6 where it might be a bit more likely that selectivity had been tested, but from which no conclusion about other compounds could be drawn without testing.

The inventive step challenge based on 288 therefore failed. The judge noted that:

> [T]he central problem facing the claimants [for revocation] seemed to me to be the poor quality of the disclosure of 288 ... It could not be assumed that any β3-AR agonist would work, and it could not be predicted that the results for one would necessarily apply to another. ...
>
> This does not mean that the skilled addressee would positively think that mirabegron or the other Examples in 288 would not work, but it does mean that there would be a substantial degree of uncertainty.

If the problem-solution were used instead, with 288 as the closest prior art, the objective technical problem could have been defined as identification of an Agonist that was effective to treat overactive bladder. On the evidence before the Judge, the solution was not made obvious by 288 because it did not disclose to the notional skilled person that mirabegron was likely to be effective. This outcome should be uncontroversial.

However, imagine that instead the issue instead was whether or not a claim in 288 for mirabegron as an effective Agonist was valid? 288 **asserted** that mirabegron was an Agonist. If the skilled person were expected to have faith in that assertion, then the tribunal considering the validity of the claim would adopt the mantle of the same skilled person, read the same specification, and conclude that the claim was valid because the invention was disclosed in the specification.

This example illustrates how nonsensical outcomes would arise if a skilled person were to adopt a secular approach when considering the teaching of a patent specification when it is cited as prior art, but a religious, faith based, approach when its validity is in issue.

PREGABALIN

The case was about Warner-Lambert's patent for the use of pregabalin for the preparation of medicaments to treatment certain types of pain. As at the priority date, pregabalin was already known to be useful for treating seizure disorders. Claim 3 was for:

26 [1985] FSR 59.

27 Pozzoli SpA v BDMA SA [2007] EWCA Civ 588.

28 Teva v Astellas [2023] EWCA Civ 880 (25 July 2023).

> Use of [pregabalin] for the preparation of a pharmaceutical composition for treating neuropathic pain.[29]

As discussed above, a claim in this Swiss form requires that the compounds exhibits some degree of efficacy, though nothing in the claim could be taken as suggesting that the compound would need to meet the standards of efficacy and safety required for approval in a regulatory sense.[30]

The patent contained the results of an animal experiment, which suggested to a skilled person that pregabalin was effective in the treatment of inflammatory pain. It also referred to two well-known assays, designed by researchers Bennet and Kim, which could be performed to ascertain whether or not pregabalin was effective in the treatment of peripheral neuropathic pain (**PNP**). The patent did not say whether any of these assays had been performed.

The trial Judge found that:

> 1. A concept known as central sensitization was involved, at least as an amplifying mechanism, both in inflammatory pain and PNP.
> 2. If pregabalin was effective for the treatment of inflammatory pain because it overcame the problem of central sensitization, then it could also treat PNP since PNP was associated with central sensitization.
> 3. The patent accordingly made it plausible that pregabalin could treat PNP.

The Court of Appeal agreed that Warner-Lambert had done enough to make it plausible that pregabalin could be used to treat PNP. Floyd LJ explained:

> A test designed to prevent speculative claiming need go no further than requiring the patentee to show that the claim is not speculative: the specification does not need to provide the reader with any greater degree of confidence in the patentee's prediction than that.

Warner-Lambert argued in the Supreme Court that a patent needed some theoretical basis or experimental evidence in support of a second medical use claim only if the patentee's assertion that the compound was effective to treat the relevant medical condition was **inherently implausible**. The Supreme Court hearing the appeal was constituted by five law lords. The majority explicitly rejected this argument because, if it were accepted, it would follow that, if nothing was known either for or against the claimed therapeutic effect, then the patent would not need to contain any disclosure in support of it.

Lord Sumption, who gave the leading judgment of the majority, considered that the disclosure of the patent did not support a claim that pregabalin could treat PNP. He reasoned that, while it was known that central sensitization had a role in inflammatory pain and PNP, the experiment in the Patent did not show that pregabalin reduced inflammatory pain by influencing central sensitization. Further, the patent did not propose this as a theory. A skilled reader who closely read and considered the disclosure might well conclude that pregabalin worked for inflammatory pain because of its effect on a cause that was not shared with PNP.

In Lord Sumption's words:

> The rat paw formalin test, as I have said, models inflammatory pain. It shows a diminution of pain in the second phase, associated with the administration of pregabalin. But in the absence of anything in the specification about the effect of pregabalin on the mechanism of pain, there is no reason to suppose that the diminution of pain is associated with its effect on central sensitisation as opposed to its effect on any other agent of inflammatory pain.

So, while it remained **possible** that pregabalin could have an effect on PNP, the disclosure in the patent did not support any positive reason for supposing that it did.

> More generally, it cannot in my view be enough to justify a monopoly that it is "possible" *a priori* that a drug which was effective for inflammatory pain would also be effective for neuropathic pain, in the absence of any reason to suppose that the possibility had some scientific basis or that it was more than speculative. Everything is possible that is not impossible, but "not impossible" is very far from being an acceptable test for sufficiency. Plausibility may be easy to demonstrate, but it calls for more than that.

Warner-Lambert argued that the skilled reader would have been encouraged by the reference to the Bennett and Kim assays to carry out the tests, which could be done relatively easily, and thus establish that pregabalin did treat neuropathic pain. However, Lord Sumption considered that this submission just supported the conclusion that, while the patent posed a problem, it did not make any contribution to its solution.

In summary, Lord Sumption considered that "the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true". He thought that, as a matter of logic, this wasn't the case in Warner-Lambert's patent.

29 Neuropathic pain is pain sensation which arises by reason of something being wrong with the nerve itself as opposed to any external stimuli at the nerve ending.

30 Of course, it would be open for a claim to specify a minimum degree of efficacy and/or how efficacy is to be measured. See for example the discussion by the Full Court of the Federal Court of Australia in *AstraZeneca v Apotex* [2014] FCAFC [118] to [143], albeit in the context of entitlement. Method of treatment claims are permitted in Australia.

The minority of the Supreme Court thought that Lord Sumption's test could be read as "a requirement that the plausibility of the claim must appear to be established prima facie through scientifically cogent reasoning or experimental evidence set out in the specification", and was therefore a higher standard than EPO case law required. Lord Mance considered that EPO case law accepted:

> ... as sufficient a tailored claim which appears scientifically possible, even though it cannot be said to be even prima facie established, without for example testing or assays according to the state of the art. Only if a person skilled in the art would have significant doubts about the workability of the invention would it, in such a case, fail for insufficiency of disclosure.

Unfortunately, while the minority put the "plausibility" standard lower than the majority, they did not go on to explain why they thought claim 3 nevertheless failed to meet it.

In any event, the outcome of the case is that in order for a Swiss form claim to be valid in the UK, the patent must contain enough information to enable the notional skilled person to conclude, upon reading the patent application on the date it is filed, that the claimed product may well be useful as a treatment for the relevant medical condition. The test is not satisfied by a patent that contains merely assertion, but otherwise leaves the question open.

SUMITOMO[31]

The patent in Sumitomo is about insecticides. The relevant claim was originally for an insecticide composition comprising thiamethoxam (**T**) and another compound chosen from a class represented by a Markush formula. The Markush class covered approximately 10 million compounds.

Both T, and the Markush class, were separately known in the prior art as having insecticidal activity. However, according to the patent, the inventors had found that the claimed compositions were synergistic. The patent identified various species of insects which could be controlled by the compositions, including, among a long list, *Spodoptera Litura* (cotton leafworm), *Plutella xylostella* (cabbage moth), and *Chilo Suppressalis* (rice borer). The patent also contained two test examples, comprising a test of one composition against cotton leafworm, and another composition against cabbage moth, which were said to demonstrate a synergistic effect on the death rate of the pests. In both cases the two ingredients in the composition were present in equal amounts (a ratio of 1:1).

Since synergism was not a feature of the claims, the question of whether or not the effect was achieved across their scope was dealt with under inventive step.

During the opposition, the opponent filed experimental reports, showing compositions within the claims containing certain ratios of T and a compound within the Markush class (**C**), were not synergistic against cotton leafworm or cabbage moth, and at some ratios T and C were antagonistic. In response, the patentee filed an experimental report to show that a certain composition of T and C had a synergistic effect on the death rate of rice borer.

A key question for the TBA was whether the patentee's report (identified in the proceeding as D21) could be taken into account in relation to the assessment of inventive step. If not, based on the available evidence the compositions were not synergistic across the scope of the claim, and, in accordance with *Agrevo* "arbitrarily combining compounds known to have insecticidal activity to achieve an alternative insecticide composition does not require an inventive step."

On the other hand, if D21 could be taken into account, then, in the absence of any evidence from the opponent that compositions within the claims were not synergistic against rice borer, the TBA considered that "there was no reason not to acknowledge this synergistic effect against [rice borer] for other insecticide compositions covered by claim 1". Accordingly, "the objective technical problem would have to be [re-]formulated as the provision of an insecticide composition in which the insecticides act synergistically against [rice borer]", and an inventive step would have to be acknowledged.

The TBA reviewed numerous prior cases and identified conflicting approaches in them. A reference to the EBA was therefore appropriate. For the purpose of the reference, the TBA organised the cases into three categories:

> (a) Post published evidence can be taken into account only if, given the application as filed and the common general knowledge at the filing date, the skilled person would have had reason to assume the purported technical effect to be achieved. Examples of justification include experimental data or a scientific explanation in the application as filed (a*b initio* plausibility).
>
> (b) Post published evidence can only be disregarded if the skilled person would have had legitimate reasons to doubt that the purported technical effect would have been achieved on the filing date of the patent in suit. Such doubts may arise, for example, from the fact that either the application as filed or the common general knowledge on the filing date of the patent in suit give an indication that the purported technical effect can in fact not be achieved. In other words, post-published evidence must always be taken into account if the purported technical effect is not implausible (*ab initio* implausibility).
>
> (c) Plausibility is altogether rejected as a test for determining whether post published evidence of a beneficial effect can be relied on by the patentee (no plausibility).

31 T 0116/18 and G 2/21.

The TBA indicated in its reference to the EBA that the *ab initio* implausibility test was the right one.

Early in its reasoning, after setting out the problem solution approach, the EBA explained:

> The technical problem must be derived from effects directly and causally related to the technical features of the claimed invention. An effect could not be validly used in the formulation of the technical problem if the effect required additional information not at the disposal of the skilled person even after taking into account the content of the application in question.

This is another way of saying that the skilled person can't rely on "additional information", which is not contained in the patent, in order to identify how or why the invention is useful. The EBA then proceeded:

> According to the established case law of the boards of appeal ... it rests with the patent applicant or proprietor to properly demonstrate that the purported advantages of the claimed invention have successfully been achieved.

These paragraphs could be interpreted as the EBA squarely putting the onus on the patentee to include sufficient information in the specification to enable the skilled person to identify the invention's utility over the prior art, since he or she is not entitled to rely on "additional information" for that purpose.

However, there is another way of interpreting these paragraphs. In this alternative reading, the skilled person can rely on unsupported assertions in the patent about the claimed invention's utility, and then use those assertions in the formulation of the problem that the patent is said to solve. If the patentee is then called upon to demonstrate that the asserted utility is delivered, for example during opposition or examination proceedings, he can satisfy the onus by relying on post published information, which is, by definition, additional to that contained in the patent.

Such an interpretation would, however, be illogical. Why should the patentee be able to rely on technical information, not contained in the patent, about the synergy of the claimed compositions against rice borer, when the only experimental data was about cotton leaf worm and cabbage moth, and the opponent had already established, contrary to the assertion in the patent, that claimed compositions were not synergistic against them?

Nevertheless, the EBA's reasoning, particularly when distinguishing the role of "plausibility" in challenges to sufficiency compared with challenges to inventive step, and its critical conclusory paragraphs, leave open the possibility that this alternative, illogical, interpretation is the one that it intended to convey.

In relation to sufficiency, the EBA said:

> The reasoned findings of the boards of appeal in the decision referred to above make clear that the scope of reliance on post published evidence is much narrower under sufficiency of disclosure (Article 83 EPC) compared to the situation under inventive step (Article 56 EPC). In order to meet the requirement that the disclosure of the invention be sufficiently clear and complete for it to be carried out by the person skilled in the art, the proof of a claimed therapeutic effect has to be provide in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the skilled person that the therapeutic effect is achieved. A lack in this respect cannot be remedied by post-published evidence.

What role can post-published evidence have in inventive step cases, if it is not limited to bolstering an assertion that has already been made credible by information in the patent? The EBA's reasoning implicitly suggests that in inventive step cases, post published evidence can be relied on to bolster an assertion of utility that is not made credible by information in the patent.

As discussed above, whether an attack based on the paucity of information about the utility of an invention is considered under sufficiency or inventive step, depends on whether an integer requiring utility appears in the claims. In accordance with the EBA's reasoning, the patentee could be in a better position if he does not include such an integer in the claim. In other words, the quality of information in a patent application that is necessary to support a broad claim (susceptible to an inventive step challenge) might be lower than that required to support a narrow claim (susceptible to a sufficiency challenge).

The EBA then explained in its conclusionary paragraphs:

> Hence, evidence submitted by a patent applicant or proprietor to prove a purported technical effect relied upon for acknowledgement of inventive step of the claimed subject-matter may not be disregarded solely on the ground that such evidence, on which the effect rests, had not been public before the filing date of the patent in suit and was filed after that date.
>
> ...
>
> The relevant standard for the reliance on a purported technical effect when assessing whether or not the claimed subject-matter involves an inventive step concerns the question of what the skilled person, with the common general knowledge in mind, would understand at the filing date from the application as originally filed as the **technical teaching** of the claimed invention. The technical effect relied upon, even at a later stage, needs to be encompassed by that technical teaching and to embody the same invention, because such an effect does not change the nature of the claimed invention. [emphasis added]

In these paragraphs, the EBA's focus is on what the skilled person would understand to be the patent application's "technical teaching", and whether the invention's utility was "encompassed by that technical teaching", rather than whether or not the skilled person could derive the invention's utility without "additional information".

It seems likely that this change of language and emphasis was intentional. As a matter of language, it is more acceptable to describe a bare assertion in a patent that the invention has a particular utility as a "teaching", than as "information", about the utility.

Accordingly, these conclusionary paragraphs suggest that the EBA has adopted the abovementioned illogical interpretation of its own explanation of the problem solution approach.

Indeed, this is how the referring TBA has interpreted the EBA's opinion. In minutes of a hearing on 28 July 2023, which were published on 8 September 2023, the TBA held that the patentee could rely on D21. The minutes record:

> The parties were then heard on whether, in view of G 2/21, the [patentee] could rely on this synergism against [rice borer] shown in D21. The parties explained their understanding of order no. II of G 2/21 and the implications of that understanding for the facts of the case. ...
>
> After deliberation, the Chairman informed the parties that the Board – ... had concluded that the [patentee] could rely on the effect of synergism against [rice borer] shown in D21. ...
>
> After that, the Chairman explained that since the effect of synergism against [rice borer] shown in D21 could be relied upon, the objective technical problem could be formulated as the provision of an insecticide composition which acts synergistically against [rice borer], and in view of this an inventive step could be acknowledged, so that the main request was allowable.

Accordingly, the patentee has been permitted to rely on additional information, not disclosed in the application, nor derivable by the skilled person from the application, to establish inventive step. If the patentee had applied to amend the patent to include the information in D21, there is no doubt that the application would have been rejected, on the ground that the amendment would have added matter. Permitting the patentee to rely on the information in D21 without amending the application is equivalent to permitting added matter by the back door.

APIXABAN[32]

The patent in issue was for Apixaban *per se*. Apixaban is an anticoagulant, useful for the treatment of thromboembolic disorders. Thrombosis is the formation of a blood clot, and is one of the leading causes of death and disability in the world[33].

Claim 1 of the patent was for:

> A compound represented by formula 1 or a pharmaceutically acceptable salt thereof.

A purpose limited claim, was also discussed by the Court:

> A compound of claim 1 that is a factor Xa inhibitor for use in treating a thromboembolic disorder.

Apixaban is the only compound within formula 1.

The latter claim contains limitations relating to utility and purpose. However, according to the UK Court, it didn't matter which form of claim was in issue, and it didn't matter whether the validity challenge was considered under inventive step or insufficiency. In both cases, the asserted utility of the compound was as an anticoagulant, and the issue was whether or not the patent application contained information justifying that assertion to the skilled person.

It is worth pointing out, in order to illustrate how the approach in the UK differs from that in the EPO, that the trial judge (Meade J) made clear early in his judgment that post-published information was irrelevant to his assessment:

> [20] BMS emphasised that apixaban has proved to be a very important and widely used drug by virtue of being a potent and selective factor Xa inhibitor. Indeed its closing written submissions said that this was the "central" issue. BMS also relied on the researchers behind apixaban having been awarded the "Heroes in Chemistry Award" from the American Chemical Society.
>
> [21] I think those matters are irrelevant. I have to assess plausibility on the basis of the relevant specification for these purposes. Later findings about apixaban do not enter the picture. As to the award referred to, I am sure that it was merited, but I am equally sure that it was not given just for the work in [the relevant specification].

As at the priority date of the patent, it was common general knowledge that (a) a number of companies were actively searching for a synthetic Factor Xa inhibitor with sufficient potency, selectivity, and bioavailability to make it suitable for therapeutic use, (b) the structure of some promising molecules had been published, and, (c) for a Factor Xa inhibitor to be therapeutically useful, it needed a "nanomolar potency".[34]

32 *Sandoz v BMS* [2022] EWHC 822 (Pat) (Apixaban).

33 Blood clots cause heart attacks and strokes.

34 An IC_{50} value in the nanomolar range.

In a section headed "utility", the patent recorded:

> The compounds of this invention are inhibitors of factor Xa and are useful as anticoagulants for the treatment or prevention of thromboembolic disorders in mammals.

This statement was followed by descriptions of a relatively straightforward test for measuring the potency of factor Xa inhibitors, which was, in turn, followed by the following paragraph (at page 170):

> Compounds tested in the above assay are considered to be active if they exhibit [an IC_{50}] of ≤ 10μm. Preferred compounds of the present invention have [an IC_{50}] of ≤ 1μm ... Still more preferred compounds of the present invention have IC_{50}'s of ≤ 0.001μm. Using the methodology described above, a number of compounds of the present invention were found to exhibit IC_{50}'s of ≤ 10μm, thereby confirming the utility of the compounds of the present invention as effective Factor Xa inhibitors.

The patent also contained long lists of compounds, several Markush formula, and synthesis and characterizing data for 110 compounds. Example 18 of the patent described the synthesis of 3g of Apixaban, but no details of its activity were disclosed.

BMS submitted that the skilled reader would understand from the passage on page 170 that all (or at least most) of the 110 compounds synthesized had been tested, but accepted that the skilled reader would also infer that not all of the compounds tested were successful, and that some may have failed.

The Judge considered that it was impossible to draw any inference from the passage about the activity of a particular compound, whether apixaban or otherwise:

> In my view, the only statement of work actually done is that "a number of compounds" were tested and had [an IC_{50}] of 10 μM or less. The statements about lower IC_{50}'s for preferred/more preferred/still more preferred compounds are aspirational targets, and the statement that the utility of "the compounds of the present invention" was confirmed is an assertion that an inference can be drawn from the tests that were done. I understood that BMS accepted this.
>
> ...
>
> I note that there is no indication in this text itself of which or how many compounds were tested or with what specific result, and there is no reference to apixaban. BMS accepted this but said that the whole picture of the disclosure of `652 must be considered, and at that general level I agree. So, I must go on to consider the other later disclosure and the evidence before reaching any conclusion about this passage.

BMS therefore focused on Example 18, and emphasized that 3g was the largest amount of any of the compounds in the examples that was synthesized. However, the Judge thought that, of itself, didn't disclose anything more to the skilled person than, possibly, the patentee thought that apixaban could be promising. The skilled person would appreciate that there could be a number of reasons why a large amount was synthesized, for example it was easy to make and/or a useful intermediate in the synthesis of other compounds.

In any event, even if the arguments and evidence could have supported the proposition of Apixaban been active to the extent identified on page 170 (i.e. IC_{50} ≤ 10μM) it would not make it plausible that apixaban could be useful in therapy, because the skilled person would know that nanomolar potencies[35] were required for that.

Finally, the Judge was not impressed by the argument that simple tests were available to determine the potency and selectivity of the compounds of the invention. This was the equivalent to an argument that the Supreme Court had dismissed in Pregablin. That is, the argument

35 IC_{50} ≤ 0.001μM.

simply highlighted the absence of experimental information in the patent.

Accordingly, the Judge found the patent to be invalid.

BMS appealed. By the time of the appeal hearing, the EBA had published its opinion in Sumitomo. BMS submitted that the Court of Appeal was not bound to apply the test established by the majority of the Supreme Court in Pregabalin, because the claim was for a compound *per se*, rather than a second medical use, and therefore Pregabalin could be distinguished. Further, as far as possible the law in the UK should conform to that applied in the EPO, and the test advocated by the EBA in Sumitomo was more lenient than the Pregabalin test.

In response to these submissions, the Court of Appeal observed that many of the authorities considered by the Supreme Court were about patents for compounds. It decided that Pregabalin was binding.

The Court also observed that even if the appropriate test regarding the quality of disclosure was only designed to exclude speculative claims, it didn't understand how to determine whether or not a claim was speculative other than by assessing whether it was plausible. That is "[t]hey are two sides of the same coin."

In relation to whether or not the EBA's test was more lenient, the Court of Appeal set out the EBA's "concluding considerations" in full, and then explained:

> It is clear from these observations as well as the Enlarged Board's earlier reasoning that the fundamental consideration when a court or tribunal is considering whether a claimed invention involves an inventive step is whether the technical effect asserted by the patent applicant or proprietor is derivable by the skilled person from the application as filed read with the common general knowledge.

Later in the judgment the Court said:

> It is fair to say that the standard adopted by the majority [of the Supreme Court in Pregabalin] corresponds to the "ab initio plausibility" test identified in Sumitomo, while the standard espoused by the minority corresponds to the "ab initio implausibility" test. As discussed above, the Enlarged Board has taken the view in G 2/21 that the two approaches can be reconciled. I am bound to say that it seems to me that the divergence of opinion in the Supreme Court shows that the two approaches do not necessarily produce the same outcome. It also appears to me, however, that the harmonised approach adopted by the Enlarged Board, while eschewing the language of "ab initio plausibility" and "ab initio implausibility", is as a matter of substance much closer to the former than to the latter.

At the time of handing down its decision, the referring TBA in Sumitomo had not applied its understanding of the EBA' opinion to the facts before it. So, the Court of Appeal was not aware of the TBA's interpretation of the opinion.

In any event, for the reasons given above, while language used by the EBA early in its reasoning was consistent with the Court of Appeal's summary, the language in its concluding considerations was materially different. It shifted from whether or not the relevant technical effect could be derived by a skilled person from the application, to whether or not the technical effect was encompassed by the application's technical teaching. This leaves the door open for arguments in the EPO to the effect that skilled person is entitled to have faith in assertions made in patent specifications, and equate **unsupported assertions** of a technical effect to a **teaching** of that effect.

It is noteworthy that in addition to referring TBA in Sumitomo, the Court of Appeal of the Hague in the Netherlands interpreted the EBA's opinion in this way, in parallel litigation about Apixaban. For example, the Dutch Court of Appeal explained:

> According to Sandoz et al., the test formulated in G2/21 means that an alleged technical effect may only be invoked in the assessment of inventiveness if the average professional already understands from the patent application that the alleged effect is actually achieved by the invention and that the problem is actually solved, or at least that this is made plausible. That position is rejected.
>
> ...
>
> In this context, the EBA has in par. 77 of G2/21 considered that the possibility of relying on post-published evidence to demonstrate that the alleged effect actually occurs, compared to the assessment of inventiveness, is much more limited in the assessment of sufficiency of disclosure. In the case of an invention in which the technical effect achieved by it is included in the claim, such as the therapeutic effect in the case of a second medical indication claim, such evidence may only be taken into account if evidence of the alleged effect is already included in the application, in particular if, in the absence of experimental data, it is credible that the effect has been achieved. In the preliminary view, it is incompatible with that recital to interpret G2/21 in such a way that, in assessing inventiveness, the condition must be made that the alleged effect has always been demonstrated in the application, as advocated by Sandoz et al.
>
> ...
>
> Contrary to what Sandoz et al. argue, this interpretation of G2/21 by the court does not lead to a licence for speculative patents. Protection is granted on the basis of a purely speculative patent for an invention made only thereafter by requiring that the technical effect is already covered by the technical doctrine of the application and embodies the same invention revealed therein. Moreover, it is common ground that EP 415 does not constitute a speculative patent. BMS has undisputedly argued that the inventors had

> already experimentally established the favourable affinity and selectivity of apixaban prior to the filing of the patent application.[36]

The Dutch Court of Appeal decision is therefore a precedent for Courts in Europe, applying the EBA's opinion in Sumitomo, to consider that the "plausibility" test, which was intended to be generous for policy reasons to would-be patentees in second medical use cases, does not even have to be satisfied in other classes of cases.

The author would add that, while BMS may have established apixaban's favourable properties prior to filing its patent application, it kept that information secret and did not disclose it in the application. Of course, if it had subsequently applied to amend the patent application to include such information, there is no doubt that the amendment would have been rejected as "added matter".

CONCLUDING REMARKS

The requirement that assertions made in patents be plausible, simply reflects a requirement that a notional skilled person is expected to think rationally when assessing what is disclosed in the patent. Plausibility is not a ground of revocation, it is merely a convenient word against which to measure to the quality of information disclosed. Is the asserted utility plausible or not? The word "credible" could be used instead of "plausible".

Lord Sumption explained in Pregabalin, in the context of second medical use claims:

> The principle is that the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true. Plausibility is not a distinct condition of validity with a life of its own, but a standard against which that must be demonstrated.[37]

Real researchers are more likely to read some journals than others, are more trusting of some resources than others, and, in some fields, may have technical prejudices. Real researchers think rationally, and do not have blind faith in assertions made in patent specifications[38]. In circumstances where the potential value of a patent monopoly provides significant temptation to would-be patentees to mischaracterise the work of their inventors and overstate their technical contributions, blind faith in assertions made in patent specifications would be a recipe for disaster.

Indeed, if it is not necessary for assertions made in patents to be supported by reasoning or results that make them credible or plausible, patents could cease to be a source of useful information. More and more patents will be filed containing assertions that may or may not turn out to be true. The potential value of the monopoly would be a sufficient justification for so called inventors to pay the patent office fees.

In the author's opinion, the EBA's reasoning and conclusions in Sumitomo comprise an invitation to use post published information in a way that is equivalent to allowing added matter by the back door. This is inconsistent with the fundamental principle, expressed in various ways across multiple areas of patent law, that in return for a monopoly a patentee must disclose an invention, not merely assert that he or she has made one.

36 Case number 200.327.532/01, at paragraphs 6.6, 6.9 and 6.12. This is not a professional translation of the passages. Rather, it is a rough translation of the passages into English facilitated by Google Translate.

37 At [36].

38 Just ask them!

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