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Opening

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An Introduction to Religious and Political Discourse on Life Patents

Roman Cholij

1. BACKGROUND TO THIS BOOK

The inspiration for the collection of essays in this volume, from contributors of widely differing backgrounds, came from an international conference convened at the University of Cambridge in 2015, on the theme ‘Patents on Life: Through the Lenses of Law, Religious Faith and Social Justice’. The conference was organised jointly by the Von Hügel Institute (VHI) for Critical Catholic Inquiry at St Edmund’s College and the Murphy Institute for Catholic Thought, Law, and Public Policy at the University of St. Thomas, Minnesota. For the first time on British soil, an interdisciplinary group of experts met to discuss intellectual property (IP), representing the Vatican and the Roman Catholic Church; other faith groups; judges, lawyers, and officials from the IP world; academics; and representatives from industry and NGOs. A prime purpose of this extraordinary meeting was to allow different groups in society and stakeholders in the complex world of IP to communicate and to hear and learn from each other’s points of view and concerns on diverse but related matters falling under the conference theme. The conference was inspired in turn by a direct invitation to the VHI from the Papal Representative, the Apostolic Nuncio, to the UN in Geneva to produce a report that might assist the Holy See in its interventions as Permanent Observer at the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC) of the World Intellectual Property Organization (WIPO). The objective was to provide a context for how the patent system could be used in a new, constructive, and positive way to achieve the objectives of a social good – in this case, the fair distribution of benefits from patented inventions reliant on indigenous genetic resources and traditional knowledge.¹ The Vatican’s engagement with

¹ *Patents on Genetic Resources? A Catholic Perspective for the World Intellectual Property Organization*, Caritas in Veritate Foundation Working Papers (Chambésy: FCIV, 2013): <http://www.fciv.org/downloads/FCIV%20WP3%20Patents%2001%20Genetic%20Resources.pdf>. Portions of the report serve as the basis for Chapter 12 in this volume.

WIPO on this theme dates back to 2001 and illustrates, perhaps in a somewhat unexpected way, the relevance of religious discourse in IP debates.

II. RELIGIOUS DISCOURSE IN THE PUBLIC FORUM: DIALOGUE, NOT EXCLUSION

It is estimated that on 19 May 2018, more than two billion people around the world tuned in to watch the television broadcast of the religious ceremony at which Prince Harry and Meghan Markle were made man and wife (and Duke and Duchess of Sussex) in St George's Chapel at Windsor Castle in the United Kingdom. That same number was exposed to the blockbuster performance of Bishop Michael Curry, head of the Episcopal Church in the United States, who gave the sermon of his life. The Bishop proclaimed to the listening world, and to the bemused royal family and guests and amused bride and groom, that love, with its source in God as revealed by Jesus Christ in his teaching, life, and death, has the transformative power to change governments, to change businesses, and to change the world. Reflecting on the principle that 'love is not selfish and self-centred', Curry proclaimed in his own inimitable style: 'He didn't die for anything he could get out of it. Jesus did not get an honorary doctorate for dying. . . . He gave up his life; he sacrificed his life, for the good of others . . . for the wellbeing of the world.'²

Contrast this with the famous intervention of the atheist Alastair Campbell, Prime Minister Tony Blair's Director of Strategy and Communications, that 'we don't do God',³ which reflected a tension in British society regarding the relevance of religion and the use of religious language in government. This comment, however, was by no means an authoritative declaration that religion has no place in the public square.⁴ Campbell's comment is illustrative of modern liberal political thought's claim that there is a neutral mode of public reason that operates over and above religious differences, as articulated pre-eminently in the twentieth century by John Rawls.⁵ However, these views have been seriously challenged by a number of recent philosophers and theologians who argue that public dialogue with religious authorities is necessary in the search for mutual understanding and is a better option for the public good than trying to relegate such views to the private domain.⁶ In any case, the

² The full text of the sermon can be found on the Archbishop of Canterbury's website: <https://www.archbishopofcanterbury.org/speaking-and-writing/sermons/power-love-bishop-michael-currys-sermon-wedding-prince-harry-and>.

³ Colin Brown, 'Campbell Interrupted Blair as He Spoke of His Faith: "We Don't Do God"', *The Telegraph*, 4 May 2003: <https://www.telegraph.co.uk/news/uknews/1429109/Campbell-interrupted-Blair-as-he-spoke-of-his-faith-We-dont-do-God.html>.

⁴ Despite the affirmation by a British Judge of the High Court that the law 'has no place for Christianity'. *R. (on the application of Johns) v. Derby City Council* [2011] EWHC 375 (admin); [2011] F.L.R. 2094. This was a case where homosexual rights took precedence over religious beliefs.

⁵ E.g. John Rawls, *Political Liberalism* (New York: Columbia University Press, 1993).

⁶ See, for example, John Milbank, *Theology and Social Theory*, 2nd ed. (Oxford: Blackwell, 2006); Jeffrey Stout, *Democracy and Tradition* (Princeton: Princeton University Press, 2004).

empirical reality is that the majority of the world's population, including within Western Europe, subscribes to religious or metaphysical views and codes of conduct, nor can this reality be ascribed simply to a pre-scientific and pre-enlightenment mindset.⁷ Mahatma Gandhi, the Reverend Martin Luther King Jr, Archbishop Oscar Romero of San Salvador, Archbishop Desmond Tutu of Cape Town, and Pope John Paul II are just some of the high-profile examples of religious figures who have influenced public life in recent times in a significant way for the common good. Scholars have likewise shown that the Roman Catholic Church in particular has been one of the most visible religious forces in the domain of world politics and that this involvement has been an effective force for the global advancement of democracy over the past several decades.⁸

Using a different style from Bishop Curry, the Vatican,⁹ with its current head Pope Francis, engages actively with people and institutions from around the world, regardless of religious affiliation, on matters of social and global importance (including patents and biotechnology), referencing its own body of collective experience and social teachings.¹⁰ It is involved at national and international levels, including variously addressing the UN and national governments, participating in the work of UN agencies, addressing the diplomatic corps accredited to the Holy See periodically on social issues of international concern, issuing encyclical letters for the attention of 'all men and women of good will', and much else besides. For example, in the encyclical letter *Laudato Si'*, in which biotechnology is mentioned, Pope Francis wrote, 'Now faced as we are with global environmental deterioration, I wish to address every person living on this planet'.¹¹ And speaking to a meeting of Judges in the Vatican, he emphasised that 'the Enlightenment slogan that the Church must not be involved in politics has no application here, for the Church must be involved in the great political issues of our day . . . [P]olitical life is one of the highest forms of charity.'¹²

⁷ According to Pew Research, in 2015 just Christians and Muslims together made up 4.1 billion of a total global population of 7 billion. The largest religious group is Christianity: <http://www.pewresearch.org/fact-tank/2017/04/05/christians-remain-worlds-largest-religious-group-but-they-are-declining-in-europe/>.

⁸ David Hollenbach, S.J., *The Common Good & Christian Ethics* (Cambridge: Cambridge University Press, 2002), 98.

⁹ The Vatican City, strictly speaking, is an independent state established by the Lateran Treaty of 1929 between the Kingdom of Italy and the Holy See, the latter being the central governing body of the entire Roman Catholic Church. The Pope is head of both.

¹⁰ Convenient summaries of the Catholic Church's Social Teaching are found in Pontifical Council for Justice and Peace, *Compendium of the Social Doctrine of the Church* (Rome: PCJP, 2004).

¹¹ Pope Francis, *Laudato si'*, encyclical letter, Vatican website, 24 May 2015, §3, http://w2.vatican.va/content/francesco/en/encyclicals/documents/papa-francesco_20150524_enciclica-laudato-si.html.

¹² Pope Francis, 'Statement to the "Judges" Summit on Human Trafficking and Organized Crime"', Vatican City, 3 June 2016, https://w2.vatican.va/content/francesco/en/speeches/2016/june/documents/papa-francesco_20160603_summit-giudici.html.

III. ENGAGEMENT WITH PATENT ISSUES

A relatively new area of engagement for the Roman Catholic Church at official levels, and indeed for all religious bodies, is the world of IP. The various essays in Part II of this volume attest to the newness of that engagement. This is not because this area of law is particularly new (the first British patent, granted to a Dutchman John of Uytynam for special techniques in making stained-glass windows, was granted in 1449). What is new are concerns about the broader impacts on members of society, at different levels, and the implications for social justice on whole sections of society in developing nations, of recent developments in the scope of subject matter protection for holders of IP rights, concentrated in the hands of a few. There is concern about IP's new geographical spread across the world based on legal models from developed countries that are not necessarily suitable everywhere. More particularly, and as discussed throughout this book, a need for attentiveness, if not concern, among churches, civic groups, and other relevant parties arises from, first, the use or misuse of the legal instrument known as TRIPS, attached to the World Trade Organization (WTO) free trade agreement (brought to being in 1994), in which, inter alia, patent protection for imported technologies from developed countries into developing countries is a prerequisite for free trade. Such concerns arise, second, from the implications of patents in the field of biotechnology, the development of which has exploded since the 1970s, which challenge moral and ethical principles and sensitivities. These developments have contributed substantially to (a) the development of a body of literature that questions the assumptions of the traditional rationale of the patenting system – namely, reward and incentive to innovate – and also to (b) political and organisational initiatives and actions that seek to address the real and perceived imbalances of the system when implemented according to narrow legal interpretations.

IV. NATURE OF INTELLECTUAL PROPERTY AND OF PATENTS: REFLECTIONS ON TRIPS

A. *IP Basics*

IP protects applications of ideas and information that are of commercial value. IP does protect works of creativity and self-expression of an artist, writer, researcher, or musician that might be non-commercial in nature (so that they are not unfairly and without permission copied and commercialised by others). But the system is adapted to allow holders of IP to reap the fruits of their labour and investment, usually through monetisation, in a proportionate way under conditions and time periods set in law. Although there are many types of IP, the four main pillars of the system are patents (our concern here), which give temporary protection to technological inventions; copyright, which covers a broad category of works protecting inter alia

literary, artistic, and musical works, as well as software; trademarks, which protect brands; and design rights, protecting the appearance of things.

B. TRIPS

TRIPS provides minimum requisites for patent law that each WTO member is in principle required to implement in its territory if not already present. Patents are to be available, for a term of not less than twenty years (Art 33), for both products and processes in all fields of technology (including biotechnology dealing with living matter and pharmaceuticals), providing that the product or process (a) is new, (b) involves an ‘inventive step’, and (c) is capable of industrial application (Art 27.1). Sufficient information must be disclosed to allow the invention ‘to be carried out by a person skilled in the art’ (hence facilitating knowledge and technology transfer). Members are barred from disallowing patents just because they originate from outside their territory or because patented products are imported rather than being locally produced. Some exceptions and limitations are permitted, although narrowly construed in practice, one being inventions ‘the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality’ (Art 27.2). All members are required to provide protection for plant varieties, by either patent or an ‘effective *sui generis* system’ or a combination of both. The rights conferred on a patent holder are essentially the negative right of excluding an unauthorised party from making, using, offering for sale, selling, or importing a product (or one using a patented process). Holders can sell their rights, assign, transfer by succession or license them.¹³

However, as the various contributors in this volume argue, patent law is just as much a social, moral, and political issue as a legal and technical one.¹⁴ Liddell and Ravenscroft, for example, explain that ethical issues implicitly permeate all aspects of patent doctrine, including definitions of invention, novelty, inventive step, utility, and disclosure. The explicit morality exclusion, optional in TRIPS but incorporated as Article 53(a) of the European Patent Convention (EPC) – although not incorporated in US patent law – in particular should be interpreted as a ‘policy lever’ which tailors patent law to its overarching objective of promoting socially beneficial inventions in a manner compatible with fair and just social organisation.¹⁵

Broyde and Weiner and El Said, respectively, introduce perspectives from the Jewish and Islamic traditions on the broader aspects of IP and as applied to

¹³ *Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement*, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, Articles 27–29, https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm.

¹⁴ See also Shobita Parthasarathy, *Patent Politics: Life Forms, Markets, and the Public Interest in the United States and Europe* (Chicago: University of Chicago Press, 2017).

¹⁵ See also Kathleen Liddell, ‘Immorality and Patents: The Exclusion of Inventions Contrary to *Ordre Public* and Morality’, in *New Frontiers in the Philosophy of Intellectual Property*, ed. Annabelle Lever (Cambridge: Cambridge University Press, 2012), 140–71.

contemporary issues in life patenting. Broyde and Weiner present the case that a distinctly *halakhic* theory of intellectual property can be derived from the application of Talmudic unfair competition principles to IP questions, these being equitable in nature and operating to protect broad social interests. This provides a contrast to the personal property basis undergirding much of secular, contemporary patent law. El Said, on the other hand, looks to the principles of *Maslaha* ('public interest') and the objectives of *Sharia*, to suggest how the conflict which arises between accessibility (for example, in relation to genetic innovation) and restrictions on private ownership would be resolved.

Bagley, representing a directly Biblical-based perspective, looks at a particular issue of huge social importance in relation to developing countries: access to medicines. She un-packages the social and ultimately biblical underpinning of compulsory licencing exceptions, which are provided for in TRIPS under very precise conditions (reducing considerably premium prices) but are vigorously opposed in practice by major pharmaceutical companies as a form of disguised IP infringement and IP 'theft'. Bagley provocatively turns the theft concept on its head, proposing that in fact it is the IP holders that should be considered guilty of 'theft' when they effectively act against the interests of those in dire need of medicines and are losing little actual reward because of the compulsory licence arrangement in place.

The power politics dimension of TRIPS has also been decisive in the Vatican's own interventions at the international level on behalf of developing nations and in the cause of social justice, especially in the areas of healthcare and food security (see the Neves and Colecchi chapters). In 2009 this led to what was for some a remarkable, even unwelcome, public statement by Pope Benedict XVI: 'On the part of rich countries there is excessive zeal for protecting knowledge through an unduly rigid assertion of the right to intellectual property, especially in the field of health care.'¹⁶ Understood in context, however, the statement is actually thoroughly unremarkable.¹⁷

Catholic social doctrine understands intellectual property to have a social function requiring that the interests of patent holders be balanced against the legitimate needs and rights of the rest of society. These rights ultimately rest on the foundation of human dignity and invoke other higher principles, such as human global solidarity and the universal destination of the earth's goods. Thomas Aquinas defined law as 'an ordinance of reason for the common good' (*Summa Theologica*, I-II, 90.4). Patent law therefore should likewise be oriented to the common good, not skewed towards the private good of the patent holder whose interests might at times conflict

¹⁶ Pope Benedict XVI, *Caritas in Veritate*, encyclical letter, Vatican website, 29 June 2009, §22, http://w2.vatican.va/content/benedict-xvi/en/encyclicals/documents/hf_ben-xvi_enc_20090629_caritas-in-veritate.html.

¹⁷ The background to this statement is analysed in Roman Cholij, 'IP in Christian Law', *Intellectual Property Quarterly* 17 (2012), 137–48.

with the common good in his pursuit of maximum monetisation of his market monopoly. These tensions play out most obviously in the field of access to essential medicines in healthcare, as well as in the field of food security. This social function of patents and all IP translates in papal teaching as the ‘social encumbrance’ or ‘social mortgage’ on IP ownership – a theme developed in the contributions here of Neves and Wojda.

Critics note that TRIPS came about through the powerful lobbying activities of US corporations to protect their business interests. In this, the corporations proved to be successful. The business models of the pharmaceutical, seed and pesticides, music, film, and software businesses were dependent on powerful IP protection. However, little regard was paid to the actual developmental needs of poorer nations in need of access to the free market, who were effectively bullied into opening up their countries to IP protection for foreign companies, even if this did not benefit their country but did the opposite.¹⁸ These corporations also appeared to pay no heed to the social history of IP globally and in their own country. The United Nations Development Programme (UNDP) noted in a report that

[m]any of today’s advanced economies refused to grant patents throughout the 19th and early 20th centuries, or found legal and illegal ways of circumventing them – as illustrated by the many strategies used by European countries during the industrial revolution . . . They formalized and enforced intellectual property rights gradually as they shifted from being net users of intellectual property to being net producers; several European countries . . . completed what is now standard protection only in the 1960s and 1970s.¹⁹

The Lord Justice Jacob, a judge in the Court of Appeal of England and Wales, has commented about TRIPS: ‘[T]o require nations such as Bangladesh, upon pain of trade sanctions, to have substantial intellectual property laws and a system of enforcement of such laws is to ask for the impossible. Although TRIPS provided some leeway for compliance, that leeway is nowhere near enough. It is hardly surprising that it causes much resentment.’ He notes also that TRIPS is a major departure from the driving force of earlier patents (such as the first one granted in the UK). This patent ‘was created so as to encourage exploitation within the realm [the teaching of the art of making stained glass by a Dutchman to English apprentices]. TRIPS and the modern worldwide patent system do not do that. They provide the monopoly but not the local industry to go with it. So it does not create an incentive to invest in third world countries. Again that is resented and again that is hardly surprising.’²⁰ In fact, according to Jagdish Bhagwati, noted Indian economist, the

¹⁸ *The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford: Oxford University Press, 2009), 8–9.

¹⁹ UNDP, *Human Development Report 2001: Making New Technologies Work for Human Development* (Oxford: Oxford University Press, 2001), 102.

²⁰ ‘Is Intellectual Property the Grit in the Wheels of Industry?’, in Robin Jacob, *IP and Other Things: A Collection of Essays and Speeches* (London: Bloomsbury, 2015), 120–130, at 127–8.

WTO has become ‘primarily a collector of intellectual property-related rents on behalf of multinational corporations’.²¹

TRIPS actually does include some flexibilities such as delayed implementation for least developed economies (although even then separate ‘TRIPS-Plus’ trade agreements might override these) and reference to ‘Objectives’ (Article 7) and ‘Principles’ (Article 8). Article 7 states explicitly that protection and enforcement of IPR should be ‘conducive to social and economic welfare, and to a balance of rights and obligations’. Article 8 in theory allows countries to adopt measures ‘necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development’. The practice, however, has proven to be different. At the Doha Round of trade negotiations among the WTO membership (which took place in Doha, Qatar, in 2001, with special focus on fairer treatment of developing countries), the Doha Declaration on TRIPS and Public Health was negotiated against a backdrop of disagreements regarding the extent to which the TRIPS Agreement allows WTO member countries to facilitate access to essential medicines to address pandemics such as HIV/AIDS. The Declaration, which referenced Articles 7 and 8, included matters such as the right to grant compulsory licences and the freedom to determine the grounds upon which licences are granted. Although by 2003 some progress had been made in implementing the spirit of the Declaration (an interim waiver allowing restricted compulsory licencing), overall the Doha Round was unsuccessful in remedying the imbalances that had been addressed.²²

V. GENETIC RESOURCES AND PATENTS

The power dynamics at the WTO, essentially dividing the Northern Hemisphere from the Southern, have also been playing out at other international fora, including at WIPO. WIPO itself has, since 2007, followed more closely a trajectory of paying more than lip service to issues of social justice in relation to the global IP regime through adoption of the Development Agenda, reflecting the Human Development policies and programmes of other UN agencies.²³ However, there is currently a stalemate because of differences between representatives of developed and developing countries at the WIPO IGC on Intellectual Property and Genetic Resources in the drafting of a new international legal instrument on the patenting of innovations using genetic resources

²¹ IPR Commission, *Integrating Intellectual Property Rights and Development Policy* (London: UK Commission on Intellectual Property Rights, 2002), 177, http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf.

²² The Doha Texts are found on the WHO website at https://www.wto.org/english/tratop_e/dda_e/dda_e.htm.

²³ See, for example, Neil Weinstock Netanel (ed.), *The Development Agenda. Global Intellectual Property and Developing Countries* (Oxford: Oxford University Press, 2009), and the WIPO website: <http://www.wipo.int/ip-development/en/agenda/>.

(GR) and/or Traditional Knowledge (TK).²⁴ The text would also incorporate within the IP system the objectives of the Convention on Biological Diversity (CBD), an international legal instrument for the conservation and sustainable use of biological diversity, presented for signature at the Rio Earth Summit in 1992. The CBD required that access to genetic resources be on the basis of prior informed consent, and on mutually agreed terms that provide a fair and equitable sharing of the benefits arising out of the utilization of such resources.²⁵ The Conference of Parties to the CBD, in the ‘Bonn Guidelines’, further recommended disclosure of the origin of GR and TK in the patent applications of those set to benefit commercially from this IP, thereby facilitating better monitoring of effective arrangements to benefit the holders of GR and TK – often the poor and marginalised. This task was eventually passed on to WIPO.²⁶

VI. THE CONTRIBUTION OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE TO MEDICINE

It is uncontroversial that historically the value of GR and TK to medicine and healthcare has been significant. It has been estimated that 33 per cent to 50 per cent of modern pharmaceutical preparations were derived originally from plants.²⁷ A recent testimony of the ongoing importance of plant-based medicines is the award in 2015 of the Nobel Prize for Medicine to Tu Youyou, the first Chinese woman ever to receive such an award, for the discovery of the most successful anti-malarial drug on the market. Tu’s team found information in a 1,600-year-old text indicating that people in 400 CE used sweet wormwood (*Artemisia annua L.*), which is known in Chinese as *qinghaosu*, to treat malaria with some success. The team used this information to create the anti-malarial drug.²⁸

Many genetic resources that possess significant economic and social value are located in territories (such as Brazil or Peru in the case of Amazonian forest-derived products) that have been inhabited since time immemorial by native communities

²⁴ The work and background of the IGC is available online: <http://www.wipo.int/tk/en/igc/>.

²⁵ UN, *Convention on Biological Diversity*, 5 June 1992, Article 1, <https://www.cbd.int/convention/text/default.shtml>.

²⁶ For a fuller discussion, see Chapter 12 and the report, *Patents on Genetic Resources?* (cited in note 1). A supplementary agreement to the CBD, and deriving from it, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS), came into effect on 12 October 2014. This aims to facilitate ABS but is independent of the work of the WIPO IGC.

²⁷ An example is digitalis, a popular cardiac medication, identified as the active component of the foxglove leaf. For other examples, see Ryan Abbott, ‘Documenting Traditional Medical Knowledge’, WIPO, March 2014, http://www.wipo.int/export/sites/www/tk/en/resources/pdf/medical_tk.pdf.

²⁸ See Rhodi Lee, ‘Malaria Cure Based on Traditional Chinese Medicine Wins Tu Youyou Nobel Prize’, *Tech Times*, 12 October 2015, <http://www.techtimes.com/articles/93754/20151012/malaria-cure-based-on-traditional-chinese-medicine-wins-tu-youyou-nobel-prize.htm>.