

A Revolution in Intellectual Property Law: COVID-19 demands a new collaborative approach to balance exclusivity rights and social benefit, with a Particular Historical Emphasis on the State of Kuwait

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Abstract:

Intellectual property law is preventing institutions from finding a vaccine or a cure for COVID-19. Historically, Intellectual Property principles ensure market exclusivity and promote private benefit, but this runs counter to jurisprudential concepts of social good, especially in times of emergency. Compulsory licencing under national law and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) and is one solution but has not been very successful in the past. Nor does it offer much help to countries like Kuwait with no generic drug manufacturing capacity. A new open licencing approach based on a global patent pool is the way forward. The World Intellectual Property Organisation (WIPO) backs this approach. Now it needs to put it into action.

Keywords: independent director, corporate governance, Kuwaiti Stock Exchange, New York Stock Exchange

This paper will discuss:

- The Jurisprudential Basis of Intellectual Property and its History in Kuwait: Public Benefit v Private Gain
- The Role of Intellectual Property Law in the Current COVID-19 Crisis and the Threat Posed by Exclusive Rights

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- **Compulsory Licencing under Article 31 TRIPS is not a Perfect Solution**
- **Intellectual Property: A New Collaborative Approach to Endorse Social Duty**

Introduction

The traditional legal sole ownership model of intellectual property law is proving itself not fit for purpose when faced with a global pandemic. Exclusivity of Intellectual Property ownership has to be eased in times of national emergency. Historically, Intellectual Property rights were implemented to provide “an exchange between society and inventors/creators, rewarding innovative and creative work while giving society the benefits of greater technological and creative diffusion”.⁽¹⁾ However, this article contends that in crisis, this ‘exchange’ cannot be a fifty-fifty partnership, rather the balancing of public interest and private profit has to weigh in favour of social and civic good. This does not imply co-ownership; rather the way forward has to centre on open licences, as part of a collective, collaborative response.

On 11 March 2020, the World Health Organization (WHO) declared COVID-19 a pandemic. Despite Herculean efforts from scientists across the globe, at the time of writing there are no vaccines available, nor any pharmaceutical drugs to successfully treat the virus. Under traditional practice, major pharmaceutical companies will look to protect any treatment they discover through intellectual property laws, primarily patents. This confers legal ownership of the drug and grants a monopoly, generally for 20 years.⁽²⁾ As legal owners, if the manufacturer wishes not to use their drug, or only sell it only in their own country, or at a vastly inflated price, in theory they have the legal right. Where does that leave the public? Other countries could be totally excluded from access to life-saving treatment. Patent protection for drugs poses especially difficult legal and

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- (1) Organisation for Economic Cooperation and Development (OECD) ‘Summary of the Expert Workshop, “Society’s Gain From The Intellectual Property Exchange”’, Chapter 8 in Enquiries into Intellectual Property’s Economic Impact (Report) (2015) 415
- (2) e.g. EU Patent Convention, 2016, Article 63 states: “the term of the European patent shall be 20 years from the date of filing of the application”. Also, the Gulf Cooperation Council Patent Agreement, Article 15, as implemented into Kuwaiti national law under Kuwait Law No. 71 2013, states that a patent lasts for 20 years.

policy-based dilemmas, giving rise “to potentially far-reaching consequences for scientific research, the biotech industry, and human health”.⁽³⁾

It is true that countries already have the right to override patent exclusivity in certain circumstances. Compulsory licencing rights under national law, and as authorised under Article 31 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),⁽⁴⁾ are very broad. Contrary to traditional scholarly interpretation, this article contends that s.31(b) simply waives the requirement of mandatory negotiation with the rights holder in times of ‘national emergency or... extreme urgency’,⁽⁵⁾ as opposed to requiring such an emergency. Importantly, especially for countries like Kuwait, Article 31 bis provides a legal amendment to no longer restrict compulsory licencing to supplies for the domestic market.⁽⁶⁾ However, the power under Article 31 is unpopular, very rarely used and, as highlighted by Dr. Donia Bastaki, the Head of Kuwait’s Drug Registration Department Pharmaceutical and Herbal Medicines Registration and Control Administration Ministry of Health, does not provide a practical and effective means to serve the nation’s common good in times of emergency.⁽⁷⁾

Because Intellectual Property law exists as an exception to anti-monopoly laws, as recognised over history, it has to be used circumspectly. In 2014, Lord Neuberger cautioned against allowing Intellectual Property law to develop in a way whereby it “will grant a monopoly over a class of chemicals to a single drug company at a stage when it is far more in the public interest that there is a free and competitive market in working and experimenting on those chemicals”.⁽⁸⁾ And yet existing patent law incentivises each company and research institute to act independently, to

(3) *Eli Lilly & Co v Activis UK Ltd & Others* [2017] UKSC 48

(4) Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1994, Article 31 (Annex 1C Marrakesh Agreement Establishing the Trade Organisation)

(5) *ibid*, Article 31(b)

(6) *ibid*, Article 31 bis

(7) Interviews with Dr Donia Bastaki, Head of Drug Registration Department Pharmaceutical and Herbal Medicines Registration and Control Administration Ministry of Health, Kuwait, 28 April 2020 and 1 May 2020.

(8) Lord Neuberger, ‘Intellectual Property in the UK and Europe’ ‘Burrell Lecture for the Competition Law Association, (1 April 2014)

develop their new product in-house, in secret and then file for patent protection as soon as possible. This is the opposite of what we need.

Kuwait is at risk. The history of Intellectual Property law in Kuwait, as in all other countries, is governed by national laws and also commitments under international treaties, primarily TRIPS, the Berne Convention,⁽⁹⁾ Paris Conventions,⁽¹⁰⁾ and also as part of the GCC Patent Office. Since 2019, patents are granted via ministerial decision. Pharmaceuticals are covered. However, Kuwait does not have a sophisticated domestic drug manufacturing industry, relying instead on major international pharma companies. Despite recent growth of regional drug production facilities in the GCC, it is still in very early stages. Therefore, Kuwait, as an importer, is effectively bound by the Intellectual Property protection of those drugs or the Intellectual Property laws of generic producers authorised under Article 31. For this reason, it is very welcome that Kuwait was not one of the 37 countries that, effective 2017, decided to opt out of a TRIPS amendment which allows a country to be an “eligible importing member” and import drugs made under a compulsory Intellectual Property licence.⁽¹¹⁾

The world acknowledges this danger. As Bonadio and Baldini write, “can we really justify Intellectual Property laws that are used in a way that limits the availability of medicines and aims at increasing profits in times of health emergency?”⁽¹²⁾

But there is no consensus on the best way to address it. The key issue is whether - and, if so, how - Intellectual Property law can allow public benefit to override the total monopoly rights of the patent holder. TRIPS, Article 8, outlaws any “abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade

(9) Berne Convention for the Protection of Literary and Artistic Works, 1886

(10) Paris Convention for the Protection of Industrial Property, 1883

(11) James Love, 'Open Letter Asking 37 WTO Members to Declare Themselves Eligible to Import Medicines Manufactured Under Compulsory License In Another Country, Under 31bis of TRIPS Agreement' (7 April 2020) Knowledge Ecology International.

(12) Enrico Bonadio & Andrea Baldini, 'COVID-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health' 11 (2) (2020) European Journal of Risk Regulation, 390

or adversely affect the international transfer of technology”.⁽¹³⁾ The WTO Ministerial Conference in Doha in 2001 issued a declaration confirming that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health".⁽¹⁴⁾

Instead of compulsory licencing, a more revolutionary approach to Intellectual Property law is needed: the creation of a new, collaborative, open source basis for Intellectual Property law. This is not a completely novel proposal: patent pools (a voluntary aggregation of Intellectual Property rights) have previously been touted as a solution for various technological issues.⁽¹⁵⁾ However, this has been rare for pharmaceuticals, and has not been implemented on a global scale. Different versions are possible. Costa Rica recently made a proposal to the WHO for a worldwide patent and data-sharing pool,⁽¹⁶⁾ which has since been backed by the MMA, the EU, many governments and even some leading drug companies. There is also growing commitment to the Open Pledge that “grants to every person and entity that wishes to accept it, a non-exclusive, royalty-free, worldwide, fully paid-up license (without the right to sublicense) under Pledgor’s patents and copyrights.....”.⁽¹⁷⁾ This does not mean that Intellectual Property rights are abandoned but it commits the pledgors to share their data, their legal rights and to allow scientists around the world to work together in a way that it is not constrained by fear of litigation. A different approach has been to simply bypass Intellectual Property laws by offering a major financial incentive, as a prize, for discovering a cure. This has historical origins and shows another method of achieving Intellectual Property law’s goals and objectives. All ways must be considered.

(13) Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1995, Article 8

(14) World Trade Organisation (WTO), 'Declaration on the TRIPS Agreement and Public Health', Doha WTO Ministerial 2001, WT/MIN(01) /DEC/2, Para 6

(15) Estaban Burrone, 'Patent Pooling in Public Health', in Margaret Chon, Pedro Roffe, Ahmed Abdel-Latif (Eds), *The Cambridge Handbook on Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development* (CUP 2018). See also the United Nations-backed Medicines Patent Pool (MPP) at medicinespatentpool.org.

(16) Letter from the Costa Rican President and Minister of Health to the WHO, dated 23 March 2020, available at: www.healthpolicy-watch.org/wp-content/uploads/2020/03/Picture.png, accessed 5 May 2020

(17) Open COVID Pledge, 'Open COVID License - Patent and Copyright (OCL-PC) 1.1' (17 April 2020)

This is a global pandemic. We need a global response. Kuwait's Intellectual Property strategy needs to be in line with the rest of the world. Every person has the right to access effective health care and the Intellectual Property legal framework needs to enable this. There is pressure on the drug companies to behave in a morally responsible way. Many will rise to this challenge. However, a global crisis has called into question the existing legal regulations. Now is the perfect time to revisit the history of Intellectual Property law, what it strives to achieve and the different legal methods to do so. An open, sharing platform is the way forward during the Covid-19 crisis. It may even pave the way for a more permanent change in the world's understanding of intellectual property law.

The Jurisprudential Basis of Intellectual Property and its History in Kuwait: Public Benefit v Private Gain

The concept of Intellectual Property law is often portrayed as a balancing exercise between public benefit and private gain. Article 7 of TRIPS, states that:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.⁽¹⁸⁾

As Torrance and Tomlinson write:

The traditional assumption underlying justification of patent systems is that the prospect of patent protection for new inventions should lead to higher rates of technological innovation, along with greater attendant benefits to society.⁽¹⁹⁾

This paper contends that there is no conflict in the private/public aims - the underlying purpose of patent IP, as with all law, is to promote public benefit and companies' interests need to be respected precisely to serve the same aim. Historically, Intellectual Property works as an

(18) Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1995, Article 7

(19) Andrew W. Torrance & Bill Tomlinson, 'Patents and the Regress of Useful Arts' 33 (2009) Southern Illinois University Law Journal, 239

incentive to companies to invest, create, and bring to market inventions and innovations that will benefit the world. Shareholders benefit, but only inasmuch as there is a public demand for the product. Encouraging innovation therefore benefits all. Professor Shapiro writes that this is the second rationale behind TRIPS, ensuring the “public policy perspective in which property rights can be legitimately encumbered with public regulation to strike a balance between the interests of producers and consumers of intellectual property rights”.⁽²⁰⁾ The state, therefore, implements Intellectual Property law in order to encourage companies to produce medicines that will benefit its citizens. It is the benefit to the citizens that is at the root of the law.

The Legal Ethics of Big Pharma

However, the ethical dilemma is rarely seen this way in practice. Rather, large pharma companies have significant power and sway, politically, and their interests are often prioritised. The private property model, what Professor Shapiro calls the ‘first rationale’ for TRIPS,⁽²¹⁾ relies on contractual autonomy and the presumption that legal ownership allows any owner to treat his/her property as they see fit. Self-interest will, supposedly, lead owners to create more property by dedicating more to invention and innovation, thereby maximising profits. This more commercial focus of Intellectual Property is largely tied to the size and power of the industry. The recent IQVIA Institute for Human Data Science Report states that the industry is currently worth approx. \$1.2 trillion, reaching \$1.5 trillion by 2023.⁽²²⁾ This generates corporate interests and a tax base that is highly influential to government. Importantly, too, the industry is ‘intensely concentrated’⁽²³⁾, with a limited number of highlight influential players, hence the risk of exclusion to smaller countries such as Kuwait.

(20) Robert Shapiro, ‘Patent Infringement During a Time of National Emergency’, 37 (18) (2004) Winsor Rev. Legal & Soc., 50

(21) *ibid*

(22) IQVIA Institute for Human Data Science, ‘Global Use of Medicine in 2019 and Outlook to 2023 Report’, Jan 19 2019.

(23) Kenneth C. Shadlen et al, Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries, (Edward Elgar Publishing Ltd, Cheltenham 2011) 2

Lobbying plays a vital role, too. The industry invests heavily to try and get government to prioritise their interests, over and above those of the general public. From 1998 to 2014, “Big Pharma spent nearly \$3 billion on lobbying, drowning out the voices of consumers and the interest groups that try to represent them”.⁽²⁴⁾ This gives them leverage in how patent laws are formed and passed or - importantly - not passed.

Even worse, patient rights groups who are supposed to be the counterbalance and represent the public's interest actually are often working in cohort with the very same drug companies. The New England Journal of Medicine study shows that “among 104 of the largest U.S.-based patient-advocacy organizations, at least 83% received financial support from drug, device, and biotechnology companies, and at least 39% have a current or former industry executive on the governing board”.⁽²⁵⁾ If the consumer bodies are basically controlled by the pharma companies, who will actually protect the interests of the public?

The problem, therefore, is that although the law is trying to promote the overall benefit to the public, the balance of power is wrong, and the original ethos has been lost. As part of the growing demand for a more collaborative legal approach in face of the Covid-19 pandemic, it is important to recognise this ethos, its origins and its continued applicability today.

The Essence of Intellectual Property: Creations, innovations and 'work'

IP laws are a codification of the concept that new and original work created qualifies as 'property' and therefore can be owned, with all the additional benefits - and burdens - that ownership entails. The different methods of Intellectual Property (copyright, trademarks, patents etc) are simply different versions of the same principle, in recognition that original and intangible work can take many forms and therefore the protection required needs to take different forms to reflect this.⁽²⁶⁾

(24) Leslie E. Sekerka & Lauren Benishek, 'Thick as Thieves: Big Pharma Wields its Power with the Help of Government Regulation', 5 (2018) Emory Law Corporate Governance and Accountability Review, 113

(25) Matthew McCoy et al, 'Conflicts of Interest for Patient Advocacy Organizations', 376 (9) (2017) New England Journal of Medicine, 880

(26) Tanya Applin & Jennifer Davis, Intellectual Property Law (OUP 2017) 2

There are many academic theories that justify this position. Utilitarianism recognises Intellectual Property as being necessary to encourage and promote technological, scientific and intellectual progress.⁽²⁷⁾ There is a distinction between long- and short-term benefit, but the aim is the same: Intellectual Property rights will create some social good that will confer a short-term benefit on an institution or certain individuals, i.e. the inventors, but will also confer a long-term benefit on society as a whole. This is the basic tenets of the such influential legal philosophers as Jeremy Bentham and John Stuart Mill, based on the 'greater good' theory.⁽²⁸⁾ The good that will come from the action, is balanced against the negative effects of the action and the best decision that which results in the most net benefit overall. Interestingly, this theory is seen in many important legal and constitutional documents. The UK Statute of Monopolies 1623, some 500 years ago, outlaws monopolies as being against 'public good', but makes an exception for patents.⁽²⁹⁾ The US Constitution states that: "[The Congress shall have power] To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."⁽³⁰⁾ The importance of scientific progress, not commercial profit, is clear.

Alternatively, for instance, the Labour-Desert theory expounds the premise that the effort put into the work deserves to be recompensed. As John Locke writes, this is based on the natural right to property with which we are born, the right to help ourselves to the world's resources, add our work to those resources, and take ownership of what we create as a consequence.⁽³¹⁾ However, although this may correspond better to reality, Locke's analysis struggles rather to explain intellectual property (e.g. exclusivity).⁽³²⁾ More importantly, placing more emphasis on

(27) *ibid*

(28) Jeremy Bentham, *A Manual of Political Economy* (New York: Putnam, 1839); John Stuart Mill, *Principles of Political Economy* (OUP, 1998, 1st published New York 1862)

(29) Statute of Monopolies (UK) 1623

(30) US Constitution, Article 1, Section 8, Clause 8

(31) John Locke, *Two Treatises of Government* (P. Laslett, ed., Cambridge: CUP, 1970), Second Treatise, Sec. 27.

(32) William Fisher, 'Property and Contract on the Internet,' *Chicago-Kent Law Review*, 73 (1998) 1203, 1207

'taking' from the earth, and the God-given right to then own what you make, ignores any concept of public good.

Middle Eastern scholars, on the other hand, focus heavily on the social purpose of Intellectual Property law. As Dr. Al-Hindiyan writes:

Rights originally have social goals and purposes. The right must be exercised in accordance with the social goal for which it was granted. Rights are not ends in themselves but rather a means to achieve the desired goal of granting them, and legal protection is linked to achieving this social goal. This means that private rights are not separated from the social goal that these rights exist to serve.⁽³³⁾

This is a succinct summing up of the power and relevance of Intellectual Property rights, as well as others. The general non-Western approach understands the dilemma between private interest and public good, between the "interests of the author regarding his exercise of his literary right and of the interest of the group", but does not see a conflict as such.⁽³⁴⁾ While private interest is recognised, the main premise is that the use of the right must be legitimate, in accordance with its original form and must not deviate or veer from the social utility function.

The traditional, cultural Arabic commitment to the civic duty that property imposes, as seen over history, can be seen explicitly in the Kuwaiti constitution. Article 16 states that:

Ownership, capital, and work are essential ingredients of the state's social entity and national wealth, and they are all individual rights with a social function regulated by law.⁽³⁵⁾

IP rights are held by an individual but for a social and civic function, as recognised by law. The individual's rights are not paramount, they only exist within the legal and social framework which strives to promote a common good. The Explanatory Memorandum further develops the idea of a cohesive whole aimed at promoting the wealth and the social good of the country by stating that the three pillars of ownership, capital

(33) Khaled Al-Hindiyan, 'Abuse of Copyright', 1 (2016) Kuwait University Law Journal, 91

(34) Muhammad Abdul-Sadiq and Abdul Rashid Mamon, cited in Khaled Al-Hindiyan, 'Abuse of Copyright', 1 (2016) Kuwait University Law Journal, 249

(35) Kuwaiti Constitution of 1962, Article 16

and work are “each complementing and controlling the other” and must all function “without extravagance or domination or exploitation of social justice”.⁽³⁶⁾ It is, therefore, clear that the creator exercises his rights only insofar as it is consistent with the collective interests and benefits of the community, the interests of the author may be exposed to the interests of the group. Therefore, a balance must be struck between both sets of interests.⁽³⁷⁾ In similar fashion, Dr Adel Al-Tabtabai writes that these rights have “a social function that was not specifically intended to define ownership, but rather intended to organize its function in the interest of the group, in addition to the right of the owner”.⁽³⁸⁾ The dual aspect of public-private is well balanced, based on the social organization of property, and an overriding aim to “prevent harm to the interest of the masses or abuse of the right”.⁽³⁹⁾ Furthermore, as Dr. Abdulaziz Al-Khanfousi expounds, in times of dispute, the “the public interest is always a priority over the private interest”.⁽⁴⁰⁾

Article 20 of the Kuwaiti Constitution goes one step further, stating very clearly that the country’s economy is based on ‘social justice’,⁽⁴¹⁾ showing that the very heart of Kuwait is rooted in social good. It is therefore not surprising that, although Article 18 explicitly respects private property rights,⁽⁴²⁾ intellectual property law in Kuwait has a broader aim, namely to advance social and civic benefit.

A similar emphasis is seen in Kuwait’s Civil Code. Article 30 states that “the use of the right is unlawful if its owner deviates from its purpose or from its social function”.⁽⁴³⁾ Again, the essential nature of public utility is at the root of the law: private rights are upheld insofar as they

(36) Kuwaiti Constitution of 1962, Explanatory Memorandum

(37) Ainsi, applique a notre discipline, l’abus de droit permet de determiner un ‘code de bonne conduit a l usage des auteurs qui exercent leurs droit.” Pierre Sirinelli, ‘Exceptions Et Limites Aux Droit D’auteur Et Droits Voisins. Atelier Sur La Mise En Oeuvre Du Traite De LOMPI’, Geneve December 1999, 36. From Abuse of Copy Rights , cited in Khalid al Hendyani, cited in Khaled Al-Hindiyani, ‘Abuse of Copyright’, 1 (2016) Kuwait University Law Journal, 88

(38) Adel Al-Tabtabai, *The Constitutional Order in Kuwait*, (Third Ed. 1998), 478

(39) *ibid*

(40) Abdulaziz Al-Khanfousi, *Introduction to Intellectual Property Law*, (Centre of Academic Books 2018) 42

(41) Kuwaiti Constitution of 1962, Article 20

(42) Kuwaiti Constitution of 1962, Article 18

(43) Kuwaiti Civil Code, Law No. 67, Article 30

support the social benefit that the law is trying to promulgate. The law also is premised on an Islamic principle of 'la Darar Wala Derar',⁽⁴⁴⁾ the duty to do no harm. The enforcement of a right can only be considered as proportional to the harm done to others.⁽⁴⁵⁾ Equally, a right is not upheld if it would cause uncommon, unscrupulous harm to others. Although Kuwaiti Civil Law is based very much in its French roots, the influence of Islamic traditions and cultural principles place greater emphasis on the common good of society. In this sense, the utilitarian philosophical principles are accepted, as a balancing exercise, but with a strong focus on society as a whole, rather than private commercial interests.

It should also be noted that, although it is readily accepted as a self-evident principle, not everyone believes that Intellectual Property law actually achieves the goal of encouraging innovation. Boldrin and Levine write that "while patents can have a partial equilibrium effect of improving incentives to invent, the general equilibrium effect on innovation can be negative".⁽⁴⁶⁾ Other scholars take it further: Torrance & Tomlinson writes that "little empirical evidence actually links the prospect of patent protection for inventions to increased rates of invention".⁽⁴⁷⁾ This matter deserves further academic research: if the fundamental premise of the commercial need for Intellectual Property law is actually false, the whole intellectual legal argument is flawed.

The COVID-19 crisis shows us that our law is not simply a theoretical exercise, it must have a practical purpose, to increase the common good. The law will be judged against how well it serves that purpose. Following the scholarly approach in both western and Middle Eastern cultures, it is therefore important to see where Kuwait stands in practical terms, as per the country's domestic and international commitments to Intellectual Property law.

(44) Ubadah ibn al-Samit reported: The Messenger of Allah Mohammed, peace and blessings be upon him, issued a decree, "Do not cause harm or return harm."

Source: Sunan Ibn Maja 2340 Grade: Sahih (authentic) according to Al-Albani

(45) Kuwaiti Civil Code, Law No. 67, Article 30

(46) Michele Boldrin & David K Levine, 'The Case Against Patents', 27 (1) (2013) The Journal of Economic Perspectives: 3, 3

(47) Andrew W. Torrance & Bill Tomlinson, 'Patents and the Regress of Useful Arts' 33 (2009) Southern Illinois University Law Journal, 240

The History of Intellectual Property Law in Kuwait

Kuwait's Intellectual Property journey has been rather a chequered one. The commitment to patent protection is clear: following Kuwait's independence, patent law was passed as one of the very first set of laws, to protect inventors and creators. Law No. 4 1962 covered patents only.⁽⁴⁸⁾ Drugs were covered based on patentable methods. Kuwait Patent Law No. 4 1962, Article 2(2), says:

“Patents for chemical inventions related to food, medical drugs, or pharmaceutical compounds are not granted unless these products are manufactured by special chemical methods or processes. In this last case, the patents do not go into the products themselves but rather the way they are made.”⁽⁴⁹⁾

Law No. 64 1999 extended cover to all intellectual property.⁽⁵⁰⁾

International treaties and conventions are also very important and show Kuwait's commitment to Intellectual Property law on the global stage. The State of Kuwait has signed up to many regional and international agreements to protect Intellectual Property rights, as shown by Law No. 16 1986 which was issued to approve the accession of the State of Kuwait to the Arab Convention for the Protection of Copyright⁽⁵¹⁾ and Law No. 2 1998 approving the accession of the State of Kuwait to the agreement establishing the World Intellectual Property Organization (WIPO).⁽⁵²⁾ On 1 January 1995, the State of Kuwait became a member of the World Trade Organisation (WTO), under which, inter alia, Kuwait agreed to the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Equally, in 2014, under Law No. 36,⁽⁵³⁾ Kuwait approved its accession to the Paris Convention and the Berne Convention for the Protection of Literary and Artistic Works of 9 September 9, 1886, as revised in Paris in 1971 and

(48) Kuwaiti Law No. 4, 1962

(49) *ibid*, Article 2(2)

(50) Kuwaiti Law No. 64, 1999

(51) Kuwaiti Law No. 16, 1986

(52) Kuwaiti Law No. 2, 1998

(53) Kuwaiti Law No. 36, 2014

further amended in 1979.⁽⁵⁴⁾ With respect to Kuwait, the Berne Convention entered into force on 2 December 2, 2014, under Law No. 35;⁽⁵⁵⁾ as such, Kuwait is now a member of the International Union for the Protection of Literary and Artistic Works (the "Berne Union").

More recently, Intellectual Property law has been a major focus of Kuwaiti lawmakers. The 1999 Law No. 64 had been roundly criticised as being too ambiguous and with procedural flaws.⁽⁵⁶⁾

To demonstrate its commitment to global Intellectual Property law and to show that it was keeping pace with its international developments, Law No. 22 2016 was passed.⁽⁵⁷⁾

However, this focuses on copyright, not patents. Very recently, in June 2019, the National Assembly also approved the Copyright and Neighbouring Rights Law No 75.⁽⁵⁸⁾ Equally, the Patent Office in Kuwait announced an update in the fees for all patent related matters. As per Ministerial Decree No. 287 of 2019,⁽⁵⁹⁾ the new fees entered into force on July 21, 2019. The Secretary General of the National Council for Culture, Arts and Literature, Mr Kamel Al-Abduljalil, has stated that the new Intellectual Property rights law is “a civilized, elegant and important law, and represents a shift that places Kuwait in the ranks of developed countries in the field of intellectual property rights protection”.⁽⁶⁰⁾

In Kuwait, patent law, rather than copyright, is now governed not by specific domestic law but by Kuwait’s signing up to the GCC Patent Agreement. This regional treaty was passed by the Kuwaiti parliament into national law via Law No. 71 2013,⁽⁶¹⁾ an amended in 2018. An important further development in Kuwait’s role as regards Intellectual Property protection can be seen in the re-opening of the Patent Office. Previously, the Patent Office had been open for the filing of patents, but

(54) Berne Notification No. 268, Berne Convention for the Protection of Literary and Artistic Works, Accession by the State of Kuwait, 2 Sept. 2014

(55) Kuwaiti Law No. 35, 2014

(56) Kuwaiti Law No. 64, 1999

(57) Kuwaiti Law No. 22, 2016

(58) Kuwaiti Law No. 75, 2019

(59) Kuwaiti Ministerial Decree No. 287, 2019

(60) Yosra Al Khashab, 6 January 2020

(61) Kuwait Law No. 71, 2013, promulgating the Patent Law (Regulation) for the Countries of the Cooperation Council for the Arab Gulf States

frozen in terms of actually assessing and issuing them. Sarah Al-Hubail of the Kuwaiti Patent Office⁽⁶²⁾ highlights that after Kuwait's signing up to the GCC's Gulf Patent Agreement became effective, in 2016⁽⁶³⁾, the Kuwait Patent Office was suspended, as the terms of this agreement stated that the office shall be run as a unified Gulf office. The Patent Office in Kuwait delegated its functions as a Receiving Office to the International Bureau. Moreover, for both international and national filings, the Patent Office of Egypt and the European Patent Office were appointed by Kuwait as the appropriate International Searching and Preliminary Examining Authorities. It is therefore not altogether surprising that after Kuwait joined the PCT Treaty issued by the General Organization of Intellectual Property WIPO, Kuwait received a violation warning for not having a functioning office.

Kuwait has therefore been working hard since 2019 to make up for lost time and re-energise its Intellectual Property presence.⁽⁶⁴⁾ Currently, patents are being awarded by ministerial decisions. GCC patents can also be filed. Importantly, of the 40 approved Kuwaiti patents in the last year or so, about 50% of these patents are for medicines. However, these medicines, although patented as original work, are not yet approved by a Medical Board such as the FDA in the USA, the European Medicines Agency or the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

Kuwait is trying to move very swiftly into the 21st century with an Intellectual Property legal system that encourages business and innovation, as part of the country's move towards diversification of income. However, the public benefit aspect underlying all Intellectual Property law must not be forgotten, as the COVID-19 crisis is perfect illustration.

The Intellectual Property Dilemma in Public/Private Sectors

One important area of discussion re the crossover between public and private benefit is the realm of publicly-funded medical research and

(62) Interview with Sarah Al-Hubail, Chemical Engineer, the Kuwaiti Patent Office

(63) PCT Notification No. 208 Patent Cooperation Treaty (PCT), Accession by the State of Kuwait, June 2016, effective September 2016

(64) Interview with Sarah Al-Hubail, Chemical Engineer, the Kuwaiti Patent Office

innovation. Although many drug companies are purely private, bearing the burden of their own R&D costs, some are public institutions and many more are private but receive public funding. But with public privileges comes public responsibilities, “we must not allow private corporations developing medical tools with EU funding to place profit maximisation ahead of public health considerations at such a critical point in time”.⁽⁶⁵⁾

As seen historically, Kuwait has an important public sector and policy of state involvement. The Kuwait Research Institute applies for patents, generally in the US, on behalf of products it believes to be worthwhile and patentable and is then the holder of the patent. This is easier as the patent is then publicly owned.

However, publicly-owned Intellectual Property protection will only apply to that state. Most of the potential drugs for COVID-19 drugs currently being tested are being developed in the US, China, UK, Germany etc. If people in Kuwait cannot access the COVID-19 vaccine, it makes very little difference if that is because the patent is owned by a foreign company or a foreign government. Diplomatic pressure may be easier to exert on a government, but the legal issues are fundamentally the same.

More generally, many private companies and research facilities are actually publicly funded or, at least, receive significant public grants. There seems to be something wrong in a system where public money funds the development of a treatment that is essential to public health and yet the public (or sections of the public) may be legally excluded from accessing it. Again, the US provides a clear example, having tried to pass at least three times the Fair Access to Science and Technology Research Bill, but without success.⁽⁶⁶⁾ This is a successor to a similar, and equally unsuccessful, bill entitled the Federal Research Public Access Bill.⁽⁶⁷⁾ It is difficult to see why the fruits of tax-funded research should then be privately held, excluding the very tax payers who paid for it.

(65) Letter from Members of European Parliament, 27 March 2020, available at: <https://haiweb.org/wp-content/uploads/2020/03/MEP-Covid-Letter-March-2020.pdf>, accessed 5 May 2020

(66) US Fair Access to Science and Technology Research Act (Bill) 2013

(67) US Federal Research Public Access Act 2012

Moreover, the Bayh-Dole Act 1980⁽⁶⁸⁾ allows private and public universities carrying out publicly funded research to apply for patents in their own name.

This reverses the previous status quo whereby if the government funded the research, then the government would file and own the patent and issue non-exclusive licences, allowing the benefit to be spread back among the public. As Rimmer points out, the act of filing patents by public institutions is precisely for the 'greater public good'.⁽⁶⁹⁾ However, not only are the universities now claiming the invention for their own property portfolio, but many of them are selling these patents to 'patent trolls' (companies who collect Intellectual Property for no other purpose than to bring highly speculative litigation). Ewing & Feldman describe this as an "extortion and a drag on innovation".⁽⁷⁰⁾ It is hoped that as Kuwait develops its patent law and pursues its policy of income diversification, with an expected expansion in drug companies, amongst others, that the country does not follow the same path.

Based on the above, the theory of Intellectual Property law stands to create harmony between the interests of the whole Intellectual Property community. However, this is not so true in practice: the short-term importance of drug companies based on political power has often overridden the long-term benefits of citizens. Allowing public institutions to commercialise patents also has a negative effect on the jurisprudential legal balance between the public and private sectors.⁽⁷¹⁾ The COVID-19 pandemic has questioned this. There is a demand for more collaboration in the common good. It is therefore necessary to consider the impact of Intellectual Property law in the current crisis and the alternative approaches to create the most beneficial outcome.

(68) US Bayh-Dole Act 1980 (also called Patent and Trademark Law Amendments Act)

(69) Matthew Rimmer, 'The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines', 5(2) (2004) Melbourne Journal of International Law 335

(70) Robin Feldman & Thomas Ewing, 'The Giants Among Us' 1 (2012) Stanford Technology Law Review

(71) Matthew Rimmer, 'The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines', 5(2) (2004) Melbourne Journal of International Law 335

The Role of Intellectual Property Law in the current COVID-19 crisis

Law does not stand in isolation to the world around it, as a purely scholarly and academic pastime. Rather the law must be reactive and proactive. As John Finnis writes, “the philosophy of law is not separate from ethics and political philosophy, but dependent upon them.”⁽⁷²⁾ Legal systems are not ‘simply sets of norms’ but must be “engaged with ethical and political issues and challenges, both perennial and peculiar to this age”.⁽⁷³⁾

This premise is illustrated perfectly in the current legal dilemma as to how Intellectual Property law should both react to the crisis and proactively help find a solution to the crisis. Drug companies are currently working flat out to find a drug/vaccine to treat COVID-19 but the sole-ownership model of Intellectual Property means that the first company to discover the successful drug will, in theory, have complete ownership and control over that drug for 20 years. All other producers will be blocked.

The opportunity to exploit the Intellectual Property is huge. Price fixing and product control are two extremely important areas of concern.⁽⁷⁴⁾ Whole countries may be excluded: Kuwait would have no legal leverage to ensure access for Kuwaiti citizens to the cure. Equally, whole strata of the world’s population, in particular the lower-income, may be priced out.

An even worse outcome is if current Intellectual Property actually prevents a cure being found in the first place. Vaccines and treatments will not be found quickly if all parties work in isolation. The law needs to provide a framework to allow findings and ideas to be exchanged or else there is, as Rimmer writes, a “danger that such competition for patent rights may undermine trust and cooperation within the research network”.⁽⁷⁵⁾

(72) John Finnis, ‘What is the Philosophy of Law?’ 59 (2) (2014) *The American Journal of Jurisprudence*, Volume, 133

(73) *ibid*

(74) Hannah Brennan et al, ‘A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health’ 18 1 (2017) *Yale J.L. & Tech*

(75) Matthew Rimmer, ‘The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines’, 5(2) (2004) *Melbourne Journal of International Law* 335

IP law is also dictating our response to COVID-19 by providing an intricate mesh of related rights. As well as the patents for pharmaceutical vaccines and drugs, there are also copyright issues regarding IT software for ventilators, for instance, and their user manuals. Equally, trade secret Intellectual Property law stands in the way of data sharing as it applies to keep information confidential. Added to this is the fact that patents and copyright must be filed in multiple countries and/or regions. The expiry date for each is not the same. Licencing arrangements might already be in place. Governments will need to act quickly to ensure supply to a 'miracle' cure/treatment but may find themselves bogged down, trying desperately to disentangle the web of different Intellectual Property rights, causing significant delays.

IP Rights: the potential for abuse

The risk of being held captive to drug companies by their use of intellectual property law during public health crises is not new. Post 9/11, when US authorities believed there was a threat of anthrax attacks,⁽⁷⁶⁾ the Intellectual Property rights for the only approved drug to treat anthrax, ciprofloxacin, were owned by Bayer.⁽⁷⁷⁾ However, seemingly, the company would take twenty months to fulfil government production requests and refused to lower prices. Despite other producers offering to perform the task in three months, the company refused to authorise production of a generic version.⁽⁷⁸⁾

This was not a one-off: similar problems were encountered with outbreaks of SARS, MERS, HIV/Aids and H5N1. Drug accessibility for poorer nations depends on global Intellectual Property laws that create an appropriate and equitable framework.⁽⁷⁹⁾ There is what Yu refers to as a 'serious tension' between first and third world countries. The question is whether lessons have been learnt. As Yu says:

(76) USA Congressional Hearings, 'S. Hrg. 107-440 - Effective Responses To The Threat Of Bioterrorism' (October 9th 2011), Committee on Health, Education, Labor, and Pensions

(77) Keith Bradsher, 'A Nation Challenged: CIPRO; US says Bayer will cut costs of Anthrax drug', The New York Times (24 Oct. 2001)

(78) *ibid*

(79) Adrian Towse, Eric Keuffel, Hannah Kettler & David Ridley, 'Drugs and Vaccines for Developing Countries' in *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, (Ed. Patricia M. Danzon & Sean Nicholson, Oxford, 2012) 302

Will the global patent system be able to strike the balance between research and development initiatives and consumer costs?⁽⁸⁰⁾

Similar Intellectual Property problems have already been encountered regarding COVID-19 drugs. On 23rd March, the large pharma company, Gilead Sciences Inc, applied to the FDA under the Orphan Drug Act 1983,⁽⁸¹⁾ for orphan drug status for Remdesivir, an experimental but promising anti-viral drug. Orphan status is an added 7-year layer of Intellectual Property protection and incentive, aimed at encouraging research into drugs to treat rare diseases. The argument is that if a disease is very rare, there will never be a large demand for medicine, therefore, no company will pursue research as, financially, it makes no sense. This leaves victims of rare diseases without treatment. The European Medicines Agency (EMA) offers even more generous incentives than the US, granting 10-years of market exclusivity.⁽⁸²⁾ Shockingly to many, the FDA granted approval.

It is important to note, firstly, that Bayer was eventually 'forced' to backdown and agreed a major price reduction, under threat from the US Secretary of Health and Human Services.⁽⁸³⁾ Gilead actually applied to rescind the orphan status for Remdesivir only a couple of days later, stating that it was "waiving all benefits that accompany the designation" and that it recognised the "urgent public health needs".⁽⁸⁴⁾ Similarly, Roche in the Netherlands initially refused to share its testing expertise for COVID-19, causing major delays in testing but quickly backed down.⁽⁸⁵⁾ However, the capitulations were due to intense media scrutiny and public pressure, not - seemingly - from any fundamental change of heart by the companies.

(80) Peter Yu, 'SARS and the Patent Race: An Introduction to the "Patent Law, Social Policy, and Public Interest" Symposium' 22 (2004) Cardozo Arts and Entertainment Law Journal

(81) US Orphan Drug Act 1983

(82) European Medicines Agency, 'Orphan Incentives', available at: www.ema.europa.eu/en/human-regulatory/research-development/orphan-designation/orphan-incentives, accessed 2 May 2020

(83) 'Bayer Cuts Price of Anthrax Drug', The Guardian, London (24 October 2001)

(84) Gilead Company Statement, 'Gilead Sciences Statement on Request to Rescind Remdesivir Orphan Drug Designation', (2020)

(85) Ed Silverman, 'Roche Backpedals And Agrees To Provide A Solution For Covid-19 Tests In The Netherlands', Stat (27 March 2020)

Equally, it is important to ask why the orphan drug legal status was granted in the first place. Would Kuwait accord special protection in similar circumstances? One criterion for orphan drug status is that the disease targeted is very rare. COVID-19 is not 'rare'. Nor was it 'rare' in the middle of March. It has already been classified as a pandemic, a global threat, to the world population. Furthermore, the principle of no financial reward is equally hollow. By according orphan drug status to Remdesivir, the US authorities were effectively saying that no drug company would make a profit from finding a cure for COVID-19. A difficult position to maintain.

Furthermore, in the midst of global pandemonium and with focus elsewhere, some Intellectual Property laws are actually being tightened, without due transparency. Recently, Senator Ben Sasse introduced a bill ostensibly to limit medical litigation re Intellectual Property relating to COVID-19 but actually also constituting a 'patent grab' for large medical companies, giving an extra ten years of patent protection.⁽⁸⁶⁾ This seems disingenuous, at best.

More direct criticism of states' attempts to abuse their power in Intellectual Property law is seen in the report in *Welt am Sonntag* that the American President had offered approx. \$1bn to entice German pharma company, CureVac, to move to the US to develop its vaccine there. The crucial condition, supposedly, was that any vaccine developed would belong solely to the US.⁽⁸⁷⁾ This was confirmed by senior German ministers and has been roundly condemned by politicians across the EU and elsewhere:⁽⁸⁸⁾ in an open letter, 33 European Members of Parliament said "we are alarmed and shocked by reported efforts by the United States' Government to obtain an exclusive licence on a purportedly

(86) 116th Congress, 2nd Session, Bill 'To Provide Certain Limitations On Liability For Actions Taken By Health Care Providers To Combat COVID-19' (March 2020) available at: www.sasse.senate.gov/public/_cache/files/9e3d592b-7741-4b1d-9d08-24b26d9d6c0f/facilitating-innovation-to-fight-coronavirus-act.pdf, accessed 20 April 2020

(87) 'Dams J. Donald Trump Greift Nach Deutscher Impfstoff-Firma' [Donald Trump reaches for German Vaccine Company]. *Welt am Sonntag* (15 March 2020)

(88) Owen Dyer, 'Covid-19: Trump Sought To Buy Vaccine Developer Exclusively For US, Say German Officials' 368 (2020) *BMJ* 2020

promising vaccine candidate developed by the German company CureVac”.⁽⁸⁹⁾ Reaction was swift, with Jens Spahn, the German health minister, confirming that CureVac would only develop vaccines “for the whole world, not for individual countries.”⁽⁹⁰⁾ However, this is hardly a guarantee. Also, it must be noted that, on 16 March, the day after the story hit the press, the EU offered CureVac \$80bn in support financing.⁽⁹¹⁾ Other countries or regions might not have such deep pockets and be so able to ward off potential buyers.

Another potential example of Intellectual Property exploitation can be seen earlier this year when, in Jan 2020, the Wuhan Institute of Virology of the Chinese Academy of Sciences in China tried to patent Remdesivir, the drug mentioned above, as a potential treatment for COVID-19. Remdesivir was already owned and patented by Gilead (including in China).⁽⁹²⁾ However, second-use or new-use Intellectual Property law allows a new patent to be filed for a drug that is Intellectual Property protected if the use of the patented drug is to treat a new disease.⁽⁹³⁾ Although there is not complete clarity on the nature of the filing, China’s patent request, at the start of a pandemic, was highly controversial. In their statement (as translated), the Chinese authorities claimed that their interest was not commercial and the application was “from the perspective of protecting national interests in accordance with international practice”.⁽⁹⁴⁾ However, under Intellectual Property law, patent protection also covers non-commercial uses. It is true that the two parties now seemingly are cooperating. But China’s application has been

(89) Letter from European Members of Parliament to European Commission, (March 2020).

(90) Owen Dyer, ‘Covid-19: Trump Sought To Buy Vaccine Developer Exclusively For US, Say German Officials’ 368 (2020) BMJ

(91) European Commission Press Release, ‘Coronavirus: Commission Offers Financing to Innovative Vaccines Company CureVac’ (16 March 2020)

(92) Yu Dawei & Denise Jia, ‘China Grants Three Patents to Gilead’s Remdesivir as Hopes Rise for Effective Treatment’ Caixin (27 Feb 2020).

(93) Wu Xiaoping and Zhang Mengqian (Wanhuida Intellectual Property), ‘Patent Applications on Inventions for Pharmaceutical Use’ China Business Law Journal (17 April 2020)

(94) Wuhan Institute of Virology, ‘Chinese Scholars Have Made Important Progress In Screening Anti-2019 New Coronavirus Drug’, Official Statement (translated) (4 Feb. 2020), available at: www.whiov.cas.cn/kjyz_105338/202002/t20200204_5497136.html, accessed 21 April 2020

called “ethically questionable and may have a negative impact on China’s public health and medical research cooperation efforts”.⁽⁹⁵⁾

The impact of big pharma companies’ Intellectual Property power plays will not be felt so directly in Kuwait or other GCC countries. However, this does not mean that Kuwait is less at risk, rather the opposite. Kuwaiti medical research is a growth area but not one that, as yet, is likely to challenge the world’s main actors. As such, there is no pressure from domestic pharma companies on the government, unlike the cases above. Equally, Kuwait does not have a significant drug production capacity and so the government has limited options - manufacturing generics is not feasible. Production facilities for generics in other GCC countries are increasing but are currently still relatively low. Therefore, Kuwait is vulnerable to the Intellectual Property laws of producing countries. The state is reliant on importing pharmaceuticals, hence on generic production by third countries. Kuwait, therefore, has a strong interest in allowing strict traditional Intellectual Property laws to be relaxed or circumvented via compulsory licencing, or new innovative methods.

Article 31 TRIPS: Traditional Intellectual Property Law Solutions in Times of Crisis

Instead of allowing proprietorial Intellectual Property players to enjoy complete exclusivity, there are several possible solutions to the crisis, allowing a more open access but also maintaining respect for the sole ownership model. This chapter analyses the traditional Intellectual Property exceptions to monopoly rights, as authorised under national law and Article 31 TRIPS.

Compulsory licencing and Article 31 TRIPS

According to the WHO, “compulsory licensing enables a competent government authority to license the use of a patented invention to a third

(95) Enrico Bonadio & Andrea Baldini, ‘COVID-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health’, 11 (2) (2020) European Journal of Risk Regulation, 390

party or government agency without the consent of the patent-holder”.⁽⁹⁶⁾ Hence, exclusive rights can be overridden.

Article 31 TRIPS gives international authorisation, stating that “where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government”, that will be legal if certain conditions are followed.⁽⁹⁷⁾

This is not a problem: nearly all national Intellectual Property law allows the sovereign country to exercise compulsory licencing and forcibly expropriate the Intellectual Property exclusivity rights of the Intellectual Property holder, without authorisation, in the case of overwhelming public interest. In the US, the government can “appropriate any invention necessary or convenient for natural defence or for beneficent public use...”.⁽⁹⁸⁾ A response to a pandemic is obviously of paramount national interest. The French recognise a public health justification for compulsory licencing under Law No. 68-1, 2 January 1968.⁽⁹⁹⁾

In GCC countries, a patent can be compulsorily taken over if it has not been used for three years (and other requirements are met).⁽¹⁰⁰⁾ More directly applicable, under Article 20(3), a GCC member country may grant a compulsory license if important national interests require it.⁽¹⁰¹⁾ This is drafted broadly, allowing any GCC government to use the patent rights in their own institute due to national interest.⁽¹⁰²⁾ Again, nothing could be more important to national interests than the health of its citizens in a pandemic, however there is no demand for national emergency. The GCC clause is very similar to the WTO: it requires fair compensation to be paid but does not require a mandatory offer to be made for a regular licence.

(96) World Trade Organisation (WTO), ‘Declaration on the TRIPS Agreement and Public Health’, Doha WTO Ministerial 2001, WT/MIN(01) /DEC/2

(97) Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 31

(98) US House Committee on Patents’ Report, 28 U.S.C. 1498, 1910

(99) French Law No. 68-1, 2 January 1968, Article L613-16, R 613-10 et seq.

(100) Gulf Cooperation Council Patent Regulation 1992, Article 19

(101) *ibid*, Article 20(3)

(102) *Ibid*

Compulsory licencing does not nullify the patent, rather it permits generic copies to be made, for which the patent holder must be compensated and “paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”.⁽¹⁰³⁾ However, neither “adequate remuneration” nor “economic value” are specifically defined.

The commitment to the principle of compulsory licencing was clearly affirmed and significantly strengthened by the 2001 Doha Declaration on TRIPS Agreement and Public Health. Part of the deliberate policy of TRIPS, according to Professor Nag, is to allow for global surroundings to form part of a country’s Intellectual Property legal policy.⁽¹⁰⁴⁾ The driving forces behind Doha were the importance of public health for all and recognition that a greater humanitarian approach was needed to ensure that low and middle-income countries had access to medicines.⁽¹⁰⁵⁾ Indeed, as Anderson states, “compulsory licensing inherently seems to advocate a moral and altruistic duty to protect society from unreasonable patent exclusivity”.⁽¹⁰⁶⁾ As India is a large producer of generic drugs, it is maybe not surprising that it was the Indian delegation that was the main protagonists behind the push for TRIPS to take a stronger position in favour of compulsory licencing.

It is important to note that, despite being generally accepted, the recognised right under Article 31 to compulsory licencing is not linked, per se, to any public emergency or national interests. Professor Shapiro writes that it is ‘unclear’ if a country is under an obligation to declare a public emergency before exercising its right to compulsory licencing.⁽¹⁰⁷⁾ Dziuba goes one step further and starts from the premise that Article 31

(103) Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 31(h)

(104) Aditi Diya Nag, ‘Th Bird Flu and the Invoking of TRIPS Article 31 National Emergency Exception’ (2007) 34 Syracuse Journal of International Law & Com 689

(105) Kyung-Bok Son, ‘Importance of the intellectual property system in attempting compulsory licensing of pharmaceuticals: a cross-sectional analysis’ 15 (2019) Global Health, 42

(106) Brin Anderson, ‘Better Access To Medicines: Why Countries Are Getting Tripped Up And Not Ratifying Article 31-Bis’, 1 (2) (2010) Case Western Reserve Journal of Law, Technology & the Internet

(107) Robert Shapiro, ‘Patent Infringement During a Time of National Emergency’, 37 (18) (2004) Winsor Rev. Legal & Soc., 50

provides an 'emergency exception to patent protection'.⁽¹⁰⁸⁾ However, it is not obvious where Shapiro finds this lack of clarity or Dziuba justifies this interpretation. From a purely semantic reading of the clause, public emergency is only relevant as regards a waiver of one of the conditions, not as a requirement for the right in its overarching form. TRIPS Article 31 serves as a permit, stipulating that compulsory licencing, if legal in domestic law, is also permissible under international Intellectual Property law but only on certain preconditions. It is not, however, a prerequisite to have a national emergency. Rather, one of the preconditions is the duty to try first to negotiate a voluntary licence. As regards compulsory licencing, Article 31(b) states that:

such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.⁽¹⁰⁹⁾

However, this can be overridden. Article 31(b) allows this requirement to be waived "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use".⁽¹¹⁰⁾ It is here that 'national emergency' or 'circumstances of extreme urgency' are relevant, to exempt the need for negotiation for a voluntary licence. Although this is not an issue in the case of a pandemic (clearly a case of extreme urgency, and also a declared national emergency in the vast majority of countries) the fact that the clause is often misinterpreted is worrying.

Other conditions include the that use must be non-exclusive,⁽¹¹¹⁾ the government cannot simply appropriate the patent rights for itself. The decision is also open to judicial review,⁽¹¹²⁾ as is the setting of remuneration which must be offered to the Intellectual Property holder.⁽¹¹³⁾

(108) Dawn Dziuba, "Trips Article 31bis and H1N1 Swine Flu: Any Emergency or Urgency Exception to Patent Protection?" (Jan 2010) *Indiana International & Comparative Law Review*

(109) *Trade-Related Aspects of Intellectual Property Rights (TRIPS)*, Article 31(b)

(110) *ibid*

(111) *ibid*, Article 31(d)

(112) *ibid*, Article 31(j)

(113) *ibid*, Articles 31(h) and 31(l)

In this manner, TRIPS is not prescriptive, rather it grants a broad flexibility, meaning “countries are free to determine the grounds for granting compulsory licences, and to determine what constitutes a national emergency”.⁽¹¹⁴⁾ Intellectual property protection of private companies can therefore be expropriated, without negotiation, if there are questions of national emergency, public interest, anticompetition practices or even for more general non-commercial state use. As Reichmann argues, “the very existence of these conditions only magnified the legitimacy of every complying government’s right to resort to compulsory licensing whenever its domestic self-interest so required”.⁽¹¹⁵⁾

Compulsory licensing was traditionally intended only to apply to the domestic market. This makes sense: if the compulsory licence overrides the proprietary nature of Intellectual Property law because, generally, the country is in a state of emergency, it makes little sense to allow that drug to be exported. A ‘national’ crisis is, by nature, domestic. Article 31(f) TRIPS expressly stipulated that products manufactured under a compulsory license had to be “predominantly for the supply of the domestic market”.⁽¹¹⁶⁾ ‘Predominantly’ presumably means over 50%, hence countries that had used their compulsory licensing right could only export less than half of total production output. Hence, countries such as Kuwait, with very limited drug production capacity, would be reliant on ‘Good Samaritan’ countries with a large drug production base, such as India, to issue their own compulsory licences and then export supplies to Kuwait.⁽¹¹⁷⁾ However, these friendly helper countries would be seriously limited under TRIPS law in terms of the amount of drug could be supplied. This put Kuwait, and many other countries, at risk and makes them even more beholden to generic producer countries.

However, under TRIPS new Article 31(bis), a temporary waiver of this requirement was agreed on 30 August 2003, and then approved as an

(114) World Trade Organisation (WTO), ‘Compulsory Licensing of Pharmaceuticals and TRIPS’, (TRIPS and Health)

(115) Jerome Reichmann, Compulsory Licensing Of Pharmaceutical Inventions: Evaluating The Options’, 37(2) (2009)

(116) Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 31(f)

(117) Jerome Reichmann, Compulsory Licensing Of Pharmaceutical Inventions: Evaluating The Options’, 37(2) (2009)

official TRIPS amendment in December 2005.⁽¹¹⁸⁾ This allowed countries to become an “eligible importing member” and import drugs made under a compulsory Intellectual Property licence, so effectively becoming the “first-ever compulsory licence for export of medical products”.⁽¹¹⁹⁾ This is a very significant change. Although it does not alter the fact that Kuwait is still dependent on friendly generic producer countries, it does mean that there is no export restriction on that third country’s production, hence freeing up supply.

However, the idea of compulsory licencing laws as a saviour for smaller countries remains a myth. Kuwait is a good case in point. Although the Kuwaiti Ministry of Health was very in favour of H1N1 compulsory licensing for H1N1 drugs, Dr. Donia Bastaki, the Head of Kuwait’s Drug Registration Department Pharmaceutical and Herbal Medicines Registration and Control Administration Ministry of Health says that:

there were negotiations on that but we couldn’t implement it because our local manufacturers didn’t manufacture the drug. The other option was to import the generic version from India but also it was not approved and accordingly we didn’t use the compulsory license and managed to get good prices for the reference drug “tamiflu”.⁽¹²⁰⁾

This shows that, while the theory of compulsory licencing works, in practice the power is not of much use if that country does not have the capacity to manufacture and using a third party as generic supplier is often complicated.

Moreover, the use of compulsory licencing is rare, mainly because it is politically very sensitive as it is effectively ‘confiscating’ the property right of a company in another country. Souillé at the University of Leiden writes that the traditional view is that ‘in practice, this measure is

(118) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Article 31(bis)

(119) William New, ‘It’s Official: TRIPS Health Amendment In Effect, First Ever To A WTO Agreement’ (23 Jan 2017) Intellectual Property Watch.

(120) Interviews with Dr Donia Bastaki, Head of Drug Registration Department Pharmaceutical and Herbal Medicines Registration and Control Administration Ministry of Health, Kuwait, 28 April 2020 and 1 May 2020.

never implemented’.⁽¹²¹⁾ Various studies have found it to be a “limited and sporadic” heavy-handed tool.⁽¹²²⁾

Indeed, many larger countries were so unhappy with the political message of the new TRIPS amendment allowing import of patented drugs manufactured under compulsory licences that a large number formally requested to opt out of being an ‘eligible importing member’ and declared themselves ‘ineligible’. In 2017, this was codified as a formal amendment to TRIPS. Consequently, pre COVID-19, there were 37 ‘ineligible’ WTO members, which voluntarily declared themselves not allowed to import patented property, such as medicines, that had been produced in another country under a compulsory licence. The countries who chose to opt out includes the United Kingdom, the United States, the EU, Japan, Canada, Australia and others.

Kuwait is not on the list. Indeed, none of the GCC countries is, either individually or collectively. Kuwait’s choice not to ally with the 37 countries above was sensible. With hindsight, given the COVID-19 crisis, it is shown to be even more sensible. Kuwait needs to be flexible to allow itself to the opportunity to access COVID-19 treatment drug and vaccines no matter where in the world they are being (legally) made. By being an ‘eligible importer’, this gives that flexibility and will allow the country to enter into deals with India or other generic producers if Big Pharma countries or their governments try and use global and domestic Intellectual Property law to squeeze out smaller countries.

What is somewhat ironic is that there has since been a complete backlash by many in the first-world countries above, who now realise they are also risk being denied access to crucial drugs. COVID-19 is a great leveller. On 7 April 2020, a large group of experts sent an open letter to the governments of the 37 WTO countries asking each country “to notify the WTO that they have changed their policy and now consider itself an eligible importing country, and in addition, to also use

(121) Raoul Souillé, ‘In Case Of A Cure: A Compulsory Licence As The Last Resort’ (University of Leiden Law 2020)

(122) Kyung-Bok Son, ‘Importance of the intellectual property system in attempting compulsory licensing of pharmaceuticals: a cross-sectional analysis’ 15 (2019) *Global Health*, 42

whatever legal means are available to revoke the opt-out as importing members, for goods manufactured under a compulsory license.”⁽¹²³⁾

Despite the paucity of countries exercising compulsory licencing rights, there have been occasional successful cases, such as in India, in 2010. The European Intellectual Property Review highlights how Nacto, a generic drug-maker in India, was granted a compulsory licence for a drug to fight cancer when India’s patent office decided that Bayer AG, the patent holder of the drug, had failed to make the drug available in the way it should to Indian citizens.⁽¹²⁴⁾ Following UN guidelines, Natco paid Bayer 6% royalties, allowing it to sell its generic version for a huge discount of 97% below Bayer’s price.

However, it is a rare case. Seemingly, compulsory licences are even explicitly allowed in China, under Articles 48-50 of domestic patent law, and yet the country has not yet ever issued one.⁽¹²⁵⁾ The controversy mentioned above regarding the Chinese application for a patent for Gilead’s drug Remdesivir could have been avoided if they had pursued the legal avenue of compulsory licencing. The fact they did not illustrates the problem. A senior lawyer in Beijing is quoted as saying that: “The government is compelled to avoid using the compulsory license because it has been making efforts to show China respects intellectual property rights and the abuse of compulsory licensing will draw international criticism.”⁽¹²⁶⁾

However, the Covid-19 pandemic is forcing states to rapidly amend domestic legislation to make their compulsory licencing laws more effective. Canada passed an amendment bill on 24 March 2020 whereby, under Part 12, the Canadian Patent Act,⁽¹²⁷⁾ inter alia, provides that “the

(123) James Love, ‘Open letter asking 37 WTO Members to declare themselves eligible to import medicines manufactured under compulsory license in another country, under 31bis of TRIPS Agreement’ (7 April 2020) Knowledge Ecology International.

(124) Enrico Bonadio, ‘Compulsory Licensing of Patents: The Bayer/Natco Case’ 10 (2012) European Intellectual Property Review 719

(125) Enrico Bonadio & Andrea Baldini, ‘COVID-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health’, 11 (2) (2020) European Journal of Risk Regulation, 390

(126) Bloomberg News, ‘China wants to patent Gilead’s experimental coronavirus drug’ (2 May 2020)

(127) Canada Patent Act 1985, Part 12,

Commissioner shall, on the application of the Minister of Health, authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern”.⁽¹²⁸⁾ Ecuador, Chile and Brazil are all in the process of reviewing and amending their domestic legislation.⁽¹²⁹⁾ Germany has recently passed the ‘Act for Protecting the Population in the Event of an Epidemic Situation of National Importance’,⁽¹³⁰⁾ which allows the German government to issues ‘use orders’ for patents in the interest of public welfare, effectively suspending patent rights. Equally, in France, the recent emergency law No. 2020-290⁽¹³¹⁾ added a new article to the public health code whereby, if there is a declared state of emergency, and if the singular purpose is to guarantee public health, the government has the right to requisition, as necessary, any services and/or goods to tackle the public health crisis. Also, even more broadly, the government may take all measures, as appropriate and on condition that the action is proportionate, so as to provide patients with access to all medical treatments, as needed, to combat the virus. Compulsory licencing, therefore, provides one solution to the problem of the sole ownership Intellectual Property in times of crisis. The Health Minister of France recently stated “I do not exclude the possibility of applying for compulsory licenses or price ceilings for drugs that would not be produced in France”⁽¹³²⁾

(128) House of Commons of Canada Bill, ‘C-13An Act respecting certain measures in response to COVID-19’, s.19.4(1), 24 March 2020

(129) , ‘Legislative Committee in Ecuador approves resolution on compulsory licensing of patents relating to the coronavirus’ (20 March 2020), Knowledge Ecology International; Resolution 896, Chile Chamber of Deputies, 2020: ‘Resolution for the granting of non-voluntary licenses referred to in article 51 n° 2 of industrial property law n° 19.030 to facilitate access and availability of medicines and technologies for the prevention, treatment and cure of coronavirus covid-19’, English translation available at < www.keionline.org/chilean-covid-resolution > , accessed 2 May 2020

(130) Bundesministerium für Gesundheit, (Ministry for Health: Germany) ‘Gesetz Zum Schutz Der Bevölkerung Bei Einer Epidemischen Lage Von Nationaler Tragweite’, (27 March 2020) available < <https://www.bundesgesundheitsministerium.de/covid-19-bevoelkerungsschutz-2.html> > accessed 16th September 2020

(131) LOI n° 2020-290 Du 23 Mars 2020 D’urgence Pour Faire Face L’épidémie De Covid-19 (Emergency Law to Deal With Covid-19 Epidemic) No. 2020-290, 23 March 2020 (France)

(132) Public sitting of March 19, 2020 in the French Senate: www.senat.fr/cra/s20200319/s20200319.pdf

Dr. Donia Bastaki, the Head of Kuwait's Drug Registration Department Pharmaceutical and Herbal Medicines Registration and Control Administration Ministry of Health, also stated: "certainly in the COVID-19 pandemic, we will definitely use the compulsory license".⁽¹³³⁾ However, although a country like France has options, this is not of much use to countries like Kuwait without generic production facilities or guaranteed help from a friendly third-party country, as shown by the failure of compulsory licencing in Kuwait during the H1N1 outbreak.⁽¹³⁴⁾

Intellectual Property: A New Collaborative Approach?

Although the traditional solution of compulsory Intellectual Property licencing has appeal and, due to the strains of the Covid-19 outbreak, seems to be more becoming more readily accepted, it is not the only way. Alternative new and collaborative approaches are being proposed. The aim is to bring the world together, as a team, to work collectively to find a cure/vaccine to help defeat the pandemic. This requires thinking outside the box. There is no reason to be bound by conventional Intellectual Property thoughts and teachings. It seems obvious that together we are stronger than the sum of our parts. This is not a completely novel idea,⁽¹³⁵⁾ especially for medical drugs. However, it has never been properly implemented in previous health scares, probably because - thankfully - other potential crises (SARS, H1N1, H5N1, MERS etc) never reached the stage of a pandemic. However, COVID-19 is different. Researchers need to share information, share data, share strategies, and share ideas. And this open pooling of ideas will not be to the detriment of the pharma companies: reputations will be made as companies realise that, as Shulman argues, there is a "huge payoff that can result when researchers put aside visions of patents and glory for their individual laboratories".⁽¹³⁶⁾

(133) Interviews with Dr Donia Bastaki, Head of Drug Registration Department Pharmaceutical and Herbal Medicines Registration and Control Administration Ministry of Health, Kuwait, 28 April 2020 and 1 May 2020.

(134) *ibid*

(135) Jeanne Clark et al, 'Patent Pools: A Solution to the Problem of Access in Biotechnology Patents', United States Patent and Trademark Office (2000)

(136) Seth Shulman, 'Thinking Like a Virus: The Success of a Global Network in Identifying the Severe Acute Respiratory Syndrome, or SARS Pathogen' 106 (2003) *Technology Review* 74

Patent Pools

A powerful and more radical solution is to create a worldwide patent pool. A patent pool has been defined as:

the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool.⁽¹³⁷⁾

This involves forming a voluntary pool that would collect existing patent rights, and - for an all-encompassing pool - trade secret rights, data from test and trials and any other relevant information that, if shared, researchers would find useful for developing vaccines, drugs and/or diagnostics.⁽¹³⁸⁾ From a functional point of view, the most commonly touted version would therefore allow other researchers or developers wanting to use that Intellectual Property to seek a license from the pool against the payment of royalties, enabling generic drugs to be made, or different drugs be developed based on the existing patented techniques or chemicals, without fear of litigation.⁽¹³⁹⁾ Complete open access is also possible. As a voluntary instrument, success is dependent on “the willingness of pharmaceutical companies to participate and commit their Intellectual Property to the pool”.⁽¹⁴⁰⁾ This would make all important COVID-19-related drugs and data open to other scientists so that there are no barriers to progress. The key principle is to have a communal pool, to bring researchers from around the world together in their joint goal.

Patent pools have been used previously, in a limited way, as seen with Medicines Patent Pool (MPP), which claims to be the “first patent pool with a clear public health mandate”,⁽¹⁴¹⁾ and is a UN-backed

(137) Jeanne Clark et al, 'Patent Pools: A Solution to the Problem of Access in Biotechnology Patents', United States Patent and Trademark Office (2000)

(138) E. Sukkar, 'Patent pools: an idea whose time has come', *BMJ* (2009) 338

(139) Jorge Bermudez and Ellen 't Hoen, 'The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good' 4 (Jan 2010) *The Open AIDS Journal* 37

(140) *ibid*

(141) Estaban Burrone, 'Patent Pooling in Public Health', in Margaret Chon, Pedro Roffe, Ahmed Abdel-Latif (Eds), *The Cambridge Handbook on Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development* (CUP 2018). see also the United Nations-backed Medicines Patent Pool (MPP)

organisation, also backed by the WHO, dedicated to public health. Its main work to date has been on licences related to HIV, tuberculosis, and hepatitis C. Indeed, on 3 April 2020, MPP expanded its mandate. All health products/technology relevant to the global battle against COVID-19 are now included. Shortly prior to that, drug company, AbbVie, had informed MPP that, due to the pandemic, they would waive any Intellectual Property restrictions over their drugs lopinavir/ritonavir, allowing generic producers, thus becoming the first major pharma company to waive its rights to potentially enormous future profits from a possible effective treatment for Covid-19.⁽¹⁴²⁾

However, although MPP's mandate is "working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries", there have been many concerns about MPP licences not sufficiently including middle income countries because those countries are viewed as commercially very attractive for pharma companies.⁽¹⁴³⁾ This would conceivably be a concern for Kuwait, a rich country but without a pharmaceutical production base. Professor Contreras also highlights that MPP is not a patent pool, in the normal sense of the term. Rather, it is a "clearinghouse or intermediary that obtains inbound licenses from willing Intellectual Property holders and then sublicenses those rights to generic drug manufacturers operating in developing countries".⁽¹⁴⁴⁾ As such, it is rather an ad hoc arrangement which do not draw together all the Intellectual Property rights.

However, the patent pool solution regarding Covid-19, as proposed by Costa Rica and supported by World Intellectual Property Organization (WIPO) and the World Health Organization (WHO), has a more open basis and widespread support. In early March 2020, Costa Rica wrote a letter to the WHO, proposing the idea, as it was worried that

(142) Ellen 't Hoen, 'Covid-19 and comeback of compulsory licencing' *Medicines Law and Policy* (23 March 2020)

(143) Estaban Burreras, 'Patent Pooling in Public Health', in Margaret Chon, Pedro Roffe, Ahmed Abdel-Latif (Eds), *The Cambridge Handbook on Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development* (CUP 2018). See also the United Nations-backed Medicines Patent Pool (MPP)

(144) Jorge Contreras, 'Patents and Coronavirus - A Role for Patent Pools?' (13 April 2020) Infojustice (American University Program on Information Justice and Intellectual Property.

smaller countries would be locked out of access to anti-COVID-19 medicines.⁽¹⁴⁵⁾ The WHO director-general endorsed the idea, hoping that it would help create a powerful voluntary community comprising governments, NGOs, industry players, universities and non-profit organisations. This proved to be the case, with a quick uptake in support.⁽¹⁴⁶⁾ Interestingly, one serious advocate of the concept seemingly is the ex-chief patent officer at Gilead Sciences.

The EU is also strongly in favour of the concept, both in general and via the WHO patent pool initiative. The EU recently proposed a draft resolution to the World Health Association (WHA), a part of the WHO.⁽¹⁴⁷⁾ The idea, again, is to voluntarily pool Intellectual Property rights, as well as all other relevant data and information, in order to help ensure “equitable access” to all drugs, vaccines and other treatments and products that may help to overcome the virus.

Financial investment firms and fund managers have also recently thrown their support behind the idea. Resnik calls this a way of Intellectual Property law serving companies’ ‘enlightened self-interest’.⁽¹⁴⁸⁾ Indeed, this is a roll-out of the concept of sustainable investment. Drugs companies’ share prices depend on their attractiveness to investors. As such, three dozen pension funds, asset managers and insurers have sent a letter to more than fifteen important drug companies asking that “financial considerations should take second place in the global challenge of getting the coronavirus under control as quickly as possible”. The fund managers have said clearly that the drug firms’ reaction will be taken into account when they decide which firms to invest in during the coming months.

(145) Letter from the Costa Rican President and Minister of Health to the WHO, dated 23 March 2020, available at: www.healthpolicy-watch.org/wp-content/uploads/2020/03/Picture.png, accessed 5 May 2020

(146) Claire Cassidy, ‘WHO Director-General Remarks in support of global pooling of rights in COVID-19 Technologies and data, in open science and open data’ (6 April 2020) Knowledge Ecology International

(147) Draft of ‘EU proposal for a CONSOLIDATED zero draft on a WHA73: “Covid-19 Response”’ The 73rd World Health Association Assembly (17-21 May 2020).

(148) David Resnik, ‘A Biotechnology Patent Pool: An Idea Whose Time Has Come?’ 3(9) (2003) *Journal of Philosophy, Science and Law*

Open COVID Pledge: An Open Licence

A similar initiative is the 'Open COVID Pledge'. A patent pledge is defined by Ehrnsperger and Tietzea as a “publicly announced intervention by patent-owning entities ('pledgers') to out-license active patents to the restricted or unrestricted public free from or bound to certain conditions for a reasonable or no monetary compensation”.⁽¹⁴⁹⁾ Open licences allow the “copyright holder (creator or other rightholder) to grant the general public the legal permission to use their work”.⁽¹⁵⁰⁾ It does not grant a transfer of Intellectual Property rights to the public, simply gives legal permission for third parties to use the property.

For the Open COVID Pledge, a coalition of international scientists, experts, business people and lawyers is asking companies and other research organizations to pledge that their Intellectual Property will be freely available for anyone who needs it to further the battle against COVID-19. Two levels of commitment are possible: the first is simply a public statement of support for the initiative and the second is to actually sign the pledge, therefore granting a licence over some or all of that body's IP. The underlying ethos is to foster “creativity and generous sharing of knowledge” to allow practical scientific advances to be made as quickly as possible.⁽¹⁵¹⁾ Researchers need to focus on the scientific challenge and not be bogged down by fears about lawsuits. “The last thing people rushing to figure out how to prevent, treat, and stop this pandemic need is to worry about who owns what IP,” said Dr. Michael Eisen, Professor of Molecular and Cell Biology and HHMI investigator at UC Berkeley.⁽¹⁵²⁾

(149) Jonas Fabian Ehrnsperger & Frank Tietze, 'Patent Pledges, Open IP, Or Patent Pools? Developing Taxonomies In The Thicket Of Terminologies' 14(8) (2019) PLoS ONE

(150) European Commission, 'Open Licence and Intellectual Property Rights', Erasmus+ Programme Guide

(151) Jennifer Doudna, Executive Director of the Innovative Genomics Institute of UC Berkeley and UCSF, 'Patent Holders Urged To Take “Open Covid Pledge” For Quicker End To Pandemic' (9 April 2020)

(152) Michael Eisen, 'Patent Holders Urged To Take “Open Covid Pledge” For Quicker End To Pandemic' Infojustice (9 April 2020) (American University Program on Information Justice and Intellectual Property)

Institutions such as the Innovative Genomics Institute of UC Berkeley and UCSF, and Intel Inc, were two of the first to sign up.⁽¹⁵³⁾ On 20 April, Amazon, Facebook, Hewlett Packard Enterprise (HPE), IBM, Microsoft, and Sandia National Laboratories also joined the pledge, committing to “making all of their patents freely available to the public for use in the fight against COVID-19”.⁽¹⁵⁴⁾ That global giants such as Amazon and Microsoft are allowing others to use their IP, for free, is a major gamechanger in the world of intellectual property. It not only shows the enormity of the challenge that is posed by Covid-19 but that a disruptive, novel approach may well change the nature of Intellectual Property law, long after the crisis has (hopefully) passed.

In terms of form and given that the pandemic is - hopefully - temporary and the health community is not trying to assert rights over a company's Intellectual Property indefinitely, the full pledge consists of a licence. Three simple versions of this Intellectual Property licence are available, giving organisations a standard format whereby they give permission to the world to use any of their Intellectual Property rights (patent and copyright), free of royalty fees. Open Pledge Version 1.1 (OCL-PC v1.1) states that:

The Pledgor grants to every person and entity that wishes to accept it, a non-exclusive, royalty-free, worldwide, fully paid-up license (without the right to sublicense) under Pledgor's patents and copyrights that we have the right to license (the “Licensed IP”) to make, have made, use, sell, and import any patented invention, and reproduce, adapt, translate, distribute, perform, display, modify, create derivative works of and otherwise exploit any copyrights, solely for the purpose of diagnosing, preventing, containing, and treating COVID-19.⁽¹⁵⁵⁾

Two different end-dates are available. Version 1.0 runs from 1 December 2019 to one year after date on which the WHO declares

(153) Eric Steuer, 'Creative Commons to Steward the Open COVID Pledge', Open Covid Pledge (27th April 2020)

(154) *ibid*

(155) Open Covid Pledge Licence, Version 1.1.

officially the end to the COVID-19 pandemic. Version 1.1. has a termination date that is set to be the earlier of (1) the WHO declaration of the end of the COVID-19 pandemic or (2) 1 January 2023. A third alternative, OCL-P v1.1, is the same but only extends to patents, not copyright.

The Pledge also allows a company to create its own license. This is on the proviso that the terms of the freeform licence are at least as generous as the terms of the standard format Open COVID License. One company stipulated an obligation to inform as soon as the Intellectual Property was being used.⁽¹⁵⁶⁾ This provides flexibility, while guaranteeing respect for the main principles.

Separately, other world-leading universities such as Harvard, Stanford and the Massachusetts Institute of Technology have agreed to let their Intellectual Property be used freely to combat COVID-19.⁽¹⁵⁷⁾ Other variations are available too. This includes the COVID-19 Therapeutics Accelerator, a group of about fifteen famous pharma companies who will share some of their IP-protected proprietary information in a bid to further progress towards a cure. Oxford University Innovation also has publicly announced a very user-friendly, licensing framework to allow use of its Intellectual Property for relevant purposes during the pandemic. No royalties will be charged. Massachusetts Institute of Technology (MIT) and leading US universities such as Stanford, Yale and Harvard have also established the COVID-19 Technology Access Framework. These are mainly smaller and more select but all have the same common goal of opening the closed door of Intellectual Property to allow free and open access.

The Open COVID pledge, however, does throw up certain legal issues. Many companies have already negotiated licences which generate royalties in the classic method. It is unclear how this will affect different industry actors: as the National Law Review writes “such companies may already be using licensed intellectual property in projects that are

(156) Theresa Rakocy, 'The Open COVID Pledge: What Is It and Is It Right for You?' 10 (281) (2020) National Law Review

(157) Sheppard Mullin Richter & Hampton LLP, 'Open COVID Pledge Seeks to Make IP Available for Use in Ending COVID-19' JD Supra (17 April 2020)

now being directed to combat COVID-19, and their financial viability could be at risk”.⁽¹⁵⁸⁾ However, the point is that it creates a movement, with a different vision, and therefore it is hoped that all companies, whether signed up or not, will respect the spirit of the pledge. Public and media pressure may help in this regard.

An Intellectual Property 'Prize'

The fact that traditional legislative approaches are failing to balance the private incentive versus the public benefit dilemma is highlighted by the fact that certain actors have suggested side-stepping Intellectual Property issues altogether. One suggestion has been to offer a substantial prize to the first drug company to find a solution. This, it is claimed, would incentivise the drug companies but only be payable if the firm pledged to make the vaccine publicly available at zero or low cost.⁽¹⁵⁹⁾ The amount of the prize could be fixed or tied to the number of people vaccinated. The prize would “assure private-sector enterprises that they will be financially rewarded for a coronavirus vaccine while also ensuring that individuals at all income levels will be able to afford immunization”.⁽¹⁶⁰⁾

A prize/challenge approach incentivising progress is not new or radical. The UK Longitude Act 1714⁽¹⁶¹⁾ was one of many European initiatives centuries ago that famously offered very large prizes to inventors to solve the problem of how to determine a ship's exact longitude while at sea. A similar invention prize was offered in France, in the early 19th century, for inventing a solution for how to preserve and transport food.⁽¹⁶²⁾ More recently, US law 15 US Code 3719 that came into effect in 2012 allows for prize competitions with one category being for a “prize that rewards and spurs the development of solutions for a particular, well-defined problem”.⁽¹⁶³⁾

(158) Theresa Rakocy, 'The Open COVID Pledge: What Is It and Is It Right for You?' 10 (281) (2020) National Law Review

(159) Daniel Hemel & Lisa Larrimore Ouellette, 'Want a Corona Vaccine Fast? Here's a Solution' (4 March 2020) Time Magazine.

(160) *ibid*

(161) UK Longitude Act 1714

(162) Robert Curley, *Britannica Guide to Inventions that Changed the Modern World*, (Britannica Educational Publishing, 2010) 346

(163) US Law 15 US Code 3719

The idea of a prize is, therefore, not a gimmick but a different and potentially very interesting approach to Intellectual Property law. It echoes traditional successful approaches and, as Hemel and Ouellette write, “could bring us closer to a model in which private-sector innovation and public access to essential medicines are not antonyms”.⁽¹⁶⁴⁾

These open platform, collaborative ideas are not necessarily brand new. Back in 2004, Rimmer wrote that there is a “need to reform the patent system to deal with international collaborative research networks”.⁽¹⁶⁵⁾ However, with the arrival of a global pandemic, these issues have been pushed to the fore, this is not an issue that can continue simply to be debated.

Conclusion

The Prophet Mohammed said: “God will help the servant as long as the servant helps his brother”⁽¹⁶⁶⁾

It is traditionally believed that the sole ownership principle is essential for Intellectual Property law. However, the whole purpose of law is to serve society and the people. Intellectual Property law on the international plane, though, has developed in a way that has made that principle fade and lose its essence. Patent law is accepted in history as a monopoly, granting exclusive rights and outlawing competition. One justification is based on commercial arguments. But this should be read as the other side of the same coin: commercial benefits are there to induce corporations to provide a public service. As the US Supreme Court held:

[monopoly privileges] are neither unlimited nor primarily designed to provide a special private benefit. Rather, the limited grant is a means by which an important public purpose may be achieved.⁽¹⁶⁷⁾

(164) Daniel Hemel & Lisa Larrimore Ouellette, ‘Want a Corona Vaccine Fast? Here’s a Solution’ (4 March 2020) Time Magazine.

(165) Matthew Rimmer, ‘The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines’, (2004) 5(2) Melbourne Journal of International Law 335

(166) Abu Huraira reported: The Messenger of Allah, peace and blessings be upon him Saying Source: Sahih? Muslim 2699 Grade: Sahih (authentic) according to Muslim.

(167) Sony Corp. v. Universal Studios (1984) 464 U.S. 417, 429

In a time of global crisis, exclusive rights pose a threat to society, rather than a help. We need to secure creativity, but we also need to secure people's health and well-being. Al Sanhuri⁽¹⁶⁸⁾ recognised this delicate balance when he wrote that "the principle of justice should be a mix between individual justice and social justice". Article 1, Kuwaiti Civil Code, confirms the same essential philosophy:

in the absence of legislation, the judge's ruling must be in accordance with custom and the provisions of Islamic jurisprudence in a manner that is consistent with the interest of the country, thus recognising the importance of the social good of its citizens.⁽¹⁶⁹⁾

In the face of a global pandemic, social justice trumps the individual's rights.

By the time this article is read, it is sincerely hoped that the worst of this Covid-19 crisis is behind us. However, this pandemic is not finished, and another wave, a mutation or indeed another pandemic are all possible. It is for this reason that, unlike the previous attempts at open licencing during outbreaks of SARS, H1N1 etc., a new approach to Intellectual Property law is not just rooted in the COVID-19 threat but in the need to address the problem for the future too.

A vital part of the COVID-19 challenge is to (a) find drugs that can cure or prevent an infection, and (b) make sure that those drugs are widely available to the public. Intellectual Property law currently is an encumbrance to that. European Members of Parliament write that "we cannot allow patients to be refused care because of financial constraints or shortages resulting from manufacturing or supply constraints".⁽¹⁷⁰⁾ Kuwait, and other GCC countries do not have a sufficiently advanced pharmaceutical industry and so are reliant on other countries, meaning they are vulnerable to Intellectual Property constraints.

(168) Al Sanhuri, Al Waseet, 'Chapter 3: The Social Duty Of The Property Law' (1967)

(169) Kuwaiti Civil Code, Law No. 67, 1980

(170) Grace Ren, 'European Parliament Members Urge Open Licensing For Covid-19 Products Financed Through Eu Grants', (27 March 2020) Health Policy Watch

Wider use and acceptance of compulsory licencing is one solution. Even the threat of use might have some effect.⁽¹⁷¹⁾ Indeed, the Doha declaration expressly recognised that:

WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing.”⁽¹⁷²⁾

However, countries have been reluctant to use powers under Article 31, even when in a position to do so, for fear of litigation. Big Pharma companies are powerful players and smaller countries in particular will be deterred from independently exercising their legal Intellectual Property rights.

An open licencing system is the way forward. Picciotto calls for a ‘global public welfare standard’.⁽¹⁷³⁾ Derclaye and Taylor argue that the jurisprudential basis for this is a utilitarian one but not one based on the income gauge of utilitarianism, as per the Chicago School of Law and Economics, which is fundamentally flawed, being based on the premise that maximising one’s happiness is only measured by wealth.⁽¹⁷⁴⁾ Rather, Intellectual Property should be based on the concept of ‘well-being’, using ‘markers’ of well-being to correlate the many different definitions. This is controversial but so is the concept of wealth accumulation as the basis of all happiness.⁽¹⁷⁵⁾

Worldwide support of various forms of what is effectively open licencing, via the diverse methods of patent pools, the Open Pledge and smaller group initiatives, shows the flexibility of the new approach. However, if the reaction is too piecemeal, it risks losing its power and influence and will become fragmented. Although the individual efforts of

(171) Gorik Ooms and Johanna Hanefeld, ‘Threat Of Compulsory Licences Could Increase Access To Essential Medicines’, (2019), *BMJ* 365

(172) World Trade Organisation (WTO), ‘Declaration on the TRIPS Agreement and Public Health’, Doha WTO Ministerial 2001, WT/MIN(01) /DEC/2

(173) Sol Picciotto, ‘Defending the Public Interest in TRIPS and the WTO’ in P. Drahos & R. Mayne (eds) *Global Intellectual Property Rights*, (Palgrave Macmillan, London, 2002)

(174) Estelle Derclaye & Tim Taylor, ‘Happy IP: Replacing the Law and Economics Justification for Intellectual Property Rights with a Well-being Approach’, 37 (4) (2015) *European Intellectual Property Review*

(175) *ibid*

many of the major players in the Intellectual Property market are to be welcomed, a more cohesive system would be preferable.

As such, the WHO and WIPO must work together and take the lead in introducing a centralised COVID-19 patent pool as a true open platform to cover Intellectual Property rights concerning drugs, vaccines, tests, chemicals, technologies and data relating to COVID-19, on free or easily affordable licencing terms. Speed is essential. As Professor Contreras writes: the WHO “must act quickly and decisively in defining the details of the proposed arrangement and in persuading patent holders in both the public and private sectors to join this worthwhile effort”.⁽¹⁷⁶⁾ This will not only act against possible Intellectual Property abuse, from a negative stance, but also form a positive movement, expounding the benefits of collaboration and knowledge sharing. A rapid response is essential: the current groundswell of political, commercial and legal support must not be lost.

This proposed innovation is not a radical change in the underlying principles of intellectual property rights or the principles of their protection. Patent protection serves a very important function. Rather, it is an interpretation of those principles in a manner that highlight the importance of achieving knowledge for all, especially in times of crisis. The right of its owner is reserved, as respect for their right to their original work, but access and availability is granted to all, as needed, to serve humanity.

To highlight the importance of this issue, both from a legal standpoint and as a policy matter concerning the citizens of Kuwait, a letter is being sent to the Kuwaiti Minister of Health and the Kuwaiti Patent Office. This letter is a warning to the authorities of the potential risks of the current legal situation and highlights the scope for great benefit if a new approach is adopted going forward. We may escape this pandemic, but we may not escape the next one. Intellectual Property law needs to be a legal tool for help, not hindrance.

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جائحة كورونا بين تاريخ فلسفة حق الاستثناء في براءة الاختراع لحماية الملكية الفكرية ووظيفة الحق الاجتماعية دراسة تحليلية نقدية

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ملخص:

عندما ننظر في التاريخ نجد أن فلسفة الاستثناء في حق الملكية الفكرية صيغت لحفظ حقوق الأشخاص في إنتاجهم الفكري، إذ إن الحق الاستثنائي للملكية الفكرية هو بلا شك الحافز المشجع للابتكار والإبداع لدى المخترعين والعلماء، ولكن فلسفة هذا الحق - وإن كانت مهمة - فإنها قد تخفق في بعض الحالات الاستثنائية التي تواجه المجتمع مثل جائحة كوفيد ١٩ -، حيث إن بعض مبادئ قانون الملكية الفكرية الواردة في المعاهدات التي تمت المصادقة عليها من دولة الكويت مثل التريس وبيرن وباريس وقانون ٧١ لسنة ٢٠١٣ بإصدار براءات الاختراع لدول مجلس التعاون الخليجي، وأيضاً قانون حقوق الملكية الفكرية رقم ٧٥ لسنة ٢٠١٩، قد لا تسعفنا في ظل وجود مثل هذه الجائحة.

وقد نرى أحياناً تعسفاً في استخدام الحق الاستثنائي أو قصره فقط على شركات محددة أو حبسه لمدة معينة، وبالتالي يتم إيقاع أضرار جسيمة بالأشخاص والمجتمع، فمبدأ الاستثناء - وإن كان مهماً لحفظ حق صاحب الملكية الفكرية- إلا أنه يجب أن يتماشى مع الفلسفة التاريخية الراسخة؛ وهي أن القانون له أيضاً وظيفة اجتماعية نص عليها الدستور، والمادة ٣٠ من القانون المدني الكويتي.

وهنا تجب الموازنة بين الوظيفة الاجتماعية للحق وحفظ الحق الاستثنائي لصاحب هذه الملكية.

ولذا، أدركت منظمة الصحة العالمية حجم هذه المعضلة، ودعت إلى تبني فكرة جديدة لحقوق الملكية الفكرية؛ ألا وهي إنشاء (مجمع معرفي متاح لحقوق الملكية الفكرية) لعلاج كوفيد ١٩-، وهو نهج جديد سيجعل الأفكار والمعلومات متاحة ومتوفرة للبحث والتطوير.

على ضوء ما سبق، نقدم دراسة تاريخية تحليلية نقدية، ثم نقترح جملة من التوصيات والحلول ممكنة التطبيق في ظل القانون الكويتي.

