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# Second Medical Use Patents and Compensation for the Delay in Marketing Authorisations: The Curious Case of Vietnam

There has been a concern that developing countries which join new-generation FTAs might jeopardise their population's access to medicines because those FTAs mandate TRIPS-plus patent standards. This article, however, argues that Vietnam, through its unusual legislative steps, has avoided increasing patent protection for medicines without (yet) violating international obligations. Its practice is examined via two specific patent-related issues: second medical uses and compensation for the delay in marketing authorisations. Regarding the first issue, the author finds that the law is deliberately ambiguous, as it neither rejects nor allows second medical use inventions. Regarding the second issue, Vietnam's newly amended law in 2022 has arguably adopted a unique form of compensation: it waives the patent maintenance fees instead of extending the patent term. The paper concludes that because of the country's sluggish local industry as well as its legislators' struggle to keep pace with increasingly changing IP standards in the new FTAs, language ambiguity and lip service have become Vietnam's weapons of choice.

## I. Introduction

The beginning of IP globalisation was marked by the Paris Convention for the Protection of Industrial Property in 1883 and the Berne Convention for the Protection of Literary and Artistic Works in 1886. Since then, global IP governance has been further strengthened by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995, setting minimum protection of intellectual property (IP) rights. TRIPS has tipped the balance in favour of the pharmaceutical industry by imposing a mandatory patent regime for medical products and processes<sup>1</sup> for 20 years.<sup>2</sup>

Since TRIPS 'establishes minimum levels of protection that each government has to give to the IP of fellow WTO members',<sup>3</sup> it provides the 'floor', not the 'ceiling', for international standards. For example, patents will be granted for new, inventive and industrially applicable inventions in all fields of technology, but the definitions of newness, inventiveness and industrial application are left to the discretion of member states.<sup>4</sup> They can freely determine whether a new formulation of medicine, a new combination of different compounds or a new way of drug delivery meets patent eligibility. As another example, WTO members might extend the term of a drug patent beyond the prescribed

20-year period to compensate for the delay in the marketing authorisation. Taking advantage of TRIPS' floor of IP protection, subsequent bilateral or regional free trade agreements (FTAs) have incorporated standards dubbed 'TRIPS-plus' because they are higher than those required by TRIPS.

This article seeks to analyse the case of Vietnam, which exemplifies how a country with a low level of technological development has responded to a new wave of FTAs. Since 2018, Vietnam has signed a series of trade pacts: the CPTPP (Comprehensive and Progressive Agreement for Trans-Pacific Partnership),<sup>5</sup> the EVFTA (European Union–Vietnam Free Trade Agreement),<sup>6</sup> the UKVFTA (UK–Vietnam Free Trade Agreement)<sup>7</sup> and the RCEP (Regional Comprehensive Economic Partnership).<sup>8</sup> All

<sup>5</sup> CPTPP is the abbreviation for the Comprehensive and Progressive Agreement for Trans-Pacific Partnership, signed on 8 March 2018. CPTPP evolved from the Trans-Pacific Partnership (TPP), which never entered into force due to the withdrawal of the United States in January 2017. President Trump withdrew from the deal on his first day in office. See the USTR's announcement at <https://ustr.gov/sites/default/files/Press/Releases/1-30-17%20USTR%20Letter%20to%20TPP%20Depositary.pdf> accessed 11 February 2022.

<sup>6</sup> EVFTA is the abbreviation for the European Union–Vietnam Free Trade Agreement signed on 30 June 2019. The EVFTA came into force on 1 August 2020.

<sup>7</sup> UKVFTA is the abbreviation for the United Kingdom–Vietnam Free Trade Agreement signed on 29 December 2020. The UKVFTA came into force on 1 January 2021.

<sup>8</sup> RCEP is the abbreviation for the Regional Comprehensive Economic Partnership, which was signed on 15 November 2020 and came into force on 1 January 2022. It is a free trade agreement among 15 Asia-Pacific nations. Ten countries are members of the Association of Southeast Asian Nations (ASEAN), and the other five are Australia, China, Japan, New Zealand and the Republic of Korea. RCEP. Further discussion on RCEP IP can be found in María Vázquez Callo-Müller and Pratyush Nath Upreti, 'RCEP IP Chapter: Another TRIPS-Plus Agreement?' [2021] GRUR International 667–71.

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<sup>1</sup> TRIPS, art 27.1.

<sup>2</sup> TRIPS, art 33.

<sup>3</sup> WTO, 'Intellectual property: protection and enforcement' <[https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm)> accessed 11 February 2022.

<sup>4</sup> TRIPS, art 27.1.

require TRIPS-plus standards on IP protection. There has been a concern that being a signatory in those FTAs will erode the Vietnamese population's access to medicines.<sup>9</sup> Given the country's low bargaining power in trade negotiations, such a concern is not unfounded. For instance, Vietnam is the least developed economy among 11 members of the CPTPP as judged by GPD per capita. The history of TRIPS scholarship also supported the view that rich countries imposed stringent IP standards on poorer countries through political influence and economic linkage.

This article, however, argues that Vietnam, through its unusual legislative steps, has avoided increasing patent protection for medicines without (yet) violating international obligations. Its practice will be analysed via two specific patent-related issues: second medical uses and compensation for the delay in marketing authorisations. The rest of this paper is organised as follows. Section II will study the historical development of Vietnam's patent law to appreciate its shift towards medicine patents. Sections III through V will then provide an overview of the country's pharmaceutical industry, explaining why Vietnam takes its particular stance on second medical uses and compensation for the delay in the marketing authorisations. Section 6 provides conclusions.

## II. The historical development of Vietnam's patent law

The earliest patent system in Vietnam can be dated as far back as the late 19th century, when France applied its 1844 Patent Law to its Indo-China colonies, including Vietnam, while the patents were issued in the mother country.<sup>10</sup> Before the era of French colonisation, there had been no written record of any similar local framework. Despite such an inceptive patent regime, it was not until 1981, six years after the country's reunification, that Vietnam established the first patent system via Ordinance 31-CP.<sup>11</sup> This event marked the starting point of sovereign Vietnamese IP legislation.

Following the then Soviet patent law, Ordinance 31-CP provided two types of protection for an invention: a patent and an inventor's certificate.<sup>12</sup> If the former recognised

the inventor as the patent owner and granted him exclusive rights, the latter only rewarded him with the right to be named as an inventor and limited remuneration.<sup>13</sup> The amount was calculated and imposed by the government, which owned the patent. During that period, Vietnam was a staunchly communist country with a centrally planned economy; the concept of private ownership did not exist concerning either tangible or intangible property.

Nevertheless, an economic crisis in the 1980s coupled with the collapse of the Soviet Union brought about change. In 1986, the government launched a political and economic reform campaign (*Đổi Mới*, known as Renovation in English) to transform the economy from state-controlled to market-oriented. Vietnam's newly created economic model has been officially termed as a 'socialist-oriented market economy'.<sup>14</sup> *Đổi Mới* also led to an overhaul of the country's legal system. Many areas of law, including IP, have shifted from the socialist-based model to those typically found in Western legal systems. In 1989, the government enacted a new Ordinance on the Protection of Industrial Property, marking a momentous change in the IP regime.<sup>15</sup> The concept of 'industrial property' was introduced for the first time. The government went as far as recognising patents as exclusive rights,<sup>16</sup> putting an end to the inventor's certificate.

In 1995, Vietnam got one step closer to gaining market economy status by applying to become a WTO member.<sup>17</sup> To comply with TRIPS, Vietnam enacted its first Civil Code in the same year, recognising IP rights as civil rights. This marked another milestone because IP rights were enshrined in the Civil Code,<sup>18</sup> the instrument having the highest legal status in Vietnam after the Constitution.<sup>19</sup>

Despite the enactment of the Civil Code, IP-related provisions were patchy and scattered over as many as 40 legal documents. What's more, the requirements were not always consistent with each other. In 2001, the US and Vietnam signed a sweeping bilateral trade agreement which devoted an entire section to IP rights.<sup>20</sup> Vietnam voluntarily adopted WTO standards for IP protection although it was not even a WTO member. As a scholar commented, the IP chapter was the most difficult to implement due to poor IP enforcement in Vietnam at that time.<sup>21</sup> However, the country's effort to

<sup>9</sup> Brook K Baker, 'Trans-Pacific Partnership Provisions in Intellectual Property, Transparency, and Investment Chapters Threaten Access to Medicines in the US and Elsewhere' (2016) 13(3) PLoS Med 1; Piergiuseppe Puscetdu, 'Assessing Access to Medicines in Preferential Trade Agreements: From the Trans-Pacific Partnership to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership' (2018) 49 IIC 1049.

<sup>10</sup> Décret rendant applicables en Indo-Chine les lois des 5 juillet 1844, 31 mai 1856 et 23 mai 1868, sur les brevets d'invention (Du 24 juin 1893), art 1 (in English: Decree making applicable in Indo-China the laws of 5 July 1844, 31 May 1856 and 23 May 1868, on patents of invention (from 24 June 1893).

<sup>11</sup> Điều lệ về cải tiến kỹ thuật, hợp lý hóa sản xuất và sáng chế [Ordinance on Technical Innovation, Production Rationalisations and Inventions], 23 January 1981 (hereinafter: Ordinance 31-CP).

<sup>12</sup> Ordinance 31-CP, art 14.1 When the USSR was formed, together with its communist ideology, the idea of the inventor's certificate also spread in other communist countries such as China. See John R Allison and Lianlian Lin, 'The Evolution of Chinese Attitudes toward Property Rights in Invention and Discovery' (1999) 20 University of Pennsylvania Journal of International Economic Law 735, 749. The inventor's certificates were maintained in the USSR until 1990 when the Soviet Union Patent Law was adopted, and titles were renamed 'patents'.

<sup>13</sup> Ordinance 31-CP, c 4.

<sup>14</sup> It was not until 2001 that the term 'socialist-oriented market economy' officially appeared in the National Congress of the Vietnamese Communist Party and later incorporated into the 1992 Constitution (amended in 2001).

<sup>15</sup> Pháp lệnh Bảo hộ Sở Hữu Công Nghiệp của Hội Đồng Nhà Nước số 13-LCT/HĐNN8 ngày 28/1/1989 [Ordinance on the Protection of Industrial Property, hereinafter: Ordinance 1989].

<sup>16</sup> Ordinance 1989, art 1.

<sup>17</sup> WTO, 'Vietnam' <[https://www.wto.org/english/thewto\\_e/acc\\_e/a1\\_vietnam\\_e.htm](https://www.wto.org/english/thewto_e/acc_e/a1_vietnam_e.htm)> accessed 22 December 2022.

<sup>18</sup> This Civil Code follows the continental tradition (838 articles, divided into seven Parts) rather than the general principles of the socialist tradition. See H Patrick Glenn, *Legal Traditions of the World: Sustainable diversity in law* (4th edn, CUP 2014) ch 9 at 37 (e-book).

<sup>19</sup> Private ownership had not been recognised in Vietnam until the adoption of the Constitution in 1992, under arts 15 and 16.

<sup>20</sup> The Agreement between the United States of America and the Socialist Republic of Vietnam on Trade Relations, c II.

<sup>21</sup> David A Gantz, 'Doi moi, the VBTA and WTO Accession: The Role of Lawyers in Vietnam's No Longer Cautious Embrace of Globalization' (2007) 41(3) International Lawyer 873, 882.

increase IP protection ‘signal[led] its desire to join the world economy’.<sup>22</sup> In 2005, two years before becoming a WTO member,<sup>23</sup> Vietnam codified its first-ever IP Law to regulate all IP rights under a single legal instrument.<sup>24</sup> The new IP law conformed with TRIPS and thus became closer to the standards of developed countries. It was the most comprehensive and detailed set of rules yet, marking Vietnam’s transition away from the command economy to its somewhat more liberal form – the socialist-oriented market economy. The adoption of the new law was a tremendous achievement following 19 years of *Đổi Mới* reforms and 10 years of WTO accession talks.

Since then, the 2005 IP Law has undergone three amendments. The first amendment occurred in 2009,<sup>25</sup> two years after Vietnam joined the WTO, to ensure that the law would be TRIPS-compliant. The second amendment was adopted in June 2019 to bring IP provisions in line with the CPTPP,<sup>26</sup> while the CPTPP entered into force in January. Before the ink was dry, in September 2020, the government released the third amendment to conform to the EVFTA and the RCEP. The EVFTA is regarded as ‘the most comprehensive trade agreement’ between the EU and a developing country and accelerates the goal of achieving ‘the early recognition of Vietnam’s market economy status’.<sup>27</sup> The RCEP forms the world’s largest trading bloc, representing almost a third of the global population and over \$26 trillion in GDP.<sup>28</sup> The amended law was adopted on 16 June 2022 and will take effect on 1 January 2023.<sup>29</sup>

In less than 20 years, Vietnam – a complete novice in the IP arena – has taken significant legislative steps to satisfy TRIPS-plus requirements. Nevertheless, the country’s social and economic infrastructure has struggled to meet the demands of the newly adopted goalpost in the latest FTAs. Firstly, as Vietnam’s society experienced the feudal regime and Confucianism for 1000 years, the general public has not been very receptive to the concept of IP as

private rights.<sup>30</sup> Although Vietnam has had the IP Law since 2005, for a long time, copying and imitation were considered part of the learning process and distribution of original works.<sup>31</sup> Secondly, the country’s judicial system, which strictly adheres to written law,<sup>32</sup> gives judges little room to interpret IP law, which has been inherently foreign to the Vietnamese. Thirdly, Vietnam is a socialist country built upon the Soviet Union model, in which private ownership was not encouraged or even forbidden. Although collective ownership has been abandoned to a great extent, its effect is still lingering.<sup>33</sup> The Soviet legacy can be found in Vietnam’s mode of legal thought – ‘hyper-positivism’ – where the judges (and other competent authorities) ‘mechanically “[apply]” legal texts to facts’<sup>34</sup> without discussing legal reasoning by balancing interests or referring to underlying policies.<sup>35</sup> This approach is best illustrated in Section IV.3, which presented a decision of Vietnam’s National Office of IP (NOIP) regarding a patent application for second medical uses. The legal loopholes are therefore only be filled by the National Assembly amending the laws or relevant ministries issuing by-law documents<sup>36</sup> to implement the law.

Last but not least, Vietnam lacks advanced technology and adequate R&D expenditure to develop IP products. Research activities have overwhelmingly focused on improving existing products rather than on ground-breaking R&D, which is prone to be more resource-intensive.<sup>37</sup> Vietnam’s R&D investment rate of 1.6% (2014–2017) is the lowest among Southeast Asian countries.<sup>38</sup>

<sup>22</sup> Cara A Boyle, ‘The U.S.-Vietnam Bilateral Trade Agreement: How Vietnam’s Efforts to Strengthen its Trademark and Copyright Laws Signal its Desire to Join the World Economy’ (2001) 14(1) *Loyola Consumer Law Review* 4.

<sup>23</sup> Vietnam joined the WTO on 11 January 2007.

<sup>24</sup> Vietnam does not have separate acts for different categories of IP rights. Instead, all IP rights are stipulated under the same legislation, Law No 50/2005/QH11 on Intellectual Property (IP Law). Again, this reflects the French colonial impact. Also, 2005 is when Vietnam’s government adopted or drafted a series of legislation such as Business Law, Commercial Law, Investment Law, Law on E-Transactions, etc, to speed up the WTO accession process. See WTO, ‘Chair says Viet Nam must complete bilaterals quickly to meet ambition’ <[https://www.wto.org/english/news\\_e/news05\\_e/acc\\_vietnam\\_20may05\\_e.htm](https://www.wto.org/english/news_e/news05_e/acc_vietnam_20may05_e.htm)> accessed 23 June 2022.

<sup>25</sup> Law No 36/2009/QH12 of 19 June 2009, amending and supplementing a Number of Articles of the Law on Intellectual Property.

<sup>26</sup> Law No 42/2019/QH14 of 14 June 2019, amending the Law on Insurance Business and the Law on Intellectual Property. This amended IP Law took effect retroactively from 14 January 2019, the date the CPTPP entered into force in Vietnam.

<sup>27</sup> EU-Vietnam Framework Agreement on Comprehensive Partnership and Cooperation (2012) (PCA), Annex: Joint Declaration on Market Economy Status.

<sup>28</sup> ‘RCEP: Asia-Pacific countries form world’s largest trading bloc’ (BBC, 16 November 2020) <<https://www.bbc.co.uk/news/world-asia-54949260>> accessed 11 February 2022.

<sup>29</sup> Law No 07/2022/QH15 of 16 June 2022, amending and supplementing a Number of Articles of the Law on Intellectual Property.

<sup>30</sup> William Alford, *To steal a book is an elegant offense. Intellectual Property Law in Chinese Civilization* (Stanford University Press 1995) 19–29. This is a well-known book discussing how Confucianism affects IP protection in China. Other scholars, nevertheless, hold different views. See Peter K Yu, ‘Common Misconceptions About Copyright Piracy’ (2003) 26 *Loy. L.A. Int’l & Comp. L. Rev* 127; Wei Shi, ‘Cultural Perplexity in Intellectual Property: Is Stealing a Book an Elegant Offense?’ (2006) 23(1) *North Carolina Journal of International Law and Commercial Regulation* 2.

<sup>31</sup> Tran Thi Lan Anh, ‘Vietnam’s Membership of the WTO: An Analysis of the Transformation of a Socialist Economy into an Open Economy with Special Reference to the TRIPS Regime and the Patent Law’ (PhD thesis, University of Leeds 2009) discussed how cultural and Confucian thoughts had shaped the Vietnamese society’s attitude towards IP protection.

<sup>32</sup> More discussion of Vietnam’s application of precedent at Ngoc Son Bui, ‘The Socialist Precedent’ (2019) 52 *Cornell International Law Journal* 421.

<sup>33</sup> Van Anh Le, ‘The Soviet Legacy on Vietnam’s IP law’ (unpublished manuscript; on file with the author).

<sup>34</sup> Rafał Mańko, ‘Survival of the Socialist Legal Tradition? A Polish Perspective’ (2013) 4(2) *Comparative Law Review* 1, 6.

<sup>35</sup> *ibid.*

<sup>36</sup> Hierarchically, Vietnam’s legal system consists of law and by-law documents. While the former includes the Constitution and any legislation passed by the National Assembly – the highest legislative body, the latter specifies content prescribed by the former. By-law documents may concretise and provide detailed provisions for the laws but must not deviate from them. By-law documents including ordinances, resolutions, decrees, decisions and circulars play an essential role in implementing the laws in Vietnam. Practically, without a by-law document, a law is hardly effectuated.

<sup>37</sup> Duong Thanh Long, ‘Impacts of National Patent Strategies and Policies toward Corporate Attitude and Investment in Patent Activities of Pharmaceutical Industry – Experience from Japan’ 13 (*Japan Patent Office*, October 2019) <[https://www.jpo.go.jp/e/news/kokusai/developing/training/thesis/document/index/2019\\_04.pdf](https://www.jpo.go.jp/e/news/kokusai/developing/training/thesis/document/index/2019_04.pdf)> accessed 14 February 2022.

<sup>38</sup> *ibid* 11.



It is therefore safe to argue that the country is not well prepared to deal with the TRIPS standards, not to mention TRIPS-plus. Consequently, Vietnam faces challenges in adapting to the new IP commitments. The need to modify the IP law twice (2019 and 2022) over a four-year period has illustrated such difficulties. Piecemeal regulatory revisions have caused problems for the private industry and relevant stakeholders to keep up with the changes. It also demonstrates the legislators' struggle to balance the requirement to honour Vietnam's international obligations while safeguarding the public interest. Even worse, the local pharmaceutical industry is mismatched with the stringent patent system.

### III. Vietnam's pharmaceutical industry and its patenting activities

Like many countries in the developing world, Vietnam has a limited pharmaceutical industry. Although it has about 180 pharmaceutical manufacturing enterprises and 224 domestic manufacturing establishments, those companies rarely engage in R&D activities to make new products, technologies and production processes.<sup>39</sup> The country's pharmaceutical industry conducts two main activities: making generic drugs with non-sophisticated components or producing finished products from imported materials for foreign pharmaceutical companies.

Vietnam's domestic sector, which heavily relies on imports from China and India, suffers from a growing trade deficit. It imports approximately 60% of pharmaceutical end products and 90% of active pharmaceutical ingredients and raw materials. Local companies have an R&D investment rate of 5%, which is in excess of three times the rate across the entire economy. However, the figure appears relatively meagre when benchmarked against the typical rate of 15% adopted by foreign firms domiciled in Vietnam.<sup>40</sup>

Pharmaceutical patenting activities also reflect the modest R&D investment of local companies. Foreign applicants file 90% of the country's pharmaceutical patents, and 10% are Vietnamese nationals. Between 2006 and 2017, only 28 patents were granted to local inventors. Even the largest local company, DHG PHARMA, which in 2018 had a net sales revenue of roughly \$175 million, has no record of a patent in the industry.<sup>41</sup>

Several reasons can explain why the country's pharmaceutical R&D investment is inadequate – if the threshold for adequate R&D spending is set at approximately 19% of revenues, which is the average figure measured over the past two decades in the US.<sup>42</sup> Firstly, Vietnam's

economy relies on sectors in which patenting is not considered essential for business operations, such as agriculture, textiles, food, furniture, plastics and paper.<sup>43</sup> Secondly, the centrally planned economic model, which was long maintained in the country, coupled with the two-decade US embargo after the Vietnam war, has contributed to the low level of technological development. Finally, society at large lacks awareness when it comes to protecting their IP rights and respecting such rights of others.

To sum up, Vietnam's pharmaceutical industry has reached an intermediate level of international integration where it can manufacture simple generics and export them to other countries. However, Vietnam must act quickly to reduce the pharmaceutical trade deficit and engage more in R&D activities to achieve a higher degree of self-sufficiency.

The following sections will investigate two specific patent issues – second medical uses and compensation for delays in marketing authorisations – since they have raised some concerns.

### IV. Second medical uses

Second medical use patents refer to the protection of new uses of a known pharmaceutical substance. Whether patent law should protect such an invention has long been the subject of much debate.<sup>44</sup> In the US, further uses can be protected as a medical treatment method under Sec. 101 of the US Patent Code.<sup>45</sup> In the EU, the situation is quite nuanced. Up until 2007, the European Patent Office (EPO) allowed the protection of 'the use of substance X in the manufacture of a medicament for the treatment of disease Y', also known as the 'Swiss-style' claim.<sup>46</sup> When the European Patent Convention (EPC) was revised in 2000 and came into force in 2007, the Swiss-style claim was no longer permitted, as Art. 54(5) now allows second (and subsequent) medical uses to be protected under the form 'substance X for use in the treatment of disease Y' if the use is new and inventive. This form is also termed the 'EPC 2000 claims'.<sup>47</sup>

In Asia, the law on this issue varies from one jurisdiction to another. The Philippines and South Korea<sup>48</sup> protect second medical use patents, but Indonesia does not.<sup>49</sup>

<sup>43</sup> The country is one of the world's largest paddy rice producers and the second-largest coffee exporter after Brazil. 'Agriculture in Vietnam – statistics & facts' (Statista, 2 February 2022) <<https://www.statista.com/topics/5653/agriculture-in-vietnam/#dossierKeyfigures>> accessed 22 December 2021.

<sup>44</sup> Clara Ducimetière, 'Second Medical Use Patents – Legal Treatment and Public Health Issues' (South Centre, December 2019) <[https://www.southcentre.int/wp-content/uploads/2019/12/RP101\\_Second-Medical-Use-Patents-Legal-Treatment-and-Public-Health-Issues\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2019/12/RP101_Second-Medical-Use-Patents-Legal-Treatment-and-Public-Health-Issues_EN.pdf)> accessed 3 August 2022; Philip W Grubb and others, *Patents for Chemicals, Pharmaceuticals, and Biotechnology. Fundamentals of Global Law, Practice, and Strategy* (6th edn, OUP 2016) 279–81.

<sup>45</sup> The United States Code Title 35, s 101: 'Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent, therefore, subject to the conditions and requirements of this title.'

<sup>46</sup> For more on the Swiss-style claim, see Grubb and others (n 44) 277–79.

<sup>47</sup> *ibid* 279–81.

<sup>48</sup> AIPPI, 'Summary Report. Second medical use and other second indication claims' (2014) 2 <[https://www.aippi.fr/upload/Totonto2014/sum-rep\\_q238\\_e\\_150814\\_final.pdf](https://www.aippi.fr/upload/Totonto2014/sum-rep_q238_e_150814_final.pdf)> accessed 26 December 21.

<sup>49</sup> Indonesian Patent Law No 14/2016, art 4(f).

<sup>39</sup> *ibid* 15.

<sup>40</sup> 'Vietnam – 2019 Health Care' (Business Centre of The British Business Group Vietnam) 3 <<http://www.ukabc.org.uk/wp-content/uploads/2019/04/Sector-Briefing-Healthcare-In-Vietnam-2019.pdf>> accessed 14 February 22.

<sup>41</sup> 'VietnamCredit: Vietnam's pharmaceutical market worth more than USD 5 billion' (FEBIS, 19 August 2020) <[https://www.febis.org/2020/08/19/vietnamcredit-vietnam-s-pharmaceutical-market-worth-more-than-usd-5-billion/#:~:text=According%20to%20the%20Drug%20Administration,standards%20\(good%20manufacturing%20practice%20\)>](https://www.febis.org/2020/08/19/vietnamcredit-vietnam-s-pharmaceutical-market-worth-more-than-usd-5-billion/#:~:text=According%20to%20the%20Drug%20Administration,standards%20(good%20manufacturing%20practice%20)>)> accessed 14 February 22.

<sup>42</sup> US Congressional Budget Office, 'Research and Development in the Pharmaceutical Industry' (Congressional Budget Office, April 2021) <<https://www.cbo.gov/publication/57126>> accessed 25 February 2022.

Indian authorities relied on Sec. 3(d) of the 1970 Indian Patents Act to reject the patent for such an invention, in this case Glivec.<sup>50</sup> For Vietnam, protection of second medical uses is deemed unavailable because national law is silent on this topic. The 2005 IP Law also excludes methods of medical treatment from patenting. However, the Vietnamese approach is much more complex than has been presumed<sup>51</sup> because of its deliberate legal ambiguity. If national law plainly prohibits second medical uses from patenting, the government might be challenged by its trading partners. Being lexically ambiguous, arguably, enables Vietnam's patent office (National Office of Intellectual Property – NOIP) to quietly deny use patents without attracting much global attention, which happened in the case of Glivec in India.

Nevertheless, only the TPP, the predecessor of the CPTPP, demanded patent protection for second medical uses. It required each party to make sure that 'patents are available for [...] *new uses of a known product* [emphasis added], new methods of using a known product, or new processes of using a known product'.<sup>52</sup> This US-backed IP provision sparked controversy until it was suspended due to the US withdrawal in 2017.<sup>53</sup> CPTPP members have highlighted that the removed provisions are only suspended, a distinction intended to signal that they could be reinstated if the United States decides to rejoin.

In the next part, the author will delve more into second medical uses under the current framework. But before that, the author will retrace Vietnam's previous approach, as the historical narrative has played a strong role in influencing the direction of change in the country's treatment of this issue.

## 1. The legal framework before the 2005 IP Law

Ordinance 31-CP, the first IP legislation after the Vietnam war, explicitly permitted patent protection for *a new use of a known substance*.<sup>54</sup> However, such a permissive approach did not translate into more patents, because pharmaceutical inventions were only given the inventor's certificate.<sup>55</sup> Meanwhile, what lies in the centre of patent law is exclusivity, the one that allows the owner to be the only beneficiary. The inventor's certificate took away such a privilege; as a result, Vietnamese patent protection for new uses of medicines was virtually 'toothless'.

In 2003, Vietnam adopted a by-law document – Circular No. 30/2003/TT-KHCN.<sup>56</sup> In contrast to

Ordinance 31-CP, where the wording openly allowed second medical uses, the language of Circular No. 30/2003 was much vaguer. It stated that only a technical solution or *the use* of a technical solution was entitled to patentability.<sup>57</sup> Implicit in such vagueness was the assumption that a use claim was a patentable subject matter.<sup>58</sup> However, the author of this paper found no record of such a patent having been granted following Circular No. 30/2003.

Although there is no written account explaining why Vietnam protected second medical use, understanding its political and social-economic conditions in the early 2000s can shed some light. While Vietnam has never been classified as a least-developed country,<sup>59</sup> it was a low-income country with a GNI per capita of \$500 in 2003.<sup>60</sup> Providing broad patent protection could be 'a carrot' to attract foreign direct investment to Vietnam in the wake of the economic and political transformation of *Đổi Mới*. Moreover, Vietnam lacked IP expertise and the resources to assess the impact of such protection on access to medicines. Nevertheless, the number of patent applications filed with the NOIP was too insignificant to have a meaningful impact on public health.<sup>61</sup>

## 2. The legal framework after the 2005 IP Law

Vietnamese laws possess a certain degree of opacity. So does the 2005 IP Law. It does not openly allow or exclude second medical use inventions. Article 4.12 defines an invention as a technical solution in the form of a product or a process intended to solve a problem by applying rules of nature.<sup>62</sup> Article 59 excludes certain subject matters, including treatment methods, from patentability. Reading these two articles together, it is unclear whether second medical uses meet patent eligibility criteria. Such ambivalence is particularly salient when compared with the clarity of the EPC. Article 53(c) of the EPC adopts a similar exclusion for treatment methods, but Art. 54(5)

<sup>57</sup> Circular No 30/2003, art 32.2.

<sup>58</sup> Nguyen Nguyet Dzung, 'Vietnam Patent Law. Substantive Law Provisions and Existing Uncertainties' (2007) 6 Chicago-Kent Journal of Intellectual Property 138, 142.

<sup>59</sup> UNCTAD, 'Viet Nam not an LDC, says UNCTAD' (UNCTAD, 6 June 2003) <<https://unctad.org/press-material/viet-nam-not-ldc-says-unctad>> accessed 22 December 2021.

<sup>60</sup> According to the World Bank's data, in 2021, the country is a low middle-income country with a GNI per capita of \$2,660.

<sup>61</sup> Although there is no data available for medicine patents in the 2000s, the total amount of patents filed with the NOIP was relatively small: 1,150 in 2003; 1,431 in 2004 and 1,947 in 2005. See WIPO – UNU Joint Research Project, 'Impact of the Intellectual Property System on Economic Growth. Fact-Finding Surveys and Analysis in the Asian Region. Country Report – Vietnam' (WIPO, 2007) 7 <[https://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/wipo\\_unu\\_07\\_vietnam.pdf](https://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/wipo_unu_07_vietnam.pdf)> accessed 25 November 21.

<sup>62</sup> This definition is similar to that of art 2(1) of the Japan Patent Act (art No 121 of 1959), which defines an invention as 'the highly advanced creation of technical ideas utilizing the laws of nature'. When drafting the 1995 Civil Code, Vietnamese legislators reviewed relevant laws in France, Germany, Thailand, Japan, China, Canada, the Russian Federation and Poland. Such experiential learning was mentioned in the Government's report on the Civil Code Project of the Socialist Republic of Vietnam at the 5th session, IX National Assembly, 7 June 1994 (Tờ trình của Chính phủ về dự án bộ luật Dân sự năm 1995 của nước cộng hoà xã hội chủ nghĩa Việt Nam tại kì họp thứ 5, Quốc hội khoá IX, ngày 7/6/1994).

<sup>50</sup> *Novartis AG and another v Union of India and others* W.P. Nos 24759 and 24760 of 2006.

<sup>51</sup> Ducimetière (n 44) 23.

<sup>52</sup> The TPP, IP Chapter, art 18.37.2.

<sup>53</sup> The Australian Department of Foreign Affairs and Trade, 'CPTPP suspensions explained' <<https://www.dfat.gov.au/trade/agreements/in-force/cptpp/outcomes-documents/Pages/cptpp-suspensions-explained>> accessed 16 February 22.

<sup>54</sup> Ordinance 31-CP, art 13(1).

<sup>55</sup> Ordinance 31-CP, art 15.

<sup>56</sup> Circular No 30/2003/TT-BKHCN of 5 November 2003, on the procedures for establishing industrial property rights to inventions/utility solutions.

grants patents for a new use provided that such use is not in the state of the art.

To clarify the ambiguity in the IP Law, the government issued a by-law document that provided further insights. Circular No. 01/2007/TT-BKHCN, Point 25.5.d(i) reads as follows: ‘The essential feature of a technical solution can be a function, *utility* [emphasis added] [...]’ Some practitioners happily assumed that ‘utility’ or a use was patentable if it amounted to an essential feature.<sup>63</sup> The joy did not last long, as Circular No. 1/2007 was amended in 2016.<sup>64</sup> A new sentence was quietly added to emphasise that ‘the functions and utility of a subject matter [...] are not essential features, but are the *purposes and results* [emphasis added] achieved by that subject matter’.<sup>65</sup> What is meant by that is anybody’s guess. Point 25.3 further provides that a subject matter of an application is deemed incompatible with the title of protection applied for [the invention] if it is not a technical solution, in particular failing to be either a product or a process’. Unlike other IP offices, which often rely on the novelty step to assess an invention of subsequent uses,<sup>66</sup> Vietnam’s NOIP adopts a definitional approach towards the ‘technical solution’ to reject such claims.<sup>67</sup>

However, the Regulation for Patent Examination detailed by the NOIP adds another layer of confusion and complexity to an already complex topic.<sup>68</sup> Like other legal instruments, the Regulation is equally obscure and perplexing. It does not dismiss second medical uses at the formal examination stage. But the Regulation requires the patent examiner to consider if the claim (the invention) implies any change in the structure and composition of the product compared with the prior art.<sup>69</sup> If the answer is no, the invention is not new. If the claim indicates some changes, such use might meet the threshold of newness.

The Regulation then goes further, stating that if the current form of a known substance is unsuitable for the use claim, the claim is new. If it is suitable, the claim is anticipated even though the substance may have never been described for that use (purpose).<sup>70</sup> One exception to this provision is the exclusion from patenting applied to methods for prevention, diagnosis or treatment of disease

practised on the human and animal body.<sup>71</sup> However, apparatuses and compounds for the treatment of disease remain patentable.

In conclusion, Vietnamese lawmakers have tried hard to address the controversy of second medical use patents.<sup>72</sup> Their attempt has not been truly successful, as the deliberate ambiguity has created a greater level of legal uncertainty. On the other hand, by not excluding such inventions from patenting, the government safeguards itself from a potential complaint of treating patentable subject matters differently. Vietnam is worried that other WTO members could challenge such treatment on the basis that it might violate the equal treatment principle of Art. 27.1 of TRIPS.<sup>73</sup> Although this concern sounds unfounded theoretically, discrimination was used (albeit unsuccessfully) to challenge the NOIP’s decision to reject an application for the second use of a known substance. That will be analysed next.

### 3. The real test of second medical use

The country’s nonsensical approach was tested in the case of International Application No. PCT/JP2006/318675. This patent application entered the national phase in Vietnam in August 2008 under No. 1-2008-00901. The applicant, a Japanese company – Otsuka Pharmaceutical – applied for a patent involving a combination drug containing probucol and a tetrazolylalkoxy-dihydrocarbostyryl derivative with superoxide suppressant effects. This medicine helps to prevent and treat cerebral infarction, arteriosclerosis, diabetes and various renal diseases.

In March 2014, the NOIP refused the application because the claims did not meet the novelty and inventiveness steps. The applicant filed an appeal against the decision in June. More than five years later, in November 2019, the NOIP issued Decision No. 5698/QD-SHTT, dismissing the appeal because the composition mentioned in the claim was anticipated in the prior art (D1: SEKIYA M. et al. American Journal of Cardiology 1998, Vol. 82, No. 2, 144-147, hereinafter: D1).

Although the appellant agreed with the NOIP that the composition was available in D1, it argued that D1 did not mention the potential treatment claimed by the invention. The NOIP, citing Point 25.5.d(i) of Circular No. 1/2007 (amended in 2016), counter-argued that the new treatment is not an essential feature of the invention but a result of its composition. Finding a new medical function of known components does not render an agent novel and inventive.

Otsuka Pharmaceutical made a case stating that Vietnam must protect second medical use inventions, as required by Art. 27 of TRIPS. This article obliges member states to grant patents for inventions in all technology fields except those contrary to public policy or morality (Art. 27.2) or

<sup>63</sup> Thang Duc Nguyen, ‘Patentability of Use Inventions in Vietnam’ (Tilleke & Gibbins, 18 May 2020) <<https://www.tilleke.com/insights/patentability-use-inventions-vietnam/#:~:text=In%20sum%2C%20use%20inventions%20are%20being%20refused%20in%20Vietnam.&text=%E2%80%9CAs%20a%20matter%20of%20principle,relating%20to%20second%20medical%20uses.%E2%80%9D>> accessed 22 December 2021. Other practitioners also shared this view during the discussion with the author during her research trip to Vietnam in June 2022.

<sup>64</sup> Circular No 16/2016/TT-BKHCN of 30 June 2016.

<sup>65</sup> Circular No 16/2016, art 23.b.

<sup>66</sup> See *Adhesive Dry Mounting v Trapp* (1910) 27 RPC 341 (UKIPO); Second Medical Indication: Switzerland [1984] OJ EPO 581; *IGF-I-Genentech/Method of administration*, I 1020/03 [2007] OJ EPO 204.

<sup>67</sup> Le Hoai Duong, ‘Patentability of new medical uses in Vietnam’ (Le & Le, 14 November 2018) <<https://www.lele.com.vn/index.php/en/news/261-patentability-of-new-medical-uses-in-vietnam>> accessed 25 November 21; ‘FAQ about Patent in Vietnam’ <<https://kenfoxlaw.com/faq-about-patent-in-vietnam>> accessed 25 November 21.

<sup>68</sup> Vietnam’s Regulation for Patent Examination 2010, art 22.2.2.5, pp 62-63.

<sup>69</sup> *ibid.*

<sup>70</sup> *ibid.*

<sup>71</sup> Vietnam’s IP Law, art 59.

<sup>72</sup> Discussion on the controversial nature of second medical uses can be found in Lionel Bently and others, *Intellectual Property Law* (5th edn, OUP 2018) 567-70; Nuno Pires de Carvalho, *The TRIPS Regime of Patents and Test Data* (5th edn, Wolters Kluwer 2018) 262-66.

<sup>73</sup> This view is based on the author’s discussion with a Vietnamese expert at the NOIP during her research trip to Vietnam in June 2022.



excluded subject matters (Art. 27.3). The NOIP disagreed and claimed that the invention was refused because it did not meet the novelty and inventiveness thresholds in Art. 27.1. The other parts of the article were irrelevant since the subject matter was not prevented from commercial exploitation or an excluded subject matter.

Otsuka Pharmaceutical finally reasoned that since many patent offices such as the USPTO and the EPO have granted patents for the invention, it is patentable. The NOIP dismissed this argument, affirming that Vietnam's patent law differs from other countries, particularly concerning '*the matter of new use of a known substance*' [emphasis added].

By Decision No. 5698/QĐ-SHTT, Vietnam's approach towards second medical use inventions has been firmly clarified. Although Vietnam is part of many FTAs, no other FTA apart from the short-lived TPP makes similar demands. The newly amended IP law does not modify the provisions concerning second use patents; thus, getting protection for such inventions remains challenging.

## V. Compensation for the marketing approval delay

### 1. Pharmaceutical research and development

Developing a medicine is complex, laborious, costly and lengthy, as it can take 10 to 15 years to place a safe and efficacious drug on the market. A patented medicine is often wrongly believed to monopolise a market throughout 20 years of protection. However, there is a difference between the 'theoretical' patent term and the 'commercial' patent term. The 'theoretical' term usually commences at the discovery stage, when scientists search for a 'lead compound' that can potentially become a medicine. The sponsor company will file a patent application soon after the lead compound is found. To be patented, the new compound needs to be new, inventive and have industrial application, regardless of whether it works safely and efficaciously on patients.

Nevertheless, if the company wishes to sell that medicine, it must obtain the corresponding marketing authorisation, which can take up to 12 years.<sup>74</sup> The 'commercial' term begins when the company obtains the marketing authorisation to sell the medicine. As a result of the overlap between these two stages, the 'theoretical' patent term starts much earlier than the 'commercial' term. When the approved drug reaches the market, the 'commercial' patent time may have less than half of its 20-year period left to run.<sup>75</sup> Such a delay between patenting and marketing a new medicine erodes the practical patent life.

### 2. Compensation for the delay in marketing authorisations

Many countries have adopted different regimes to compensate for the delay in marketing authorisations. The

US's Hatch-Waxman Act provides that a patent may be extended up to five years if the extension does not result in a total remaining patent term of more than 14 years.<sup>76</sup> These 14 years are measured from the date the drug product receives the regulatory approval until patent expiration (with term extension).<sup>77</sup> Similarly, Japan's Patents Act allows an extension of up to five years from the date of patent grant or when the clinical trial starts, whichever is later, to the date of marketing approval.<sup>78</sup> Unlike the US, a product would be eligible for patent extension under the Japanese Patents Act even if the product's patent life after approval has 14 or more years.

The EU has a separate form of compensation – the supplementary protection certificate (SPC).<sup>79</sup> This *sui generis* IP right extends the patent term for specific pharmaceutical and plant protection products. An SPC will enter into force once the standard patent term expires. It has a duration equal to the delay period between patent filing and the grant of the marketing authorisation. No SPC can be obtained if this period is less than five years. If the delay is between five and ten years, an SPC for up to five years may be granted.<sup>80</sup> If this period is more than ten years, any SPC granted will have a maximum five-year term.<sup>81</sup> The SPC aims to allow the right holder to 'enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product [...] first obtains authorisation to be placed on the market in the Community'.<sup>82</sup> Unlike the US and Japan, where the date of patent grant and the duration of clinical testing are relevant to the patent extension, it is not the case in the EU.

### 3. Compensation required in the EVFTA and Vietnam's amendment

The EU incorporated a compensation clause through the EVFTA. Article 12.40.2 requires both parties to 'provide for an adequate and effective mechanism to compensate the patent owner for the reduction in the effective patent life resulting from unreasonable delays in granting the first marketing authorisation'. Although this article does not mandate any specific form of compensation, it suggests 'an extension' of the patent term equal to the time of the delay while not exceeding two years.<sup>83</sup>

As Vietnam's current law does not operate any compensation scheme for such delay, the 2020 draft amendment put forward two options on which it was seeking public consultation. The amendment explicitly referenced the EVFTA to justify incorporating a new article – Art. 131a.<sup>84</sup>

<sup>76</sup> 35 USC 156 (b). Patent extension can also be applied to other products subject to regulatory approval for marketing, such as agrochemicals.

<sup>77</sup> 35 USC 156 (c).

<sup>78</sup> Japan's Patents Act 1998, art 67(2).

<sup>79</sup> Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version).

<sup>80</sup> Regulation (EC) No 469/2009, art 13

<sup>81</sup> *ibid.*

<sup>82</sup> Regulation (EC) No 469/2009, Recital 9.

<sup>83</sup> art 12.40.2 reads as follows: 'Such compensation may be in the form of an extension of the duration of the rights conferred by patent protection, equal to the time by which the period referred to in the footnote to this paragraph is exceeded. The maximum duration of this extension shall not exceed two years.'

<sup>84</sup> Vietnam's draft amendment of IP Law – Version 2.0 dated 17 November 2020.

<sup>74</sup> Above n 44 at 170.

<sup>75</sup> In the UK, the effective patent life fell from 13 years in 1960 to less than five years in 1986. In the US, the commercial patent term fell from 16 years in the early 1960s to below eight years in the early 1980s. Between 1960 and 1986, some patents expired when they received marketing approval in Germany. See Aubrey Silberston, *Patent Policy: Is the Pharmaceutical Industry a Special Case?* (Scrip 1989) 29-31.

- Option 1: The patent holder will be waived the patent maintenance fee associated with the delay in obtaining the marketing authorisation. If the patent owner has paid the delay's maintenance fee, the payment will either be deducted from the next maintenance period or refunded.
- Option 2: After a patent expires, the right owner can request that anyone using the off-patent invention pays a fee for a period corresponding to the period for which the marketing authorisation application is delayed. The amount to be paid is equivalent to the royalty in government use licensing within the scope and corresponding use period.

The marketing authorisation procedure is considered to be delayed if the Drug Administration of Vietnam does not give the first response to the applicant without justifiable reasons after 24 months following the date of filing the marketing authorisation application. The delay period is counted after 24 months following the filing date and ends when the Drug Administration gives its first response. Under either circumstance, the compensation shall not exceed two years, per Art. 12.40.2.

While the amendment was under discussion, Members of the National Assembly raised concerns that Art. 131a must be consistent with the 2016 Law on Pharmacy<sup>85</sup> to avoid adding more red tape to the marketing approval stage. This author argues that both options were problematic and undesirable from the patent holder's perspective. As patent maintenance fees in Vietnam are set at nominal values, Option 1 is highly unattractive. The annual renewal fee for each independent claim for the first two years is approximately USD 12, with the subsequent two years costing USD 18.<sup>86</sup> The cost increases every two years but is still modest.<sup>87</sup>

Regarding Option 2, Vietnam has never issued any government use licence, although it threatened to do so in 2005 when the country's population was endangered by Asian influenza.<sup>88</sup> However, as Roche – the patent holder of Tamiflu, the medicine treating influenza – agreed to transfer technology to Vietnam to manufacture the drug, the government withdrew their threat. Since Vietnam has no experience in dealing with government use licensing, it would need to learn from other countries' practices to establish what constitutes an adequate remuneration for the patent owners. Southeast Asian countries such as Thailand, Malaysia and Indonesia paid patent-holding companies as little as 0.5% and 1.5% of revenue.<sup>89</sup> However, the royalties are much higher in countries with a prominent pharmaceutical industry. For example, the

average figure in the US is 5%.<sup>90</sup> In Germany, it can be as high as 10%.<sup>91</sup>

Option 1 was voted to be the mechanism for compensation under the newly amended law.<sup>92</sup> Although the discussion papers on the amendment did not present the reasoning behind this choice, it is not difficult to understand why this is the case. Firstly, this option is more straightforward to implement because it saves the competent authorities from the hassle of 'learning' lessons from other countries. Secondly, establishing adequate remuneration has never been an easy task.<sup>93</sup>

Regardless of how much better Option 1 is, the author anticipates that once the law comes into force, it will generate discontent amongst patent-holding companies, who would only receive modest monetary compensation for the delay in obtaining the marketing authorisation. Undoubtedly, extending the patent term would have been a more favourable arrangement from the standpoint of pharmaceutical companies. Since the EU already adopted a *sui generis* extension regime for pharmaceuticals, they might have reasonably expected Vietnam to implement a similar policy. It is evidenced by the language prescribed in Art. 12.40, stating that 'Such compensation may be in the form of an extension of the duration of the rights conferred by patent protection'. Although Vietnam's unorthodox legislative step might not necessarily violate the EVFTA, the adopted provision appears to be a form of tokenism rather than having any practical value. The author foresees that it is only a matter of time until this issue is brought to its reckoning.

## VI. Conclusions

Since IP is one of Vietnam's newest yet fastest-growing areas of law, the government has struggled to keep pace with increasingly changing IP standards in the new series of FTAs. This struggle is evidenced by Vietnam's repeated IP law amendments. The law is deliberately ambiguous, making it difficult to understand and apply. While clarity and precision are matters not only of 'good law' but also of legal certainty,<sup>94</sup> these principles are being compromised by Vietnamese legislators. On the one hand, they want to respect the commitments in the FTAs, portraying Vietnam as an IP-respecting environment. On the other hand, they need to protect the broader national interest regarding medicine patents. Moreover, the domestic pharmaceutical industry is ill-prepared to compete against big international pharma. Consequently, language ambiguity and lip service have become Vietnam's weapons of choice.

<sup>85</sup> The Law on Pharmacy No 105/2016/QH13 (adopted by the National Assembly of Vietnam on 6 April 2016 and effective since 1 January 2017).

<sup>86</sup> National IP Office of Vietnam, 'Fees and Charges' (quoted from Circular No 22/2009/TT-BTC of 4 February 2009 of the Ministry of Finance) <<https://ipvietnam.gov.vn/web/english/fees-and-charges>> accessed 14 February 2022.

<sup>87</sup> The reason why Vietnam provides a low patent fee is to attract filing from the locals. However, as analysed in Section II, the domestic industry has not been keen on filing patents.

<sup>88</sup> Van Anh Le, *Compulsory Patent Licensing and Access to Medicines: A Silver Bullet Approach to Public Health* (Palgrave 2021) 114.

<sup>89</sup> James Packard Love, 'Recent examples of the use of compulsory licenses on patents' (KEI, 8 March 2007) <<https://www.keionline.org/book/publications-and-research-notes/kei-rn-2007-2-recent-examples-of-compulsory-licensing-of-patents>> accessed 14 February 22.

<sup>90</sup> Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicine* (OUP 2007) 248.

<sup>91</sup> *ibid.*

<sup>92</sup> Law No 07/2022/QH15 of 16 June 2022, amending and supplementing a Number of Articles of the Law on Intellectual Property, art 131a.

<sup>93</sup> Above n 91 at 61-62 discussing different approaches to setting an adequate remuneration.

<sup>94</sup> UK Parliament, Select Committee on the Constitution. The Legislative Process: Preparing Legislation for Parliament, 4th Report of Session 2017-19 – published 25 October 2017 – HL Paper 27, para 109.