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Patent evergreening: technological advancement and abusive commercial practices. Availability of essential medicine in the case of access to insulin

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Abstract *The article analyses problems caused by patent evergreening in the pharmaceutical industry, with a particular focus on access to insulin. It points out how abusive commercial practices prevent the most vulnerable to benefit from scientific developments of the modern world and evidence-based medicine. This article does not only examine crucial legal aspects, such as a coexistence of fundamental human rights and the TRIPS Agreement, but also considers the impact of the patent system's procedural norms. Finally, the article argues how secondary patenting prevents the harmonisation of public interest and the enforcement of private rights, where safeguarding equal access to essential medicine is required.*

1. Introduction

It is said that the "most important source of the economic value creation is a society's ability to generate, exploit and share technological advances."[1] Although patents are usually claimed to boost innovation and improve people's lives, they are currently the biggest barrier to access essential medicine.[2] Moreover, it is argued that patent protection is not always necessary to drive incentive for some industries - especially when it comes to pharmaceutical giants.[3]

Patent evergreening is a deceptive device in patent rights.[4] The phenomenon, also referred to as "incremental patenting,"[5] is accused of delaying the entry of cheaper, generic versions of medicines into the marketplace,[6] by creating private monopolies which abuse the patent system

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[1] Ralf Boscheck, 'Intellectual Property Rights and the Evergreening of Pharmaceuticals' (Intereconomics, 2015) 222.
[2] Arun Kumar and Arun Nanda, 'Ever-greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries' Pharmaceutical Regulatory Affairs: Open Access, Vol 6, Issue 1, 6.
[3] Boscheck (n 1) 222; Mark A Lemley, 'Faith-based Intellectual Property' (62 UCLA LRev 1328, 2015) 1334.
[4] G Dwivedi, S Hallihosur, L Rangan, 'Evergreening: A deceptive device in patent rights' (2020) Technology in Society, Vol 32, No 4, 324-330.
[5] Roger Magnusson, 'Advancing the right to health: the vital role of law - Chapter 15: Access to essential medicines, TRIPS and the patent system' (World Health Organization, Switzerland, 2017) 240.
[6] ibid.

and affect vulnerable segments of society that are unable to afford essential drugs.[7] The term "patent evergreening" may be used to label practices that extend the exclusive right of a patent holder by seeking trivial improvements or adjustments to a medicine.[8] Although the literature does not give a clear definition of "evergreening", and the term is still debatable,[9] patent evergreening is an abuse of the patent system, causing serious damage to society at large.[10] While in principle a patent should reward the inventor who shares the innovation with society, it is the process of enrichment at the expense of vulnerable persons that conflicts with the fundamental right to life and health.

The obligatory patent protection for pharmaceuticals directly contributes to limiting access to medicine in most developing countries.[11] Because of the mandatory nature to grant market exclusivity for drugs, the only power of authority to abolish barriers to access essential medicines vests in the states themselves. Although developing countries are worse off economically, they are being criticized for not easily allowing secondary patents.[12] However, raising patentability standards is often the only solution to limit patent evergreening.[13]

This article presents the relationship between secondary patents and access to medicine. Although the dispute is not novel, the purpose of this paper is to give new insights into an ongoing debate of the repercussions caused by a prolonged monopoly in the pharmaceutical industry. The article will stress that the state, as a guardian of fundamental rights, must give diabetics secure and safe means of approach to generic medicine. The discussion will concern not only how intellectual property rights may interfere with the right to health, but also how administrative procedures related to secondary patents and other forms of abusive evergreening processes contradict with access to essential medicine.

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[7] Lisa P Lukose, 'Patent ever greening: Law and Ethics' (7th International Conference on Information Law and Ethics, ICIL 2016) 1.
[8] ibid.
[9] Reed F Beall, Jason W Nickerson, Warren A Kaplan, Amir Attaran, 'Is Patent "Evergreening" Restricting Access to Medicine/ Device Combination Products?' (2016, PLoS One) 8.
[10] Lukose (n 7) 5.
[11] Cynthia Ho 'Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights' (2011, Loyola University Chicago) 2.
[12] Bhaven N Sampat, Kenneth C Shadlen, 'Secondary pharmaceutical patenting: A global perspective' (2017, Elsevier BV) 693.
[13] ibid.

The paper will present not only the value, but also the consequences of technological advancement that result in abusive commercial practices together with secondary patenting. It will analyse the insulin affordability crisis in consideration of the problem of patent evergreening present in the pharmaceutical sector and underline how those processes create a barrier to equal access to medicine. In addition, the importance of administrative and procedural aspects of patent law regime in secondary patent grants will be examined. Finally, the author will demonstrate the power of governmental health care policies and international agreements in safeguarding the fundamental human right to health and life.

2. The price of innovation

Intellectual property rights are said to be a form of government regulation of the free market, which tries to improve the life of society by restricting the freedom of other people to do what they want with the work of their minds.[14] Since developing a drug requires a large investment of time, as well as financial resources, and nevertheless is an uncertain process,[15] the true and first inventors may be rewarded "an exclusive privilege" by being granted a patent.[16] There is a common understanding that patents are essential assets in developing innovations and thus benefitting society by improvements in medicine, science or technology.[17] Nonetheless, the notion is often criticized for depriving poorer individuals of having access to those improvements.[18] The patent law regime is also blamed for unequal drug distribution, due to pharmaceutical companies' unwillingness to properly balance the risks and benefits during the introduction of the new medicine into the market.[19]

There are certain arguments in favour of granting patent rights which shall not be

[14] Mark A Lemley, 'Faith-based Intellectual Property' (62 UCLA LRev 1328, 2015) 1330.

[15] Kumar et al (n 2) 1.

[16] Lukose (n 7) 1.

[17] Edwin C Hettinger, 'Justifying Intellectual Property' (18 PHIL & PUB AFF 31, 47 (1989)), ("[T]he strongest and most widely appealed to justification for intellectual property is a utilitarian argument based on providing incentives."); Peter G Groves, *Source Book on Intellectual Property Law* (Cavendish Publishing Ltd, London, 1997); Promoting access to medical technologies and innovation. Intersections between public health, intellectual property and trade. Geneva: World Health Organization, World Intellectual Property Organization, World Trade Organization; 2012:56 (http://www.who.int/phi/promoting_access_medical_innovation/en/); Lukose (n 7) 3.

[18] Lukose (n 7) 1.

[19] Magnusson (n 5) 240; Lukose (n 7) 1.

undermined. Just like copyright "imposes taxes on the readers" to reward the writers,[20] patents protect the inventor by offering 20 years of monopoly on the market. During this time, a patent holder may enrich himself from being the only supplier of that particular invention, and simultaneously, the state benefits from the disclosure of the innovation. However, medicines differ from other (technological) inventions as they need to be approved by a regulatory body and therefore do not immediately enter the marketplace.[21] Because the process of medical review is time-consuming, pharmaceutical companies often try to seek patent protection when the market authorization process occurs.[22] Due to the high volume and intensity of work put into the development of a drug, compensation in a form of market exclusivity is desirable in the scientific field.[23]

Despite being granted market exclusivity for 20 years, enterprises are tempted to prolong their position by strategically aiming to achieve the "life cycle management" of a medicine through secondary patents.[24] Since generic manufacturers can launch a biosimilar version of the drug as soon as its patent has expired, secondary patents result in restricting patients from receiving cheaper versions of essential medicine which they can afford. Maximizing the monopoly in this way typically occurs with best-selling drugs;[25] for example, with drugs that are often used to treat conditions such as diabetes, arthritis or cancer.[26] Secondary patents for which pharmaceutical companies file are often "disguised or artful" and they mostly focus on delivery profiles of a drug, its packaging, dosing rage or a new use for an old molecule.[27]

Regardless of the fact that requirements such as novelty or inventive step should, in

[20] Thomas Macaulay, Speech Before the House of Commons: Copyright (Feb 5, 1841) in Speeches on Politics and Literature 176, 182 91924).
[21] See eg European Medicines Agency, 'Marketing Authorisation' < https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation>; US Food & Drug Administration, 'Development and Approval Process -Drugs' < https://www.fda.gov/drugs/development-approval-process-drugs>.
[22] Kumar et al (n 2) 1.
[23] Lemley (n 14) 1342; Edmund W Kitch, *The Nature and Function of the Patent System*, 20 J L & ECON 265, 266 (1977) (describing "[t]he conventional view of the patent system" as "a device that enables an inventor to capture the returns from his investment in the invention").
[24] Sampat et al (n 12) 693.
[25] Kumar et al (n 2) 1.
[26] I-MAK, Overpatented, Overpriced <https://www.i-mak.org/overpatented/> Accessed 4 July 2020.
[27] Kumar et al (n 2) 1.

principle, make secondary patent applications more troublesome to succeed,[28] incremental patenting nonetheless takes place. Improperly harmonised patent law regime enables known substances and new compounds of an old drug to be protected, as the claims often relate to improved use of a particular medicine, concerning discoveries which occur while clinical trials take place. Although patents are said to promote dissemination of innovative knowledge, in countries such as the United States and Australia, secondary patenting is possible.[29] Due to very low patentability requirements of inventive step and utility, negligible drug improvements may be monopolised.[30]

Patents are likely to result in "welfare-reducing monopolistic pricing, licensing or standard-setting behaviour".[31] For many years, pharmaceutical protection was not present in many countries as it was claimed that doing so would abuse vulnerable citizens.[32] However, as the price of research and development increased in parallel with the risk accompanied with this process, pharmaceutical companies were eventually allowed to receive patent protection.[33] It was the implementation of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) that made it compulsory for all its members to respect pharmaceutical patent enforcement.[34] At the same time, it enabled developing countries to define standards of patentability independently, which resulted in the introduction of a more restrictive approach towards secondary pharmaceutical patents.[35] The implementation of TRIPS enabled originator companies to file "first" secondary patents in jurisdictions of developing countries, as those secondary patents were of products that had already been patented in other states.[36] Some drugs, for which the patent applications were filed in the 1990s, were unable to receive a primary patent there, and hence, granting secondary patents was the only type of protection that developing countries could give to innovators.[37]

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[28] Sampat et al (n 12) 694.
[29] Lukose (n 7) 1.
[30] ibid 6.
[31] Boscheck (n 1) 222.
[32] ibid.
[33] ibid.
[34] Magnusson (n 5).
[35] WIPO, Committee on Development and Intellectual Property (CDIP), 'Study on Pharmaceutical Patents in Chile', ANNEX, 1.
[36] ibid.
[37] Sampat et al (n 12) 695.

Although TRIPS aimed to strengthen IP protection in between its members,[38] the Agreement also claimed to primarily serve as a "reliable guide for the commercial and investment decisions of profit-maximizing firms".[39] Most TRIPS-compliant patent protection makes the majority of life-saving drugs unavailable, while delaying the competition of generic drugs and undermining local production.[40] The importance of generic drugs is predominantly recognized by individuals who lack access to medicine. It is argued that if the quality of traditional patent granting procedures is decreased, it will have a greater impact on allowing low-quality secondary patents in developing countries.[41] Although, understandably, safeguarding patent law is used as a tool for boosting technological advancement, an inability to provide equal healthcare distribution is a threat to citizens' fundamental rights.[42] The states are obliged by the right to health to enable every person to be as healthy as possible by meeting the four requirements: availability, accessibility, acceptability and quality.[43]

The problem of restricted access to medicines was firstly most prominently discussed when the South African government established legislation allowing the import and manufacture of generic versions of patented drugs.[44] Since access to medicines is based on the affordability of the drugs, administrative procedures should assist in enabling the society to take advantage of the availability of the medicine. Consequently, generic versions of the drugs produced locally might eventually become one of the most fundamental factors fulfilling the right to health and enabling patients to access essential medicines without being proposed overpriced drugs which might have been evergreened for more than 20 years.

3. Patent evergreening and technological advancement

A fundamental justification for intellectual property rights has utilitarian roots,[45] since

[38] ibid.
[39] Boscheck (n 1) 226.
[40] Boscheck (n 1) 223.
[41] Sampat et al (n 12) 694.
[42] UN General Comment on the Right to Health in 2000; United Nations Economic and Social Council, General Comment No 14: The right to the highest attainable standard of health. United Nations document E/C12/2000/4 (11 August 2000): para 43(d); Hogerzeil H, Mirza Z, The world medicines situation 2011: access to essential medicines as part of the right to health. Geneva: World Health Organization; 2011.
[43] Lukose (n 7) 7.
[44] *Minister of Health & Others v Treatment Action Campaign & Others* (Case CCT 8/02, 5 July 2002).
[45] Lemley (n 14) 1328.

public disclosure of innovations enables the society to benefit when people conceive of new inventions.[46] It might be said that scientific progress occurs as a product of exploiting ideas and developing innovations that have been shared with the public.[47]

The "secondary patent" notion is typically used to refer to a particular claim type in pharmaceuticals.[48] When the secondary patent prolongs market exclusivity without significant, usually therapeutic, improvement,[49] it allows patent holders to increase the return on investment while simultaneously increasing the prices of the drug.[50] Patent evergreening is thus criticized, as it is claimed that the secondary patent does not require as much research and investment as the primary one.[51]

A typical example of patent evergreening practice may be observed in device patents being granted after the initial molecular substance has already obtained monopoly rights, strengthening the commercial position of companies by restricting generic drugs to enter into the competition. This results in an absence of a proportionate public benefit which subsequently undermines the initial utilitarian idea of granting monopoly rights to boost incentives and improve the quality of lives. The clinical value of the improvement is a vague point in patent device evergreening since it is possible to achieve the same therapeutic result when administering the same drug with another device.[52] Nevertheless, in some cases, a new device does improve the therapeutic benefit of the medicine.[53] Pharmaceutical companies find a way to take advantage of their position in the market by issuing devices that bear several patents to conveniently enjoy market exclusivity for decades.[54]

[46] Peter S Menell, Mark A Lemley, & Robert P Merges, 'INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE: 2017', at 16 (2017)("Utilitarian theory and the economic framework built upon it have long provided the dominant paradigm for analyzing and justifying the various forms of intellectual property").
[47] Lukose (n 7) 12; Lemley (n 14) 1328; Promoting access to medical technologies and innovation. Intersections between public health, intellectual property and trade. Geneva: World Health Organization, World Intellectual Property Organization, World Trade Organization; 2012:56 <http://www.who.int/phi/promoting_access_medical_innovation/en/>.
[48] WIPO (n 35).
[49] Beall et al (n 9).
[50] Magnusson (n 5) 240.
[51] Sampat et al (n 12) 694.
[52] Beall et al (n 9) 8.
[53] ibid.
[54] Beall et al (n 9) 8.

3.1. *Secondary pharmaceutical patenting*

Patent "evergreening" is considered a rather pejorative term.[55] The biggest controversy regarding patent evergreening lies in the idea that the state should only grant a monopoly in return for an equitable public benefit.[56] The malpractice of patent evergreening is not only negligible in improving the standard of care,[57] but it also delays and restricts the entry of generic versions of drugs on the market.[58] It has been argued that secondary patents are also often of lower "quality" than primary patents, and although they may lack strong novelty and non-obviousness claims, they nevertheless efficiently restrict competition.[59] Although there is no specific distinction between primary and secondary patents in patent law, evergreening is nonetheless regarded as an unethical practice.[60]

One of the most famous cases where patent evergreening was successfully tackled was *Novartis v India*.[61] India was one of the developing countries that successfully put in place specific restrictions against evergreening using TRIPS flexibilities. India introduced section 3(d) under the India Patent Act, where new forms of old substance would only be eligible for patent protection if the applicant could establish "increased efficacy" of a product.[62] The section as a subject of controversy was challenged in the *Novartis* case, which revolutionized the way evergreening is seen. Indian Patents Act and its section 3(d) was introduced to disallow "incremental innovation" and to mitigate unnecessary monopolies being sought by pharmaceutical giants.[63] To be truly considered as novel, innovation must meet the requirement of efficacy, which is explained as a therapeutic effect on the body which is "rightly and reasonably expected to show" how the drug is effective in healing disease.[64]

The *Novartis* decision is believed to have had a great impact on access to medicine, as it reminded other nations that "making available life-saving drugs is a constitutional obligation of

[55] Sampat et al (n 12) 694.
[56] ibid.
[57] Beall et al (n 9) 8.
[58] Singh & Associates, "The Wrongs of Evergreening" (2008) 101.
[59] ibid 693.
[60] Lukose (n 7) 13.
[61] *Novartis Ag v Union Of India & Ors* on 1 April 2013.
[62] Sampat et al (n 12) 695.
[63] Singh & Associates (n 58) 102.
[64] ibid.

the state".[65] However, while it illustrated that the misuse of IP rights by evergreening must be tackled, the decision was also controversial for seemingly having a detrimental impact on the importance of recognition of R&Ds (research and developments) and discoveries.[66] The Indian judgment was therefore both praised and criticized. Medicines Sans Frontiers applauded the *Novartis* decision, claiming that it allowed Indian citizens to get treatment with Gleevec, which would have been impossible had the drug received secondary patent protection.[67] Furthermore, it encouraged other countries to follow India's example to fight pharmaceutical evergreening.[68] Those opposing the *Novartis* decision claim that the Madras court erred in ruling that efficacy only has a therapeutic value, arguing that long-life stability is indeed an improvement in efficacy.[69] It is also argued that incremental innovation should be protected, as the world through this could experience a "gradual move towards breakthrough inventions", which was a fundamental feature of current medical progress.[70] Nevertheless, it is important to note that the *Novartis* court was not against patent law, but rather, it considered public health as superior to the patentability of trivial advancement.[71]

Since the price of drugs is one of the major barriers in accessibility of essential medicine, developing countries are particularly at risk of disabling said access for their citizens due to the increased monopoly of pharmaceutical giants and the lack of manufacturing and transportation abilities for generic versions. In emerging economies, the market value of innovation may be small, and consequently, the incentives to invest in R&Ds may probably not exist at all.[72] The introduction of legal provisions aiming to hamper patent evergreening and secondary patenting is therefore vital to protect such emerging economies from "supra-competitive prices" of drugs, arising due to restricted competition and lack of generic alternatives.[73]

4. Insulin affordability crisis

[65] ibid 101.
[66] ibid.
[67] ibid 102.
[68] ibid.
[69] ibid.
[70] ibid.
[71] Lukose (n 7) 12.
[72] Magnusson (n 5) 232.
[73] Sampat et al (n 12) 694.

Nearly 63% of deaths globally occur as a consequence of non-communicable diseases, such as cancer, chronic respiratory or cardiovascular diseases, or diabetes.[74] Further, over 14 million of these patients die prematurely, between the ages of 30 and 70. This directly affects the economy of low- and middle-income countries, resulting in increased poverty.[75]

Historically, an insulin patent was sold for $1,[76] hoping to ease access for those in need. For every person suffering from diabetes, insulin, which is a hormonal substance, is indispensable to survive. Nevertheless, it is a "prohibitively expensive essential medicine".[77] Despite insulin being considered a pharmaceutical that is of priority for a fundamental health-care system,[78] it has been estimated that in 2016 over 50 million people all over the world lack access to insulin.[79] The three giants: Sanofi, Eli Lilly and Novo Nordisk,[80] control 99% of the insulin market.[81] This means that only a small number of generic drugs are allowed to break in to lower the price of insulin. By making improvements to their insulin drug or corresponding devices, these giants are securing their place in the market. As the American Diabetes Association (ADA) report establishes, the price of insulin in the US has nearly tripled in the last few years.[82] Patients who cannot afford to buy the necessary insulin vials try to skip or ration their doses, and are often subject to serious health complications, frequently leading to premature deaths.[83] Some intentionally induce diabetic ketoacidosis in pursuance of getting insulin from hospital emergency rooms.[84]

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[74] WHO, Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020 – revised draft (Version dated 11 February 2013) 1.
[75] ibid.
[76] Jessica Le Masurier, Céline Bruneau, Glenn Hartong, 'The price of insulin is killing Americans' (2019), <https://www.france24.com/en/20190402-focus-united-states-price-insulin-killing-americans-diabetics-us-health-medicine-pharma> Accessed 21 June 2020.
[77] Jenna E Gallegos, Christopher Boyer, Eleanore Pauwels, Warren A Kaplan, and Jean Peccoud, 'The Open Insulin Project: A Case Study for "Biohacked" Medicines' (Trends in Biotechnology, December 2018, Vol 36, No 12), , 1212.
[78] World Health Organization Model List of Essential Medicines, 21st List, 2019. Geneva: World Health Organization; 2019, <https://www.who.int/publications/i/item/WHOMVPEMPIAU2019.06>, 42.
[79] Novo Nordisk, 'Access to Insulin Commitment' <https://www.novonordisk.com/sustainable- business/commitment-to-access-and-affordability/our-access-to-insulin-commitment.html> Accessed 25 June 2020.
[80] Le Masurier et al (n 76); Nicholas Florko, '"Everyone is at fault": With insulin prices skyrocketing, there's plenty of blame to go around' <https://www.statnews.com/2019/02/19/no-generic-insulin-who-is-to-blame/> Accessed 27 July 2020.
[81] Schultz K 'The global diabetes care market' Bagsværd: Novo Nordisk; 2011.
[82] ADA, Insulin Access and Affordability Working Group: Conclusions and Recommendations, <https://care.diabetesjournals.org/content/41/6/1299> Diabetes Care 2018 Jun; 41(6): 1299.
[83] ibid 1306.
[84] Gallegos et al (n 77) 1213.

One of the more recent insulin affordability crises experienced by a developed country is happening in the United States. Its complexity lies in the fact that every individual has a different health support plan and insurance, and the pharmacies supplying patients are charging them in accordance with their health insurance coverage. If a patient lacks health insurance for medication, the drug is sold for its purchase price, and most frequently, with a mark-up.[85] The degree of negotiating power differs between stakeholders in the "insulin supply chain", which further complicates the process.[86] Diabetics have to bear the burden of continuous price amendments, as if one insulin manufacturer increases the price for their drug, others do the same.[87] On the contrary, in the European Union, the governments act as benefit managers and directly negotiate medicine prices with pharmaceutical companies, which seems to be a more effective approach.[88]

Due to the drastic increase of insulin prices (by even 353% - e.g., a NovoLog vial),[89] many stakeholders, pharmacists and patients asked for increased transparency of insulin pricing methods.[90] It is claimed that due to lack of transparency, manufacturers are "at a disadvantage" in setting the price for insulin products, as they are unaware of the negotiations happening between Pharmacy Benefit Managers (PBMs) and health plan insurance.[91] After the ADA Working Group investigated this inquiry, they determined that it is "unclear… how the dollars flow and how much each intermediary profits", as the negotiations are extremely confidential.[92] It has been deducted that although insulin manufacturers directly control the list price of insulin, these are also PBMs that have the biggest negotiating power, as they determine which type of insulin is available in particular insurance plans.[93]

Currently, it is more difficult for a generic drug treating non-communicable diseases, such as diabetes, to be accessible than a generic drug that treats communicable diseases.[94] Although the

[85] ADA (n 82) 1300.
[86] ibid.
[87] ibid 1301.
[88] Kasia Lipska, 'Break Up the Insulin Racket' (2016). <https://www.nytimes.com/2016/02/21/opinion/sunday/break-up-the-insulin-racket.html> Accessed 26 June 2020.
[89] NovoLog vial for example, increased by 353 per cent. See ibid, 1302.
[90] ADA (n 82) 1303.
[91] ibid 1303.
[92] ibid 1304.
[93] ibid.
[94] David Beran, Zafar Mirza & Jicui Dong, 'Access to insulin: applying the concept of security of supply to Medicines', (*Bulletin of the World Health Organization* 2019) 358.

US has a significant problem with access to insulin as a wealthy state, it should notbe forgotten that the majority of patients suffering from diabetes live in low- or middle-income countries, which adds to frustration associated with the insulin affordability dilemma.[95]

4.1. Barriers to equal access

It might be suggested that once the idea of utilitarianism faces the fatal consequences resulting from the existence of barriers to accessibility of drugs, it is problematic to determine a basis for a "pre-political right" to intellectual property.[96] One of the most recent extreme evergreening examples is the case of Sanofi's product – Lantus. Due to 74 patents, most of which were filed after the drug received market authorization in 2000, its monopoly has been extended to further 37 years.[97] The fact that Sanofi filed 1.5 times more patents in the US than it filed in the EPO,[98] seems to be a drastic American patent system failure. The primary patent for Lantus expired in 2015, which after receiving regulatory approval by the FDA in 2000, gave Sanofi a long time to enjoy the market exclusivity for at least 15 years.[99]

The issue with the generic version of insulin lies in the fact that most biosimilar companies face struggles with accessing the market, as the original companies are also often tempted to issue their generic version of insulin. Furthermore, there is almost no generic competition for human insulin in the US.[100] Supposedly, providing access to insulin generic versions could prevent breaching the fundamental right to health and life. This argument may be supported by the fact that the insulin price is able to drop by at least half, if more than two generic companies are willing to manufacture the drug on the market.[101] Hence, competition may be regarded as a vital ground for reducing the price of life-saving medicine.

Any innovation in pharmaceutical strategies is undoubtedly essential for people with

[95] Novo Nordisk (n 79).
[96] Lemley (n 14) 1338.
[97] I-MAK, 'Overpatented, Overpriced Special Edition: Lantus (insulin glargine)' <http://www.i-mak.org/wp- content/uploads/2018/10/I-MAK-Lantus-Report-2018-10-30F.pdf>, 2, Accessed 28 June 2020.
[98] ibid.
[99] I-MAK (n 97) 3.
[100] Beall et al (n 9) 8.
[101] Lipska (n 88).

diabetes, as it may lower some side effects or complications of the disease itself.[102] American Diabetes Association claims that to encourage innovation, the best option would be to "link reimbursement to value", creating a "value-based insurance design".[103] After delivering their research, ADA claims to be particularly worried by the complexity of the system.[104] Biosimilar or generic insulins are not sufficiently popular on the market, and because there are too few of them, ADA states they are unlikely to lower the price of insulin.[105] Hence, if there were more biosimilar insulin versions on the market, they would be more likely to address the problem of affordability. In ADA's report, it has also been noted that instead of providing analogue insulin, it would be more appropriate to make "human insulin more available to uninsured diabetics".[106]

Pharmaceutical companies underline that patent applications filed prior to market circulation do not constitute abuse, since they are based on a massive investment of comprehensive research and development of the drug.[107] As a response to such allegations, the Initiative for Medicines, Access and Knowledge (I-MAK) has procured an examination of patent applications filed after Lantus was approved in 2000. This examination noted that 95 per cent (69 out of total 74) constituted secondary patent applications as they were filed after the USFDA gave Lantus the market authorization.[108] As a consequence, biosimilar manufacturers must be aware of the existing secondary patents and their implications, as those hamper the generic versions of the drug to enter into the market,[109] delaying competition[110] and eventually impacting the medicine's pricing, as well as its end users' health. It was reported that Sanofi increased the price of Lantus by 18% each year from 2012 to 2016, and the American health insurance companies' (Medicare or Medicaid) spent on person increased by 89%.[111]

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[102] ADA (n 82) 1308.
[103] ibid.
[104] ibid 1309.
[105] ibid 1310.
[106] ibid.
[107] ibid.
[108] I-MAK (n 97) 4.
[109] Fierce Pharma, 'Sanofi sues Mylan over Lantus patents, seeking to defend its top-selling drug', (2017) <https://www.fiercepharma.com/legal/seeking-to-defend-key-sales-sanofi-sues-mylan-for-lantus-patent-infringement> Accessed 28 June 2020.
[110] Fierce Pharma, 'Despite scoring an FDA nod, Merck's biosim Lusduna must wait to challenge Lantus',(2017) <https://www.fiercepharma.com/marketing/despite-scoring-fda-nod-merck-s-follow-med-lusduna-must-wait-to-challenge-lantus> Accessed 28 June 2020.
[111] I-MAK (n 97) 6-7.

Barriers to access to insulin comprise of multiple factors, most of which come down to international and national restrictions. Unfortunately, the most price-influential mechanisms to deal with exhaustion of patent rights are the national patent laws,[112] which may nevertheless hamper the introduction of generic drug manufacturers by the domestic laws regulating the test data.[113] Because of the issues related to the lack of access to insulin worldwide, pharmaceutical companies cannot be safeguarded by an allegation that they are unaware of the problems of vulnerable patients. As a result of the bad reputation of insulin manufacturers, Novo Nordisk started their own accessibility programme through which it has treated over 2.9 million patients who could not afford human insulin at its usual industrial price.[114] Similarly, Sanofi has launched the "Healthcare for All" sustainability and quality action,[115] and Eli Lilly has started its responsibility programme.[116]

Although most patents on insulin are soon to be expired, patents on insulin delivery devices pose a major risk to insulin accessibility nowadays.[117] Patents on devices, such as insulin pens, outlast medical ingredient patents. Evergreening of devices shall not be considered as a separate topic, as competing with generic manufacturers through creating a collective relationship of patenting drugs and devices, and thereby forcing prolonged market exclusivity, also puts biosimilars off the market. Most recently, Mylan won a patent battle with Sanofi, where two device patents were invalidated, enabling the generic version of insulin glargine to be brought as a more affordable version of Sanofi's best-selling drug Lantus.[118] Device evergreening also poses a growing risk of impairing the patent system by stimulating most patentable improvements rather than the most genuine and beneficial ones.[119] A good example establishing this issue may be Combivent Respimat ® which original patents on active compounds were granted in the

[112] Magnusson (n 5) 238.
[113] ibid 242.
[114] Novo Nordisk (n 79).
[115] Sanofi, Healthcare for all, <https://www.sanofi.com/en/our-responsibility/healthcare-for-all/> Accessed 2 August 2020.
[116] Lilly 2018 United Nations Global Compact Communication on Progress Report <https://assets.ctfassets.net/srys4ukjcerm/5lPZvzVSQwTdph8mK17C24/8921cd76726893bdbd034ac8de62c23d/Lilly_2018_United_Nations_Global_Compact_Communication_on_Progress_Report.pdf> Accessed 2 August 2020.
[117] Beran et al (n 94) 361.
[118] --, 'Mylan Wins District Court Decision Against Sanofi's Lantus® SoloSTAR® Patent' <http://newsroom.mylan.com/2020-03-10-Mylan-Wins-District-Court-Decision-Against-Sanofis-Lantus-R-SoloSTAR-R-Patent>.
[119] ibid.

1970s and, by being attached to the medicine's inhalers were respectively prolonged for over 58 years.[120] Trivial improvements can be observed with diabetics' delivery devices, such as Novo Nordisk ® insulin aspart pens, having solely their mechanical features changed, usually bearing no efficacy or therapeutic improvement.[121]

Besides delivering innovative and allegedly improved modes of drug injection, device innovation implies the growth of prices, as an increased introduction of prefilled and cartridge devices is more expensive than vials.[122] Other barriers having global implications are exchange rates, since most medicines are purchased in US dollars, and national policies such as an effective distribution system and government health expenditure.[123] The concept of "security of supply" applicable to insulin seems to be a prominent option for states to introduce a further step to ensure insulin being available for those in particular need.[124] The notion is based on equipping the state's reserves in supplies of a particular material, such as oil or food, from various sources.[125] Security of supply of medicine has been determined by the United Nations Children's Fund (UNICEF) by three factors of supply: uninterrupted, sustainable and affordable quality medicine.[126] These components applied to the security of supply of insulin amount to, inter alia, diversity of supply, an expenditure of insulin, stability of prices, access and equity, affordability, and intellectual property management.[127] National governments are therefore strongly encouraged to seek to amend their patent laws to grant a monopoly for only those inventions genuinely meeting the benchmarks of novelty and inventive step,[128] or issue compulsory licenses, when necessary, to ensure access to essential medicine.[129]

5. Playing the patent game[130]

Absence of generic competition not only empowers the oligopoly of pharmaceutical giants,

[120] Beall et al (n 9) 8.
[121] Beall et al (n 9) 11.
[122] David Beran, 'Improving access to insulin: what can be done?' (2011) Future Medicine, Diabetes Manage, 69.
[123] Ibid 70.
[124] Beran et al (n 94) 358.
[125] ibid.
[126] UNICEF HIV-related medicines & diagnostics supplies. New York: UNICEF; 2007. <https://comtrade.un.org/> Accessed 8 August 2020.
[127] Beran et al (n 94) 359.
[128] Magnusson (n 5) 240.
[129] ibid 233.
[130] I-MAK, Overpatented, Overpriced (infographics) <https://www.i-mak.org/overpatented/> Accessed 4 July 2020.

but also directly impacts customers by creating a solid barrier for the right to health enforcement. Prohibitive drug prices are mostly the result of strong intellectual property protection.[131] In consequence, commercial medicines may become totally unaffordable in the future.[132] Most international policies and agreements aim to intensify the legitimacy of patent protection rather than to recognize access to medicine promulgation, although concerns are being raised by countries with both emerging and emerged economies.[133] This raises the question of why abusive secondary patenting is not expressly prohibited if the society is facing so many obstacles to get the drug. It would be difficult to restrict secondary patenting as patents in general are the best assets to prompt risky research, but also because they require innovators to disclose their findings and thereby benefit the rest of the society.[134]

However, patent law regimes in some countries do impose penalties against evergreening,[135] which may inspire other states to do the same. The WHO encouraged countries to amend their national legislations to enable universal access to affordable pharmaceuticals and promulgate the existence of a fundamental right to health.[136] Although the cycle is designed to empower innovation and to eventually benefit us all,[137] findings regarding secondary patenting, if any, show the opposite results.[138]

It is claimed that the only social responsibility and morality of any business is to increase its profits,[139] and evergreening practices are occurring as a kind of response to market incentives.[140] This is often supported by the infamous Lockean *labour theory of value*, which promotes labour, instead of mutual consent, as the grounds of ownership.[141] The economic value of patented

[131] Ellen Hoen, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha' (Chicago Journal of International Law, 2002) 41.
[132] Gallegos et al (n 77) 1211.
[133] Boscheck (n 1) 221.
[134] ibid 222.
[135] Lukose (n 7) 1.
[136] Medium-term strategic plan 2008-2013. Geneva: World Health Organization: 96, <http://apps.who.int/gb/ebwha/pdf_files/MTSP-08-13-PPB-10-11/mtsp-3en.pdf>.
[137] ibid 3.
[138] Boscheck (n 1) 222.
[139] Milton Friedman, 'The Social Responsibility of Business is to Increase its Profit' (NYT Magazine, 13 September 1970).
[140] Boscheck (n 1) 221.
[141] Matthew G Sipe, 'Patent Law's Philosophical Fault Line' (Wisconsin Law Review, Vol 2019, No 5, 2019) 1038-1039; John Locke, 'Two Treatises on Government', 185 (3d edn 1698).

technological information derives from the fact that it may be used in the industry for commercial purposes.[142] Furthermore, patents are important assets in correcting the market failure, since the manufacturers using the innovation without incurring costs of R&Ds will have an advantage over firms that had to invest substantial intellect, capital and time.[143] As long as the company maximizes its prices, its profits are also maximized, and there is no need to support the enterprise by non-market-based income, which eventually is said to exclude the actual losses to the society.[144] Based on this concept, society is tempted to value work for its own sake, which may lead to justifying intellectual property as the "moral end" in itself, disregarding evidence proving how it affects the world.[145]

Pharmaceutical companies sustain their monopoly not only through patenting active compounds, molecule modifications or upgrading specialized delivery systems, but also by attaining their dominance within the therapeutic class or reference of the product.[146] Filing multiple patents on different aspects of a drug is also a common evergreening practice.[147] Furthermore, firms also focus on legal protection based on trade marks, together with differentiation of branding, exclusive distribution, as well as differential pricing and product strategies.[148] Still, some argue that although the public benefits most from lower prices, companies are expected to take up practices allowing them to balance costs paid for the R&D, which may reach up to $1.4bn, with their return, requiring at least $0.5bn sales.[149]

As a counter-argument to secondary patenting critics, it may be said that inventions cannot always be planned. Some might start from a discovery that may, together with research and development, solve the problems of previously unrecognized therapeutic needs. Therefore, one cannot predict the need to claim a secondary patent for the same thing in the future. Besides investing large amounts of money in research and development, innovator companies must face marketing approval of one single product, selected from thousands of those investigated by the

[142] Lukose (n 7) 3.
[143] ibid.
[144] Boscheck (n 1) 223.
[145] Lemley (n 14) 1328.
[146] Boscheck (n 1) 224.
[147] Sampat et al (n 12) 693.
[148] Boscheck (n 1) 224.
[149] Boscheck (n 1) 224.

developer.[150]

Although 20 years of trumping competitive generic companies should be sufficient for innovators to recover after such a huge investment, the strategies that they procure to maintain exclusivity are still very aggressive.[151] Most national health systems are based on the assumption that the country shall ease access to medicine for the individuals.[152] Emerging states do not always impose price controls, giving citizens of poorer countries another obstacle of increased drug pricing to overcome.[153] Because wealthy countries are financially contributing to help poorer states to provide drugs for their society in most cases, there is a common consideration that the issue of drug pricing shall be considered by every state.[154]

Evergreening can also happen in forms other than claiming a secondary patent for the same drug. It may occur when the pharmaceutical giant is launching its improved generic version of a branded drug and significantly decreases its price.[155] Another form of evergreening is switching a medicine to an Over the Counter (OTC) drug, allowing the company to enhance their monopoly by directly advertising their product to consumers, and consequently minimizing generic competition which the public is not aware of.[156] Pharmaceutical giants may launch a successor drug, a blockbuster, with a different name and trade dress, to prolong their monopoly and again to undermine the generic competition.[157]

Innovators also try to extend the monopoly by switching the drug's route of administration by Novel Drug Delivery Systems.[158] Both the European Union's and the United States' laws have legal provisions to protect combinations of two or more drugs. This is another form of evergreening by which companies release a soon-to-go-off patented drug with another one, to tackle "closely

[150] Kumar et al (n 2) 3.
[151] ibid.
[152] United Nations Economic and Social Council, General Comment No 14: The right to the highest attainable standard of health. United Nations document E/C.12/2000/4 (11 August 2000): para. 43(d); Hogerzeil H, Mirza Z. The world medicines situation 2011: access to essential medicines as part of the right to health. Geneva: World Health Organization; 2011.
[153] Ho (n 11) 2.
[154] ibid 4.
[155] Kumar et al (n 2) 3.
[156] ibid 2.
[157] ibid.
[158] ibid 3.

associated medical conditions".[159] Biosimilars are often the only hope for poorer citizens as their prices might be significantly lower than the branded drug,[160] and hence their presence among pharmaceutical giants is desired. The search to find an equilibrium for limiting and imposing both private and public rights is challenging. In making this assessment, one shall determine whether patentability standards and requirements might be a notion that, if altered, could bring more excellence and balance in the modern world.

5.1. Facing aggressive patent practices

25 % of global health spending is caused by pharmaceuticals.[161] Since generic companies are producing biosimilar versions of drugs that have already been researched and developed by the original innovator, they can offer medicines with significantly lower prices. It is argued that original companies are taking unfair competitive approaches because generic companies are "reducing the market share of the branded drugs" by offering lower prices for poorer consumers.[162] This reasoning is not deeply convincing as the existence of a variety of competing undertakings is guaranteeing a higher quality of products released and lower prices on the market share, and if competitors were enabled to produce biosimilars, they would immediately lower the prices of those medicines by even 70-80%.[163] For that reason, an accurate national procurement policy is a crucial device in supplying the quality drugs at the lowest prices possible.[164]

The approach to competition differs from state to state. In the United States, generic companies are encouraged to challenge the creator's patent, basing their claim on the Hatch-Waxman Act of 1984, which was enacted to ensure a balance being achieved between generic and innovator companies.[165] It is claimed that the 180-day period of market exclusivity granted for a generic manufacturer is "a recognition of the public interest" to reduce monopolies created by parent companies.[166] Generics can also rely on the America Invents Act of 2011 which was

[159] ibid.

[160] ibid 3.

[161] Kohler JC, Baghdadi-Sabeti G. The world medicines situation 2011: good governance for the pharmaceutical sector. Geneva: World Health Organization; 2011:2 <http://apps.who.int/medicinedocs/documents/s18061en/s18061en.pdf>.

[162] Kumar et al (n 2) 4.

[163] ibid.

[164] Magnusson (n 5) 229.

[165] Kumar et al (n 2) 4.

[166] ibid.

meant to "fight abusive patenting and cut healthcare costs".[167] Nevertheless, the US regulatory system visibly favours existing insulin manufacturers, which makes it more burdensome for biosimilars to compete.[168]

In contrast, it is difficult to find provisions addressing aggressive patent practices in European law. The European Union's 2014 Action Plan on the enforcement of IP rights aims to strengthen the position of intellectual property, which was said to be a direct incentive for growth, and fight against counterfeiting.[169] The European Commission highlighted the importance of enhancing the EU's industrial competitiveness through IP rights, so that companies "generate returns for their investment in knowledge".[170] The internal market of the European Union is protected by the establishment of Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU) that restrict unfair competition and the abuse of a dominant position. Some refer to Article 102 as the article corresponding to the wrongs of evergreening. However, this provision is ineffective as patent laws are governed nationally, rather than by the Community law.[171] Consequently, EU laws are said to be too lenient and insufficient to tackle evergreening.[172]

5.2. Attempts to tackle incremental patenting by the implementation of TRIPS flexibilities

Several emerging countries have previously tried to prevent pharmaceutical patenting in their citizens' best interest. As mentioned above, TRIPS flexibilities were tested in the *Novartis v Union of Indi*a case, which was said to be an example of a state's interest to protect the right to health. However, the majority of restrictions that were introduced to tackle patent evergreening were found to be ineffective, as there is no remarkable difference in grants for primary patents and secondary patents in neither Argentina, Brazil, Japan, nor the US and Europe.[173] It has also been proven that it is easier to obtain a secondary patent in Europe (EU) and in the US, rather than in

[167] Boscheck (n 1) 223.
[168] Gallegos et al (n 77) 1213.
[169] Communication from the Commission to the European Parliament, The Council and the European Economic and Social Committee Towards a renewed consensus on the enforcement of Intellectual Property Rights: An EU Action Plan /* COM/2014/0392 final */ (1).
[170] ibid.
[171] Kumar et al (n 2) 4.
[172] ibid.
[173] Sampat et al (n 12) 699.

Argentina, Brazil, Japan or India.[174] Undoubtedly, national differences in patent systems' characteristics can play a crucial role since not all states file their application under the Patent Cooperation Treaty.[175] The data shows Argentina as the country that has most successfully observed its secondary patenting restrictions, as the grant rate for secondary patents is much lower than for primary applications.[176] As evidence suggests, neither Brazil's nor India's policies are very effective.[177]

Although TRIPS aimed to harmonize patent law, the evidence does not support this view.[178] Brazil seemed to have become a country that successfully dealt with the new patent granting lawsuit implemented by TRIPS and its flexibilities, despite the fact that Brazil's differences in primary and secondary patent grants are currently almost identical.[179] To tackle the problem of pharmaceutical patent evergreening, the new laws were introduced together with ANVISA – the Ministry of Health surveillance agency whose "Prior Consent" was required to grant patents on drugs.[180] ANVISA took an approach to limit secondary patents and developed its examination guidelines.[181] Although the Prior Consent system has been revised, pharmaceutical patents must still be approved by both ANVISA and the Brazilian patent office (INPI).[182]

Similarly, Argentina allowed pharmaceutical products to be patentable from 2000.[183] In 2012 the new guidelines introduced by the Argentinian patent office directed examiners to dismiss a vast majority of secondary patent application claims for pharmaceutical products. A more restrictive approach taken by Argentina is noticeable, and does not seem to be complex, as the policy only instructs patent examiners to reject secondary patents using usual patentability criteria.[184] This approach suggests that administrative procedures is the most effective tool in tackling secondary patenting. In contrast, Mexico fails to observe flexibilities, and the consequence

[174] ibid 698.
[175] ibid 699.
[176] ibid.
[177] ibid.
[178] ibid 703.
[179] ibid.
[180] ibid 695.
[181] ibid.
[182] ibid.
[183] ibid.
[184] ibid 702.

of its wide margin of patentability results in one of the highest prices of drugs in Latin America.[185]

Since the prices of pharmaceuticals in the Philippines have started to become one of the most expensive in Southeast Asia, the country has decided to implement TRIPS flexibilities for the sake of public health and accessibility of cheaper medicines.[186] Following the example of India's patent law and the *Novartis* decision, the Philippines was motivated to prescribe Section 22 of the Republic Act No 8293 (following Section 3(d) of the Indian Patents Act) restricting "mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy" from being patentable.[187]

The differences in grant patents are based on the features of national patent system policies in developing countries.[188] The US and Europe established the highest grant rates for secondary patents, whereas Brazil and Argentina had the lowest grant rates,[189] although it is claimed that in developing countries "formal rules are often not consistently enforced".[190] In India, the vast majority of secondary applications were refused on conventional patentability grounds, and it is suggested that although they cited Section 3(d), they might have been rejected even in the absence of the relevant secondary application restriction policy.[191] The study concerning Brazil establishes that it is not always rejection that causes the grant rate to decrease, but rather withdrawals due to applicants' negligence and inadequate fee payments before the examination process takes effect.[192] Furthermore, it was proven that the Prior Consent rejections are uncommon.[193]

However, the implementation of TRIPS flexibilities also enabled other countries to introduce arrangements allowing opposition or filing observations by the third parties.[194] A pre-grant opposition procedure is established in Australia, where opposition on the patentability

[185] Tahir Amin, 'Re-Visiting the Patents and Access to Medicines Dichotomy: An Evaluation of TRIPS Implementation and Public Health Safeguards in Developing Countries' (Global Governance of HIV/AIDS: Intellectual Property and Access to Essential Medicines, O Aginam, J Harrington, P Yu, eds, Edward Elgar, 2010) 12-13.
[186] ibid 5; Kumar et al (n 2) 5.
[187] Section 22 of the Philippine Republic Act 8293.
[188] Sampat et al (n 12) 700.
[189] ibid 701.
[190] ibid.
[191] ibid 700.
[192] ibid.
[193] ibid.
[194] Amin (n 185) 13.

requirements can be done by anyone.[195] The pre-grant opposition regime is also prosperous in extracting voluntary licenses which, when enforced, may significantly lower the price of a drug.[196] It is not sufficient to merely introduce policies aiming to limit secondary patenting claims, but other procedural aspects must also be considered.[197] Due to many additional difficulties that developing countries face, TRIPS flexibilities offered by the patent system may be the only solution to tackle monopoly and unequal access to essential drugs. Although there is little evidence that attempts of developing countries to "curb" the grant of secondary patents are effective,[198] administrative and procedural features of patent systems must be taken into account when aiming to understand how the patent system functions, what the impacts of patent policies are, and how to prevent abusive secondary patenting strategies.[199]

6. Private rights and public goods – in search of equilibrium

The transition process of a new drug into its generic version is slow and results in diminishing patients' welfare.[200] The example of the insulin crisis is a clear representation of the state's attitude and responsibility towards patients' well-being, as well as the power of pharmaceutical firms establishing their private rights. Some claim that rather than patent exclusivity, it is the national regulatory environment that poses the main threat to insulin accessibility.[201] Hence, the price of insulin being regarded as a "prohibitively expensive essential medicine",[202] may be set by IP holders in response to the "complex regulatory environment surrounding biological drugs".[203]

Pharmaceutical companies often claim that patents are the exclusive stimulus to invest in drug development.[204] The method of filing secondary patents for medical products seem to be exclusively fair for R&D teams' reimbursement. Accordingly, regulatory costs constitute a major

[195] Australian Patents Act 1990 (Amended 1994), Section 59.
[196] Amin (n 185) 15.
[197] Sampat et al (n 12) 693.
[198] ibid.
[199] ibid 703.
[200] Nicoleta Tuominen, *An IP perspective on defensive patenting strategies of the EU pharmaceutical industry*, (EIPR 2012, 34(8)) 541.
[201] Gallegos et al (n 77) 1211.
[202] ibid 1212.
[203] ibid 1213.
[204] I-MAK (n 97) 9.

obstacle for biosimilar manufacturers to enter the market, which results in high drug prices to recoup themselves after costly clinical trials.[205] Existing insulin producers are also rarely subject to strict regulatory oversight, enabling them to issue their own versions of biosimilars, which are often only slightly cheaper than the original medicine[206] and make it difficult for other manufacturers to compete with the giants.

Adjusting administrative and procedural aspects of the patent law regime to balance private and public rights is burdensome. The regime is justified by a belief that pharmaceutical companies should involve the right to eliminate the competition from making use of a patented invention for a limited time, to recur the costs of R&Ds.[207] When an old debate relating to restrictions posed to the accessibility of essential medicine is raised, the opposition argues that patents do not restrict patients of elemental choices, as patients are not forced to stick to improved versions of their drugs, but are allowed to choose the cheaper, not upgraded version of the medicine.[208] Consequently, it is claimed that well-designed patent systems already deal with some types of evergreening,[209] which do not pose a threat to human beings' lives. It is further disputed that patents should not be regarded as a monopoly, but rather as exclusive rights, because the "built-in" balances and checks within the regime, such as compulsory licenses and permitted use schemes, are designed to prevent abuse of patents.[210] Although these mechanisms are enforceable, abuse of patentability bar, especially novelty, very frequently occur by marginal modifications made to an invention.[211]

EU and US patent term extension provisions are said to be "rather restrictive", as legal provisions in some cases allow companies to restore investors' funds and extend patent term protection by a small period.[212] Furthermore, patents are allowed to be challenged which could accelerate generic versions to enter the market.[213] Post-grant opposition is available at the EPO in the European Union, and in the US the Hatch-Waxman Act provides Abbreviated New Drug

[205] Gallegos et al (n 77) 1215.
[206] ibid 1213.
[207] Boscheck (n 1) 225.
[208] ibid 224.
[209] ibid.
[210] Lukose (n 7) 1.
[211] ibid.
[212] Boscheck (n 1) 225.
[213] ibid.

Application (ANDA) for generic bioequivalents, to enable them to reach the market.[214] Nevertheless, there are still some concerns regarding ANDA's efficacy - if a potential patent opposition claim is successful, a patent may either expire or a duopoly may be created by two firms existing in the market.[215]

In 2013, WHO issued the Global Action Plan for the Prevention and Control of Noncommunicable Diseases from 2013 until 2020, where it called for developing health equity and accessibility to essential medicines through full use of TRIPS flexibilities.[216] The Members were encouraged to adopt evidence-informed strategies, such as including drugs on essential medicines lists, regressive mark-up schemes and controlling wholesale to ensure affordable access to essential medicines.[217] Furthermore, they were involved to promote the use of safe, quality and affordable medicine including generic drugs.[218] Also, to reduce the price paid by the patient and improve access to medicines, various programmes were created to incent generic drugs by encouraging pharmacists and medical practitioners to dispense and prescribe generic versions of drugs.[219] Still, restricted access to insulin experienced by many diabetics around the world is only a sole example among others.

The UDHR 1948 and the UN's International Covenant on Economic, Social and Cultural Rights highlight the importance of the right to health which is crucial for every human being. Access to medicine is one of the most important aspects of fulfilling this right, as a third of the global population cannot enjoy it.[220] The debates have always focused on infectious diseases such as HIV/AIDS, TB and malaria, but not necessarily on non-commutable diseases (NCD) such as diabetes. Still, issues preventing insulin from being available to every diabetic not only focus on price, but also cover distribution, governmental policies and the creation of a new health system.[221] Although WHO claims that insulin must be regarded as essential medicine,[222] and its prices have

[214] ibid.
[215] ibid.
[216] WHO (n 78) 42.
[217] ibid 43.
[218] ibid.
[219] Cameron A, Ewen M, Auton M, Abegunde D. The world medicines situation 2011: medicine prices, availability and affordability. Geneva: World Health Organization; 2011:13.
[220] Beran (n 122) 67.
[221] ibid.
[222] WHO (n 78).

dropped significantly over the past years, its access is still an issue for many.[223] Certainly, only states can be pursued to comply with international provisions and be liable for human rights violations, such as the socio-economic human right to health. At the same time, businesses cannot be deprived of their fundamental rights to development; and patent owners, to benefit from inventions. Still, the extent of the problem of insulin inaccessibility is illustrated by examples of hospitals which have started to formulate plans to produce their own biosimilars,[224] and projects, such as The Open Insulin Project, which aims to increase competition in the insulin market.[225]

While pharmaceutical giants argue that secondary patents are the only possibility for them to recur their investment costs, it shall be noted that many R&Ds are, in fact, funded by governments, by using public money. The new coronavirus vaccine is a great example of "global public goods" being administered to tackle a disease.[226] Not only had the UK government sponsored R&Ds of the COVID-19 vaccine at the University of Oxford, but it has also implemented compulsory licenses to ensure that both therapeutic drugs and vaccines are easily, cheaply and widely accessible, as soon as possible, which was strongly recommended by the report released by the International Trade Committee.[227]

The problem associated with the production of insulin is that there is too little evidence to ensure that most insulin giants are getting grants for R&Ds from public funds. Had this been the case, the financial value of absurdly overpriced and over-patented insulin would have an opportunity to dramatically decrease. Privately, pharmaceutical giants, such as Novo Nordisk, Eli Lilly and Sanofi, can play the patent game without respecting fundamental human rights. Although differential pricing is said to be fundamental to the business' moral model,[228] the catastrophic effects of controlling insulin market shares by the oligopoly are very likely to deepen.[229] This also

[223] Beran (n 122) 68.
[224] Gallegos et al (n 77) 1211.
[225] ibid, 1212.
[226] James Love, 'The Use and Abuse of the Phrase "Global Public Good"' <https://www.indiachinainstitute.org/2020/07/09/the-use-and-abuse-of-global-public-good/> Accessed 1 August 2020.
[227] Trade policy response to COVID-19 examined in Committee report <https://www.parliament.uk/business/committees/committees-a-z/commons-select/international-trade- committee/news-parliament-2017/covid-19-impact-trade-policy-report-published-19-21/>.
[228] Friedman (n 139).
[229] Dana Brown and Elizabeth Pfiester, "Insulin: a case study for why we need a public option in the

leads to issues of so-called "entrepreneurial science", which praises the risk-taking entrepreneurs that "interconvert the knowledge and wealth".[230] Biotech companies are being recognized for their contribution in producing drugs using complicated recombinant DNA techniques, despite the fact that this method had initially been developed by academics.[231] Since the success story of entrepreneurial science is often accompanied by the company's products and patents, one does not question occasional entrepreneurial thefts that often happen within in this industry.[232]

It may be suggested that diabetics are being forgotten in this dispute. Had the essential medicines been researched, developed, manufactured and sold by the public institutions, public interest would have been observed.[233] A model where the state funds the majority of R&Ds may result in allowing generic companies to compete and enter the market more easily, and public entities would be subject to transparency laws, making private pharmaceuticals more transparent.[234] As a consequence, the fundamental human right to health and life would have a lesser chance of being undermined.

7. Conclusion

There is no other area where market and non-market functioning is subject to as many conflicts as in case of conflict between pharmaceuticals and patients in need.[235] There is an indisputable need to ensure access to medicine for all patients in both developing and developed countries. At the same time, protection of intellectual property rights shall not be put aside. Although it is immaterial how much time, effort and money has been invested in research and development, there still exists a risk of a drug being unsuccessfully put into circulation. Furthermore, it is claimed that due to regulatory procedures being too complex and time-consuming, the "patent clock" starts ticking in the early development process of the medicine.[236] Innovator companies increased their aggressive evergreening practices to reimburse the costs invested in drug development, forgetting about the humanitarian approach and especially, about their role in

pharmaceutical industry" (2019) <https://www.statnews.com/2019/09/10/insulin-public-option-pharmaceutical-industry/> Accessed 1 August 2020.
[230] Yarden Katz, "Entrepreneurial Science" (2018) 1.
[231] ibid.
[232] ibid 2.
[233] Brown et al (n 229).
[234] ibid.
[235] Boscheck (n 1) 226.
[236] Kumar et al (n 2) 5.

addressing complicated diseases.

It is understandable for innovators to expect solid compensation for their hard work, however, unreasonably procuring secondary patent applications and maintaining monopoly for as long as possible indeed impair the entry of cheaper, generic drugs on the market. TRIPS is frequently blamed as the instrument because of which its Member States are obliged to grant patents.[237] Although there is much criticism against TRIPS, countries acknowledge that abandoning the agreement (and the WTO) would be a step leading to genuinely distressing trade relations with the rest of the world.[238]

States' struggles to hamper secondary patent applications have been analysed to understand what enabled one to get into the "black box" of patent examination procedures in developing and developed countries. As learned from examples of patent grants in Brazil and India, there are no lower grants for secondary patents than for primary ones. Instead, these states give applicants more time to reconsider whether their applications are important enough, and of sufficiently high quality, leading them to eventually abandon the application.[239] However, the most successful state in tackling the pharmaceutical evergreening was Argentina, where patent examiners were taught to assess secondary patent applications precisely with the original patentability criteria.

After conscientious interpretation of the findings enclosed in this paper, the most obvious recommendation to ease the access to essential medicine, and in particular to insulin, would be primarily to revise patentability requirements for secondary patents. The most vital role in securing the market share from irrationally prolonged exclusivity is the "inventiveness" requirement. It is claimed that if this patentability bar was raised, patients would experience a decrease in drug prices in 20 years through widened competition of biosimilars or generic drugs on the market.[240] In patent law regime, both for primary and secondary applications, a level of inventiveness is not recognized as a requirement - the invention might be either a "breakthrough or an incremental step".[241] It has also been suggested that the pre-grant opposition system which is used by states such as Australia,

[237] Ho (n 11) 1.
[238] ibid.
[239] Sampat et al (n 12) 694.
[240] I-MAK (n 97) 10.
[241] Boscheck (n 1) 224.

and the USPTO in trademark registration, might be a prominent idea to enable third parties to file opposition while the initial patent application is still under review.[242]

The infamous example of the *Novartis* case in India establishes that states can face pharmaceutical giants and review patentability requirements to protect the poorest from inaccessibility to life-saving medicines. India, as well as other emerging countries that are taking the opportunity to use TRIPS flexibilities, are criticized for not enforcing intellectual property rights, claiming that it restricts companies from benefiting and economically advancing.[243] India is being treated as an IP offender by the US and is being criticised by the EU for its decision to restrict patent evergreening. These approaches have also been criticized by the pharmaceutical industry as unfair obstacles to be rewarded for their inventions.[244]

It is claimed that "affordability is impacted by purchasing power".[245] Therefore, the broad examination highlights that the knowledge of how medicines are preserved from competition shall be widely recognised.[246] Since patent law most frequently is an international barrier in accessing medicine, enhancing national healthcare policies and strengthening the health systems would be a promising step towards improving insulin affordability. Although the pharmaceutical industry is usually private, expanding public investment to insulin R&Ds would ensure more transparency and could commit to wider responsibility towards patients suffering from non-communicable diseases.

Safeguarding equitable access to quality medicine shall be an elementary component for all, and with the increase of diabetes, adopting security of supply of insulin must be supported by the promotion of local production, generic competition and diversity of suppliers, as well as harmonization of regulations.[247] There is an indisputable need to adopt appropriate measures to address unmet patients' needs by imposing an obligation on governmental and non-governmental organizations to increase affordability programmes, as restricted access to essential medicine is

[242] I-MAK (n 97) 11.
[243] Boscheck (n 1) 226.
[244] Sampat et al (n 12) 694.
[245] Beran (n 122) 68.
[246] Ho (n 11) 3.
[247] Beran et al (n 99) 361.

observed not only in low- and middle- but also in high-income settings.[248] If any state considers fighting abusive secondary patenting, it would first need to admit that patent evergreening does exist, define the patent evergreening term on their own and, subsequently, work on regulation, as well as administrative aspects of patent law improvements.

Addressing the problems caused by patent evergreening includes the continuous debate on balancing inalienable human rights and the recognition of private rights. It has been argued that strong barriers to access to medicine still exist, with secondary patenting being one of those that globally affects pricing, distribution and lack of competition in the market. Patent evergreening does exist in the insulin industry and is frequently present in device evergreening. The oligopoly occurring as a result of practices procured by the pharmaceutical giants controlling the insulin market, restricts access to insulin and impacts the quality of lives of many vulnerable patients who live in low- or middle-income countries, or those citizens of high-income states who rely on their insurance package rather than their government. In any case, the value of human life and health is being underestimated and immediate change is required to enhance access to essential medicine, especially for those patients whose needs are currently unmet.

[248] ibid.