

Evergreening Patents and Discontinuous Innovations

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ABSTRACT

This article approaches the evergreening patent issue in the context of blocking innovation by seeking to extend exclusivity on patent rights since intellectual property law can provide immunity from competition law enforcements up to some extent. In consequence of evergreening patent practices, patentees extend and, consequently, cement their privileged positions pursuant to their patent rights (in an anti-competitive way). Patenting a follow-on innovation limits generic competition on the old one and therefore, any inconveniences in the patent system would likely distort competition since other manufacturers with the intention to penetrate the same market are restricted from the competition. Yet, innovation remains a crucial factor as technology companies cannot be expected to act responsibly regarding the use of their market powers unless the legal framework for promoting innovation is defined. They might, for instance, formulate a strategy that suppresses their innovations for the same reasons, such as evergreening patents offering new features for their latest products rather than providing compatible updates. In this regard, this study argues whether and to what extent gaps in the current patent system could be filled by the complementary nature of competition law provisions, in particular Article 102 TFEU.

Keywords: Evergreening patents, Innovation, EU Competition Law, Article 102 TFEU

A. INTRODUCTION

Innovations in proprietary technologies have become one of the most important economic constituents. Businesses are encouraged by being furnished with tools for recouping investment in the form of substantial intellectual property (IP) rights including patent protection to produce and implement their innovations.

Once patent protection expires, others can copy and sell the product, competing with the original version of the product. It should be noted that a patent expiration, does not necessarily mean that the product can be copied because product could be protected by other non-expired patents, meaning the invention in the patent can then be copied. As from the expiration of the original product's patent protection, it is expected that the replacement product in the market will be enlarged with generic versions of the product. This would likely decrease the price and increase the competition between generic manufacturers.¹ Therefore, regulations should support boosting generic competition by facilitating access to the market. The evergreening of patents may lead to abuse and mis-

use of the patent system to fend off competition law.² Such conduct will likely pave the way for taking benefit from monopoly rights given by law.³

B. THE LEGAL CONTEXT OF THE EVERGREENING ISSUE

Evergreening refers to patentees' conduct to extend their exclusive rights granted by patent protection. This is also known as strategic patent planning where originator manufacturers take precautions against generic manufacturers in advance to get a competitive edge. The evergreening patent indicates the exploitation of patent protection in which patent holders draw advantages from sore points of patent regulations and related regulatory processes just before the end of this protection. This strategy is gener-

¹ One may argue that not always does the patent expiry lead to an immediate price decrease – e.g. the former patent product may still enjoy a dominant position, or competitors may lack the know how to compete with the patented product.

² L Lukose, 'Patent ever greening: Law and Ethics' in M Bottis and E Alexandropoulou-Egyptiadou (eds), *Broadening the Horizons of Information Law and Ethics – A Time for Inclusion* (University of Macedonia Press 2017) 351.

³ A Kumar and A Nanda, 'Ever-greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries' (2017) 6(1) *Pharmaceuticals Regulatory Affairs* 4; M Törnvall, 'The Use and Abuse of Patents – Evergreening in the Pharmaceutical Sector' (Graduate Thesis, Lund University 2013) 26–51.

ally used by innovators having a large volume of research investment costs through making slight modifications to extend the period of exclusive rights.⁴ The European Commission (EC) did not explicitly use the term ‘evergreening’ to justify its decisions. Instead, this situation has been mentioned as a tool for preventing or delaying generic products’ entries.⁵ Some of the evergreening practices specified in the EC’s Pharma Report include but are not limited to patent filing strategies,⁶ patent-related litigation,⁷ patent settlements,⁸ life cycle strategy⁹ but not limited to.

As patent evergreening is a broad concept, this section limits itself to the introduction of second-generation products by obtaining new patent protections through showing only incremental innovations. The introduction of second-generation products is one of the most frequently used strategies to keep rivals away from generic competition. Despite the expiration of patent protection, generic product manufacturers will always have market entry barriers as consumers are directed towards improved second-generation products.¹⁰ Patent holders generally introduce second-generation products; in other words, follow-on products, into the market to return more profits by using their original products’ fundamental structure via incremental innovations. Although this innovation contributes to the existing technology leastwise, second-generation products will also benefit from patent protection if they meet patentability conditions.

There are strident criticisms in the literature against evergreening patenting strategies not only in pharmaceuticals but also other technology-intensive industries as they suppress the benefits of introducing generic substitution.¹¹ Since generics are copies of the product that is already on the market, one prima facie sees no suppression but there are two issues, which can cause suppression here. First, the product or service may be bound or tied such that the consumers are likely to purchase a latter-generation product. For instance, in the context of the software market, consumers will not be keen on changing their software, which they have already become accustomed to using. Moreover, the plug-ins in the software may not be compatible with generic substitutions. Furthermore, consumers may be under obligation to pay during the contract term, and they may get a better

deal before the expiration of the contract in return for a renewal of the contract with the new product. These are just a few examples of how generic manufacturers can be excluded from the competition, and therefore, doctrinal discussions concerning tying and bundling concepts are open to change in terms of Article 102 TFEU.¹² Second, the innovator may misinform the patent office and apply for a patent, which shows just an improvement (not novelty) of the patented product or has already been obtained by itself or third parties. However, Becker highlighted that the evergreening patents problem does not exist since it is not possible to re-file the same invention for an extension.¹³ Every patent office elaborates on both breakthrough and incremental innovation applications whether there are usefulness, novelty, and non-obviousness to issue patent protection. Therefore, the problem ensues from the patent system, and the likely solution is to raise the bar for patenting by asking for better quality patents.

Patentees will obtain a monopoly position with the help of their exclusive right since they are the sole sellers or manufacturers of certain products. From this perspective, patents block competition. More specifically, they block price competition because others cannot copy the patent-protected product. This will likely constitute a contradiction with the purposes of EU competition law. However, IP rights stimulate dynamic (innovative) competition by motivating competitors to innovate and introduce competing products.¹⁴

The issue concerning evergreening patents will appear when patent holders restrict (delay) generic competition by abusing IP systems’ regulatory laxness through obtaining follow-on patents.¹⁵ There will accordingly be two main headings in light of evaluating Article 102 TFEU: (i) whether and to what extent an extension of exclusivity may be considered as anti-competitive conduct, (ii) and whether and to what extent businesses making incremental innovations deserve monopoly rights.

In the grand scheme of things, the innovativeness of countries indicates the level of their social welfare.¹⁶ As

⁴ Kumar and Nanda (n 4) 1–6.

⁵ European Commission, Pharmaceutical Sector Inquiry (Preliminary Report, 2008) para 466 <https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf> accessed 3 November 2020.

⁶ Ibid, paras 467–546.

⁷ Ibid, paras 547–644.

⁸ Ibid, paras 202–855.

⁹ Ibid, paras 987–1049.

¹⁰ Such products are nearly the same with primary products but having innovative contents.

¹¹ G Dwivedi, S Hallihosur and L Rangan, ‘Evergreening: A deceptive device in patent rights’ (2010) 32(4) *Technology in Society* 324–330; S Midha, ‘Strategies for drug patent ever-greening in the pharmaceutical industry’ (2015) 3(3) *International Journal of Pharmaceutical Sciences and Business Management* 11–24.

¹² S Holzweber, ‘Tying and Bundling in the digital era’ (2018) 14(2-3) *European Competition Journal* 342–66; Communication from the Commission 2009/C 45/02 of 24 February 2009 Guidance on the Commission’s enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings [2009] OJ C 45/7 (Guidance of enforcement priorities in applying Article 82 of the EC).

¹³ K Becker, ‘Pharma patents in Europe: where are we going?’ (2009) 1(2) *Future Medicinal Chemistry* 227–228.

¹⁴ See for a general reading, S Anderman, *The Interface Between Intellectual Property Rights and Competition Policy* (Cambridge University Press 2007); S Anderman and H Schmidt, *EU Competition Law and Intellectual Property Rights: The Regulation of Innovation* [OUP 2011]; C Villarejo and T Kramler, ‘Intellectual Property Rights and Competition Rules, a Complex but Indispensable Coexistence’ in S Anderman and A Ezrachi (eds), *Intellectual Property and Competition Law: New Frontiers* [OUP 2011] 61–73.

¹⁵ The patentee relies on the rules of the patent system to obtain follow-on patents, and if the invention meets the patentability requirements, the patent will be granted. However, the patentee may misinform the patent Office or take advantage of weak patent systems.

¹⁶ OECD, ‘The Knowledge-based economy’ [1996] OCDE/GD(96)102, 3; OECD, ‘A new economy? The Changing Role of Innovation and Information Technology in Growth’ [OECD Publishing 2000] 27–81.

such, the effectiveness of patent protection systems matters to encourage businesses to be more innovative. An effective patent system can promote technological innovation by presenting judicious compromises. At the same time, such a system also gains favour to the frequency of innovations by providing an appropriate environment for new inventions.¹⁷ However, on the other hand, any deficiency in the patent system may lead to evergreening applications, which eradicate all the benefits of IP protection.

I. Theoretical Examination of Evergreening Patents

The term 'evergreening', as explained above, refers to several behaviours towards further exploiting granted patent protection via legal and illegal strategies. These strategies are generally lawful, but it does not mean that they are exempted from the application of Article 102 TFEU. Whish and Bailey, accordingly, stress the importance of applying this article in case of exercising patent rights in an abusive way.¹⁸ In regard to the theoretical background of evergreening practices, patent law aims to contribute to industrial progress by inspiring scientific works and newer technologies.¹⁹ With this regard, it can be claimed that patents as temporary monopoly rights are necessary for the prevention of likely market failures because innovators will be discouraged in the absence of patents where newcomers can freely make copy-paste and penetrate the market without any research costs.

The theoretical base of evergreening can be explained from Lockean and Schumpeterian perspectives. From the labour theory of Locke, as a moral principle, the state ought to grant a right to an innovator, who puts a mental effort into an invention.²⁰ As this (tangible or intangible) invention contributes to the public, it deserves protection. However, arguably, this theory does not support evergreening patents when it is considered that there is a lack of creative efforts on evergreening patents,²¹ which are not availed to the public. According to Posner, if IP rights encourage businesses to innovate, the pitfalls of granting such exclusivity could be tolerated.²² Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) similarly stated that granting IP rights contributes to the development of technology through increasing technological knowledge, the effective spread of innovation, and socioeconomic welfare by

holding the balance between holders' rights and obligations. If granting a patent is accepted as a social contract between innovators and society, innovators will have monopoly rights where the society tolerates for a length of time to gain favour from innovators' creations. This theory is vital for the emergence of innovations, which lay foundation for patent systems.²³ Nevertheless, breach of covenant will likely come in sight when it comes to patent evergreening in which innovators abuse this contract by extending their monopoly rights by showing minor alterations. In other words, in the case of evergreening patent issues, the supposed contract becomes unjust and theoretically deficient.

From the Schumpeterian perspective, innovators should always be promoted via exclusive rights as those innovations will eventually be beneficial to society. Otherwise, investments in research and development will decrease because of free-riding strategies, and consequently, technological progression will decelerate.²⁴ However, on the other hand, evergreening patents require relatively fewer investment costs and efforts. Therefore, one can claim that evergreening practices are not deserving of patent protection²⁵ even though they are commonly examined under monopoly-profit incentive theory, which supports rewarding monopolies in exchange for their innovations.²⁶ It would be highly controversial to grant patent protection (as a property or a privilege) for evergreening practices where the risks are very low due to the inessentiality of time and cost for introducing a new product. One may accordingly claim to shorten/weaken patent protections for evergreening patents. However, it would not be appropriate because technology is developed cumulatively by depending on previous technologies. Hence, any restrictions on IP laws would likely result in suppressing technologies.

In conclusion, providing a reasonable economic incentive for an innovator seems instrumental to leverage consumer welfare and, more generally, public benefit from different theoretical perspectives. By courtesy of exclusive rights stemming from patent protection, the innovator will be able to estimate its potential profit before introducing the innovation.²⁷ However, the vagueness of determining novelty and non-obviousness of inventions is the essence and the abstract of the matter where patent holders push the limits of the patent system, and arguably

¹⁷ W Cornish, D Llewelyn and T Aplin, *Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights* (Sweet and Maxwell 2003) 114.

¹⁸ R Whish and D Bailey, *Competition Law* (OUP 2018) 814–827.

¹⁹ P Groves, *Source Book on Intellectual Property Law* (Cavendish 1997) 48.

²⁰ J Locke and R Filmer, *Two Treatises on Civil Government* (Routledge 2018); E Maughan, 'Protecting the rights of inventors: how natural rights theory should influence the injunction analysis in patent infringement cases' [2012] 10 *Georgetown Journal of Law and Public Policy* 233–234.

²¹ J Mueller and D Chisum, 'Enabling Patent Law's Inherent Anticipation Doctrine' [2008] 45 *Houston Law Review* 1101.

²² R Posner, *Economic Analysis of Law* (Aspen 1998) 43.

²³ W Landes and R Posner, *The Economic Structure of Intellectual Property Law* (Harvard University Press 2009) 294–295.

²⁴ B Ilic and B Pretnar, 'The Economic notion of the incentive to invent in the legal perspective of patent protection' (2004) 6 *Economic and business review for Central and South-Eastern Europe* 286.

²⁵ M Abbas, 'Evergreening of Pharmaceutical Patents: A Blithe Disregard for the Rationale of the Patent System' [2019] 15(2) *Journal of Generic Medicines: The Business Journal for the Generic Medicine Sector* 56.

²⁶ For counter argument concerning broader incentives for innovators, see E Kitch, 'The Nature and Function of the Patent System' (1977) 20 *Journal of Law and Economics* 265.

²⁷ J Kesan, 'Economic rationales for the patent system in current context' [2014] 22 *George Mason Law Review* 897; M Lemley, 'Ex ante versus ex post justifications for intellectual property' [2004] 71 *University of Chicago Law Review* 129.

abuse it, via slight modifications, which are the Achilles' heel of the system.

II. An application of TFEU Provisions in Evergreening Issues

Manufacturers, who have patent protection, can benefit from monopoly rights and derive a profit without competitive pressure in each period. They generally resort to evergreening patent rights for extending this privilege through patenting follow-up inventions as long as these inventions only make a minor addition to first-generation products.²⁸ This intellectual monopoly privilege is at the centre of both international trade and intellectual property laws, particularly for the pharmaceutical industry. However, it also has a clear link with Article 102(b) TFEU in terms of limiting technical development to the prejudice of consumers because the expiration of a patent prevents patent holders from retaining more royalties, which are provided by the monopoly market. Such patenting strategies lead to market entry barriers, which restrict fair competition.²⁹ Therefore, the evergreening problem needs further examination from a competition law paradigm.

Evergreening patents are considered lawful under patent law as well as currently under EU competition law.³⁰ What is certain is that the lawfulness of evergreening patents *prima facie* seems to be governed by patent law rather than competition law and as per Article 345 TFEU, the Union law is not entitled to examine patent rights whether they are obtained lawfully or not because they are granted as national rights. However, it is evident that IP rights do not provide effective immunity if they are against EU competition law.³¹ Competition law only controls the exercise of IP rights by preventing all potential monopolistic abuses arising out of misusing IP rights.³² Hence, conducting a detailed investigation is a must to

evaluate whether evergreening patenting practices are competition on merits or breach of Article 102 TFEU since patenting of second-generation products by originator manufacturers likely restricts the market access of generic manufacturers.

Even though it is hard to establish a link between evergreening practices and special conditions of Article 102 TFEU, those practices can still be prevented under this article. When determining fresh types of abuses in the context of Article 102 TFEU, an intention to eliminate competition is considered by the Commission. Hence, the link can be established by assessing the competitiveness of evergreening practices and their impact on competitive markets. However, the claim of eliminating competition intention shall be supported with objective and economic data. In these premises, Article 102 TFEU would be enforceable when considering anti-competitive results and detrimental effects on consumer welfare.

EU patent law has arguably a weak legal infrastructure to cope with evergreening practices. Hence, as concerns evergreening practices, Article 102 TFEU will always come up even though it constitutes a contradiction with member countries' national patent laws. In terms of EU law, the *AstraZeneca* decision provided useful principles that may be relevant to evergreening.³³ Hence, the trace of evergreening can be found in the *AstraZeneca*³⁴ case in the context of Article 102 TFEU.³⁵ However, there was no such a similar decision in regard to the strategic use of patents before this case where *AstraZeneca* delayed and even prevented the introduction of its generic products by abusing its dominant position through bending the rules of the patent system. The concerned case redressed the frame of Article 102 TFEU enforcement, and the current frame indicates that every conduct, which seems completely lawful and has a likely anti-competitive effect, may be subjected to an abuse of dominance investigation. Therefore, bending the patent protection issue (evergreening) requires further explanation to make out the degree to which it contrasts with the aims of competition law.

III. Case Law regarding Evergreening Issues

Evergreening patenting issues have so far been mostly encountered in pharmaceutical companies' cases³⁶ such

²⁸ European Commission, Pharmaceutical Sector Inquiry (Preliminary Report, 2008) para 480, 994 <https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/pre-liminary_report.pdf> accessed 3 March 2022.

²⁹ The BEUC accordingly made the following opinion: "patent strategies can constitute barriers to the entry of new generic medicines into the market. We are very much concerned by the phenomenon of so-called "evergreening", which describes a specific tactic used by originators to extend patents by seeking to obtain as many patents as possible during the development of the product and the marketing phase, and to obtain a patent extension for new manufacturing processes, new coating and new uses of established products. Originators can also slightly change an active ingredient and present an old medicine as a new product and register a new patent. We consider that these practices are anti-competitive and prevent generics' entry into the market. They also incur higher health care expenditures and/or higher prices for consumers." See, European Commission, 'Pharmaceutical Sector Inquiry – Final Report' (2009) SEC(2009)952, COM(2009)351 final, para 1107.

³⁰ H Gubby, 'Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective' (2020) 11(1) *Global Policy* 46–55; M Törnvall, 'The Use and Abuse of Patents – Evergreening in the Pharmaceutical Sector' (Graduate Thesis, Lund University 2013) 26–51.

³¹ See argument to the contrary, L Kjølbjerg, 'Article 82 EC as Remedy to Patent System Imperfections: Fighting Fire with Fire?' (2009) 32(2) *World Competition* 163–188.

³² R Boscheck, 'Intellectual Property Rights and the evergreening of pharmaceuticals' (2015) 50(4) *Intereconomics* 221–226.

³³ It should be noted that *AstraZeneca* case was about the misuse of the patent procedures, i.e. the company provided incorrect information to the patent offices. So, there was some unlawful behaviour on the side of the patentee. See, J Drexler, 'AstraZeneca and the EU Sector Inquiry: When do patent filings violate competition law?' in J Drexler and N Lee (eds), *Pharmaceutical Innovation, Competition and Patent Law* (Edward Elgar 2013) 290–322.

³⁴ Case C-457/10P, *AstraZeneca AB and AstraZeneca plc v European Commission* [2013] ECLI:EU:C:2012:770.

³⁵ This cannot be simply classified as an evergreening practice since there was an unlawful behaviour by misusing the patent procedures where *AstraZeneca* provided incorrect information to patent offices.

³⁶ Recent trend is referring evergreening patent, particularly in the pharmaceutical market with trivial amendments and tweaking existing formulas to demonstrate originality. See, Lukose [n 2] 1.

as the *AstraZeneca* and *Lundbeck* cases,³⁷ where patent holders had strived to extend the duration of their granted exclusive rights.³⁸ However, exploiting IP rights to the core is significant for all other high technology-intensive markets, such as electronics and software markets. Such strategies cement patentees' negotiating and competing positions, which established an anti-competitive environment for generic product markets.³⁹

The European Court of Justice particularly emphasised in detail in the *Lundbeck* that follow-on patent claiming (on escitalopram) did not prevent rival producers from introducing generic versions of original products after the patent protection expires.⁴⁰ Most importantly, in terms of the use of patents, more specifically evergreening patent issue, has been thoroughly discussed in the *AstraZeneca* renounced its marketing authorisation for Losec -in Denmark, Norway and Sweden- to have an advantage over its competitors when it introduced its second-generation product, namely Losec MUPS. This complicated producing generic versions of Losec as there was no announced formula, and consequently, competitors encountered market entry barriers because producing an equivalent product would likely be costly and time-consuming.⁴¹ Even though *AstraZeneca's* conduct of withdrawing its marketing authorisation of Losec seemed prima facie lawful, other parties claimed that such a conduct eliminates effective competition for rival businesses.⁴²

The court carried out an investigation against *AstraZeneca* because of two main conducts. First, the claim that *AstraZeneca* extended its original patent protection for its medicine named Losec by providing patent offices and courts with deceptive statements. *AstraZeneca*, in its defence, stated that the General Court misinterpreted the notion of competition on merits and it made a mistake by applying Article 102 TFEU without showing intentional fraud or deceit. Second, it has also been claimed that *AstraZeneca* has rightly but differently interpreted 'the Supplementary Product Certificate Regulation' in good faith by adding that patent applications would likely be decreased, and this consequently distorts competition in the absence of this alternative interpretation.⁴³ However, it would also be irrelevant to argue good faith for the application of Article 102 TFEU, which is generally based on objective justifications.

Courts can consider the alternative interpretation as a misinterpretation of law even if likely anti-competitive effects are seen.⁴⁴ By looking at *a contrario*, courts are also able to find the conduct lawful even if it has a restrictive effect on generic competition as long as objective justifications are seen. However, Article 102 TFEU will become an issue in any circumstance if businesses wander from the competition on merit.⁴⁵ The CJEU revealed that relevant conduct prevents generic competition, and therefore, it should not be evaluated in the context of competition on merit.⁴⁶ As a result, the CJEU dismissed the appeal from the EC decision of *AstraZeneca* of abusing its dominance by the deregulation of Losec (in other words, withdrawing marketing authorisation). Therefore, the anti-competitive effects of this deregulation process were found enough to apply Article 102 TFEU even though *AstraZeneca* claimed lawfulness of withdrawing on the strength of its intellectual property right.

IV. Evergreening in the context of Article 102 TFEU

To establish a relationship between EU competition law and evergreening patents, it is necessary to refer to the Commission's Guidance on Article 102 Enforcement Priorities, which ensures market integration.⁴⁷ All concerning provisions are significant to stabilise the functioning of the market by levelling the playing field for all undertakings.⁴⁸ Hence, the CJEU lays a burden on dominant undertakings to not anyhow distort competition in the internal market by mentioning their special responsibilities.⁴⁹ The standard of undistorted competition indicates that business decisions shall not fit the purpose of eliminating competitors without any economic justification. The lawfulness of business conduct under their special responsibilities is taken into consideration with the concept of 'competition on merits'⁵⁰ which also has an amphibology. The use of intellectual property rights may cause trouble at this juncture even though having an exclusive right will not per se present an infringement if it is not being abused.⁵¹ Therefore, it is required to specify

³⁷ Case C-457/10P, *AstraZeneca AB and AstraZeneca plc v European Commission* [2013] ECLI:EU:C:2012:770; Case C-591/16P H. *Lundbeck A/S and Lundbeck Ltd v European Commission* [2021] ECLI:EU:C:2021:243.

³⁸ Evergreening patent issue is a highly controversial topic concerning to both patent law and competition law. This issue is not bounded with pharmaceutical industries, it is also seen in technology-intensive industries.

³⁹ World Intellectual Property Organization, The Changing Face of Innovation (Report, 2016) <<https://www.wipo.int/publications/en/details.jsp?id=227>> accessed 1 November 2021.

⁴⁰ Case AT.39226 *Lundbeck* [2013] C[2013] 3803 final.

⁴¹ Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* [2012] ECLI:EU:C:2012:770, para 130.

⁴² *Ibid.*, paras 125–127.

⁴³ *Ibid.*, para 69.

⁴⁴ *Ibid.*, paras 94, 99, 112; C-209/10 *Post Danmark A/S v Konkurrencerådet* [2012] ECLI:EU:C:2012:172, para 64.

⁴⁵ *AstraZeneca* [n 42] para 129.

⁴⁶ *Ibid.*, para 131.

⁴⁷ Guidance of enforcement priorities in applying Article 82 of the EC (n 13) para 1.

⁴⁸ V Korah, *An Introductory Guide to EC Competition Law and Practice* (Hart Publishing 2007) 13.

⁴⁹ Case 322/81 *Nederlandsche Banden-Industrie-Michelin v Commission* [1983] ECR 3461, para 57; *AstraZeneca* [n 42] para 134; Case T-83/91 *Tetra Pak International SA v Commission of the European Communities* [1994] ECLI:EU:T:1994:246, para 114; Case T-203/01 *Manufacture française des pneumatiques Michelin v Commission of the European Communities* [2003] ECLI:EU:T:2003:250, para 97; Case C-497/99 P *Irish Sugar plc v Commission of the European Communities* [2001] ECR 2001 I-05333, para 112.

⁵⁰ Case 62/86 *Akzo Chemie BV v Commission of the European Communities* [1991] ECLI:EU:C:1991:286, para 70.

⁵¹ Case C-53/87 *Consorzio Italiano della Componentistica di Ricambio per Autoveicoli (CI-CRA) and Maxicar SPA v Regie Nationale des Usines Renault* [1988] ECR 6089, para 18.

an objective justification in terms of the enforcement of Article 102 TFEU and this justification is formed by case law to offer a remedy. In accordance with the above, courts should bring in a verdict by evaluating economic justifications after they determine actual or likely conduct, causing the elimination of competitors.⁵² Hence, the EC must put forward an objective justification, which would reverse the burden of proof to the detriment of the EC. However, the CJEU frequently refused economic efficiency defences as they only rest upon commercial interest, which does not overlap with consumer interests.⁵³

One can claim that the EC now considers a more economic efficiency-based approach in Article 102 TFEU examinations,⁵⁴ but this approach cannot be applied to all concerning issues. For example, the EC concludes an infringement decision when it comes to royalty discounts without examining any actual or likely anti-competitive effect as it was the case with the *Michelin II*.⁵⁵ However, it seems that undertakings are frequently able to put forward their efficiency defences in case they are on trial even if it is debatable how much the Commission leaves the door open for such defences.⁵⁶ Nevertheless, it is certain that the concept of special responsibility has been expanded considerably by way of case law.⁵⁷ In *Michelin I*, the CJEU determined that dominant undertakings have special responsibilities not to distort competition in the internal market via exclusionary abuses. Besides, the *AstraZeneca* case consolidated the enlargement of the special responsibility concept, which has already been enlarged with the *Michelin I*.⁵⁸ As stated by Friedman, businesses have special responsibilities to raise their profits.⁵⁹ However, they shall also behave accordingly not to harm competition. Businesses, as a matter of fact, keep their profitability on the forefront, they are disposed to suppress innovations by retarding, non-introducing or in other similar ways. Therefore, they generally have tendencies to explore all avenues for exploiting the patent system as much as they can. However, since no patent system allows double patenting (unless the patent applicant shows novelty and

non-obviousness),⁶⁰ the exploitation of the relevant patent most of the time appears completely lawful. However, it does not mean that undertakings fulfil their special responsibilities under competition law, and therefore, it ought to be required to imply competition law provisions. To summarise, concerning the affiliation between patent protection and the progression of innovation, there is a need for an absolute statement of 'special responsibility' concept because businesses may likely suppress innovations and make their strategic decisions counterproductive. Therefore, broad-in-scope concepts like undistorted competition and competition on merits should be supported by more accurate statements in case law.⁶¹

C. CONCLUSION

Evergreening strategies have negative impacts in terms of continuity of innovation and access to innovation. Especially in cases related to such innovation, suppression practices become more complex. For this reason, the evergreening patent, eliminating generic competition and its price-reducing effect, has often been a more frequently discussed subject in the pharmaceutical sector. Some of the specific evergreening practices may be listed as patenting existing medicines with new formulations or compositions, patenting new combinations of drugs, patenting an in-use drug for a new use, or patenting a known drug with a new dosage.⁶² These products, generally called next or second generation, have insignificant and minor changes and do not put the product in an entirely new form. However, this does not mean that the evergreening issue only occurs in the pharmaceutical sector; patent holders from different sectors also have effective strategies with regard to patents' lifecycle management.

The advancement of technology depends on providing patent protection for both incremental and breakthrough innovations. Therefore, it is necessary to provide substantial incentives to actualise and ensure follow-on innovations.⁶³ Patent granting authorities control all applications firmly, but some applications are approved even if they do not deserve any protection. This issue is due to the weakness of the patent authority or patent system itself. More particularly, evergreening issues are stemming from -including but not limited to- strategic patenting, lax rules, and the malfunction of patent examination

⁵² Case C-202/07 P *France Télécom v Commission* [2009] ECR I-2369.

⁵³ *Irish Sugar* (n 50) para 189; Case T-201/04 *Microsoft Corp v Commission* General Court [2007] ECLI:EU:T:2007:289; Commission Decision of 27.6.2017 relating to proceedings under Article 102 of the Treaty on the Functioning of the European Union and Article 54 of the Agreement on the European Economic Area, para 711.

⁵⁴ Case T-286/09 RENV, *Intel Corporation v Commission*; General Court of the European Union, 'The General Court annuls in the part the Commission decision imposing a fine of EUR 1.06 billion on Intel' [Press Release No 16/22, 26 January 2022].

⁵⁵ Case T-203/01 *Manufacture française des pneumatiques Michelin* (n 50).

⁵⁶ It would not be wrong to say that most of the time, the Commission leans towards approving efficiency claims as seen in: *Microsoft Corp* (n 52); Case AT.39740 – Google Search (Shopping) [2017] C[2017] 4444 final.

⁵⁷ F Murphy, 'Abuse of Regulatory Procedures-the AstraZeneca Case: Part 3' [2009] 30(7) *European Competition Law Review* 314.

⁵⁸ *Nederlandsche Banden-Industrie-Michelin* (n 50) para 57.

⁵⁹ M Friedman, 'The Social Responsibility of Business is to Increase its profits' in W Zimmerli, K Richter and M Holzinger, *Corporate Ethics and Corporate Governance* (Springer 2007) 173–178.

⁶⁰ An invention regardless of it is a product or process should have novelty and non-obviousness to get a protection according to article 27 of the TRIPS agreement. It also needs to be available for an industrial application. See, *Abbas* (n 26) 53–60.

⁶¹ The CJEU gave the first signs of this new move in *AstraZeneca* with regard to flexibly apply Article 102 TFEU.

⁶² *Abbas* (n 26) 54; G Gonen, 'Innovation in known drugs – the European Angle' [2017] 12(3) *Washington Journal of Law, Technology and Arts* 278.

⁶³ C Holman, T Minssen and E Solovy, 'Patentability Standards for Follow-on pharmaceutical innovation' [2018] 37(3) *Biotechnology Law Report* 136; R Merges, 'Uncertainty and the Standard of Patentability' [1992] 7(1) *Berkeley Technology Law Journal* 33.

mechanisms through filing several patent applications to prevent third parties' research initiatives.⁶⁴

The most likely solution of evergreening is to apply patentability requirements as strictly as possible by delving into the existence of an inventive step. This would be one of the best possible ways to nail down the continuity of introducing technological advancements by calculating the innovator's actual contribution to innovative progress. Therefore, it seems that realising inconveniences in the patent system will likely answer the evergreening problem⁶⁵ such that the determination of the extent to which new patent applications contribute to innovation is under the patent office's responsibility.



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⁶⁴ S Parker and K Mooney, 'Is 'evergreening' a cause for concern? A legal perspective' (2007) 13(4) *Journal of Commercial Biotechnology* 235–241.

⁶⁵ Holman, Minssen and Solovy (n 62) 160.

