

When speed matters: a discussion on the benefits of a grace period in patent law to accelerate pharmaceutical innovation in times of pandemic

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ABSTRACT

The unprecedented coronavirus disease 2019 (COVID-19) pandemic is a solemn reminder of the need to accelerate pharmaceutical innovation. The desire for fast access to vaccines triggered discussion of unrestricted access to research findings with the hope of facilitating the drug discovery process to combat COVID-19. Increasingly, abolition of the patent system is being discussed in connection with the fight against the pandemic. This may accelerate discovery of and increase access to medicines.

However, society's desire for immediate disclosure of research findings conflicts with the inventor's legitimate interest to protect his or her invention as well as the need to recover investments made to develop the drug. The call for immediate disclosure of research results contradicts the interest of the inventor, whose primary goal is to secure his intellectual property rights, usually by applying for patent protection. In Europe, where patent law is based on the principle of absolute novelty, disclosure of the results reduces novelty and prevents subsequent patenting. Consequently, patenting remains the top priority for pharmaceutical companies in Europe, while disclosure of the results is secondary.

The following article looks critically at the idea of using the grace period in European patent law to reconcile the conflicting interests of society and inventors in times of pandemic. In this paper, we investigate whether the implementation of a grace period in European patent law like that known in the USA, Japan, or Korea benefits the disclosure of results and increases the flow of information, ultimately leading to the promotion of innovation and rapid drug discovery. This article questions whether the use of a grace period provides a sufficient incentive to the inventor for rapid disclosure.

KEYWORDS: drug discovery, grace period, invention disclosure, novelty, open innovation, patent law harmonization

I. INTRODUCTION

Traditional R&D approaches to drug development are costly and lengthy processes. It typically takes several years to develop a new drug and bring it to market. The current rapidly evolving and changing coronavirus disease 2019 (COVID-19) pandemic has demonstrated that these drug development models are not always adequate. Open Innovation (OI), which broadly refers to opening the boundaries of a company to external innovation,¹ is an alternative approach that has been studied extensively in the context of drug discovery.² Today, OI, in its many variations, has taken a permanent place in the pharmaceutical industry as a complementary method to traditional R&D development models. Compared with conventional downstream development models, OI can drastically decrease development time.³ Leveraging OI accelerates medical research that promotes sharing results (including protocols, registering studies, reporting results, disseminating results, sharing data, sharing bio-specimens, and sharing code) from government-funded studies.⁴

A key component and essential part of OI is the concept of ‘open source’, which is understood as ‘unconditional access to otherwise and traditionally restricted resources, tools or knowledge’ including access to data, science, test protocols, etc.⁵ The ‘unconditional’ access to information in the context of OI has been shown to stimulate innovation and shorten development time.⁶ At the same time, open access poses important challenges for interpreting, managing, and appreciating the owner’s intellectual property rights (IPRs).⁷ Many misinterpret OI, believing it involves a free transfer to the underlying IPR.⁸ However, voluntary access to disclosed information does not mean that the owner relinquishes ownership of IPRs. Unjustified claims to the unrestricted use of IPR raise questions about the compatibility of OI and IPR. Increasingly, IPRs, including basic principles of the patent system and their justification for their presence in OI space, are being questioned.^{9,10}

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- 1 Henry William Chesbrough, *Open Innovation The New Imperative for Creating and Profiting from Technology* Xerox PARC The Achievements and Limits of Closed Innovation, HARVARD BUS. SCH. PRESS (2003).
 - 2 Kenneth A. Getz & Kenneth I. Kaitin, *Open innovation: The new face of pharmaceutical research and development*, 5 *EXPERT REVIEW OF CLINICAL PHARMACOLOGY* 481–483 (2012); Andy Wai Kan Yeung et al., *Open Innovation in Medical and Pharmaceutical Research: A Literature Landscape Analysis*, 11 *FRONT. PHARMACOL.* (2021).
 - 3 Henry, William Chesbrough & Andrew, R Garman, *How Open Innovation Can Help You Cope in Lean Times*, 87 *HARVARD BUS. REV.* 68–76 (2009).
 - 4 Kushal T. Kadakia et al., *Leveraging Open Science to Accelerate Research*, *N. ENGL. J. MED.* (2021).
 - 5 Niclas Nilsson & Timo Minssen, *Unlocking the full potential of open innovation in the life sciences through a classification system*, 23 *DRUG DISCOV. TODAY* (2018).
 - 6 Karen Walsh et al., *Intellectual Property Rights and Access in Crisis*, 52 *IIC—INT. REV. INTELLECT. PROP. COMPET. LAW* (2021).
 - 7 Nari Lee, Soili Nystén-Haarala & Laura Huhtilainen, *Interfacing Intellectual Property Rights and Open Innovation*, *SSRN ELECTRON. J.* (2012).
 - 8 Erin Shinneman, *Owning Global Knowledge: The Rise of Open Innovation and the Future of Patent Law*, 35 *BROOKLYN J. INT. LAW* (2010).
 - 9 Scott Duke Kominers, *Patent Protection Should Take a Backseat in a Crisis*, *BLOOMBERG OPINION*, 2020.
 - 10 Shinneman, *supra* note 8; Mohammed El Said, *Radical Approaches During Unusual Circumstances: Intellectual Property Regulation and the COVID-19 Dilemma*, 63 *DEVELOPMENT* (2020).

The current COVID-19 pandemic challenges the IP system in which society's interests for rapid disclosure of innovations conflicts with the inventors' primary interest to secure IP protection. In Europe, where Art. 2(1) of the European Patent Convention (EPC)¹¹ presupposes absolute novelty as a condition for patentability, disclosure, with certain exceptions, has a destructive effect on novelty and prevents subsequent patenting. As patenting is an essential part of company strategy, companies are unwilling to disclose their inventions until the protection of the invention can be secured. Rapid disclosure of the results therefore plays only a secondary role. This paper examines the use of a grace period to reconcile the conflicting interests of society and inventors in times of pandemic. Moreover, this paper aims to determine whether the use of a grace period can be considered an incentive to the inventor to promote rapid disclosure of the results by safeguarding the novelty of the invention. The debate about whether more transparency is required is not new. More transparency would not only create more trust and allow third-party companies to gain insight into and take advantage of the information disclosed to regulators, but also avoid scientifically incorrect results which might have been disclosed.¹²

The idea that a grace period favors the quick circulation of inventions that would otherwise be kept secret was formulated by Franzoni and Scellato.¹³ Recently, the use of a grace period to promote disclosure of inventions during national emergencies was introduced in Art. 24(1) of the amended Chinese patent law.¹⁴ In light of the ongoing COVID-19 pandemic, Art. 24(1) expands the scope of the grace period to invention-creations made public for the purpose of public interests during national emergency or exceptional circumstances.¹⁵ Referring to the amendment of Chinese patent law, we test whether the implementation of a grace period in European patent law and that similar to those of the USA, Japan, or Korea increases the disclosure of results, ultimately leading to the promotion of innovation and rapid drug discovery. To verify this, we analyze different grace periods in selected countries and the grace period proposals discussed within the context of patent harmonization.¹⁶ More precisely, we examine the terms of duration of the disclosure, the scope of protection given, and the expected incentives for the inventor. Finally, we analyze the different arguments in favor of and against the implementation of a grace period, and then relate them to the introduction of grace in European patent law with the overall goal of accelerating drug discovery.

11 2 EPO, EUROPEAN PATENT CONVENTION-EPC (2013).

12 Sven Bostyn, *Why a COVID IP Waiver Is not a Good Strategy*, SSRN ELECTRON. J. (2021).

13 Chiara Franzoni & Giuseppe Scellato, *The grace period in international patent law and its effect on the timing of disclosure*, 39 RES. POLICY (2010).

14 Linda Liu & Partners, *Comparison chart of the fourth amendment of the Chinese Patent Law (2020)*, LINDA LIU & PARTNERS (2020), http://www.lindapatent.com/en/law_patent/1110.html (accessed May 2, 2021).

15 Li Mi, *New amendments to the Chinese Patent Law will impact the pharmaceutical industry*, ROUSE (2021), <https://rouse.com/insights/news/2021/new-amendments-to-the-chinese-patent-law-will-impact-the-pharmaceutical-industry> (accessed May 2, 2021).

16 R. Carl Moy, *The History of the Patent Harmonization Treaty: Economic Self-Interest as an Influence*, JOHN MARSHALL LAW REV. (1993), <https://open.mitchellhamline.edu/cgi/viewcontent.cgi?article=1149&context=facsch> (accessed Apr 27, 2021).

II. THE GRACE PERIOD IN PATENT LAW

A. Grace period in the context of international treaties

A grace period is the duration of time provided to an inventor after disclosure of a novel invention with an allowance to still apply for a patent without terminating their right to a grant of patent.¹⁷ One of the basic principles of patent law is a novelty requirement, which states that an invention is patentable if it is new.¹⁸ Public disclosure of the invention prior to filing a patent application (with some exceptions such as confidential disclosures to outsiders) and disclosures that could not have been foreseen in the ordinary course of business to people skilled in the relevant field in the European Economic Area invalidate the novelty requirement and renders the invention not patentable.¹⁹ In addition, disclosures not included in the set of exclusions where disclosure should be disregarded invalidate the novelty requirement and render the invention not patentable.²⁰ However, not all public disclosure results in destruction of the novelty of the invention. A grace period is defined as a period prior to filing a patent during which disclosures of implemented inventions do not constitute prejudicial prior art against the patent application in question.²¹ Until the 1970s, the concept of a grace period was more widespread than now. In most countries, its abolition came with the switch from a system in which the ‘first to invent’ holds the right to patent to a system in which the right to patent is given to the ‘first to file.’²² The ‘first to file’ policy dates back to the Paris Convention in 1883, which was the first effort by several countries to adopt a common approach to intellectual property.²³ Article 4 of the Paris Convention allows an inventor who has filed a patent application in a member country 12 months to file a subsequent application in another member country.²⁴ In addition to the opportunity to file subsequent applications under the Paris Convention, an inventor can also file a single application under the Patent Cooperation Treaty (PCT), which permits him or her to claim priority to an application filed in another contracting state during the preceding 12 months if no disclosure has been made previous to the first filing.²⁵ According to Art. 27 of the TRIPS Agreement (1994), patents shall be available for any inventions proven to be new and involve inventive steps.²⁶ This does not mean that WTO members may never grant patents for inventions that have already been made available to the public before the date of the patent application.²⁷ This is possible

17 Franzoni and Scellato, *supra* note 13.

18 PAUL TORREMANS, *HOLYOAK AND TORREMANS INTELLECTUAL PROPERTY LAW* (2019).

19 *Id.*

20 *Id.*

21 INTELLECTUAL PROPERTY OFFICE, *Patent Harmonisation: US & UK Study on Grace Periods* (2015), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/561620/Patent-Grace-Periods.pdf (accessed Apr 27, 2021).

22 *Id.*

23 The USA shifted from a ‘first to invent’ system to a ‘first to file’ system with the enactment of the Leahy-Smith America Invents Act, which was signed in 2011 and fully made effective on September 16, 2012, and March 16, 2013.

24 WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO), *Paris Convention for the Protection of Industrial Property* (1883), <https://wipo.int/en/text/287556> (accessed Apr 28, 2021).

25 WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO), *Patent Cooperation Treaty (PCT)* (2001).

26 AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS. PART II STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS, (1994).

27 JUSTINE PILA & PAUL TORREMANS, *EUROPEAN INTELLECTUAL PROPERTY LAW* (2019).

because of the existence of the ‘Grace Period’. It goes without saying that the ‘grace period’ constitutes a controversial feature of the patent system and has long been the object of disagreement among different countries.

B. Implementation in national patent law: examples and current trends

The World Intellectual Property Organization (WIPO) does not provide for a grace period in the patent application process. However, it does recognize that the patenting process is largely guided by national/regional law and varies from one country to another.²⁸ The organization recognizes that various countries allow for a grace period during which an application can still be submitted even after disclosure of the organization which is usually between 6 and 12 months from the date of disclosure.²⁹

In the USA, the Leahy–Smith America Invents Act of 2011, also known as the America Invents Act (AIA), shifted the United States Patent System from a ‘first-to-invent’ to a ‘first-to-file’ rule.³⁰ This constituted the first major patent reform in the USA since the 1952 Patent Act.³¹ The AIA transformed the USA landscape on patentability and patent enforceability. The pre-AIA system typically protected the right of an earlier inventor’s right to obtain a patent, even if a later, independent inventor first filed a patent application on the same invention.³² The ‘first-to-file’ is a measure which is indicative of the novelty of the patent application. This means that after the enactment of the AIA, the ‘first-to-file’, on or after March 16, 2013, is awarded the patent. The advent of the ‘first-to-file’ system with the enactment of the AIA brings US patent law closer to the regimes of most other industrialized countries in the world. This new system preserves key features of the old system, including aspects of the one-year grace period that protects inventors who file a patent application within one year of the public disclosure of their invention.³³

Like the USA, South Korea is another country that provides a one-year grace period. In South Korea, the exclusions of public disclosure are limited to the following: applicant-derived disclosures, except for information disclosed in Korean or foreign patent publications, and disclosures that occur ‘against the intention’ of the person having the right to obtain the patent. Inventor- or applicant-derived disclosures do not include patent publication disclosures unless the disclosure is made ‘against the inventor or applicant’s intention’.³⁴

28 World Intellectual Property Organization (WIPO), *Obtaining IP Rights: Patents*, https://www.wipo.int/sme/en/obtain_ip_rights/patents.html (accessed Apr 28, 2021).

29 *Id.*

30 Erika Harmon Arner et al., *America Invents Act (AIA)*, IP UPDATE (2011), <https://www.finnegan.com/en/insights/ip-updates/america-invents-act-aia-1.html> (accessed Apr 27, 2021).

31 Shuba Haaldodderi Krishnamurthy, *U.S. Patent Reform Act of 2011 (America Invents Act): The Transition from First-to-Invent to First-to-File Principle*, 5 JIPITEC (2014), https://www.jipitec.eu/issues/jipitec-5-1-2014/3906/jipitec_5_1_krishnamurthy.pdf (accessed Apr 28, 2021).

32 Toshiko Takenaka, *Has the United States Adopted a First-to-File System Through America Invents Act?: A Comparative Law Analysis of Patent Priority Under First-Inventor-to-File*, GER. ASSOC. PROT. INTELLECT. PROP. INT. FORTHCOMING. (2012).

33 Smitha B. Uthaman, *Summary of the America Invents Act*, NATL. LAW REV. (2012), https://www.jipitec.eu/issues/jipitec-5-1-2014/3906/jipitec_5_1_krishnamurthy.pdf (accessed Apr 28, 2021).

34 Paul A Calvo, *Worldwide Public Disclosure Grace Periods—May 2017* (2017), <https://www.sternekeesse.com/news-insights/publications/worldwide-public-disclosure-grace-periods-may-2017> (accessed Apr 27, 2021).

In Japan, a new shift came into force in June 2018 that guarantees 12 months of protection of an invention after disclosure.³⁵ In 2012, Japan had made a step ahead, guaranteeing six months of protection.³⁶ Prior to this revision, Art. 30 of the Japan Patent Act listed a *numerus clausus* of disclosures held to be non-prejudicial to the applicant's entitlement to patent protection, such as publications made against the will of the inventor, experiments conducted by the inventor or with the inventor's content, and displays made for fair or exhibitions.³⁷ Decisions are made on a case-by-case basis in accordance with Japanese law.

Australia is another example of a country which expands protection by using a grace period. Previously, Australia's grace period protected disclosures in the form of a publication made in 'prescribed circumstances'. Regulation 2.2 of the Patents Regulations 1991 explained that these circumstances are related to 'disclosure in an official exhibition' or 'disclosure in a paper written by the inventor or with the inventor's consent'.³⁸ Currently, Australian patent law now offers a grace period to the applicants, enabling a complete patent application to be made within 12 months of the initial publication.³⁹

The same implementation of the national patent system in this regard has been seen in New Zealand, where, under section 9 (1)(f) of the Patents Act of 2013, one year of grace period is allowed for patent applications.⁴⁰

In the UK, a patent application may be filed within six months of disclosure at an officially recognized exhibition or when such a disclosure was made in bad faith by any third party.⁴¹

C. Grace period in European patent law: long overdue?

European law, apart from very narrow exceptions provided in the EPC, does not allow a grace period despite the fact that the absence of a grace period in Europe has been mentioned as being 'very hard on particularly innovative sectors such as researchers and small and medium-sized businesses'.⁴² This means that an inventor who has made a discovery available before filing the first patent application cannot be protected in Europe.⁴³

35 Rohan Williams & Adam Denley, *Generous patent grace period changes in Japan* (2019), <https://fpapatents.com/resource?id=502> (accessed Apr 27, 2021).

36 *Id.*

37 特許法 (PATENT ACT), (1959), <https://www.wipo.int/edocs/lexdocs/laws/en/jp/jp206en.pdf> (accessed Apr 28, 2021).

38 OFFICE OF PARLIAMENTARY COUNSEL, *Patents Regulations* (1991).

39 *Id.*

40 INNOVATION, AND EMPLOYMENT MINISTRY OF BUSINESS, *Patents Act* (2013), <https://www.legislation.govt.nz/act/public/2013/0068/latest/whole.html#DLM1419043> (accessed Apr 28, 2021).

41 INTELLECTUAL PROPERTY OFFICE, *The Patents Act 1977* (2021), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/950221/consolidated-patents-act-1977.pdf (accessed Apr 28, 2021).

42 WILLI ROTHLEY, *Report on the introduction of a grace period for innovations in national patent laws* (A4-0037/99) (1999), <https://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A4-1999-0037+0+DOC+PDF+V0//EN> (accessed May 3, 2021).

43 Bruno Van Pottelsberghe De La Potterie, *Patent fixes for Europe*, 467 NATURE (2010).

However, a limited number of the EPC member states guarantee a sort of ‘grace period’ by providing a non-prejudicial disclosure defined in Art. 55 of the EPC.⁴⁴ This article specifies that a disclosure of the invention shall not be taken into consideration for the application of Art. 54 of the EPC if it occurred no earlier than six months preceding the filing of the European patent application and if it was due to, or in consequence of: (a) an evident abuse in relation to the applicant or his legal predecessor, or (b) the fact that the applicant or his legal predecessor has displayed the invention at an official, or officially recognized, international exhibition.⁴⁵ The provision is reflected in several national legislations. In Germany, for example, Article 3(5) of the Patent Act states that the disclosure will not be taken into consideration if the disclosure happened six months before the filing of the application or if it was due to or in consequence of an evident abuse in relation to the applicant or if the applicant shows its discovery in a recognized exhibition.⁴⁶ The same legal context is present in Austria and Bulgaria, where disclosure is allowed within six months before the filing date, if they enter in the same exception seen in the German patent law.⁴⁷ In Austria, if disclosure happens without impactful change to the novelty of the invention, the applicant has to specify the exhibition where the disclosure happened within four months after the filing date. In Bulgaria, the applicant must do so within three months.⁴⁸ Estonia and Turkey offer 12 months of grace period with no specified exceptions.⁴⁹ Based on the great differences in patent law across the European Union, a sort of harmonization of patent law in terms of grace period is required.⁵⁰

D. Grace period in the context of patent law harmonization

Variation in the application of patent law among different countries arises from the different interpretation of which criteria to adopt when determining the grounds for allowing patenting.⁵¹ The European patent model is meant to create a unified set of protocols that guide the member countries in achieving a harmonized system of protection.⁵² This patent system was created by the EPC and can be traced back to the mid-20th century. At this time, various countries had their own national patent systems, posing a danger to the establishment of a harmonized patent system due to competing national interests. An alternative proposal was made to have a European system that would coexist with the national systems.

44 2 EPO, *supra* note 11.

45 *Id.*

46 BUNDESMINISTERIUM DER JUSTIZ UND VERBRAUCHERSCHUTZ, *Patentgesetz, PatG* (1980), https://www.gesetze-im-internet.de/englisch_patg/englisch_patg.html (accessed Apr 28, 2021).

47 Mewburn Ellis, *Grace Periods for Disclosure of an Invention before Applying for a Patent*, MEWBURN ELLIS, <https://www.mewburn.com/law-practice-library/grace-periods-for-disclosure-of-an-invention-before-applying-for-a-patent> (accessed May 3, 2021).

48 *Id.*

49 *Id.*

50 Karsten Königer, *A friendly reminder 25 years after TRIPS: an international harmonisation of the grace period in patent law remains preferable*, 14 J. INTELLECT. PROP. LAW PRACT. (2019).

51 Randy Campbell, *Global Patent Law Harmonization: Benefits and Implementation*, 13 INDIANA INT. COMP. LAW REV. (2003).

52 European Patent Office (EPO), *Unitary Patent*, <https://www.epo.org/law-practice/unitary/unitary-patent.html> (accessed Apr 28, 2021).

By the year 2000, numerous conferences and meetings had been convened to establish a more solid protocol. Some of the topics of discussion included the use of a grace period and criteria for determining which inventions to protect.⁵³ The EPC opted to negate the use of the grace period that allowed the filer of an application to make an invention public before seeking a patent. Under this model, an application for a patent must be filed before the disclosure of the invention. Any patent application that is filed after the disclosure is not covered by the law since it is no longer novel. However, a few exceptions are permitted, including exceptions in which the disclosure is done without the inventor's consent or foreknowledge (breach of confidentiality by a third party).⁵⁴

The harmonized policy, as adopted and ratified by member states of the EPC, is significantly different from the models adopted by the USA and Japan, whose laws provide for a grace period. From an international perspective, the discrepancies in the regulation of the general grace periods among the world's three most prominent patent offices—the United States Patent and Trademark Office (USPTO), the Japanese Patent Office (JPO), and the European Patent Office (EPO)—complicate the issue for inventors. The USA, Japan, the Republic of Korea, Mexico, Argentina, China, and Australia have implemented grace periods, leaving the EPC as the treaty which has not implemented a grace period.⁵⁵

A uniform patent protocol at the global level would be a more efficient system, lowering the cost of filing for protection across the world. The unified system undoubtedly confers a sense of collective protection through a global arbitrator, meaning cases of infringement can be handled through the international justice system.

International attempts to unify laws related to intellectual property are influenced by the desire to achieve a globally acceptable norm that addresses variations in national property systems. The move toward harmonized intellectual patent law is inevitable considering the unstoppable wave of globalization. The most cited attribute of discrepancy in patent law between nations is regulation regarding a grace period.

The history of patent law harmonization started with the Paris Convention to Protect Industrial Property in 1883. In 1967, the United Nations established the WIPO.⁵⁶ The organization's primary mandate is to promote and protect intellectual property by developing sustainable policies to encourage and facilitate global efforts to create an environment that enables patenting. By the late 1970s, the USPTO, the JPO, and the EPO were looking for ways to harmonize their operations. At this time, a wave of change was sweeping across Western Europe. The European community was being formed; member countries were aligning their national patent laws with the Strasbourg Convention (1963), and, later, the EPC in 1973.⁵⁷ This led to changes in various national laws. For example, Germany removed the provision for a grace period from its national patent laws through the Patents Act of 1980.⁵⁸ However, some interested parties were unhappy with the new changes in German Patent Laws. There was a new

53 N. Wilkof, *Paradoxes and intellectual property law*, 8 J. INTELLECT. PROP. LAW PRACT. (2013).

54 JEFFREY M. SAMUELS, *PATENT, TRADEMARK, AND COPYRIGHT LAWS* (2018).

55 Van Pottelsberghe De La Potterie, *supra* note 42.

56 OECD ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOP, *OECD PATENT STATISTICS MANUAL* (2009).

57 Moy, *supra* note 16.

58 *Id.*

initiative to reinstitute a grace period for the German Patent System.⁵⁹ Therefore, the WIPO decided to convene a committee of experts to evaluate the need for a multilateral treaty that would introduce the use of a grace period.⁶⁰ The multilateral treaty would involve countries beyond the European Community, and then amend the EPC. In 1983, discussions on the legal effects of an international grace period on patent law via the Patent Harmonization Treaty began.⁶¹

However, discussions from the committee of experts revived other procedural and substantive issues regarding patent law. These issues had to be included in the discussions. Therefore, the WIPO concluded initial committee expert discussions after just one session.⁶² The WIPO formed a second committee to not only harmonize provisions as to a grace period, but to also harmonize provisions with regard to patent law generally.⁶³ In 1990, the committee's efforts were realized when the WIPO published the Draft Patent Harmonization Treaty.⁶⁴

A review of the Draft Treaty was performed in June 1991 at the first session of the WIPO Democratic Conference held at The Hague.⁶⁵ The harmonization treaty was discussed in two other sessions. The last of these sessions was held on July 30, 1993. As a consequence of a US initiative, the Draft Treaty required its members to adopt a 12-month grace period before an applicant files for a patent.⁶⁶ The Draft Treaty only protected disclosures made by inventors to third parties.⁶⁷ The Patent Harmonization Treaty was largely not adopted by members; it came to be known as a Special Agreement under the Paris Convention.⁶⁸ Notably, the 'Basic Proposal' discussed at the Diplomatic Conference was not adopted.

Starting in 1995, discussions in the WIPO focused on requirements under patent laws. The Patent Law Treaty (PLT) was adopted by the Diplomatic Conference in June 2000, harmonizing the formal procedures concerning national and regional patent applications and laws.⁶⁹ Starting in November 2000, the need for patent law harmonization became more urgent. Therefore, WIPO began to work on this topic with the idea of concluding a Substantive Patent Law Treaty (SPLT). This was decided at the fourth session of the Standing Committee on the Law of Patents (SCP). The committee discussed several issues, namely, novelty, inventive steps, definition of prior art, and industrial applicability as well as the drafting and interpretation of claims.

However, it was not until May 2001, at the fifth session of the SCP, that the first draft of the SPLT came into being. The first draft included draft Regulations and Practice Guidelines. In November 2001, at the sixth session, a new approach was adopted

59 *Id.*

60 *Id.*

61 *Id.*

62 *Id.*

63 *Id.*

64 *Id.*

65 Vito J DeBari, *International Harmonization of Patent Law: A Proposed Solution to the United States' First-to-File Debate*, 16 FORDHAM INT. LAW J. (1992), <https://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?article=1349&context=ilj> (accessed Apr 27, 2021).

66 *Id.*

67 *Id.*

68 Moy, *supra* note 16.

69 Campbell, *supra* note 50.

which sought to integrate the PCT, PLT, and SPLT. The Working Group on Multiple Invention Disclosures and Complex Applications was formed and tasked with working on multiple issues raised at the fourth session. Several meetings continued to increase the scope of the draft SPLT. As the draft SPLT was progressively widened, several concerns were raised as to the feasibility and flexibility of the draft SPLT in relation to national patent laws. The main feature of this proposal was to eliminate national policies that mediate the patent systems and focus all effort on a unified approach under the watch of the WIPO.⁷⁰

For less developed countries, this prospect erodes the little leverage they possess in aligning patent laws with their development agenda. This model benefits the triad of the most influential nations—the USA, Japan, and the EPC—in regard to knowledge creation.⁷¹ The hegemonic nature of the triad has, however, failed to produce a united front on the issue of grace period with the EPC sticking to the *status quo* of adopting an absolute resolve.

Another impediment to this strategy is the requirement that policy should only cover technological innovations as opposed to all spheres of innovation.⁷² The USA encourages all forms of innovations and is reluctant to cede ground on the exceptions created by SPLT.⁷³ This can be attributed to a lack of consensus on the harmonization of the grace period. The uncertainty arising from disclosure before application for grant of patent places an undue pressure on inventors as they eagerly await confirmation of the application. This scenario also opens the possibility for third parties to exploit such information, decreasing the incentive to innovate. However, an argument against this thesis can be developed on the basis that such arrangements have worked in favor of the grace period.

Grace period negotiations have primarily been focused on adoption of a treaty with a general grace period. The *quid pro quo* requirement of exchanging first to invent for European adoption of an available grace period allowed the negotiations and discussions between patent offices and non-governmental organizations to remain both abstract and unnecessarily focused on showing the strength of their respective patent systems.⁷⁴ This process failed because of arguments against the grace period which are discussed later in this manuscript.

To overcome these hurdles, Group B+ was formed with the objective of harmonizing the administration of Patent Law.⁷⁵ The goal of this framework is to create a level playing field for both inventors and third-party entities. Harmonization also provides a uniform legal framework that is fair and certain. The policy is geared toward affording a grace period to inventors who suffer when their works are wrongfully disclosed.

70 OECD ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOP, *supra* note 55.

71 CHARLIE KARLSSON & THERESE NORMAN, *Intra-triad Knowledge Flows. Working Paper Series in Economics and Institutions of Innovation* 323 (2013).

72 Jakob Edler & Jan Fagerberg, *Innovation policy: what, why, and how*, 33 OXFORD REV. ECON. POLICY (2017).

73 Karen E Sandrik, *A Uniform Grace Period: Promoting International Research and Development Collaboration*, 91 TULANE LAW REV. (2016).

74 Margo A Bagley, *The Need for Speed (and Grace): Issues in a First-Inventor-to-File World*, 23 BERKELEY TECHNOL. LAW J. 1035–1061 (2008), <http://www.jstor.org/stable/24118266> (accessed Apr 27, 2021).

75 Michael Caine et al., *FICPI Position on Patent Law Harmonization (Group B+)*, in EXCO MEETING (2018), https://ficpi.org/system/files/gonzo/FICPI-WP-2018-001-Patent_Law_Harmonization.pdf (accessed Apr 27, 2021).

Harmonization guards against usurping patent rights through irregular methods. The grace period harmonization strategy should not be complicated and should equally accommodate all stakeholders. The harmonization plan recommends the application of an unbiased grace period under circumstances that predispose the author to infringements of their copyright. For any harmonization policy to succeed, countries are encouraged to forego their national interest and embrace a more global perspective.

The concept of applying a grace period to applicants raises the complex issue of double patenting, in which there are more than two applications for the same patent in the same country.⁷⁶ Under the EPC, there is no provision that bans this type of patenting. Issues arising from such circumstances are left to the discretion of individual member states. The Federation of Attorneys Specializing in Patent Matters (FICPI) is against the development of a harmonized system that excludes double patenting.⁷⁷ They observe that the general benefit from such issues far outweigh the setbacks. They assert that the time limit placed on a patent offers the possibility of a third party applying for the same patent.⁷⁸ Additionally, the federation fully supports the introduction of a grace period in future harmonization strategies. They advance the argument for the introduction of a broader concept of novelty to replace the prior art concept that is applied by the proponents of absolute novelty such as the EPC.⁷⁹ Therefore, any attempt at achieving a uniform patent protocol must resolve all controversial issues and promote a policy that will take care of all stakeholders.

III. KEY ASPECTS IN THE CONTEXT OF THE IMPLEMENTATION OF A GRACE PERIOD IN PATENT LAW

The discussion of implementing a grace period in national legislations demonstrates its role as a key element of innovation-friendly patent law. At the same time, the analysis of existing models and approaches to a grace period in different national legislations as well as the lack of harmonization demonstrate that no uniform model exists. The following chapter analyzes two relevant aspects of the grace period: the duration and the scope of protection in view of their expected effects on promotion of drug discovery.

A. Duration of grace period

At the 10th session of the SCP, the USA, Japan, and the EPO made a proposal concerning several issues, among which was a grace period.⁸⁰ Before negotiations on the draft SPLT were put on hold, the focus of the proposal with regard to a grace period was its duration. The SPLT claims that the patentability of an invention should not be affected if data were disclosed during, or under the effect of Article 9.⁸¹ Article 9 of the draft SPLT provides for prior disclosure of information. The draft SPLT continues to

76 *Id.*

77 *Id.*

78 Robert French, *A Public Law Perspective on Intellectual Property*, 17 J. WORLD INTELLECT. PROP. (2014).

79 Caine et al., *supra* note 72.

80 INTERNATIONAL BUREAU WIPO, *Draft Substantive Patent Law Treaty*, SCP/10/2 (2003), https://www.wipo.int/edocs/mdocs/scp/en/scp_10/scp_10_2.pdf (accessed Apr 27, 2021).

81 *Id.*

state that information disclosed 12 months preceding the filing date or, where priority is claimed, the priority date of the application will not affect patentability.⁸²

There are different possibilities for the scope of this definition. The duration of 12 months preceding the filing date or—where priority is claimed—the priority date of the application can cover any prior disclosure at the time the item was at the patent office.⁸³ This accommodates disclosures made at the office even 18 months prior when priority is claimed.

Since the clause was not repealed, other organizations have taken up the task of promoting substantive law harmonization. The Tegernsee Group agreed that the grace period's duration should be adjusted depending on the policy goals pursued. In field trials, 12 months was found to be the ideal length for a grace period. For academia, 3 months was found to be an appropriate grace period to first publish, then patent.⁸⁴ The Fédération Internationale des Conseils en Propriété Intellectuelle (FICPI) continued to discuss the grace period. They believed that an international, widespread, largely uniform grace period of 12 months is justified without any requirement for an inventor declaration.⁸⁵

B. Scope of protection

Concerning the scope of protection, the US patent system has never limited the disclosure of inventions. This policy is particularly popular in universities, public research institutions, small entities, independent inventors, industry, and the legal community. On the contrary, all types of disclosure are limited in Europe.⁸⁶ However, the EPO reports that too little may be known about the needs of SMEs for a grace period in Europe. Therefore, during the Tegernsee meeting, scope of protection was an important issue to discuss, considering user experiences in each country or region.⁸⁷

The scope of protection offered by grace periods is limited in Europe. Few organizations and businesses in Europe have ever effectively utilized grace periods. The same applies to businesses in the UK. However, when a uniform patent model is adopted, most businesses in Europe and the UK will have to use a system with a grace period. Europe and the UK will likely require clear, consistent, and easy interpretation of guidelines for grace period implementation. However, businesses in the UK and the USA state that the AIA is ambiguous regarding guidelines for grace period implementation. Businesses in the UK and the USA need future evaluation to increase its scope for grace period protection.

The EPC allows a very limited grace period of six months. This disclosure is limited to disclosures in a recognized international exhibition and not willful disclosure by an applicant. Article 55(1) of the EPC provides for non-prejudicial disclosures by a third party as per article 54 of the EPC. However, disclosure is not protected if the disclosure was due to an abuse by the inventor or his legal predecessor. Furthermore, disclosure is

82 *Id.*

83 *Id.*

84 INTELLECTUAL PROPERTY OFFICE, *supra* note 21.

85 *Id.*

86 Caine et al., *supra* note 72.

87 Tegernsee Experts Group, *Study mandated by the Tegernsee Heads: grace period* (2012), https://www.uspto.gov/sites/default/files/ip/global/grace_period.pdf (accessed Apr 27, 2021).

not protected if the disclosure was made at an internationally recognized exhibition in accordance with the Paris Convention.

With the revision of the Japan Patent Law in 2011, the scope of protection provided by a grace period has been extended also in Japan. Now, the type of disclosure covered by a grace period includes all inventions disclosed by an inventor, excluding material made public by gazettes, design, utility models, and trademarks. No limitation applies to the type of invention that can be disclosed in Japan. Japan accepts that disclosure can happen in many ways, including gazette, printed publications, and the internet, as well as through academic conferences and seminars. Inventions displayed at exhibitions and on national TV, along with those disclosed without the express consent of the inventor, are also protected. Therefore, the scope of a grace period in Japan covers all disclosures that may have been a result of acts of the inventor.

In the context of international harmonization, the scope of protection has been discussed by the SPLT with the aim of the harmonization to produce beneficial results for the users of the patent system worldwide. The TRIPS Agreement allows its members to customize their legislation to meet local needs. States, for example, might provide their own definitions of ‘inventive step’ and establish the technological extent of patent protection for themselves. These flexibilities give developing countries a lot of policy leeway to reap the benefits of international minimum standards while minimizing their social costs. However, dealing with these flexibility issues is costly and necessitates a sophisticated legal architecture. This is the reason why SPLT has been in favor of expanding the scope and power of the patent system by, for example, reducing the exceptions to patentability or removing the ‘technical character’ requirement.⁸⁸

IV. GRACE PERIOD: USEFUL OR HARMFUL?

A. Main arguments in favor of the grace period

i. Grace period as a key element of an innovation friendly patent law

Patent law provides a huge step in innovation-friendly patent law. Recent developments in health, climate change, environment, and genetics have come as a result of the role a grace period plays in promoting innovation.⁸⁹ Grace periods favor innovation by giving the invention a chance for interaction between the inventor and the collaborators in the industry and in corporate science.⁹⁰ Patenting and intellectual property systems are put in place to protect innovation and promote invention. The balance of rights in patenting is between promoting innovation and trading the exclusive rights for an invention.⁹¹ The owner of the patent is given exclusive rights to the monopoly. At the same time, the invention is made public for the good of society.

Where an innovator creates an invention, patents allow them to have a monopoly over the investment resulting from their invention. Patenting allows innovators to earn high rates because of their innovation as opposed to imitations devaluing their innovation.⁹² Innovators are often unsure of the value of their innovation. Innovators

88 One global patent system? WIPO’s Substantive Patent Law Treaty, GRAIN (2003), <https://grain.org/article/entries/109-one-global-patent-system-wipo-s-substantive-patent-law-treaty> (accessed Jun 7, 2021).

89 Sandrik, *supra* note 70.

90 *Id.*

91 *Id.*

92 *Id.*

find it hard to value inventions due to internal factors such as cost of production and external factors such as competitiveness. Grace periods provide inventors with a time in which they can attach value to their innovation. Grace periods also extend the period in which patent innovations can be accessed. The main reason for a general grace period is the fear that inventors would be tempted to become careless, which would be detrimental to the patent system.⁹³

Sometimes, innovative research in academia and industry interactions can result in patenting as a secondary motive.⁹⁴ A grace period is useful in this instance, as it helps an inventor to disclose an innovation publicly without risking loss of novelty. As such, in the case of inventions made in laboratories and as a pursuit of academic fulfillment, such innovators and their inventions are afforded the same rights and protections as those of owners of patented inventions.⁹⁵ Therefore, a grace period accelerates academic disclosures which have led to the invention of patentable products.⁹⁶ As a result, academic competitiveness thrives as the search for industry collaborators increases with inventions.

Not only does a grace period protect academic disclosure, but it also protects accidental disclosure. Ineligibility for grant of patents because of accidental or premature disclosure led to loss of novelty for about 50 per cent of European innovations.⁹⁷ Finally, a grace period offers inventors and innovators sufficient time to defer their patenting to a later time as they evaluate the merit of patenting.⁹⁸ Grace period therefore can be considered as an element of innovation-friendly patent law to accelerate academic publishing and promote knowledge spillover.

An important exception to the empirical analysis often conducted related to the grace period is made by Franzoni and Scellato (2010).⁹⁹ The authors analyzed a data set of patent and publication pairs (299 for the USA and 62 for Europe) to assess how often grace period exceptions are used in the USA and how significantly the patent publication lags varies between the USA and Europe. The authors discovered that grace period exceptions are used by nearly one-third of academic inventors in the USA, despite the significant risk of international extensions being denied. The authors further state that extensions outside of the USA, as well as the presence of firms among the assignees, increase publication delays for patents that do not use the grace period. Furthermore, they note that the publication lags are shorter when priority of the patent is claimed in the USA than in Europe, which shows that the absence of the grace period in Europe makes Europe-based researchers less competitive in getting scientific priority, according to their interpretation.

93 JOSEPH STRAUS, *GRACE PERIOD AND THE EUROPEAN AND INTERNATIONAL PATENT LAW—ANALYSIS OF KEY LEGAL AND SOCIO-ECONOMIC ASPECTS* (IIC-STUDIES, 20) (2001).

94 Sado Nagaoka & Yoichiro Nishimura, *Do grace periods promote knowledge spillover?: evidence from Japan*, in CEPR—RIETI JOINT WORKSHOP ON 'SCIENCE AND INNOVATION' NIESR (2018), <https://www.rieti.go.jp/jp/events/18022601/pdf/nagaoka.pdf> (accessed Apr 27, 2021).

95 *Id.*

96 *Id.*

97 *Id.*

98 *Id.*

99 Franzoni and Scellato, *supra* note 13.

ii. *Evidence for promoting innovation by encouraging innovation disclosure*

Given the differences in national patent laws with respect to the existence of grace periods as discussed above, the impact on innovation is of special interest. Research supports the idea that the existence of grace periods accelerates the disclosure of the invention and increases knowledge flow.¹⁰⁰ In the context of promoting innovation and OI, increased flow of information contributes to promoting innovation.¹⁰¹ The role of knowledge flow in promoting industrial innovation and economic development has been recognized.^{102,103}

It seems plausible to assume that the inventor is more likely to disclose an invention if the inventor has the confidence that IPR will be retained. The possibility of disclosing the invention without the risk of destroying its novelty provides the confidence to disclose information. The protection offered by a grace period seems particularly important in the context of OI, which relies on the open exchange of and free access to information. It is even more important in relation to speeding up drug discovery in the context of the COVID-19 pandemic. In this context, a grace period is key to encouraging rapid disclosure.

In addition to the impact of a grace period on the flow of information and promotion of innovation, the duration of a grace period also affects the degree of innovation disclosure. A longer duration is expected to favor disclosure of the innovation by providing a longer time for the inventor to apply for patent protection. A shorter duration reduces the incentive for the inventor to disclose the invention by increasing the risk of missing the deadline for the application and potential loss of IPR.¹⁰⁴ The recent trend toward extending the duration of the grace period in several national patent legislations—including Australia, Japan, UK¹⁰⁵—and policy discussions support that a longer grace period duration is beneficial to promoting innovation.¹⁰⁶

iii. *Knowledge Flow Effect*

A grace period offers innovators protection despite their invention not being patented yet. This is a private benefit to the inventor as well as a social benefit to society as a result of knowledge spillover.¹⁰⁷ Due to an acceleration of academic competitiveness, more inventions and innovations lead to a knowledge spillover effect likely to increase social welfare.¹⁰⁸ Mostly, inventors are likely to use a grace period for

100 Chiara Franzoni & Giuseppe Scellato, *The grace period in international patent law and its effect on the timing of disclosure*, 39 RES. POLICY 200–213 (2010).

101 SADA0 NAGAOKA & YOICHIRO NISHIMURA, *Use of Grace Periods and Their Impact on Knowledge Flow: Evidence from Japan* (2015), <https://www.rieti.go.jp/publications/dp/15e072.pdf> (accessed Apr 27, 2021).

102 Paul L. Robertson & Parimal R. Patel, *New wine in old bottles: Technological diffusion in developed economies*, 36 RES. POLICY (2007).

103 Gregorio Martín-de Castro, *Knowledge management and innovation in knowledge-based and high-tech industrial markets: The role of openness and absorptive capacity*, 47 INDUSTRIAL MARKETING MANAGEMENT (2015).

104 NATIONAL RESEARCH COUNCIL, *GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY* (1st edition ed. 1993).

105 Sandrik, *supra* note 70.

106 Nagaoka and Nishimura, *supra* note 91.

107 *Id.*

108 NAGAOKA AND NISHIMURA, *supra* note 98.

science-based inventions which have a high knowledge spillover effect to third parties.¹⁰⁹ A grace period will thus greatly benefit academia, society, and taxpayers in support of a knowledge-based economy.

A grace period is a key element of innovation-friendly patent law due to its support for academia. Universities and research organizations have often applied for a grant of patent too early as a result of institutional pressure and the obligation created by the 'publish or perish' mantra.¹¹⁰ Consequently, these premature applications either lack novelty, or are missing an inventive step, leading to the loss of patent protection in most countries. Abstracts, presentations, exhibitions, and research proposals disclosing an invention before patenting are also likely to cause an innovator to be denied a patent. A grace period could also provide a solution to this problem.

Technologies discovered by academic inventions and publications also face hurdles when it comes to transferring such high-risk technology. The Tegernsee group published that the leading cause of the use of a grace period in the USA, EPO, and Japan is the publishing of an earlier academic article.¹¹¹ As such, a grace period proves useful to academia. It has been shown by a research conducted in Japan that the acceleration of disclosure view significantly explains the effect of the grace period used by corporate inventors. This acceleration was the direct evidence of significant knowledge flow as measured by patent citations to the third parties: the level of non-self forward citations of the invention using the grace period is significantly higher than that of the invention without the grace period, relative to the corresponding difference of the level of self-forward citations. This knowledge flow effect to the third parties is larger for those to small- and medium-size enterprises (SMEs): the average is 5.5 per cent, with 2.7 per cent for large firms (listed firms) and 6.1 per cent for SMEs. Although the contribution to drug development can be attributed largely to big pharmaceutical companies rather than to SEMs, their contribution to the innovation space and technology development cannot be neglected.¹¹² Overall, the findings support the positive effect on both big and small enterprises. Interestingly, the above cited study found that the grace period is more used for inventions with higher science but it is less used for inventions with more claims which have a higher commercial value. Given that the applicant has the option of using the grace period, these findings indicate that the grace period system is likely to boost innovation and welfare. It has the potential to significantly increase knowledge diffusion while not jeopardizing the inventors' interests.¹¹³

iv. Benefits related to the pharmaceutical industry

Several benefits specific to the pharmaceutical industry have been mentioned in connection with the existence of a grace period in patent law. A grace period can be particularly valuable for pharmaceutical inventions if, for example, clinical trial data are required to support the claims. A grace period could provide security if clinical trial

109 Nagaoka and Nishimura, *supra* note 91.

110 Bart Verspagen, *University research, intellectual property rights and European innovation systems*, 20 J. ECON. SURV. (2006).

111 Van Pottelsberghe De La Potterie, *supra* note 42.

112 Nagaoka and Nishimura, *supra* note 91.

113 Nagaoka and Nishimura, *supra* note 91.

protocols are published before the filing.¹¹⁴ In the USA, the disclosure of the clinical trial is considered novelty-destroying for a later patent application unless it is disclosed when taking advantage of a grace period.¹¹⁵ In fact, it has been argued that the grace period in the USA has led to particular advantages in the pharmaceutical market, where drugs need to be tested.¹¹⁶ Introducing a grace period in patent law therefore allows for disclosure of clinical trial protocols without the risk of destroying novelty.

A grace period also has advantages in situations in which pharmaceutical drugs are sold on the market prior to patent filing.¹¹⁷ Such a scenario normally would be considered novelty-destroying under most patent laws. By using the grace period, distribution of a drug prior to filing a patent application is possible without destroying novelty in countries which apply a grace period. Such a practice is well known in South Korea; however, South Korea requires that the applicant indicates the intention to take advantage of the grace period in writing.¹¹⁸

The recent amendment of Art. 24 of Chinese patent law, which came into effect June 1, 2021, enlarges the scope of the grace period to invention-creations that are made available in the public interest during a state of national emergency.¹¹⁹ According to Art. 24, within six months before the date of application, in the case of national emergency or exceptional circumstance, an invention-creation first made public for the purpose of public interests does not lose its novelty. Considering the COVID-19 pandemic, the purpose of this amendment is to ensure that patents for new innovations (eg new drug-related technologies) can still be applied for and acquired, even after the disclosure of such innovations.¹²⁰ At present, it is unclear whether the amendment will have retroactive effect on the patents granted before June 1, 2021. If applied retroactively, the expanded scope of protection would offer a convenient way of securing patent protection and ensuring that Chinese inventors do not lose their patents, as there was much pressure to publish data and findings from the start of the pandemic. While it is expected that detailed rules regulating the use of the amendment provision will be published later in the patent examination guidelines, the FICPI believes that the provision may apply retroactively to the patents granted before June 1, 2021.¹²¹

Regardless of whether the amended provision will be applied retroactively, the expansion of the scope of a grace period can be considered an incentive to the inventors who will be encouraged to disclose relevant innovations quickly in the public interest. As discussed previously, we believe that not only society will benefit from the disclosed

114 INTELLECTUAL PROPERTY OFFICE, *supra* note 21.

115 Lorenz Kallenbach & Marco K. Vallazza, *Are the new clinical trial transparency rules incompatible with the patentability requirements in Europe?*, 36 NAT. BIOTECHNOL. (2018).

116 INTELLECTUAL PROPERTY OFFICE, *supra* note 21.

117 Min Son, *South Korea: Court rules on novelty when drug is sold before filing*, MANAGING IP (2019), <https://www.managingip.com/article/b1kbylp4bhwy/south-korea-court-rules-on-novelty-when-drug-is-sold-before-filing> (accessed May 2, 2021).

118 *Id.*

119 Linda Liu & Partners, *supra* note 14.

120 Mi, *supra* note 15.

121 Chuanhong Long, *Patent Term Extension In China*, INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS (FICPI) (2021), <https://ficpi.org/ip-news/patent-term-extension-china> (accessed Jun 8, 2021).

inventions, but that it will have a positive effect on knowledge flow and contribute to promotion of rapid innovation.

B. Main arguments against the grace period

While the grace period has been identified as beneficial for the academic sector, the large industry seems to be strongly opposed to its introduction in the national or in the EPC.¹²² Several arguments against the introduction of a grace period in Europe have been discussed in the study on the economic analysis of a grace period for European patents carried out by the EPO's Economic and Scientific Advisory Board (ESAB).¹²³

i. Increase in legal uncertainty

The first point is the legal uncertainty that might be more prominent after the introduction of a grace period. Once an invention is disclosed, it would take longer before third parties could understand if the application has been filed or it remains in the public domain.¹²⁴ Moreover, there would be a legal uncertainty once the invention has been granted to determine the status of potential prior art for the assessment of the validity of granted patents or it could lead to a prevalence of simultaneous invention, giving false expectations to inventors about the priority of their invention.¹²⁵ The argument against the introduction of a grace period therefore promotes the illusion that without a grace period, certainty is preserved.¹²⁶ Certainly, including a grace period may lengthen the period of uncertainty to some amount if applicants purposefully postpone files until the grace period expires. However, the pro-disclosure pressure mitigates such uncertainty, and thus is not always damaging to the patent system.¹²⁷ Moreover, there is no documentation proving that a patent system with a grace period creates legal uncertainties to third parties. Opponents think that increasing the period of uncertainty would disrupt the fair balance between the inventor and the public, leading to a detrimental effect for the patent system, as it would raise difficulties in the identification of the applicable prior art.¹²⁸ They claim it is unnecessary as it holds no benefit to the inventor and to third parties.¹²⁹ Critics of a grace period argue that it increases the uncertainty time between the time of filing for a grant of patent and the time when public disclosure about the application is made.¹³⁰ Dr. Jan Galama, head of intellectual

122 COMMISSION OF THE EUROPEAN COMMUNITIES, *An assessment of the implications for basic genetic engineering research of failure to publish, or late publication of, papers on subjects which could be patentable as required under Article 16(b) of Directive 98/44/EC on the legal protection of biotechnological inventions SEC(2002) 50* (2002), <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2002:0002:FIN:EN:PDF> (accessed May 3, 2021).

123 EPO ECONOMIC AND SCIENTIFIC ADVISORY BOARD, *Introducing a grace period in Europe?* (2015), [http://documents.epo.org/projects/babylon/eponet.nsf/0/c4a001f6453f3d48c1257e0b0034cb2b/\\$FILE/esa_b_statement_grace_period_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/c4a001f6453f3d48c1257e0b0034cb2b/$FILE/esa_b_statement_grace_period_en.pdf) (accessed Apr 28, 2021).

124 *Id.*

125 *Id.*

126 Renee E Metzler, *Not All Grace Periods Are Created Equal: Building a Grace Period From the Ground Up*, 13 MARQUETTE INTELLECT. PROP. LAW REV. (2009), <https://scholarship.law.marquette.edu/iplr/vol13/iss2/6> (accessed Apr 27, 2021).

127 STRAUS, *supra* note 90.

128 EPO ECONOMIC AND SCIENTIFIC ADVISORY BOARD, *supra* note 119.

129 Metzler, *supra* note 122.

130 *Id.*

property within Philips International, believes that the grace period is a double-edged sword for scientists themselves.¹³¹ In certain fields, such as biotechnology, pharmacy, and information technologies, the risk of intellectual property theft is high. The high-speed communication through the Internet, the growing economic significance of patents, and world-wide competition require a clear-cut patent system on which everyone can rely.¹³² Moreover, another argument against the grace period is that absolute novelty is preferable since it protects inventors from their own mistakes.¹³³ Therefore, inventors risk deteriorating the exploitability of their inventions by disclosing it under a grace period. Such a prolonged time, in fact, without filing for a patent is likely to lead to an expiration of novelty and exclusivity.¹³⁴ Absolute novelty regimes, such as those employed in first-to-file nations in Europe, appear to see invention as a distinct event that occurs privately and is identifiably complete at a specific point in time. If this assumption is correct, the argument that grace periods encourage legal uncertainty seems plausible, as there would be no reason not to mandate prompt patent application. While the former situation may be achievable by large, well-funded entities, the latter is more likely to be the case for smaller, early-stage companies, particularly when they attempt to partner with academic researchers. This criticism results in a lack of understanding of small-business entrepreneurship and an undue focus on the abilities and resources of larger entities.¹³⁵

ii. Increase in litigation costs

Another consequence of the introduction of the grace period is the lengthening of the granting procedure, a loss of operational efficiency, and an increase in patenting costs due to potential additional communications between the examiner and the applicant. Stating the difficulties of certainty concerning the granted patents, the introduction of a grace period could also increase the costs of litigation and disputes over entitlement. There is, in fact, an increased risk of infringement by competitors who may be unaware it will eventually be patented.¹³⁶ Increased risk of infringement by competitors is a particularly difficult predicament for SMEs with potentially fewer financial and legal resources to successfully litigate such cases.¹³⁷

131 JAN E.M. GALAMA, *Expert Opinion On The Case For And Against The Introduction Of Grace Period In European Patent Law*, submitted on request of the European Patent Organisation (2000).

132 Emmanuel Roucouнас, *The Debate Regarding the Grace Period in International Patent Law: A Reminder*, ALLEA BIENN. YEARB. NEW PERSPECTIVES ACAD. 31–46 (2006), https://allea.org/wp-content/uploads/2016/02/Roucouнас_Debate_Grace_Period.pdf (accessed May 3, 2021).

133 Frederik W Struve, *Ending Unnecessary Novelty Destruction: Why Europe Should Adopt the Safety-net Grace Period as an International Best Practice*, 39 WILLIAM MITCHELL LAW REV. (2013), <https://open.mitchellhamline.edu/wmlr/vol39/iss4/12> (accessed Apr 27, 2021).

134 Franzoni and Scellato, *supra* note 13.

135 STRAUS, *supra* note 90.

136 Matthew Graff & Armin Ayatollahi, *Disclosing Before Filing? Grace Period Disharmony Creates Uncertainty for Applicants Seeking Design Protection Around the World*, BERESKIN & PARR (2017), <https://www.bereskinparr.com/doc/disclosing-before-filing-grace-period-disharmony-creates-uncertainty-for-applicants-seeking-design-p> (accessed May 3, 2021).

137 Sati-Salmah Sukarmijana and Olivia De Vega Saponga. The importance of intellectual property for SMEs; Challenges and moving forward. UMK Procedia 1 (2014) 74–81.

iii. *Complication of the patent system*

A few major criticisms of the grace period regard the lack of understanding of its scope in the inventor's own country and those of other countries in which the inventor wishes to protect his or her invention.¹³⁸ In fact, European inventors can be in a disadvantageous position, as they need to understand both the grace period of their own country and those of the other countries in which they want to file a patent application. Despite numerous calls for global harmonization, grace period provisions vary greatly from country to country.¹³⁹ According to some reports, in fact, most countries revert to the lowest common denominator, which is to avoid the grace period entirely.¹⁴⁰ Broad differences of opinion exist, particularly on the issues of scope of coverage acts/disclosures by the inventor (all or limited to certain venues and cases of abuse), terms of the grace period, and the need for statements and declarations.¹⁴¹

Dr. Jan Galama and some European governments stress that there is no evidence that the introduction of this system in Europe will lead to more innovation. They also assess that if the inventors apply the rules correctly, they can be amply protected, avoiding more loopholes to be introduced in the patent law.¹⁴² Additionally, universities, which benefit most from the introduction of a grace period, do not specifically need it if they discard some old habits.¹⁴³

In the USA, where the grace period is widely utilized, some publications consider the change introduced by the AIA from a first-to-invent system to a first-to-file system very controversial.¹⁴⁴ Particularly, provisions in the AIA concerning the grace period seem less robust than before the enactment of the AIA.¹⁴⁵ Regarding third-party disclosures, the current American grace period applies only to disclosure of the same subject matter obtained from the inventor. The exceptions do not apply to variations of the subject matter. If, for example, an inventor discloses the invention before filing a patent, a third party could disclose an invention which includes not only the inventor's original idea, but also an improvement or modification of the idea. In this case, the third-party's disclosure can be a prior art with regard to the original inventor's patent application. The original inventor cannot rely on the date on which the disclosure to the third party was made.¹⁴⁶

iv. *Provisional Patent Applications*

Grace periods are not the only option for obtaining temporary protection from patent novelty loss. Provisional patent applications have been available from the USPTO

138 James Yang, *Dangers of 1 yr grace period under first-inventor-to-file system*, OC PATENT LAWYER (2014), <https://ocpatentlawyer.com/dangers-of-1-yr-grace-period-under-first-inventor-to-file-system/> (accessed May 3, 2021).

139 Sandrik, *supra* note 70.

140 THIERRY CALAME ET AL., *Grace Period for Patents (Question 233)* (2013), <https://www.aippi.fr/upload/Helsinki2013/sr233english.pdf> (accessed May 2, 2021).

141 *Id.*

142 Roucounas, *supra* note 128.

143 *Id.*

144 Dale S. Lazar, Lisa K. Norton & Nick Panno, *The AIA's one-year grace period—a trap for the unwary?*, DLA PIPER (2013), https://www.dlapiper.com/en/italy/insights/publications/2013/03/the-aias-one-year-grace-period--a-trap-for-the-un-_/ (accessed May 3, 2021).

145 *Id.*

146 *Id.*

since 1995.¹⁴⁷ According to the USPTO, ‘In view of the one-year grace period provided by 35 U.S.C. 102(b)(1) in conjunction with 35 U.S.C. 102(a)(1), a provisional application can be filed up to 12 months following an inventor’s public disclosure of the invention . . . A public disclosure (eg publication, public use, offer for sale) more than one year before the provisional application filing date would preclude patenting in the USA.’¹⁴⁸ Thus, provisional patent applications protect inventions, which are considered ‘patent pending,’ from the loss of novelty during the 12 months of pendency of the provisional application.¹⁴⁹ Applicants for Australian and US patents have the option of filing for provisional patent applications. In fact, inventors or assignees may file US provisional patent applications regardless of their citizenship, residency, or nationality.¹⁵⁰ According to U.S.C. 35 U.S.C. §111(b), applicants for US patents may submit provisional patent applications without having to include either declarations or formal patent claims.¹⁵¹ Specifically, formal patent claims, declarations, and prior art disclosures need not be submitted during the 12 months subsequent from the provisional application filing date.¹⁵² However, in order to preserve the novelty requirement for an invention protected by a provisional patent application, the inventor(s) must file a nonprovisional patent application containing formal patent claims, declarations, and prior art disclosures prior to the expiration of the 12 month period of pendency.¹⁵³

Several advantages exist for utilizing the provisional patent application system. These include the establishment of a priority filing date, having a ‘patent pending’ status to alert others of the invention, and allowing an inventor additional time to optimize and market the inventions.

Pharmaceutical and biotechnology provisional patent applicants who apply through the USPTO obtain the advantage of the establishment of a priority filing date for the nonprovisional patent application with the provisional patent application.¹⁵⁴ The provisional patent application allows the inventor to benefit from earlier priority filing dates without initiating the standard 20-year patent term of the patent obtained with the nonprovisional patent application.¹⁵⁵ This is an advantageous measure in rapidly-moving fields such as the sciences in which highly prolific competitors are an ever-present concern.¹⁵⁶ Thus, the provisional application filing period can extend the amount of time an invention can be afforded some protection from invalidation or infringement if the nonprovisional patent application is eventually successful.¹⁵⁷ Inventors who rely solely on the grace period instead of filing the provisional patent application may not benefit from the earlier priority filing date in the same manner as

147 Provisional application for patent. United States Patent and Trademark Office. Jun 28, 2021. 08:36 AM EDT. <https://www.uspto.gov/patents/basics/types-patent-applications/provisional-application-patent>. (accessed Dec 20, 2021).

148 *Id.*

149 *Id.*

150 *Id.*

151 *Id.*

152 *Id.*

153 *Id.*

154 U.S.C. 35 U.S.C. §111(a).

155 35 U.S.C. 354(c)(1).

156 *Regents of the Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286, 1289 (Fed. Cir. 2018).

157 Intellectual Property Rights: Patent. eds. Sakthivel Lakshmana Prabu, Suriyaprakash TNK, Eduardo Jacob-Lopes, Leila Queiroz Zepka. Books on Demand. 2020. p. 5.

those who file provisional patent applications prior to nonprovisional patent applications.¹⁵⁸ Alerting competitors to the ‘patent pending’ status of an invention serves to put competitors—along with the public—on notice as to the status of the invention without the necessity of executing a full disclosure in the provisional patent application.¹⁵⁹ Ideally, this should serve as a disincentive to competitors who might otherwise attempt to infringe upon the ‘patent pending’ invention. In addition, filing a provisional patent application may allow inventors additional time to optimize inventions. Furthermore, inventors may file additional related provisional patent applications for the same invention prior to filing the nonprovisional patent application.¹⁶⁰ If applicants require additional time for invention disclosure research, the provisional patent application process allows this additional time.¹⁶¹ Additionally, more thorough market research may be completed during the provisional application period.¹⁶²

Although provisional patent applications have several advantages, there are also many disadvantages. For instance, if inventors fail to file a nonprovisional patent application in a timely manner during the provisional patent application period (within 12 months), they risk failing to meet the novelty requirement for patent rights to their invention. Next, provisional patent applications are neither examined nor published. Moreover, provisional patent applications can lengthen the amount of time it takes for an inventor to eventually obtain a nonprovisional patent. Even more so, a longer time interval from invention to eventual patent may increase the risk of exposure to patent invalidation or infringement litigation. Prohibitive costs of provisional patent applications could exclude socioeconomically poorer patent applicants from being able to participate fully in the patent application process. This could be detrimental for the perpetuation of innovation on a larger societal scale. Additionally, adequate details concerning the invention must still be provided in the provisional patent application. Finally, provisional patent applications are not available through the EPO or through European national patent offices.

First, unless the inventors or assignee file a nonprovisional patent application prior to the end of the 12-month pendency period, the novelty of the invention could be forfeited.¹⁶³ Unlike the nonprovisional patent application, extensions are not available.¹⁶⁴

Next, provisional patent applications are not examined.¹⁶⁵ The lack of a requirement for the USPTO to examine provisional patent applications could unnecessarily lengthen the amount of time it takes to obtain a nonprovisional patent when the applicant could have filed solely for the nonprovisional patent in the first instance. For

158 35 U.S.C. 102(b)(1); 35 U.S.C. 102(a)(1).

159 What do the terms ‘patent pending’ and ‘patent applied for’ mean? Patent FAQs. USPTO. https://www.uspto.gov/help/patent-help#type-browse-faqs_330. (Accessed Dec 23, 2021). Although a provisional patent application is not publicly disclosed, provisional patent applicants may affix the label ‘patent pending’ on their inventions and notify the public of the ‘patent pending’ status of their inventions.

160 35 U.S.C. § 119(e)(1).

161 Brent E. Matthias. The Promise and Pitfalls of Provisional Patent Applications. 6 *Nat Law Review* 357 (2021).

162 *Id.*

163 Provisional application for patent. United States Patent and Trademark Office. Jun 28, 2021 08:36 AM EDT. <https://www.uspto.gov/patents/basics/types-patent-applications/provisional-application-patent>. (accessed Dec 20, 2021).

164 *Id.*

165 *Id.*

instance, international scientists are only afforded the 12-month pendency period to refine their inventions.¹⁶⁶ Moreover, the absence of a rigorous review could also be disadvantageous in the long run for patent applicants who are new to the patent process and/or have inventions which could benefit from a more thorough formal vetting.

Furthermore, while more sophisticated patent applicants may benefit from an earlier priority date and a longer time frame for both provisional and nonprovisional patent applications, a longer patent application process which includes a provisional patent application can be disadvantageous—even detrimental—for less experienced inventors, novice partnerships, smaller companies, startups, and inventors with limited financial resources. Costs for the provisional patent application and the nonprovisional patent application can be higher due to fees associated with filing two patent applications (provisional and nonprovisional). Longer patent application processing times due to the addition of a provisional patent application could also mean increased exposure to the threat of patent invalidation and infringement claims from larger companies and other entities with greater financial resources which could involve the smaller company or startup in financially wasteful litigation.¹⁶⁷ Thus, prohibitive overall potential costs of provisional patent applications could preclude applicants from poorer nations within the European Union from filing provisional patent applications. Such activity among provisional patent applicants could eventually create and perpetuate a two-tiered system of socioeconomic disparity among patent applicants in Europe or the European Union in which wealthier patent applicants could avail themselves of all of the resources and benefits that filing both provisional and nonprovisional patent applications have to offer. The exclusion of potentially socioeconomically disadvantaged patent applicants in Europe or the European Union from enjoying the resources and benefits of both provisional and nonprovisional patent applications bodes quite poorly for advancing overall innovation for the benefit of societies-at-large.

Furthermore, even though provisional patent applications do not require formal patent claims, declarations, or prior art disclosures, sufficient detail must still be provided so that a person with ordinary skill in the art of the invention would be able to interpret claims in the provisional patent application.¹⁶⁸ In addition, the claims in the nonprovisional patent application should closely follow and bolster the claims in the provisional application.¹⁶⁹ Failure to do so could result in a loss of the priority filing date privilege afforded by the provisional application.¹⁷⁰ Regardless, provisional patent applications do not provide the same level of protection as nonprovisional patent applications.

166 35 U.S.C. 111; 37 CFR 1.53.

167 Competitors with greater legal and financial resources could be made aware of the invention, using the inventor's provisional application period of pendency to consider and/or prepare for legal action for patent invalidation and/or infringement when the inventor eventually files the nonprovisional application.

168 Specifically, if reasonable efforts at claim construction result in a definition that does not provide sufficient particularity and clarity to inform skilled artisans of the bounds of the claim, the claim is insolubly ambiguous and invalid for indefiniteness. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1379 (Fed. Cir. 2011); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1371 (Fed. Cir. 2008) (citing *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249-51 (Fed. Cir. 2008)).

169 35 U.S.C. § 119(e)(1).

170 *Dynamic Drinkware, LLC, v. National Graphics, Inc.*, 800 F.3d 1375, 1382 (Fed. Cir. 2015).

Finally, a significant disadvantage of provisional patent applications relevant to this paper is that provisional patent applications are only available through the patent offices of Australia and the USA. Provisional patent applications are not offered through national or regional patent offices in Asia, Africa, North America outside of the USA, South America, or Arab nations. Most pertinent to the discussion in this paper, provisional patent applications are also not available in national patent offices in Europe.¹⁷¹ Moreover, provisional patent applications are not offered through the regional EPO or to members of the EPC administered by the EPO.¹⁷²

V. CONSIDERATIONS REGARDING THE USE OF A GRACE PERIOD TO ACCELERATE DRUG DISCOVERY

The following section outlines some considerations with regard to the implementation of the grace period in European Patent law and the associated benefits regarding acceleration of drug discovery. The question that arises in this context concerns the design of the grace period. How should a grace period be specifically designed to create the greatest possible incentive for the disclosure of results in the pharmaceutical industry and to promote the flow of information?

171 Provisional patent protection may be conferred when the official language of the applicant for the invention differs from that of the patent proceedings, provided that certain conditions are met. Specifically, 'If the Euro-PCT application is published in another language, a translation into one of the official languages shall be filed with the European Patent Office, which shall publish it. Subject to Article 67, paragraph 3, the provisional protection . . . shall be effective from the date of that publication.' Article 153(4)—European Patent Convention. Article 67 of the European Patent Convention states that 'Any Contracting State which does not have as an official language the language of the proceedings may prescribe that provisional protection . . . shall not be effective until such time as a translation of the claims in one of its official languages at the option of the applicant or, where that State has prescribed the use of one specific official language, in that language: (a) has been made available to the public in the manner prescribed by national law, or (b) has been communicated to the person using the invention in the said State.' Still, this is a process which must be distinguished from the provisional patent applications of the USA.

172 The provisional patent applications of the USA should also not be confused with provisional measures utilized in suspected infringement actions in TRIPS Agreement Member States. Provisional measures refer to mechanisms to prevent patent infringement and intercede when unauthorized imports of patented goods are suspected. Article 50—TRIPS Agreement. Typically, provisional measures are conferred when a patent infringement action is in the process of adjudication before a court in a formal matter of litigation. During this time the patent owner is provided with the opportunity to present evidence to the court indicating rightful ownership to contest the patent infringer's claims. Article 50(3)(5)—TRIPS Agreement. In this manner, the court may also utilize the time to gather and preserve evidence of the alleged infringement activities. *Anton Pillar K.G. v. Manufacturing Processes Ltd.* [1976] RPC 719. See also Chapter 14: Enforcement of IPRs. §14.01 [B][6] Provisional Measures. Introduction to Intellectual Property. Theory and Practice. World Intellectual Property Organization. 2nd edition. p. 342. Specifically, Article 50(2) of the TRIPS Agreement states that '[t]he judicial authorities shall have the authority to adopt provisional measures *inaudita altera parte* where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.' The European Court of Justice ruled that Article 50 of the TRIPS Agreement may be interpreted and applied concerning a provisional measure when 'the measure is characterized under national law as an "immediate provisional measure" and its adoption must be required 'on grounds of urgency'. Judgment of the Court of 16 June 1998.—*Hermès International* (a partnership limited by shares) *v* *FHT Marketing Choice BV*.—Reference for a preliminary ruling: Arrondissementsrechtbank Amsterdam—Netherlands.—Agreement establishing the World Trade Organisation—TRIPS Agreement—Article 177 of the Treaty—Jurisdiction of the Court of Justice—Article 50 of the TRIPS Agreement—Provisional measures.—Case C-53/96. In summary, provisional measures are designed to emend and ameliorate deliberations just prior to or during the remedy phase of adjudication.

While these considerations are certainly intriguing from a scientific point of view, they have little significance from a practical point of view. Given the rather hesitant and skeptical attitude toward the introduction of grace periods in Europe, a broad consensus in favor of a tailor-made solution for a specific sector seems very unlikely. A survey conducted among Swiss companies on the benefits of introducing a grace period revealed that a majority of large companies do not think that the concept of grace period is poorly defined but believe it creates legal uncertainty for third parties.¹⁷³ A survey performed and published by the FICPI and the Tegernsee group in October 2013 revealed similar findings for German respondents; 61.5 per cent were against implementation of grace period.¹⁷⁴ Moreover, a ‘tailor-made’ solution aimed at one industry would violate Art. 27 of TRIPS,¹⁷⁵ which prevents discrimination in the field of technology.

Considering this, we believe that the benefits of introducing a grace period should therefore be guided by existing proposals and solutions such as the discussions and proposals carried out in the framework of the international harmonization of patent law; this includes the SPLT¹⁷⁶ and the recommendations formulated by the ESAB.¹⁷⁷ The international context is all the more important, considering that companies usually apply for protection not only in Europe, but usually in multiple countries, including the USA, Japan, and Korea, which complicates the process due to different protection regimes.¹⁷⁸ This point of view is also reflected in the ESAB statement; they advocate for an internationally harmonized grace period within key global patent systems including, besides Europe, at least the USA, Japan, Korea, and China.¹⁷⁹ The following section analyzes proposals related to the grace period duration and scope of protection in relation to expected benefits.

A. Duration of the grace period

In terms of the potential incentive that the grace period might provide to the inventor, the duration of the associated protection is essential. It appears that a longer duration offers a greater incentive to inventors since it provides precious time to prepare applications for subsequent filing while enabling inventors to dedicate time to continue working on the invention. When thinking about scientific discoveries, for example, time is important to improve the discovery, especially in university research groups, which are closely intertwined with industries. The necessity of publication and discussing one’s research with colleagues are both important aspects of a scholar’s research and

173 NIKOLAUS THUMM, *Research and Patenting in Biotechnology: A Survey in Switzerland* (2003), <http://www.ge.ch/E/jurinfo/documents/j10005e.pdf> (accessed Apr 27, 2021).

174 Robert Watson et al., *FICPI Urges the Adoption of a Grace Period Creating a Level Playing Field for Inventors* (2016), https://ficpi.org/system/files/gonzo/Briefing_Paper_on_Grace_Period.pdf (accessed Apr 27, 2021).

175 AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS. PART II STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS, *supra* note 25.

176 INTERNATIONAL BUREAU WIPO, *supra* note 77.

177 EPO ECONOMIC AND SCIENTIFIC ADVISORY BOARD, *supra* note 119.

178 Kyu Yun Kim et al., *Drafting for Multiple Jurisdictions Miniseries: Part 1—Grace Period Provisions*, FINNEGAN (2020), <https://www.finnegan.com/en/insights/blogs/at-the-ptab-blog/unitary-patent-series-part-1-grace-period-provisions.html> (accessed May 2, 2021).

179 EPO ECONOMIC AND SCIENTIFIC ADVISORY BOARD, *supra* note 119.

career. The success of a researcher stems primarily from the professor's ability to publish. Due to the pressure of publishing, academics may choose to publish, potentially forfeiting the right to patent. Considering the time needed to publish, a longer duration of the grace period would help the researcher not to lose his right to patent, even if this may increase the legal uncertainty.¹⁸⁰ We should state that time is required for product refining, prototype creation, and market testing. Those activities are frequently required to get funding or determine whether cost-effective manufacturing is possible. Twelve months is not an unreasonable time given the amount of labor involved.¹⁸¹

The actual time required to collect, prepare, and write the final patent application is a matter of debate. Certainly, the time available to scientists to support patenting activities is limited during a pandemic due to the fact that resources are limited. Put simply, once can imagine that the focus of activities of a scientist in an R&D department of a pharmaceutical company during a pandemic shifts toward laboratory work, while time available to support patenting activities remains limited. A meaningful incentive should provide sufficient time to compensate for the time spent on development and administrative work related to patenting activities.

The duration of the grace period in countries that have implemented the grace period in their national patent laws is usually either 6 or 12 months,¹⁸² while in some countries the duration depends on the circumstances.¹⁸³ While duration of 12 months seems sufficient in relation to the time needed to prepare the necessary documentation for subsequent filing, 6 months' time may be too rushed. Since the USA already provides for a 12-month grace period through the AIAs, it is crucial for Europe to adopt the same to level the playing field.¹⁸⁴ Six months is a short time in comparison to the 12 months' time necessary to prepare for patent filing; a 6 month grace period increases the risk of missing the patent application deadline. In this context, the duration of 6 months proposed by the ESAB¹⁸⁵ is inadequate. We remain doubtful whether 6 months would provide an adequate incentive for the European inventor and compensate for the risk associated with disclosure. In contrast, the 18 month grace period proposed by FICPI¹⁸⁶ seems to provide a more adequate incentive.

In interpreting the impact of the duration and expected benefits of the grace period, the comparison with the time needed for drug development is particularly interesting. While drug development normally takes several years, the COVID-19 pandemic has impressively demonstrated that development time can be dramatically shortened. Can we go even faster? If so, can the grace period make an additional contribution? Admittedly, the question about the benefits of a grace period to speed up drug development

180 Metzler, *supra* note 122.

181 William G. Giltinan, *The Disclosure Function, Academic/Private Partnerships, and the Case for Affirmatively Used, Multinational Grace Periods*, 22 TEX. INTELL. PROP. L.J. 109-undefined (2014).

182 WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO), *CERTAIN ASPECTS OF NATIONAL/REGIONAL PATENT LAWS* (2020), https://www.wipo.int/export/sites/www/scp/en/national_laws/grace_period.pdf (accessed Apr 28, 2021).

183 CALAME ET AL., *supra* note 136.

184 Bolte-Meissner, *Will the UK introduce a 12 Month Grace period for filing patent Applications?* (2021), <https://www.lexology.com/library/detail.aspx?g=d9e1f831-1387-4377-a62b-c92822a80c18> (accessed Apr 27, 2021).

185 EPO ECONOMIC AND SCIENTIFIC ADVISORY BOARD, *supra* note 119.

186 Caine et al., *supra* note 72.

may seem irrelevant given the experience with the COVID-19 pandemic, where it took less than a year from the first documented case to the start of vaccination in Europe.

However, in drawing fast conclusions using the example of the current pandemic, we do not need to forget about the role the existing know-how played in the development of the vaccines. At this point, we emphasize that without pre-existing scientific knowledge in the field of mRNA technology, the incredible pace at which the vaccines were developed would not have been possible. In addition, vaccine development relies heavily on the existing knowledge protected by trade secrets and patents. One should note that while several vaccines have been already developed building on existing knowledge, the development of drugs to treat the disease is still in its early stages.

We would like to highlight that the considerations presented in the context of the use of the grace period to promote innovation concern a more pessimistic scenario in which humanity will face a challenge which will not likely be solved by drawing from existing knowledge, but will rely on radical innovations. While we believe that a grace period can have its contribution to promote radical innovation, we are skeptical as to whether duration of less than 12 months can provide such advantages.

B. Scope of protection

In addition to the duration, the scope of protection, defined by the content of information that is protected by the grace period, plays a central role. It seems evident that any restriction or additional obligations on how information is disclosed—such as a mandatory declaration requirement or differentiation between the intentional and unintentional disclosure—create unnecessary hurdles that diminish the incentive for the inventor to disclose the invention. According to the mandatory declaration requirement proposed by the ESAB the inventor must submit a list of disclosures specifying when, how, and what information about the invention was made available to the public.¹⁸⁷ This automatically narrows down the scope of protection and increases the risk that information may be unintentionally omitted. Information disclosed without being included in the mandatory declaration as proposed by the ESAB is not protected.¹⁸⁸ A broader scope of protection, as proposed by the FICPI, which does not foresee any formal requirement with respect to inventor declaration, is beneficial in the context of creating an incentive to the inventor.¹⁸⁹

Another aspect that needs to be considered regarding disclosure of information and scope of protection relates to the question of further developments and amendments based on the information disclosed by the original inventor. Following the ESAB proposal,¹⁹⁰ the grace period would only apply to disclosures of the applicant's invention. Potential problems arise when the disclosure is subject to further developments and inventions which then fall outside the claims of the original disclosure. The associated risk includes a scenario in which the invention is further developed or amended by a competitor and filed for patent protection. This could have negative effects of the freedom to operate for the primary inventor. It also creates an additional hurdle to the inventor for filing patent applications that expand on the primary invention.

187 EPO ECONOMIC AND SCIENTIFIC ADVISORY BOARD, *supra* note 119.

188 *Id.*

189 Caine et al., *supra* note 72.

190 EPO ECONOMIC AND SCIENTIFIC ADVISORY BOARD, *supra* note 119.

Contrary to the proposal by the ESAB,¹⁹¹ the FICPI¹⁹² is of the opinion that a grace period 'would allow the patent drafter to expand on an idea, which was disclosed eg inadvertently or accidentally, so as to obtain a reasonable scope of protection and to meet the disclosure requirements'.¹⁹³ In relation to providing a meaningful incentive to the pharmaceutical industry, we consider the broader scope of the protection as proposed by the FICPI must be considered preferably over the ESAB proposal.

VI. CONCLUDING REMARKS

This paper discusses the potential use of a grace period in European patent law to promote disclosure of inventions related to drug discovery during a pandemic. Benefits arising from the safeguarding of the novelty and increased disclosure were considered by analyzing the relevant proposals regarding implementation of the grace period in European patent law and at the international level.

Following the analysis of the recent proposals related to the implementation of the grace period in the European and international contexts, we remain skeptical about the practicality and benefits of introducing a grace period into European patent law in the context of accelerating drug discovery. Given the potential disadvantages and the skeptical attitude toward a grace period in the European community, the proposals related to the duration and scope do not seem to offer any meaningful incentive to promote disclosure of the inventions by pharmaceutical companies.

The successes of European companies in the race to develop vaccines against COVID-19 demonstrate that Europe's ability to innovate does not suffer notably from the absence of a grace period. This justifies the European approach. While the implementation of a grace period in its proposed form does not have the potential to notably accelerate drug discovery in Europe, we believe that a grace period might offer advantages, especially in countries where the practice of a grace period is established and well known in national patent law.

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191 *Id.*

192 Caine et al., *supra* note 72.

193 *Id.*