

September 24, 2021

Dear Mr Strömbäck,

In reply to your letter of 25 May 2021, we would like to inform you that, despite our intensive work, we have not been able to agree on a revised package of the Elements Paper.

You will find attached the Draft Industry Trilateral Elements Paper dated September 7, 2020. There have been no changes (i.e., additions or deletions) to the Draft other than the cover sheet (i.e., page 1). The cover sheet no longer includes any restrictive legends (i.e., without restriction “for Circulation to Group B+ Members Only”). The release of the Draft to others by Group B+ is conditioned on the cover sheet always being included as part of the Draft.

We would like to emphasise that the version of the Elements Paper attached to this letter is not the final agreed position of IT3 nor any of its individual member associations; BE, JIPA, AIPLA or IPO, since we are still continuing our discussions.

We wish to express our resolve to work together toward producing further version of the Elements Paper which is agreed by all associations involved. This consensus is highly important to the harmonisation process and to achieve the desired benefits.

Finally, we thank the Group B+ for its support in our discussions and we look forward to joining the upcoming meetings of the B+ Subgroup and B+. We further emphasize the importance of continued support for these endeavours by the B+, the B+ Subgroup and its Members. We remain at your disposal to answer any questions that you may have.

Yours sincerely,

The Industry Trilateral

American Intellectual Property Law Association (AIPLA)
BUSINESSEUROPE (BE)
Intellectual Property Owners Association (IPO)
Japan Intellectual Property Association (JIPA)

Draft Working Document*

Policy and Elements for a Possible Substantive Patent Harmonization Package

7 September 2020

Industry Trilateral (IT3):

American Intellectual Property Law Association (AIPLA)

BUSINESSEUROPE (BE)

Intellectual Property Owners Association (IPO)

Japan Intellectual Property Association (JIPA)

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7 September 2020

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I. INTRODUCTION

1. The Industry Trilateral (IT3) was formed in 2003 as a basis for industry stakeholders in the jurisdictions of the Trilateral Offices (European Patent Office - EPO; Japan Patent Office - JPO; and United States Patent and Trademark Office -USPTO) to jointly engage the Offices in a discussion of substantive and procedural issues involving intellectual property (IP). The IT3 includes the associations of the American Intellectual Property Law Association (AIPPLA), BUSINESSEUROPE (BE), Intellectual Property Owners Association (IPO), and the Japan Intellectual Property Association (JIPA).
2. Since April 2014, the Industry Trilateral has engaged in a process of determining whether it would be possible to achieve consensus on a limited package of substantive patent law harmonization issues, or at least an agreement on scope and content of the basic elements to be contained in such a package. The IT3 also has worked toward achieving an agreement in principle on several patent law issues and, where agreement cannot be reached, a narrowing of the issues and an identification of the practical issues that may arise. The desired end result would be an agreement on an overall package that fairly balances the interests of all entities, large and small, individuals and universities, in a patent system that encourages innovation and protects the rights of innovators and third parties. The IT3 recognized that, given the currently wide diversity in relevant practice and principles with respect to these issues internationally, some laws will have to change in nearly every jurisdiction, to some extent, in order to achieve a globally harmonized package. All relevant national and regional laws and practices would be subject to review and revision; none were too sacred to be questioned.
3. A “First Elements Paper” that outlined the possible bases for an over-all harmonization package was prepared in 2015 and summarized the prior views of the IT3 on the policy objectives, policy issues, elements for inclusion in a harmonization package, and issues open for discussion. A further version was produced in June 2017 and then in September 2019.
4. The IT3 has continued discussing the basic elements that may form the basis of a substantive patent law harmonization package and has also considered the results of similar discussions on many of the substantive patent law issues for a harmonization package that are being held by other entities, both private (*e.g.*, AIPPI/FICPI) and government (*e.g.*, Tegernsee Report/B+ discussions). The IT3 also recognizes that open and comprehensive discussions of these issues among a broad spectrum of stakeholders will be held in the future.
5. In support of both private and government initiatives and further to continuous IT3 consultations, this next version of the “Elements Paper” has been prepared. In addition, high level statements on Prior Art, Objectives and Principles on Grace Period, Conflicting

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Applications, Prior User Rights, Defense for Intervening User and Mandatory Publication of all Patent Applications, as well as a summary of individual features are attached as Exhibits for reference. This version of the Elements Paper, in identifying the elements of possible solutions to some of the most critical issues involving substantive patent law harmonization, represents the results of an additional three years of discussion by representatives within the Industry Trilateral. It is presented as a basis for further dialogue with regard to substantive harmonization, by (1) presenting policy objectives, (2) identifying policy issues relevant to those objectives as well as relevant interests that have been discussed but not necessarily resolved, (3) explaining proposed and consensus positions, and (4) identifying open issues, where possible, on key issues that could be included in an overall substantive patent law harmonization package.

6. New emerging technologies, including artificial intelligence (AI), are advanced technology tools that have not to date been considered in detail in many international discussions of patent law harmonization. Additionally, the related policies and protocols that will be first adopted 5 to 10 years from now should be effective for decades thereafter. The capability of these technology tools has advanced significantly in only the past 5 years and that advance is expected to accelerate, as evidenced by numerous news reports, opinions and even IP seminars concerning them. In the patent field, these tools are expected to be useful in numerous applications, including the following: (1) drafting of patent applications, (2) searching prior art, (3) classification of applications, (4) translations of documents, (5) cooperative search and examination, (6) work sharing, (7) determination of unity, and (8) Office procedures, including publication of applications and issue of patents, to name a few.
7. Within the next 10 years and thereafter, at the time that any harmonization program is realistically implemented, new emerging technologies, including AI, will have a significant impact on the policies and procedures that will be relevant to the six topics that are the focus of the IT3 and B+ initiatives: Prior art, Conflicting Applications, Grace Period, Prior User Rights, Defense for Intervening User and Mandatory Publication of all Patent Applications. The IT3 has considered the impact of these advanced technology tools in the preparation of its recommendations.
8. This harmonized package as a whole is intended by the IT3 to benefit all stakeholders who participate in a global marketplace, from large entities to small and medium enterprises, universities, and individual inventors, by providing a uniform set of clear and balanced principles that will be applicable in all jurisdictions, without preference to any particular interest. A globally accepted set of principles would make patent rights more predictable, reduce costs and improve the efficiency of the patenting process. It was expressly recognized that this objective can only be achieved by compromise, guided by best practices and in consideration of a fair balance of interests of Applicants, Third Parties and society.

II. PRIOR ART

A. Policy Objectives:

9. A pre-requisite for any useful discussion of substantive patent law harmonization is an agreement on a common definition as to what constitutes, in principle, prior art against the subject matter claimed in a patent or patent application. Such prior art is an unrestricted public disclosure by anyone, including the Inventor, of all or part of the subject matter claimed in a patent or patent application, where the disclosure occurs before the filing/priority date of the patent or patent application. The risk that there may be a public disclosure, prior to the filing of a patent application on the subject matter of such public disclosure, provides an incentive for an Inventor to prepare and file a patent application as soon as possible. Nonetheless, such public disclosures may be non-prejudicial under certain conditions related to a grace period.¹

B. Policy Issues:

10. A fundamental principle for a disclosure to be considered as prior art in a first-to-file system is that the disclosure must be public, thereby making it available on an unrestricted basis. A related issue, however, is whether an activity that does not result in access to all details of the invention, where there is no ability to analyze the entire content of the disclosure, is a public disclosure that makes the disclosure prior art. A further related issue is whether a disclosure that is made in secret or is covered by a confidentiality agreement, is a public disclosure that makes the disclosure prior art. Yet another issue is whether there are any limitations on the medium, language or geographical location by which a public disclosure is made and becomes prior art.
11. One possible definition of “prior art” that addresses these issues may be derived from Article 8 of the Draft Substantive Patent Law Treaty (SCP/10/4), prepared by the International Bureau of WIPO in 2004, the modified text adding “filing” to show the earliest date would apply and replacing the phrase “consist of” with “be” for clarity in international interpretation:

“The prior art with respect to a claimed invention shall be all information which has been made available to the public anywhere in the world in any form, before the earlier of the filing or priority date of the claimed invention”.

¹ The enablement of prior art is not discussed herein.

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Note that the critical date is the filing/priority date of the claimed invention, and not of the application, because the pending application may claim priority to a prior filed application that does not include a disclosure of the claimed invention.

12. A further fundamental principle for discussion is the set of conditions for prior disclosures by/for/from the Inventor or original Applicant to be prejudicial against an invention claimed in an application or patent of the Inventor or original Applicant. The policy issues related to this principle are discussed in connection with section IV, non-prejudicial disclosures (grace period).

C. Elements To Be Included As Part Of A Package:

13. The IT3 considers the definition provided in WIPO's SCP 10/4, as amended above, to be acceptable as a basis for harmonization. Thus, there would be no limitation on the criterion for a disclosure being prior art based on the medium, language or geographical location of the disclosure.² Nonetheless, such public disclosures may be non-prejudicial under certain conditions related to a grace period.

² IT3 expressly acknowledges that a disclosure, including but not limited to a sale, made under confidentiality is not "public", as long as the confidentiality is respected. A non-confidential sale that embodies any or all elements of a claimed invention is a public disclosure only of such elements that can be accessed by one of ordinary skill in the art before the earlier of the filing or priority date, *e.g.*, by analysis or reverse engineering.

III. CONFLICTING APPLICATIONS

A. Policy Objectives:

14. A coherent set of rules with regard to conflicting applications is needed:
 - To prevent the grant of multiple patents on substantially the same or identical inventions in the same jurisdiction and minimize the risk to Third Parties of multiple enforcement proceedings in the same jurisdiction;
 - To promote early filing of patent applications and discourage a “publish first” strategy; and
 - To permit an appropriate scope of protection for incremental inventions.
15. Protection of incremental improvement inventions is needed to promote innovation and encourage continuous development with proper protection. Multiple patents on substantially the same or identical invention, however, whether owned by the same or different entities, may lead to “patent thickets” that can entrap a Third Party, because the number and complex relationship of the patents may prevent the Third Party from identifying and satisfying all rights and holders of such rights for a technology of interest. The coordinated management of conflicting applications in one or more portfolios has the potential to become anti-competitive activity.
16. Consistent with a first-to-file policy, an earlier filed application may serve as a basis for the rejection of a later filed application. Where the earlier filed application is not published before the filing date of the later filed application, however, the earlier filed application does not strictly meet the standard definition of “prior art” against a later filed application; nonetheless, the earlier filed application may be considered as “Secret Prior Art” (SPA). Where the claimed invention in the earlier and later applications is identical, the claims may be rejected for “double patenting”. However, where there are incremental differences between the claimed inventions, there is a need for a clear and uniform standard for determining whether both the earlier and later filed inventions can be patented in the same jurisdiction.

B. Policy Issues:

1. Treatment of First Applicant and Third Party

17. One approach is that the first-to-file Applicant for an initial invention should be able to freely file subsequent applications on incremental inventions. This approach prevents a first Applicant's own earlier application from being used as prior art against the Applicant's subsequent applications, thereby permitting the first filing Applicant to protect details of the subsequent invention that are only a short "distance" away from the initial invention, subject to a prohibition on double patenting, where by definition there is no "distance". Applicants otherwise need to wait to file until all refinements can be included in the application, which (1) discourages early filing and delays public disclosure, (2) increases the risk to Applicants of intervening independent filings or publications by Third Parties, and (3) may increase the risk to Applicants of Prior User Rights (PURs).
18. One view is that the first filing Applicant's right to get patents on incremental inventions should be limited by a requirement for a "terminal disclaimer" that forces all related patents to expire at the same time and forces common ownership to be maintained. Another view is that having a terminal disclaimer is too complex and bureaucratic and that other ways of avoiding double patenting are preferable.
19. An additional view is that the later filing third party Applicant must meet a higher "distance" standard than the first filing Applicant, and must show that the claims of the later filed application are not obvious or meet an "enhanced novelty" standard with regard to the first filed application.
20. An alternative approach is that a later filed application should be novel in relation to the "whole contents" (*i.e.*, the entire disclosure) of an earlier unpublished application, irrespective of whether or not the applications are filed by the same Applicant.

2. Same or Different Treatment of First Applicant and Third Parties

21. In some jurisdictions, while the first filed application becomes prior art against Third Parties upon its publication, the published application is subject to a further grace period for the first filing Applicant.

22. There is agreement that a harmonized treatment of the published application, for both later filing Third Parties and the first filing Applicant, would require at least that, after publication of the first filed application, the published application is prior art as of its publication date for the first filing Applicant and later filing Third Parties. Thus, in order to get a patent on a subsequently filed application, both the first filing Applicant and the later filing Third Party must demonstrate that the invention claimed in the subsequently filed application is “patentably distinct” from the disclosure in the first filed application under conventional standards of novelty and inventive step.
23. Because there is agreement for such equal treatment of the first filing Applicant and the later filing Third Party for filings after publication of the first filed application, the remaining issue to be harmonized is the manner in which the first filed application is to be treated, as between the Third Party and the Applicant, during the period prior to publication of the first filed application.
24. There is agreement that claims that are in a later application that are of a broader or narrower scope than is supported by the disclosure of an earlier application of the same Applicant, which was not published at the filing date of the later application, cannot be held unpatentable on the grounds of either novelty or obviousness over the earlier application.
25. This principle encourages innovation in that the first filer is able to file additional patent applications that readily reflect further developments of its invention. A counter argument, which has some support in Europe, is that the Applicant and Third Party should receive equal treatment and that this approach benefits the first filer excessively.
26. There is further agreement that no two patents shall issue with claims that are of identical scope. There is also agreement that further measures needed to deal with double patenting are optional to each country to decide if such measures are needed to address possible multiple litigation issues.

3. Standard for Measuring Distance

27. The difference in content between the first filed application that has not yet been published (thus, SPA) and the subsequently filed application of the Applicant or Third Party is referred to as a legal/technological “distance” that reflects the relevance of the SPA for purposes of determining the patentability of the claims of the subsequently filed application. Where there is an approach that disfavors the patenting of incremental advances, a standard of obviousness may be used as the requisite distance, permitting the combination of SPA with

other prior art teachings (a “mosaic”) to deny patentability. Others use an “enhanced novelty” standard, which encompasses the specific disclosure of the SPA and at least matter implicit from the SPA disclosure that would be apparent to a person skilled in the art and equivalents. While such shorter distance might be appealing in some jurisdictions, there is concern that on a global basis, differences in scope and meaning of patentability terms, such as “inventive step”, “obviousness”, and “novelty” could result in a non-uniform application of a distance standard for conflicting applications.

28. A proposed standard that has achieved agreement would require that, for a claimed invention in a later application to be patentable over the SPA, the differences between the claimed invention of the later application and the unpublished SPA must “go beyond common general knowledge to one of ordinary skill in the technical field”.

4. Treatment of PCT Applications

29. The elements of a harmonized conflicting application policy must also address situations where the first filed application is a PCT application. There is no strong policy reason to treat PCT applications differently from any other applications. A PCT application when published is actually a pending application in all designated countries, and becomes abandoned when it does not enter the national/regional phase (see PCT Article 11 (3) and (4)). Thus, in order to place PCT applications on the same footing in all circumstances as national/regional applications, the PCT applications should have prior art effect in all countries for which the application has active designations as of the PCT application publication date. The view that it is necessary for the PCT application to be treated as prior art only in the offices in which the PCT application actually undergoes national/regional entry, due to a concern that PCT applications should not have such a broad effect as compared to the usual Paris-route applications, was not adopted.

C. Elements to be Included as Part of a Package:

30. **1. First Filed and Published Applications** - The first filed application, upon its publication, is prior art against filings subsequent to such publication for both the same Applicant and Third Parties.
31. **2. First Filed and Unpublished Applications - Same Applicant** - The first filed application is SPA but, cannot be used against filings by the same Applicant after the filing of the first application and before the publication of that application.

32. **3. First Filed and Unpublished Applications - Third Party Applicant** - The first filed application is SPA and can be used against filings by a third party Applicant after the filing of the first application and before publication of that application. A SPA distance standard is used that requires that differences between the claimed invention of the later application and the unpublished SPA must “go beyond common general knowledge to one of ordinary skill in the technical field.”³ Common general knowledge is, for example, and not limited to, information disclosed in textbooks.
33. **4. Treatment of PCT Applications** - PCT applications shall be treated as prior art as of the earlier of the PCT filing date or priority date in all offices for which there is an active designation at the time of publication of the PCT application.

³ New emerging technologies such as artificial intelligence, in a decade and beyond, may be able to assist in determining with a reasonable degree of certainty: (i) the scope of “common general knowledge” and (ii) whether the claims of a later application are the required “distance” away from the earlier filed application, *i.e.*, go beyond “common general knowledge.”

IV. NON-PREJUDICIAL DISCLOSURES (GRACE PERIOD)

A. Policy Objectives:

34. **1. Protect All Inventors and Applicants Against Loss of Rights Due to Pre-Filing Disclosures** - Notwithstanding efforts to educate Inventors and Applicants about the risks of unrestricted disclosure of an invention prior to the filing of a patent application on the invention, and to counsel that the application should always be filed before publication, mistakes are made or intentional pre-filing disclosures (PFDs) occur. Unrestricted disclosures may be attributed to several factors, including the rapid growth of international research collaborations, the lack of knowledge and sophistication by small and medium sized enterprises (SMEs) and individual Inventors, desires by regulatory agencies worldwide for transparency with regard to information submitted to them, and growing economic pressures from investors and customers. If innovation is to be encouraged as the engine of economic growth, there is a clear need to protect Inventors from inadvertent, unauthorized, unintentional, and even intentional disclosures of their patentable information that may later be asserted as patentability-destroying prior art against their subsequently filed applications. Where a grace period applies, eliminating the need to address an Applicant's intent regarding PFDs also simplifies the system and provides certainty, particularly in jurisdictions where proving intent would be difficult or impossible due to lack of meaningful discovery.
35. **2. Provide Legal Certainty for Third Parties** - A Third Party, who becomes aware of a pending patent application claiming an invention of interest to them, and who also is aware of a public disclosure about the invention prior to the filing date of the application, wishes to know whether the public PFD is prior art to the application. However, where a grace period is permitted and the relationship between the public PFD and the pending application is not known, there is legal uncertainty for the Third Party.⁴ That legal uncertainty may continue beyond the grant of a patent on the application. Third parties (and Offices alike) would want to know with legal certainty whether the public disclosure of the invention before the filing date of the application is prior art to the claims in the pending application or granted patent. A grace period policy should not promote an intentional "publish first" practice.

⁴The identification of relationships between a PFD and a published application may be aided by new emerging technologies. Comparative analysis of third party documents to determine whether they are independent may also be aided by new emerging technologies.

36. **3. Provide a Grace Period That Discourages a Publish-First Policy** - A grace period is an exception to the absolute novelty standard and, as such, should be established with criteria and qualifications that encourages Inventors and Applicants to “file first”, while discouraging the adoption of a “publish first” policy that leads to uncertainty and unpredictability. A grace period that provides suitable protection for the interests of the original Applicant/Inventor and Third Parties would provide an acceptable balance of interests, where (1) the grace period has a reasonable duration, (2) the grace period exists as a matter of law, (3) the grace period applies only to disclosures by/for/from the original Applicant or Inventor and does not apply to independent third party disclosures, (4) entitlement to the grace period for disclosures by the original Applicant or Inventor is subject to an obligation on the Applicant to timely advise Offices and the public about items to be graced, and (5) there are adequate procedures and incentives, such as administrative fees, PURs, the prejudicial effect of intervening art, and a potential defense for an intervening user, to encourage prompt filing of an application after a public disclosure and notice to Offices and the public about items to be graced.
37. **4. Provide a Global Solution** - Because patent strategies of Applicants are necessarily global in a global economy, the protections provided by a grace period should be uniform and applicable world-wide. Thus, a globally harmonized approach, endorsed by all jurisdictions, will be necessary. Countries currently with no grace period and countries currently with differing grace periods must change their laws to implement a single international grace period. Moreover, the core principles of any international grace period should be sufficiently clearly defined to guarantee a uniform and predictable implementation in all jurisdictions.

B. Policy Issues:

1. Limited Scope of the Grace Period

38. **a. Grace Period Limited to Disclosures by/for/from the Original Applicant and Includes Disclosures Derived from the Original Applicant/Inventor** - Disclosures of a claimed invention that are made prior to the filing of a patent application may be graced only if (1) they originate with the original Applicant/Inventor himself, whether they are made due to inadvertence or necessity, or (2) they are a re-disclosure of the PFD in whole or in part by a Third Party which may be in the same or a different format or (3) they originate with a Third Party who has either obtained access to the invention, or published the invention, through an abuse in relation to the original Applicant/Inventor. All types of public disclosure by/for/from the original Applicant/Inventor, regardless of medium or forum, may be graced.

39. **b. No Grace Period for Independently Developed and Published Subject Matter** – Intervening disclosures of subject matter, which resulted from the independent work of Third Parties form part of the prior art.
40. **c. Grace Period for Partially Re-disclosed and Partially Independently Developed and Published Subject Matter** - In the case where a part of the Third Party intervening disclosure is derived from the original Applicant/Inventor and a part resulted from the independent work of a Third Party that is different from the PFD, the re-disclosed derived portion would be graced, and the different portion might be not graced depending on how significant the difference was from the re-disclosed derived portion.⁵
41. **d. Presumptions and Burden of Proof for Derived Publications** - Recognizing that it may be difficult to prove that a third party intervening disclosure was derived from a prior PFD of an original Applicant/Inventor, certain presumptions are made, subject to rebuttal. For example, where the content of the third party intervening disclosure is the same as or involves insignificant differences over the content of an earlier original Applicant/Inventor PFD, then the third party intervening disclosure is presumed derived. Similarly, where a part of the content of the third party intervening disclosure is the same as or involves insignificant differences over an earlier original Applicant/Inventor PFD and a part is not, then only the part of the disclosure that is the same as or involves insignificant differences over an earlier original Applicant/Inventor PFD is presumed derived. By the same token, where at least a part of the third party intervening disclosure involves more than insignificant differences over an earlier original Applicant/Inventor disclosure, then the respective part is presumed to be not derived. Finally, where no part of the third party intervening disclosure is the same as or involves insignificant differences over an earlier original Applicant/Inventor disclosure, then none of the third party intervening disclosure is presumed to be derived. As noted, all presumptions or lack of presumptions can be rebutted at least by further evidentiary submissions by the Applicant or any Third Party, as the case may be⁶.

⁵ Comparative analysis of third party documents by new emerging technologies may assist in determining the re-disclosed portion.

⁶ A Party's ability to prove derivation and the rebuttal by Offices and Third Parties may be aided by new emerging technologies.

42. **e. Duration of the Grace Period** - Existing grace periods are either six (6) or twelve (12) months long, and a harmonized duration that serves the interests of a broad spectrum of stakeholders should be determined on a global basis. In either case, the grace period should be counted from the effective filing date, *i.e.*, the actual filing date or the priority date, whichever is earlier.
43. A 12 month grace period encourages research and development by allowing more time for collaboration with less risk that innovators, as well as such collaborators, will lose the right to patent their invention. In addition, it provides the time necessary to prepare a complex patent application after disclosure of an invention. It has special importance to small and medium size entities which might need to try to gauge the success of a potential invention before deciding whether to incur the expense of filing a patent application, and it would also help protect innovators who have less experience with patent filing. Further, a grace period of this duration is critical to technology transfer programs at academic institutions that publish their research. It is also more consistent with a conflicting application policy that encourages Applicants to include more incremental advances in a single application.
44. Reasons stated in support of a 6 month grace period include that the purpose of a grace period is to provide a safety net against inadvertent disclosure and, occasionally, to allow intentional disclosure before a patent application is filed (for example to allow essential trials which need to be carried out in public), and that the grace period should be as short as possible whilst enabling these objectives. A grace period of 6 months should be sufficient for inadvertent disclosures. It should also be sufficient for most cases where essential trials need to be carried out in public and, when this is not the case, then 12 months may also not be sufficient (and some other mechanism should be considered for handling such circumstances). Notwithstanding the foregoing reasons in support of a 6 month grace period, a 12 month grace period would be acceptable on the condition that there are adequate safeguards that the new system will not become a “first to publish” system and that a Statement will be filed timely so that publication will occur at eighteen (18) months.

2. Possible Applicant Requirements in the Context of Limited Scope Protection

45. The following are possible Applicant requirements that may resolve outstanding issues related to a proper balance among Applicants, Third Parties, and society, and are under discussion.
46. **a. Timely Filed Prior Art Statement as a Component of Third Party Protection** - One component to achieving a balance between the interests of Applicants and Third Parties for

a policy governing graced disclosures is a requirement that the Applicant who wishes to exercise the benefits of a grace period for a PFD should be required to make a timely filing of a “Statement” that identifies all PFDs of the original Applicant/Inventor that are considered graced. Re-publication of a PFD is not considered to be a new PFD requiring filing of another Statement. The Statement would serve as a record to identify with particularity each such PFD. Ideally, the Statement would be submitted at the time of application filing or at least in sufficient time for the Statement to be made publicly available at the time the application is published by the relevant Patent Office.

47. The purpose of the Statement is to provide notice for Third Parties. When there are only insignificant differences between an intervening disclosure (re-disclosure) and the prior PFD that is referenced in a Statement, this purpose is served without the Applicant having to separately identify the re-disclosure. Incorporating these considerations, possible elements of a system are outlined below.
48. The Applicant must file a Statement identifying the PFD to be graced. The Statement will indicate what the PFD was, when and where it occurred. In the case of a written disclosure, the Statement will include a copy of the written PFD or where the PFD can be accessed. In the case of a non-written disclosure, there is no agreement on what the Statement will include.
49. When, during the grace period, the PFD was made either: (i) by the Inventor, or (ii) by another person, acting for or from the Inventor, then the Statement shall be filed together with the patent application or within 16 months of the PFD. In the event a Statement is not made relating to a PFD in accordance with these conditions, then a Statement relating to that PFD shall be submitted with a declaration of unintentionality² supported by further evidence, if appropriate by the Applicant, the Inventors named in the application, or the attorneys or agents who prepared or prosecuted the application. If no Statement is filed, then no grace period will apply.
50. Re-disclosure within the grace period of the Applicant’s filing or priority date (whichever is earlier) will also be graced (not considered prior art to the application to be graced). Re-disclosures that are or become subject of a Statement, do not need to be separately identified in a Statement if there are only insignificant differences between the intervening disclosure (re-disclosure) and the prior PFD that is referenced in a Statement.

² Some organizations have referred to the Patent Law Treaty as a helpful reference.

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51. Notwithstanding a listing in a timely filed Statement, the qualification of a PFD to be graced can be challenged by Offices and Third Parties, and the Applicant/Inventor would bear the burden of proving, subject to rebuttal, that a particular PFD meets the requirements for it to be considered as graced. For example, if the Applicant/Inventor shows that there are only insignificant differences between the third party intervening disclosure and the prior PFD, then the Office must find that the Applicant/Inventor has met its burden. Thereafter, the Third Party can submit its own evidence, which should also be taken into consideration.
52. Currently there remains no agreement as to whether, when, and under what circumstances, a Statement can be submitted after grant.
53. A component to ensure that a Statement is timely filed prior to the grant of a patent where a PFD is desired to be graced is a Defense of Intervening User described in Section VI.
54. **b. Administrative Fees as a Component of Third Party Protection** - Administrative fees would provide another component to ensuring that a Statement would be timely filed so that Offices and Third Parties would be able to know as soon as practicable whether a PFD is considered by the Applicant to be a graced disclosure. The administrative fee for failure to timely submit a Statement would be at a level sufficient to incentivize the Applicant to exercise due diligence to identify all relevant PFDs, and could be at an increasing level (including appropriate late payment fees) to provide an appropriate incentive. The application of the administrative fees would not require consideration of subjective factors, such as knowledge or intent. The details of such fees would be determined by each of the Offices.
55. **c. Accelerated Publication as a Component of Third Party Protection** – A proposed component for ensuring that a timely filed Statement is made available to Third Parties as soon as possible is the acceleration of the publication of the application to a date that is 18 months after the earliest PFD that is identified in a Statement. The details within the Statement would also be made available to the public at the same time as the publishing of the patent application. Accelerated publication ensures the same notice to Third Parties about inchoate rights as if the application was filed the day prior to the disclosure allowing parties to conduct freedom to operate studies and design around. Further consideration of how this proposal might be consistent with an application filed under the Paris Convention or PCT is required.
56. **d. Third Party Submissions Pre or Post-Grant as a Component of Third Party Protection** A final component to ensuring that a Third Party can pro-actively force an Applicant to officially declare and demonstrate whether a PFD is to be considered a graced

disclosure includes procedures for permitting Third Parties to make (1) a pre-grant submission of the disclosure to the Office (for some a “third party observation”) for use by the Examiner in an Office Action and (2) a post grant submission of the disclosure to the Office for comment and proof by the Applicant that the disclosure is graced.

C. Elements to Be Included as Part of a Package:

57. **1. A Universal Grace Period Should Apply** - As a matter of law, all PFDs of all or part of an invention that are made by/for/from an original Applicant/Inventor within a universally agreed period of time, prior to the effective filing date of the application claiming the invention, that is the “grace period”, shall be non-prejudicial, availability of the grace period being subject to certain conditions (*e.g.*, filing of a Statement claiming a grace period for a specific PFD). However, a grace period should not apply to the publication by an Office of an earlier filed application by the Inventor/Applicant.
58. **2. Duration of Grace Period** – The grace period should extend up to 12 months from the pre-filing disclosure (PFD) to the filing date or priority date, whichever is earlier, of the patent application. A 12 month grace period would be acceptable if there are adequate safeguards that the grace period system does not become a “first to publish” system and that a Statement will be filed timely so that publication of the application will occur at 18 months from the PFD date.
59. **3. Independent Disclosures are Not Graced** - Disclosures of subject-matter that is independently created by Third Parties, even if disclosed within the “grace period”, shall form part of the prior art. If a disclosure is the same as or involves insignificant differences over the original Applicant’s/Inventor’s PFD, it is presumed derived and graced. Also, a third party disclosure that is based upon an abuse in relation to the original Applicant/Inventor is graced.
60. **4. Re-Disclosures by Third Parties are Non-Prejudicial, Subject to Presumptions** - A third party re-disclosure of the original Applicant’s/Inventor’s own PFD shall be graced as it is “from” the original Applicant/Inventor. Recognizing that proof of derivation may be difficult, certain rebuttable presumptions shall apply. First, if the content of the third party intervening disclosure is the same as or involves insignificant differences over the content of an earlier original Applicant/Inventor PFD, then the third party intervening disclosure is presumed derived. Second, if the part of the content of the third party intervening disclosure is the same as or involves insignificant differences over an earlier original Applicant/Inventor PFD and part is not, then only the part of the two disclosures that is the same as or involves insignificant differences over an earlier Applicant/Inventor PFD is

presumed derived and the part that involves significant differences over an earlier original Applicant/Inventor PFD would be presumed not derived. Third, where the content of the third party intervening disclosure involves significant differences over an earlier original Applicant/Inventor PFD it would be presumed not derived. Finally, if no part of the third party intervening disclosure is the same as or involves insignificant differences over an earlier original Applicant/Inventor disclosure, none of the third party intervening disclosure is presumed to be derived. All presumptions or lack of presumptions can be rebutted by further evidentiary submissions.

61. In practice, the qualification of an intervening disclosure to be graced could be challenged by Offices and Third Parties, and the Applicant/Inventor would bear the burden of proving, subject to rebuttal, that a particular intervening disclosure meets the requirements for it to be considered graced. For example, if the Applicant/Inventor shows that there are only insignificant differences between the third party intervening disclosure and the prior PFD, then the Office must find that the Applicant/Inventor has met its burden. Thereafter, the third party can submit its own evidence which should also be taken into consideration.
62. **5. Timely Filed Prior Art Statements are a Component of Third Party Protection** - In order to balance the interests of Applicants and Third Parties/Offices, Applicants will be required to file a “Statement” that identifies all PFDs of the original Applicant/Inventor that are not to be considered as prior art. Re-disclosures that are or become subject of a Statement, however, do not need to be separately identified in a Statement if there are only insignificant differences between the intervening disclosure (re-disclosure) and the prior PFD that is referenced in a Statement.
63. **6. Administrative Fees are a Component of Third Party Protection**- Administrative fees, at levels sufficient to serve as an incentive to timely submit Statements to the Offices, would provide another component to ensuring that a Statement would be timely filed. The details of such fees would be determined by the Offices.
64. **7. Other Incentives as Components of Third Party Protection** - Additional incentives for Applicants to file timely Statements would include accelerated publication and a Defense for Intervening Users.

V. PRIOR USER RIGHTS DEFENSE

A. Policy Objectives:

65. To fairly balance (1) the interests of a Third Party, who in good faith has made commercial use of an invention or at least the serious and effective preparation to commercially exploit the invention involving a significant investment (possibly without seeking patent protection for the invention because the Third Party intends to keep the invention as a trade secret), and (2) the interests of an independent innovator, who later seeks to patent that same invention, a limited PUR defense to a charge of infringement by the owner of the patent should be provided. The Third Party should not be penalized for selecting trade secret protection over patent protection for the invention but should be permitted to benefit from its investment in the invention and continue its use of the invention, to the extent the commercial use or serious and effective preparation for commercial use of the invention by the Third Party on or before the actual filing date or the priority date, whichever occurs first, of the patent is covered by claim(s) of the granted patent. The defense must be sufficient to satisfy the policy objective of fairly and equitably balancing the interests of Third Parties and Patent Owners but should not go beyond what is necessary for entitlement to, and a proper scope of, the defense. Historically, a PUR defense has been viewed by some as an essential complement to the establishment of a grace period.

B. Policy Issues:

1. Scope of Third Party Activity

66. In order to qualify for the defense, the Third Party must have used or have made serious and effective preparation to use the invention before the effective filing date, *i.e.*, the actual filing date or the priority date; for example, the Third Party made a significant pre-filing investment in the invention that is covered by a claim of a patent held by the patent owner, including the actual commercial use of the invention or the serious and effective preparation for commercial use of the invention. The scope of investment is determined on the basis of activity conducted on or prior to the effective filing date of the application that ultimately issues as a patent. The investment must be directed to the commercialization of the patented invention, and must be more than activity directed to basic research or the acquisition and preservation of knowledge about the invention. At a minimum, the qualifying activity must be directed to the invention as set forth in one or more claims in the patent, and not simply a part thereof. Further, the qualifying activity may be conducted directly by the Third Party or indirectly through business arrangements with suppliers, vendors, partners or joint ventures. Where the qualifying activity only involves serious and effective preparation for

commercial use of the invention, the scope of the qualifying activity may vary, depending on the underlying technology, and no bright line test may be possible. However, a non-exhaustive list of what may evidence serious and effective preparation for commercial use of an invention, directly or indirectly by a Third Party, includes the following:

- i. selecting and purchasing manufacturing, integration or testing equipment or system components specifically suited to practice the invention;
- ii. developing software that will control manufacturing equipment or system components specifically suited to make or implement the invention;
- iii. constructing manufacturing, assembly, testing or system facilities;
- iv. initiating the purchase or acquisition of sufficient quantities of raw materials, parts or components specifically directed to the practice of the invention;
- v. hiring staff and allocating budget specifically directed or dedicated to the commercial making or implementation of the invention; and
- vi. seeking formal approval from a regulatory authority prior to commercialization.

2. Third Party Activity - Independent or Reliant on Pre-Filing Disclosure?

67. Third party activity before filing by the original Applicant or Inventor, that is independent of any disclosure by/for/from the original Applicant or Inventor, will qualify as an investment for determining whether the Third Party is entitled to the PUR defense.
68. Third party pre-filing activities concerning the invention that are based on an abuse or breach of confidence cannot qualify as an investment for determining whether the Third Party is entitled to the PUR defense.
69. As a general rule, access in good faith by a Third Party to a PFD by/for/from the original Applicant or Inventor will not disqualify the Third Party from entitlement to the PUR defense. The arguments supporting this view include: (1) its simplicity, (2) its straightforward application by the parties and authorities to determine, without need for discovery or the equivalent, whether the Third Party's activity is independent or not, (3) its encouragement of early filing to avoid the possibility of PURs occurring and discouragement of a "publish first" practice, (4) its encouragement of third party innovation, as Third Parties on seeing a publication can start their own innovative activities and can incur investment of

time and money and take substantial risks in commercialization, and finally (5) avoidance of disputes in situations where the PFD does not fully enable the invention or it is not clear from the PFD what might be the subject of a later patent application.

70. However, it is also agreed that there are certain circumstances where the Third Party will not be entitled to a PUR defense, notably because there are confidentiality commitments in place or because the Third Party who starts activities that may qualify for PUR does this at its risk as there might be a patent application already filed for its content, or there may be one filed for the content of the PFD shortly. The preclusion of PURs under these circumstances would be conditioned on the timely filing of a Statement identifying the PFD. In this way, it is possible to (1) secure protection of the Inventor's investment of time and money into creating the invention and taking substantial risks in conducting the research and development necessary to invent the content of the PFD, and (2) ensure preclusion of a Third Party's ability to capitalize on an Inventor's success by copying the invention disclosed in a PFD without the Inventor's permission.

3. Geographical and Commercial Scope of the Defense

71. Since the patent right has an effect that is limited to the jurisdiction granting that right, most argue that the Third Party activity that would qualify for the PUR defense must occur in that same jurisdiction, as the purpose of the defense is to provide a reasonable scope of protection for the investment made by the Third Party, but no more. An alternative view is that, as the grace period is a right/defense that extends to all the countries where the patent application is filed, the PUR defense should also extend to those countries; most of those that hold this view accept that this is more of a long-term aspiration than something for the present discussions. A concern, however, is that fraudulent assertions in one country that cannot be effectively challenged would ultimately affect all countries. Weighing these considerations, the majority view was adopted, that is, that the Third Party's PUR defense is available only in those jurisdictions where the Third Party's qualifying activity occurred.
72. To the extent that a Third Party qualifies for the PUR defense against specific claims of a patent, the defense should allow for the continued practice of the inventions covered by these claims.
73. One view is that the court should use equitable rules that provide the court with discretion to fashion a fair scope of defense. In that case, a court determining the ultimate scope of the defense provided to a Third Party should recognize several practical factors, including at least: (1) the likely limited amount of investment by the Third Party prior to the actual filing date or the priority date, whichever occurs first, of the patent application, (2) the likely

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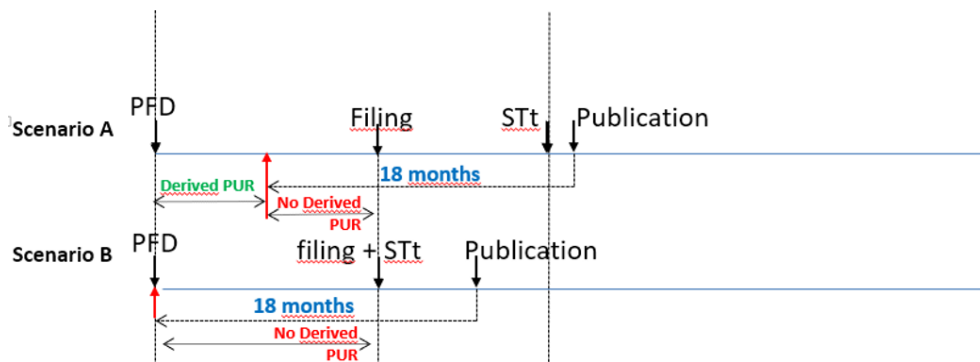
limited level of product sales, and even product development, prior to the actual filing date or the priority date, whichever occurs first, of the patent application, (3) the likelihood of design changes and improvements that will occur after the actual filing date or the priority date, whichever occurs first, of the patent application, (4) the likelihood of changed sales or production volumes, even those projected, after the actual filing date or the priority date, whichever occurs first, of the patent application, (5) abandonment, and (6) the likelihood that the Third Party may not become aware of an infringement claim until years after the original filing date that cuts off activity that creates entitlement to the PUR defense.

74. Another view is that the court should use objective criteria to determine whether there is a PUR defense.
75. The defense, once established, may be lost due to a fact of abandonment of its use of the invention by the Third Party holding the defense. A non-exhaustive list of the activity that may constitute an abandonment includes:
 - i. ceasing its use of the claimed invention in the granted patent to which the defense applies for more than a reasonable period of time, under all relevant circumstances;
 - ii. exiting a market for the commercial embodiment of the invention to which the defense applies; and
 - iii. redesign of the commercial product so that it no longer is covered by any claims of the patent to which the defense originally applied.
76. The defense is personal to the Third Party whose activities created the entitlement to the defense, and may not be assigned or sublicensed, but the defense may be transferred to the patent owner or with the sale of the Third Party's company or with an entire line of business to which the defense relates.

C. Elements to be Included as Part of a Package:

77. **1. Availability of Rights** - Rights in the nature of a defense to infringement, rather than an exception to infringement, should be made available to Third Parties whose activities meet the qualifications for such defense.

78. **2. Qualification for the Defense** - The Third Party must make actual commercial use or at least serious and effective preparations for commercial use of the subject matter covered by a claim of a patent, prior to the actual or effective filing date of the application that issued as the patent, whichever is earlier, in the relevant jurisdiction of the patent. The burden of proof to demonstrate qualification for the PUR defense shall be on the Third Party asserting such defense.
79. **3. Relation of Third Party Activity to a Patent Owner** - There are three possible scenarios. First, third party activities that are based on development wholly independent of the original Applicant or Inventor may be relied upon to demonstrate qualification for the defense. Second, third party activities that are based on abuse/breach of confidence may not be relied upon to demonstrate qualification for the defense. Third, in case of a third party activity derived from a PFD, no derived PUR defense is available for activities conducted during the 18 months prior to publication of the patent application (scenario B in the graph), but would be available for activities conducted before a date 18 months prior to publication of the application (scenario A in the graph). Filing of the Statement concurrently with the application accelerates publication to within 18 months of the PFD, that is, no derived PUR is available.



Key: PFD: Pre Filing Disclosure
 Filing: Filing date of Application
 Publication: Publication date of Application
 STt: Filing date of a Statement, which is assumed to be equal to the public availability date of the Statement if filed after publication of Application

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80. **4. Scope of Defense** - The PUR defense permits continued use of the invention on a limited basis, such as use envisioned by such preparations and covered by issued claim(s) of the patent. The defense does not extend to designs that were not the subject of the required preparations and otherwise infringe claims of the patent. All patent rights are subject to the PUR defense, without exception as to patent owner, claimed subject matter or otherwise.
81. **5. Transferability** - The PUR defense is not transferable by assignment or license, other than to a purchaser of the entire business or relevant line of business of the holder of the defense.
82. **6. Scope of Right** - The IT3 is still working on the wording of Objective Criteria at the request of the B+ Group.

VI. DEFENSE FOR INTERVENING USER

A. Policy Objectives:

83. Another component to ensuring that a Statement would be timely filed so that Offices and Third Parties would be able to know as soon as practicable whether a PFD is considered by the Applicant to be a non-prejudicial disclosure involves the creation of a Defense for Intervening Users (DIU).

B. Policy Implementation Prior to Patent Grant:

84. A DIU shall provide a defense for Third Parties who, upon first consideration of the prior art status of a PFD⁸, for which later on a grace period is claimed, reasonably relied on such PFD² because it was not identified in a filed Statement or no Statement was filed.
85. The Statement should normally be filed within 16 months after the PFD. With a declaration of unintentionality supported by further evidence if appropriate, the Statement also may be filed during a time before grant of the patent, provided that the Statement is filed within a defined relatively short period¹⁰ of the Applicant becoming aware of the PFD and its relevance to the Applicant's claimed invention.
86. In order to obtain the benefit of the DIU, such Third Party will be required to inform Office(s) of the PFD within a relatively short defined period of a product being marketed or commercial use of a process to which the PFD may be relevant. The notice may be made

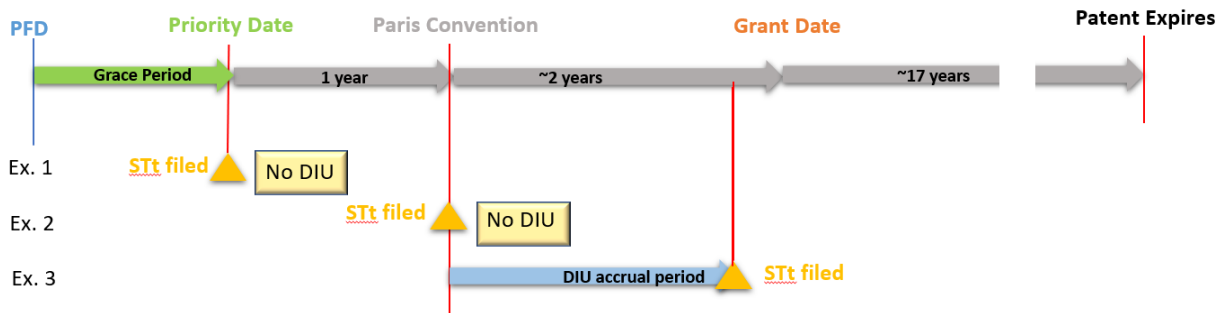
⁸ A "first consideration of the prior art status of a PFD" occurs when a Third Party, for the first time, evaluates the prior art status of the PFD against claims of a patent or application. The phrase is intended to exclude the case where a Third Party has knowledge of a PFD but has not conducted an evaluation of the PFD with regard to the patent or application. However, the Third Party is not allowed to restart "first consideration" by conducting an additional evaluation, when it has done an evaluation previously, of the PFD regarding its prior art status against the claims of a patent or application.

² Some consider that a "reasonable reliance on a PFD" occurs, for example, when the Third Party evaluates the PFD against the claims of a patent or application in accordance with applicable law and cannot reasonably determine if the PFD is graced and therefore would render a claim unpatentable.

¹⁰ No agreement was reached on the precise length of the "defined period" after the Applicant becomes aware of the PFD.

anonymously.¹¹ The Third Party loses any right to DIU accrual if the notification to the Office(s) is after the end of the defined period. The Applicant or Patentee loses the right to grace the PFD for all purposes if the Statement is not timely filed¹² after being informed of the PFD.

87. A chart illustrating when DIU can begin to accrue is shown below. There is no DIU for Example 1 because the Statement (STt) was timely filed and because there is no DIU accrual prior to the Paris Convention date. There is no DIU for Example 2, even though the Statement was not timely filed, because there is no DIU accrual prior to the Paris Convention Date and the filing of the Statement cuts off accrual of the DIU. There is DIU accrual for Example 3, so long as the Third Party has qualifying activities from the Paris Convention Date until the Statement is filed.



88. With the proposed DIU, no undue burden should be put on Third Parties and Office(s)¹³, and no confidential information of the Third Party should be disclosed. For clarification, there is no obligation on a Third Party to inform Office(s) unless such Third Party wishes to benefit of the DIU.

¹¹ The Third Party should keep record that he/she has filed the notice.

¹² No agreement was reached on the precise time for a Statement to be “timely filed,” but it should consider due process, which may be a matter of months.

¹³ Offices may have administrative tasks, but the DIU as a defense to a charge of infringement is only considered by courts.

89. The Third Party's qualifying activities for the benefit of a DIU to accrue¹⁴ are the same as the activities qualifying for the benefit of a PUR. That is, the Third Party's qualifying activity for a DIU would be judged on the basis of standards similar to those applied to PURs, namely, commercial use or serious and effective preparation for commercial use of the invention. The DIU would be personal, and subject to similar limitations applied to PURs, and would not be available for activities based on abuse/breach of confidence.
90. A further consideration is compliance with the Paris Convention Article 4B with respect to conventional filings, where qualifying activities start during the priority period. While a Third Party's activity may start prior to the end of the priority period, the DIU may not accrue until after the priority period expires.

C. Policy Implementation After Patent Grant:

91. There is no agreement within IT3 as to whether and under what conditions a Statement may be filed after grant.
92. In support of allowing filing of the Statement after grant, it has been stated that large entities, including universities, do not always know in advance that information has been disclosed, that they have invested significant resources developing the inventions described in applications/patents, and that taking away their patent rights as a result of inadvertent non-identification of the PFD would be draconian. Further, smaller entities, which are often less sophisticated, are even less likely to know about PFDs, and allowing post-grant filing would provide the confidence needed for larger companies to make investments in and collaborate with smaller entities. Further, a company acquiring a patent portfolio from a small entity or university, which inadvertently did not file a Statement about a graced PFD, may not be able to determine such failure before acquisition and would lose significant asset value if filing after grant is not permitted. Finally, a policy that encourages Third Parties to adopt a practice of holding on to a PFD until prosecution is completed so that it can be used against the Applicant is against public interest in having certainty as to the validity of patents.

¹⁴ The "benefit" to the Third Party is the defense that may be exercised in litigation involving an issued patent, and for the benefit to "accrue," the Third Party must perform (but need not start) qualifying activities during a period after the end of the priority period and before the end of the defined period.

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93. In support of not allowing filing of a Statement after grant, it has been stated that Third Parties who find the PFD, and wait until the patent issues without a statement being filed, are led to believe that it is not a PFD but a good prior art reference against the validity of the patent. Third Parties will thus have unreasonable difficulties since they cannot know beforehand whether their invalidation argument based on the PFD is appropriate. From that point in time, Third Parties should be informed that the patent is graced, and should be able to plan accordingly. It is further argued that Third Parties should not have to utilize third party submission, opposition and/or invalidation procedures to clarify whether the PFD is to be graced, but that they should have a chance to take such actions at any time according to their negotiation strategy. Finally, it is contended that submission of the Statement after grant is inconsistent with a concept of accelerated publication, which requires the Statement to be filed to accelerate the publication.

VII. MANDATORY PUBLICATION OF PATENT APPLICATIONS

A. Policy Objectives:

94. To provide a globally accepted rule for a prompt public disclosure of all patent applications that, within a uniform period of time after the earlier of the filing or priority dates of such applications, are still seeking protection of a disclosed invention. To ensure that all inventions for which patent protection is sought are promptly disseminated to the public, exceptions to this rule should be strictly limited and there should be no exceptions that allow Applicants to opt out.

B. Policy Issues:

95. Official publication of all applications at 18 months from their effective filing date should be required, unless an application has been withdrawn or refused, is subject to national security, or is a threat to public order.
96. An exception for Applicants would exist prior to the expiration of 18 months, where the application has been officially withdrawn or refused further processing, and no patent right is being sought, such that the availability of trade secret protection for the disclosure is preserved.
97. An exception for Offices would exist where publication would endanger national security or pose a threat to public order.
98. In general, the exceptions should be narrowly crafted and the period for Office exceptions should only exist for the period of time essential to serving the purposes of national security and public order.

C. Elements to be Included as Part of a Package:

99. All patent applications should be published as soon as possible, at most 18 months from their filing or priority date, unless the application has already been published as a patent, withdrawn, refused, is deemed to be withdrawn or has raised national security or public order concerns. An Applicant may not opt out of publication.

[END]