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RESPONSE DOCUMENT: A B+ SUB-GROUP RESPONSE TO THE IT3 "ELEMENTS PAPER"

prepared by the Sub-Group B+

Response Document

A B+ Sub-Group response to the IT3 "Elements paper"

Document drawn up by the B+ Sub-Group: Australia, Canada, Denmark, European Patent Office, Germany, Hungary, Japan, South Korea, Spain, United Kingdom and United States

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1. Introduction

- 1. The B+ Sub-Group recognises that for Substantive Patent Law Harmonisation (SPLH) to be successful, transparency and industry and stakeholder involvement is needed. Consequently, the B+ Sub-Group has worked alongside the Industry Trilateral (IT3) (formed by representatives from industry bodies AIPLA, IPO, BusinessEurope and JIPA) and other industry groups to consider SPLH issues relevant to all parties.
- 2. The most recent collaboration between the B+ Sub-Group and the IT3 was an Industry Symposium held on 20 June 2017 at the EPO in Munich. Attendees at this event included members of the B+ Sub-Group, IT3, the B+ Workstreams on SPLH, and other industry stakeholder groups. The topics under primary consideration were:
 - i) The grace period;
 - ii) conflicting applications; and
 - iii) prior user rights (PURs).
- 3. The basis for discussions at the Industry Symposium was a paper, prepared and presented by the IT3 entitled "Policy and Elements for a Possible Substantive Patent Harmonisation Package" (2017), (herein referred to as "Elements" paper), which was accompanied by an exhibit for each topic. Other industry stakeholder delegations were then invited to comment on the paper/exhibits and their experiences with these topics. This meeting provided a forum for attendees to hear the responses of the Industry Groups from AU, CA, NZ and KR, to the IT3 proposals as well as comments on the issues faced by industry on the relevant topics.
- 4. This paper aims to provide a response from the B+ Sub-Group to the work, ideas and discussion raised by the IT3 in relation to their paper, exhibits and presentations, including on the definition of prior art, at the request of the IT3. It provides input on areas where it would be most beneficial to focus but does not aim to provide a comprehensive analysis of every issue still under consideration by the IT3.
- 5. This response also endeavours to provide encouragement to the IT3 to continue their work on these issues, helping them to reach further consensus, while also noting some of the policy, administration and legal boundaries faced by Offices. It also highlights comments made at the Industry Symposium by other industry stakeholder delegations.
- The B+ Sub-Group is grateful for the efforts of the IT3 and their contribution to the work of the Group B+, and for spearheading the efforts on global Substantive Patent Law Harmonisation.

2. Key Objectives for Successful Harmonisation

2.1 Simplicity and Pragmatism

- 7. Harmonisation of patent law and systems between countries requires practical coherent principles in order to improve the global patent system, which can be easily implemented and administered by governing bodies.
- 8. Whilst all jurisdictions administer patent systems with the common aim of promoting innovation and economic growth, there are variations in the legal principles and practices they apply in assessing the validity of patents and protecting third party rights. Evaluation

- of these varied legal principles and practices can help in finding commonalities, best practice methods and with the identification of features or elements which could be considered suitable for a harmonised patent system.
- 9. Features lacking in pragmatism, if introduced into any patent system, would be difficult to administer and decrease the legal certainty of the system, and could lead to increased costs, decreased predictability in the acquisition of patent rights, and reduced understanding of the patent system; all of the foregoing constitute undesirable outcomes for all stakeholders, whether patent applicants, offices or third parties.

2.2 Relationships between Elements

- 10. A number of B+ Sub-Group members and IT3 stakeholders are seeking a package approach to SPLH. A package would cover all elements under consideration, and deliver a visible balance of features, or a compromise of features used by different patent systems, and could potentially include new features which would complement current patent systems.
- 11. Other members in the B+ Sub-Group are open to the implementation of individual elements where these would improve the overall system and the benefits of which would be delayed if agreement of everything is sought.
- 12. However work progresses, it is important to highlight the relationships between the elements acknowledging that some elements are potentially interlinked and can affect each another.
- 13. In particular, there is arguably a relationship between the features of a grace period and the features of PURs. Similarly, there is also a relationship between the definition of public prior art and the treatment of conflicting applications.
- 14. The B+ Sub-Group initially addressed the relationship between the grace period and the needs of third parties in the "Objectives and Principles" paper¹. The relationship between prior art and conflicting applications is initially being addressed within this response paper; and the B+ Sub-Group is seeking a definition of prior art to be agreed by the group.

3. Grace Period

- 15. In Exhibit 1 to the "Elements" paper the IT3 set out four agreed objectives and principles:
 - i) Protect all inventors and applicants against loss of rights due to pre-filing disclosures
 - ii) Provide legal certainty for third parties
 - iii) Provide a safety-net grace period that discourages a publish first policy
 - iv) Provide a global solution

^{1. &}quot;Objectives and Principles with Commentary on Potential Outcomes", issued by the B+ Sub-Group May 2015, pg. 2, *Non-prejudicial disclosures / grace period – third party rights*.

- 16. On slide 6 of its Industry Symposium presentation, the IT3 also state that "A grace period is an exception to absolute novelty and should include mechanisms that encourage inventors/ applicants to file first or promptly after a [Pre-Filing Disclosure] PFD and discourage intentional PFDs becoming the norm".
- 17. At the Industry Symposium the industry delegation from Australia and New Zealand stated their support for a safety-net approach to the grace period. They also noted a link between discussions on this topic and PURs, which they felt corresponded with a safety-net approach. PURs, particularly if they arise as a result of the applicants' own PFD, could provide an effective mechanism for encouraging file-first behaviour (PURS are discussed further in section 4).
- 18. Other aspects, such as the duration of a grace period, may influence or be influenced by conclusions in other areas, see for example the discussion on Defence for Intervening Users (DIU) at paragraph 31. At the User Symposium the industry delegations from the Republic of Korea, Canada and Australia stated a preference for a 12 months grace period. However, the Canadian industry delegation also noted that this is subject to agreement on other areas such as accelerated publication and PURs. It should be noted that a European user group had a preference for a 6 months grace period.

3.1 Accelerated Publication

- 19. As set out above, one of the objectives set out by the IT3 in relation to grace periods is to provide legal certainty for third parties. To that end, the IT3 proposal foresees that the publication of the patent application would be accelerated to 18 months after the PFD. This proposal was viewed very positively by a number of industry delegations at the Symposium as being a measure that could go a long way towards mitigating concerns over the additional uncertainty that introducing a Grace Period would bring.
- 20. However, in order to achieve a balance between applicants and third parties, the IT3 may wish to keep in mind the potential impact of accelerated publication on applicants making use of the grace period. For example, patent applications can contain more detailed information than the corresponding PFD. In such a case, information present in the patent application would be subject to accelerated publication, even if it was not disclosed in the corresponding PFD. Moreover, there is a need to consider whether it is acceptable, for all users, to turn a voluntary mechanism into a mandatory one.
- 21. From an administrative perspective, Offices would need a mechanism for linking the filing of a statement claiming a grace period to the publication of an application and mechanisms for according an accurate date of PFD, in order to avoid unfair delays in publication. As the IT3 continues to develop this proposal, it may wish to consider likely operational or administrative challenges to its implementation.
- 22. Some concern has been expressed that the accelerated publication proposal may not be in line with Art. 21 PCT². Art. 21(2)(a) PCT stipulates that "the international publication of the international application shall be effected promptly after the expiration of 18 months from the priority date of that application", by the International Bureau (IB). This would be problematic, as the publication under the IT3 proposal would take place before that date.
- 23. However, under Art. 21(2)(b) PCT, the applicant may request that the IB publish his application before the expiry of the time limit in Art. 21(2)(a) PCT. It may therefore be

² Throughout the work of the B+ Sub-Group, it has been assumed that a harmonisation package should fit into the existing international framework, including TRIPs, the PLT and the PCT

possible to introduce a rule to the effect that a statement claiming the benefit of the grace period constitutes a request for early publication within the meaning of Art. 21(2)(b) PCT, though this should be further explored.

24. In the current PCT regime, under Rule 48.4 PCT, there is a 200 CHF fee associated with early publication. The above solution to PCT compliance which links the grace period and early publication should also consider whether it is suitable for applicants relying on the grace period to be subjected to such a fee.

3.2 Statement Requirement

- 25. In order to enable accelerated publication the Offices must be made aware of the existence of a PFD. One mechanism for achieving this is through the filing of a statement indicating the relevant PFD and that the applicant is taking advantage of the grace period. The IT3 propose the applicant should be required to file such a statement, ideally together with the patent application. At the Industry Symposium, industry delegations from other jurisdictions also saw the benefit of such a statement, which would provide further clarity for third parties. The industry delegation from the Republic of Korea for example saw the statement as a way of balancing interests.
- 26. At present little detail has been provided regarding the components of the statement. It is unclear what information the statement should contain, whether all individual PFDs must be listed and to what degree of detail. The Canadian industry delegation at the Industry Symposium noted that "further consideration of full parameters [is] necessary". The industry delegation from Australia and New Zealand noted that requiring too much detail would be "undesirable" and highlighted a risk of statements being used in unforeseen and undesirable ways in later litigation. They also suggested that the information provided in the statement "could form part of bibliographic data" of the specification, and could involve "ticking a box" (Record of Proceedings). This idea was met with considerable criticism from other industry delegations, as this form of a statement assumed a level of detail which some found insufficient to fulfil the statement's purpose. However the discussion on this topic highlighted that some aspects of the statement need further development.
- 27. The procedural requirements, particularly the timing of filing of the statement, are linked closely to considerations regarding accelerated publication and the DIU (see section 3.3). Agreed proposals for procedural requirements may therefore depend on the outcome of discussions in other areas, and warrant further consideration.

3.2.1 Sanctions for Late Filing

- 28. The IT3 are clear that although applicants should be encouraged to file any statement in a timely manner, any sanctions should not include loss of rights. The IT3 instead propose that administrative fees, which may increase over time, could be used as a sanction mechanism. The industry delegation from Australia and New Zealand felt that such fees "may apply to encourage promptness and accuracy in the filing of the suggested declaration."
- 29. The IT3 suggest that the details of such fees would be determined by the Offices. However, administering such fees may not be practicable for some Offices. This is particularly true where wider Governmental fee policies prevent the charging of punitive fees or require fees to be based on cost-recovery for services rendered. The question also arises as to what happens if the fee is not paid. On another note, the threat of mere administrative fees as sanctions may not provide sufficient incentive to file a statement early (or at all, if the grace

period may be relied on even post-grant) and would potentially make accelerated publication impracticable as well. For their combination with DIU, see section 3.3.

3.3 Defence for Intervening Users (DIU)

- 30. An additional incentive to the timely filing of the statement is the DIU. This would simultaneously protect third parties making use of the contents of a PFD but unaware that it could be linked to a patent application. The modalities of the DIU have yet to be agreed within the IT3. However, in essence, the mechanism is that the applicant:
 - i) making a PFD,
 - ii) failing to file a statement in a timely manner, so that there is no publication of the application 18 months after the PFD,
 - iii) but later claiming the benefit of the grace period,

would run the risk of third parties having used or started serious and effective preparations to use his invention obtaining a DIU, similar to a PUR, allowing them to continue to use the invention thereafter.

3.3.1 DIU and relationship to the Paris Convention

- 31. The critical window of time during which qualifying activities by third parties would have to take place is not agreed by the IT3. It is noted that in all the variations representing the DIU in the IT3 slides presented at the B+ Industry Symposium, the grace period is assumed to have a 12-months' duration. Under this scenario, the critical period for accrual of a DIU would fall squarely within the priority period.
- 32. In its presentation to the B+ Industry Symposium, the IT3 itself has raised the issue of the compliance of such a situation with International Treaties, and in particular, in its "Elements" paper (p.17), with Art. 4B of the Paris Convention, which reads thus in relation to the priority period:
 - Paris Convention Article 4B. Consequently, any subsequent filing in any of the other countries of the Union before the expiration of the periods referred to above shall not be invalidated by reason of any acts accomplished in the interval, in particular, another filing, the publication or exploitation of the invention, the putting on sale of copies of the design, or the use of the mark, and such acts cannot give rise to any third—party right or any right of personal possession. Rights acquired by third parties before the date of the first application that serves as the basis for the right of priority are reserved in accordance with the domestic legislation of each country of the Union.
- 33. The DIU has been labelled a "Defence", and it has been suggested that this could save the concept from falling under the purview of Art. 4B, which refers to "rights". On the other hand, given that the DIU, as conceived, appears to be similar, if not identical, in scope and operation, to PURs, and further, to the extent that Art. 4B is understood to preclude the accrual of PURs during the priority period, a strong argument can be made that simply labelling the DIU a "defence" does not remove it from the scope of Art. 4B. Thus it would appear that the implications of the proposed DIU and the terms of the Paris Convention will need to be considered together, particularly since it has always been expected within Group B+ on SPLH that any solution should be in line with the existing international framework.

3.3.2 Link between DIU and the duration of the grace period

- 34. It should be noted, however, that the situation may be different if the grace period's duration is 6 months.
- 35. If the PFD occurs at month 0 and the application is filed up to 6 months later, the latest date for accelerated publication of an application along with a timely filed statement would be 18 months from the PFD, which would coincide with the end of the priority period. Assuming no publication has taken place and that the statement is filed late, activities qualifying for the defence would therefore begin after the end of the priority period.

3.3.3 Complexity of the DIU

- 36. A detailed analysis of the DIU concept is impossible, given the number of open issues. It is a valiant and creative effort to "think outside the box" and circumvent the difficulties inherent in attempting to enforce timely compliance with the requirement to file a statement in the absence of loss of rights. However, it introduces an additional layer of complexity to the system which was criticised by several user delegations at the Industry Symposium (see Record of Proceedings), and may go against the key objectives for successful harmonisation, as laid out in point 2.1.
- 37. In addition, the requirement of reliance on a PFD to qualify for the DIU would create a contrast between persons having relied on the PFD (whose investments would be protected), and third parties using their own invention devised after the priority or filing date of the patent, but unaware of the PFD, who would be forced to stop their activities.
- 38. Furthermore, a cross-section of the IT3 does not consider that PURs should accrue to third parties having derived knowledge from the applicant's own PFD prior to the priority or filing date. It could be considered inconsistent for the categories of persons who are eligible for protection under DIUs to differ from those eligible for PURs.

3.4 Prejudicial and non-prejudicial disclosures

- 39. In the "Elements" paper and at the Industry Symposium the IT3 presented details of the prejudicial effect of various disclosures, listed below.
- 40. The "Elements" paper notes the difficulty of showing derivation, and discussions at the Industry Symposium highlighted particular issues arising in a digital context. To address this the IT3 propose certain rebuttable presumptions:
 - i) Where the content (or part of the content) of a third party intervening disclosure is the same or involves insignificant differences over the content of an earlier PFD by the applicant/inventor, that disclosure (or that part) is presumed derived and not to form part of the prior art.
 - ii) Where part of the content of the third party intervening disclosure involves more than insignificant differences over the content of an earlier PFD by the applicant/inventor, then that part of the disclosure is presumed not to be derived and to form part of the prior art.
- 41. These presumptions may be challenged by Offices and third parties. At the Industry Symposium, the Canadian industry delegation was supportive of the presumptions in combination with the use of third party observations.

- 42. While appreciating the motivations behind the presumptions, it is worth noting a few issues for further consideration. First, in the context of patent examination, the presumptions would shift the burden of proving that a disclosure is not derived to someone who is not a party to the application procedure (the author of the second disclosure), and who may be unlikely to make a third party observation. This risks grant of the patent being the default position despite the existence of a possible novelty-destroying disclosure and consequently an increased likelihood of the resulting patent being subjected to later opposition proceedings or costly litigation over validity. Furthermore, it may be practically difficult for the author of the second disclosure to prove a negative, i.e. that he was not aware of the PFD, or if he was, that it did not influence his inventive process.
- 43. Second, in seeking to carry out one of its policy intentions—preventing slavish copies of a PFD from becoming novelty-defeating prior art against the later application—the IT3's proposed presumptions may raise questions of consistency with another of its policy intentions in the areas, that of avoiding incentivizing use of PFDs. When making a PFD, the applicant ordinarily risks that an intervening disclosure of an independent invention prior to the filing date will become prior art against his application. However, to the extent the content of the two disclosures is the same or insignificantly different, the second disclosure is presumed to be derived and thus not to be prior art, according to the IT3's approach. This could be viewed as removing a disincentive which prevents the intentional use of PFDs becoming the norm.
- 44. Indeed, in spite of policy statements from the IT3 indicating the importance of disincentives to PFDs (See paragraphs 15 and 16 above), the IT3 have yet to reach agreement on what form such disincentives should take. The IT3 may therefore wish to consider this further. For example, some suggest that the availability of PURs and the risk of a novelty destroying independent disclosure, could incentivise early filing, since at present, the IT3 proposal contains no agreed disincentives to PFDs.
- 45. Additional information on how JP and KR treat re-disclosures of the applicants PFD, to assist with the IT3 with their proposals is provided in Annex I.
- 46. The IT3 work in the area of grace period is certainly moving in a constructive direction and there are a number of new ideas which are deserving of further consideration.

4. Prior User Rights

- 47. In the "Objectives and Principles" Paper, the following two principles regarding PURs were agreed:
 - i) A third party who has started using the invention in good faith prior to the filing of a patent application for that invention by another party should have a right to continue to use that invention.
 - ii) The circumstances under which prior user rights arise, including the extent to which they rely on actual use having taken place, should balance the interests of third parties to protect their investments with the interests of the inventor/applicant.
- 48. In its "Elements" paper, the Industry Trilateral makes several references to balancing these competing interests, stating, p. 21 "The defence 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 defence." Further, it is specified that "A court determining the ultimate scope of the defence

provided to a third party should recognize several factors..." (p.22). The paper then proceeds to enumerate "likelihoods" which should inform the court's decision, almost all of them articulated so as to limit the PUR.

49. Thus, the approach taken by the IT3 appears to be to have a Court balance the interests of the parties in each case, both in terms of the accrual of the rights and of their scope. Under this approach, it was concluded by the Australian and Canadian industry delegations at the Symposium that the parties would need to go to Court in order to know where they stand.

4.1 Link between PURs and Grace period

- 50. As has been discussed above, the possibility of PURs accruing to third parties may motivate applicants to file quickly. PURs may also discourage deliberate use of PFDs becoming the norm. The IT3 have yet to come to an agreement on whether PURs may accrue to third parties who have relied on a PFD from the applicant in good faith, or whether they believe other approaches would reflect best practice. However, the IT3 may wish to keep in mind the potential link between the availability of PURs and encouraging early filing.
- 51. It is worth considering whether there should be consistency between the DIU and PUR in the defence being available to third parties having relied on a PFD, if the concept of DIU is pursued further.

4.2 Qualifying Activities and Scope of Prior User Rights

- 52. There was no consensus among industry groups at the Symposium as to how the balance between the interests of Applicants and third parties referred to in principle ii) above should be achieved.
- 53. The current approach proposed by the IT3 is to leave it to the courts to determine the balance between the applicant and third parties in individual cases. As far as the qualifying activities relating to serious and effective preparations are concerned, the paper states that "no bright line test may be possible" (p.21).
- 54. On the other hand, delegates from some offices and some industry delegations consider that this balance could be achieved by establishing the boundaries of PURs (i.e. the criteria governing the conditions under which they accrue and the scope of permissible activity which they allow) at a statutory level, which could result in better consistency and predictability for all parties.
- 55. For example at the Industry Symposium, the Canadian industry delegation's response to the IT3's approach was that "it was important that it be possible to have a black-and-white determination of whether there was a PUR or not without having to head to court" (Record of Proceedings). This was echoed by the Australian industry delegation, which was "very sympathetic to the idea of having objective tests surround the various issues, and PURs was the obvious issue where it would be really good to have some objective criteria. It seemed that it would be quite difficult to move away from a discretionary test in some way if there had to be a balancing of interests."
- 56. The view was expressed that if these determinations were left entirely to the discretion of the courts, this would not result in consistent, harmonised results. Defined criteria are impartial to the individual facts of the case and can be helpful to the courts when making a decision.

- 57. Given the different views expressed, the IT3 may wish to consider the following:
 - Qualifying Activities The IT3 has produced a non-exhaustive list of activities which could qualify as serious and effective preparations. This is undoubtedly helpful, but this remains inexact and subject to the court's discretion in the absence of objective tests. A set of criteria against which to test the activities of the third party could be helpful in making PURs both predictable and consistent across jurisdictions.
 - **Scope of Prior User Rights** Once a PUR has accrued, there are other issues that may arise related to the scope of the right: (a) changes in volume of production, (b) modifications of the embodiment of the invention, and (c) whether the rights holder can change the nature of the acts which he has carried out to exploit the invention.

Although some users have expressed an appetite for harmonisation of these provisions to provide a degree of certainty for rights holders and third parties as to the scope of the PUR, some delegations have questioned the need for these issues to be subject to detailed agreement, because these issues go beyond the mere accrual of the right itself, which is the main disincentive PURs create against use of PFDs, and instead introduce greater and perhaps unnecessary complexity.

Other delegations, however, believe that harmonising the conditions of accrual do not suffice because they consider that, as pointed out by the Australian Industry delegation at the Symposium (Record of Proceedings), it would be possible for the scope of the PUR to be so narrowly defined as to be useless to protect third parties, in which case, the PUR would have little or no disincentive effect, hence the need to address also issues of scope in harmonisation discussions.

58. If defined criteria are to be further pursued, how PURs are determined in various jurisdictions could serve as a useful reference (see Annex II).

5 Conflicting Applications

59. In Exhibit 2 to its "Elements" Paper, the IT3 set out two agreed objectives and principles for conflicting applications as an element of a harmonisation package. The first of these acknowledges the underlying purpose of the law in this area; avoiding undue proliferation of rights, whilst allowing appropriate protection of incremental innovation.

"To prevent the grant of multiple patents on substantially the same or identical inventions in the same jurisdiction and to minimize the risk to third parties of multiple enforcement proceedings in the same jurisdiction, while permitting an appropriate scope of protection for incremental inventions, a coherent set of rules with regard to conflicting applications is needed."

These objectives and principles are a valuable starting point for future work in this complex area.

5.1 Standard for Measuring Distance and Treatment of First Applicant and a Third Party

60. In Exhibit 2 to its "Elements" paper, objectives and principles item (ii) identifies a need for a "clear and uniform standard" for determining patentability where there are incremental differences between conflicting applications in the same jurisdiction. The "distance"

between a secret prior art (SPA) disclosure and the claims of a later filed application which is relevant to the patentability of the later filed application is one aspect of such a standard. Agreement on a definition of the distance standard, as well as whether the same standard applies to both third party and applicant-filed later applications, is necessary for a *uniform* approach to conflicting applications. Furthermore these elements are linked to the issue of anti-self-collision provisions.

- 61. In the "Elements" paper, the IT3 note that terms such as "inventive step" and "obviousness" could result in non-standard application of a distance standard. The paper then describes, (p. 9), an agreed proposed standard which 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, such common general knowledge not including disclosure solely in one patent disclosure or one journal article." This proposed standard is however not provided as an agreed element in Exhibit 2.
- 62. In their Industry Symposium presentation, the delegation from Australia and New Zealand's industry delegation noted a preference for same-treatment and a "novelty-only" standard which "avoids double patenting in a way that gives priority to the first applicant". The delegation also noted however that they could see a possible case for an "enlarged novelty" standard. The industry delegation from the Republic of Korea noted a preference for the "enhanced novelty" standard currently used in Korea but it was open to a more global standard.⁴
- 63. The IT3 paper does not explicitly mention whether a "whole contents" or a "prior claiming" approach is adopted. The IT3 may wish to clarify this issue to promote greater understanding.

5.2 Anti-self-collision, anti-double-patenting and terminal disclaimers

- 64. As described above, the extent to which anti-self-collision provisions are felt to be necessary (and their duration) may be influenced by the distance standard applied and whether the same standard is applied to later applications filed by both third parties and original applicants.
- 65. The industry delegation from Australia and New Zealand suggested that "adopting a package which requires anti-self-collision to reach an appropriate balance is not in keeping with a harmonisation package which avoids unnecessary complexity". The delegation from the Republic of Korea however prefers the inclusion of anti-self-collision provisions. The Canadian industry delegation also felt that anti-self-collision is necessary but stated that they would need to give further consideration to the "full parameters".
- 66. The IT3 document highlights, both in the main text of the "Elements" paper and Exhibit 2, potential mitigating measures which would prevent the grant of multiple patents for the same invention, or minimise the risk of third parties facing multiple enforcement proceedings in the same jurisdiction. These include both anti-double patenting provisions and terminal disclaimers. A terminal disclaimer would, for example, serve to link the patents in question and prevent them from being held in different hands, facilitating licensing and litigation, whilst also providing that patents thus linked all expire on the date the first of

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³ Detail of the existing differences in standards for measuring this distance is set out in "Elements" Paper, p.pg 9 and A + Background Document, issued June 2017, pp.pg 41-44.

⁴ Further discussion of "Enlarged" or "Enhanced" novelty is given in the B+ Background Document, p.pg 46.

these linked patents expire, thereby preventing undue extension of the patent term⁵. The IT3 are encouraged to reach agreement on the most appropriate additional measures, if any.

67. The industry delegation from Australia and New Zealand stated at the Industry Symposium that "the added complexity of a terminal disclaimer system, including determining the relationship between the first and second applicant, is not warranted to avoid the later expiry (up to 18 months) of the second patent" and are "Not required in a system that treats same applicants and different applicants equally". In contrast the Canadian industry delegation voiced a preference for "terminal disclaimers, with further consideration to better understand the mechanism".

5.3 Treatment of PCT applications

- 68. Two clear policy options are presented in the "Elements" Paper:
 - Treatment as prior art in all offices for which there is an active designation at the time of publication of the PCT application as of the earlier of the PCT filing or the priority date;
 - ii) Treatment as prior art only in the Offices in which the PCT application undergoes national/regional entry as of the earlier of the PCT filing date or the priority date.
- 69. As reflected in the comments from the Canadian industry delegation at the Industry Symposium, both have their limitations. Nevertheless an agreed view on this question is encouraged. It may be helpful during further discussions to keep in mind the extent to which each option harmonises and simplifies the law across jurisdictions. At the Industry Symposium the industry delegation from the Republic of Korea offered support for option i) and the Canadian delegation also found this the "least problematic" while the Australian industry delegation voiced a preference for option ii).
- 70. From the above discussion and the comments from the delegations at the Industry Symposium it is clear that there are a variety of views on the subject of conflicting applications. Nevertheless, in order to move this work forward, decisions will need to be taken on which combination of elements should be included. In coming to these decisions, the IT3 are encouraged to reflect on the complexity of the resulting combination and the need to ensure that double patenting is avoided, with the key issues appearing to be the appropriate treatment of subsequent applicants and the "distance" requirement.

6. Prior Art

71. There has been broad consensus amongst the B+ Sub-Group of the principles underpinning the harmonisation of prior art, but work had not commenced on a formal definition to be adopted.

72. In its "Elements" paper, the IT3 suggest that the definition of prior art may be derived from Article 8 of the Draft Substantive Patent Law Treaty;

⁵ Further discussion of anti-double-patenting and terminal disclaimers can be found throughout the Conflicting Applications Workstream paper of September 2015, as well as the B+ Background Document.

SCP 10/4 – Article 8 – Prior Art: (1) [Definition] The prior art with respect to a claimed invention shall consist of all information which has been made available to the public anywhere in the world in any form [, as prescribed in the Regulations,] before the filing/priority date of the claimed invention.

- 73. The SCP 10/4 definition has been slightly amended to include reference to the filing date as well as the priority date. At the Industry Symposium, there was broad agreement that this text can form a useful basis from which to define prior art.
- 74. The industry delegation from the Republic of Korea also accepted the SCP 10/4 definition with the modified text but stressed that the definition of prior art should have no limitations as to the medium, language or geographical location and should not include disclosures made in secret or covered by a confidentiality agreement⁶.
- 75. As identified by the IT3 in its "Elements" paper, a related issue is whether an activity that results in access to some details but not all details of the invention constitutes information being "made publically available" and thus constitutes prior art. The test for determining that an invention has been made available to public is not set out. However, in many jurisdictions, it is commonly referred to as an "enabling disclosure". The IT3's definition does not currently set out a requirement for an "enabling disclosure" to occur, or any exceptions to that requirement. It would be useful for the IT3 to explore this issue further and to determine if a consensus position could be reached.
- 76. The B+ Sub-Group are supportive of the consensus reached in this area and are hopeful that the IT3 can swiftly come to final agreement on this issue.

7. Conclusion

77. The B+ Sub-Group recognises the considerable progress made by the IT3 and set out in the "Elements" paper. It is hoped that the commentary provided in this paper will assist the IT3 in their further discussions and will enable them to continue to fulfil their important role in the future of SPLH.

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⁶ Republic of Korea Symposium presentation, slide 3

⁷ For example, in Helsinn v. Teva (Fed. Cir. 2017), the US Federal Circuit has interpreted the post-AIA on-sale bar of 35 U.S.C. § 102 to include sales made available to the public, even if the published portion does not fully disclose the invention.

Annex I – Treatment of re-disclosures

Treatment of re-disclosures in Japan

- 1. In Japan, applicants are allowed not to include information regarding re-disclosures in their statements if they satisfy the following two conditions: (i) the "disclosed invention" is the same or can be regarded as the same as an invention for which the application of the provision of Article 30(2) has been admitted based on the statement ("proving document"), (ii) the "disclosed invention" is an invention disclosed through a disclosure action closely related to a disclosure action of "the invention for which the application of the provision of Article 30(2) has been admitted," or the "disclosed invention" is an invention disclosed by a person who is neither the right holder nor a person who was requested by the right holder to disclose the invention.
- 2. When examiners cite the re-disclosures as prior art, applicants may present an argument by submitting a written opinion.

Treatment of re-disclosures in the Republic of Korea

- 3. In the Republic of Korea, where a patent applicant or third parties re-disclose the applicant's PFD, supporting documents to provide a grace period for the patent application are not required if the re-disclosure is inseparable from the patent applicant's PFD.
- 4. Inseparable conditions are as follows:
 - a) A test that is continued for two or more days
 - b) Instructions distributed at the test date
 - c) The first and the second edition of a publication
 - d) Manuscript and Oral presentation of a scientific academy
 - e) Presentation at a scientific academy and a handbook
 - f) A lecturing tour
 - g) Exhibition entry and its catalogue, and etc.
- 5. Where an invention, which is the same as the concerned invention claimed in the patent application which claims the benefit of grace period, is re-disclosed by third parties between PFD(of a patent applicant) and the filing date of a patent application, the concerned application is determined to be rejected based on lack of novelty; except in the case that it is clearly identified that the re-disclosure by third parties, including a patent applicant's disclosure of a periodic publication, an exhibition entry, and etc., is known from PFD of an patent applicant. Further, as for a notice of reasons for rejection in accordance with the abovementioned reasons, the burden of proof is given to a patent applicant to prove that the re-disclosure by third parties is known from PFD of an patent applicant.

Annex II - Criteria for determining PURs

Accrual of PURs

- 1. The law in Germany requires "necessary preparations" to use the invention. First, the prior user must be in "possession of the invention" before the relevant date. This requires the invention to be complete and the prior user to understand the technical teaching in a way, which allows the invention to be carried out (but no knowledge of e.g. underlying scientific principles is necessary).
- 2. For the establishment of "necessary preparations", the German courts have articulated a three-pronged test:
 - i) The serious preparations must objectively be of a nature to make the exploitation of the invention possible;
 - ii) A definitive decision to undertake a commercial use of the invention must have been taken by the user; and
 - iii) The intention must be to start the exploitation of the invention in the immediate future."8
- 3. In the UK, for "serious and effective preparations" to be recognized as such, courts in the UK have required:
 - i) Preparations which are "effective", without defining the term further; but these preparations must be advanced enough to show
 - ii) that a decision has been made to do the infringing act; and
 - iii) so as to be "about to result" in the infringing act being done".9

This approach is similar to the three-pronged test applied by German courts.

- 4. In Japan, the Supreme Court has set forth that the prior user must have expressed in a manner and to an extent which is objectively recognisable, an intention to immediately work the invention.
- 5. In the United States, the defense 10 is available to a person who commercially used the subject matter in United States. The commercial use must have occurred at least 1 year before the earlier of either the effective filing date of the invention or a graced disclosure of the invention.
- 6. Thus, these criteria can be applied to the factual constellations of the prior activities of the third party, in order to determine whether the activities qualify for a PUR.

⁸ Taken from the PUR Workstream Paper of May 2016 (p. 17).

⁹ Summary from the PUR Workstream Paper, p. 39

¹⁰ In the United States prior user "rights" are not rights per se but instead are considered a limited defense to patent infringement.

7. An example illustrating the usefulness of these criteria is that of field tests, analysed according to German law. Where a field test is carried out to determine the best embodiment of the invention, this may qualify as a serious and effective preparation. However, where tests are carried out to determine whether the invention actually works, they are geared towards the completion of the invention, and thereby fail the German criterion as to whether the prior user is in possession of the invention, which in turn forms an obstacle to the formation of a decision or intent to use the invention in the immediate future. In Germany, such tests have been deemed not to qualify for the accrual of PURs¹¹.

Scope of PURs

8. In the UK, it has been held that if the activities of the prior user had to remain exactly the same, the protection given by PURs would be illusory.

(a) Changes in volume

9. In the vast majority of jurisdictions changes to the volume of production are allowed. In the US, the statute states this explicitly 12. In Germany, the principle that volume changes are permitted is undisputed. In Australia, Switzerland and France, there are no volume restrictions, and Spain also recognises some latitude for change in this respect. In Japan, the scale of use of the invention can be expanded, as long as it remains in line with the "business purposes" or "business objectives" of the prior user.

(b) Modifications to the embodiment

- 10. German case law allows changes to the embodiment which are either plain equivalents or obvious to the person skilled in the art 13. It is of further interest that in Germany, the relevant criterion for assessing permissible modifications is not the embodiment as used prior to the critical date itself, but the scope of the objective possession of the invention by the prior user, assessed at the critical date by a person skilled in the art.
- 11. Modifications which are not covered by the patent specification are allowed. However, conversely, the prior user cannot modify his embodiment to incorporate any additional features of the invention which he has learned from the patent specification 14.
- 12. This principle appears to be applied somewhat differently in the U.S., where the statute 15 provides that "the defence extends to "improvements in the subject-matter that do not infringe additional specifically claimed subject-matter of the patent", appearing to prohibit expansion thus only with regard to what is claimed, rather than with respect to the whole contents of the patent specification.
- 13. In the UK, the Patents Court has rejected the suggestion that the nature of the "protected" acts" depends in some way on the claims of the patent specification. "An act is protected or not depending on what it was, not on the somewhat adventitious manner in which a patentee may have chosen to cast his monopoly"16.

¹³ See Desmopressin, BGH, PharmR 2012, 391, at 393

¹¹ See Taxilan, BGH, GRUR 1964, 20, at 23.

¹² See 35 USC § 273(e)(3)

¹⁴ See *Biegevorrichtung,* BGH, 2002, 231 at 234.

¹⁵ 35 USC § 273(e)(3)
¹⁶ Lubrizol Corp. v. Esso Petroleum, (No2) [1997] RPC 195, at p. 216

- (c) Changes to the acts of working of the invention
 - 14. In Australia, it would appear that there are no limitations placed on the prior user to modify his activities or manner of working the invention after the critical date.
 - 15. German courts have developed detailed rules on the scope of PURs in this respect. Where the prior user has manufactured or prepared to manufacture, he may carry out any act to work the invention: the <u>producer</u>'s PUR is comprehensive and encompasses all types of use, so that he may change the type of acts which he performs. Whoever has offered the invention for sale, may also manufacture the invention. On the other hand, where the prior user has only imported or sold the invention without making any preparations to manufacture, he cannot begin to manufacture the invention. An important criterion is that the nature of the prior user's business as it existed at the critical date cannot be essentially modified. Thus, for instance, a prior user in the import-export business cannot build a factory to manufacture after the critical date.
 - 16. In the UK, the statute is specific, the PUR is a right to continue to do "that act" which was either done or prepared for. Thus, for instance, an act of manufacture may constitute a preparation to sell and/or to use the invention. The situation appears similar in Switzerland, and in Spain, where the wording of the statute is that the prior user may exploit the invention "in the same manner as before in such a way to meet the reasonable needs of their enterprise". In Japan, courts appear to be following a similar approach.
 - 17. All these approaches are based on criteria which, if clearly enunciated, would allow parties to determine the scope of the right enjoyed by the prior user, without resorting to litigation.