Concerns about Patent Disclosure of Origin Requirements and the Chair’s Text

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Key messages

1. Biopharmaceutical companies actively engaged in innovation involving genetic resources (GRs) continue to believe that patent disclosure requirements (PDRs) inhibit innovation and thereby the creation of benefits. We therefore believe that the direct and indirect costs of PDRs far outweigh any alleged benefits.
2. The Chair’s text[[1]](#footnote-1) leaves too much discretion to signatory states to determine the scope and content of their PDR.
3. The scope of the obligation created by the Chair’s text itself is too broad.
4. Important terms are undefined and unclear.
5. The wording of the Chair’s text does not reflect its intention as expressed in the notes.
6. The Chair’s text does not achieve its stated objectives of preventing bad patents, and improving the quality, transparency and efficacy of the patent system.

## General concerns regarding Patent Disclosure Requirements

A patent disclosure requirement (PDR) is a regulatory burden. Such burdens, including those contemplated by the Chair’s text1, should not be created without clear evidence that their benefits outweigh their burdens.

Most countries that have introduced PDRs to date have done so with the objective of supporting the third objective of the Convention on Biological Diversity (CBD), and not for reasons related to patents or the patent system.

 Existing PDRs have the following negative impacts:

* They increase the cost of patent procurement.
* They delay patent application processes, particularly when they are combined with requirements to disclose, for example, evidence that the GRs were lawfully obtained and that their use is in accordance with any agreements.
* They create legal uncertainty as to whether patents will be granted or can be enforced.
* They expose innovators to various sanctions for breach in each country where there is non-compliance.

The aggregate effect of these problems is that PDRs inhibit innovation using GRs and/or associated traditional knowledge (aTK) and thereby reduce the possibility of generating benefits to share with the countries providing such GRs and/or aTK. PDRs therefore inhibit achievement of one of the objectives of the CBD. These problems are exacerbated by the fact that there is significant variation between national PDR laws, and those laws are often very unclear. As the number of such laws increases, the negative impacts also increase. As this paper sets out, although it apparently seeks to do the opposite, the Chair’s text will contribute to the proliferation of different laws.

Despite the fact that many countries have PDR regimes, there is no evidence that such regimes have led to any tangible benefits. In our view, it is clear that the costs associated with PDRs far outweigh any supposed benefits.

## Specific concerns in relation to the Chair’s Text

In the following paragraphs, we focus on how key concerns[[2]](#footnote-2) arising from the Chair’s text create issues which mean that the text does not achieve its stated objectives[[3]](#footnote-3) of enhancing the efficacy, transparency and quality of the patent system, and preventing the erroneous grant of patents.

### Key concerns

#### The Chair’s text leaves too much discretion to signatory states to determine the scope of their PDR.

Subject to a few exceptions,[[4]](#footnote-4) the Chair’s text sets a floor to the PDR obligation (i.e., it states the minimum requirements of the PDR that signatory states must have) but does limit what requirements a national PDR law may have. Sometimes[[5]](#footnote-5) this is done by expressly stating that a provision is subject to, or can be implemented in accordance with national law, either existing or future. More often it is done by not imposing limitations on the national PDR law.

This leaves significant discretion to signatories to have more extensive PDRs than those described in the Chair’s text, which creates legal uncertainty. For example, some countries already have PDRs which require, as part of the patent application process, disclosure of information relating to whether the GR was obtained in accordance with the national laws of the country of origin (through prior informed consent; PIC) and is being used in accordance with any relevant agreements (i.e., mutually agreed terms (MAT)). This information has no relevance whatsoever to patentability. There is evidence as to the harmful impact of these laws.[[6]](#footnote-6) The Chair’s text does not (but should) prohibit such laws and any laws requiring disclosure of any information relating to GRs which is not relevant to whether a patent application meets the tests of novelty, non-obviousness or sufficiency (TRIPS Article 27(i))[[7]](#footnote-7).

This approach of setting a floor means that patent applicants are likely to continue to see a wide range of different and extensive PDRs laws in signatory states. This will increase the damaging effect of PDRs on innovation, the cost of compliance and above all simply increase – and not reduce – legal uncertainty.

Instead of taking this approach, the negotiated international legal instrument should create a ceiling to many of the obligations of a PDR and only allow discretion as to its content in strictly defined areas.

#### The scope of the obligation created by the Chair’s text is too broad.

Unlike in the CBD context, there is no explicit exclusion of human genetic material. Although the notes indicate the Chair’s intent that human GRs are excluded, this is not sufficient. Unless there is an explicit exclusion, the scope of the PDR requirement is far broader than that of the relevant obligations in the CBD and Nagoya Protocol. Many biotechnological inventions, such as gene therapies, involve the development of human genetic resources and they can be taken from a human in many locations. The practical impact of an obligation to disclose the source or origin of all relevant GRs could be significant and the information disclosed would be in no way useful.

Another concern relates to the contentious issue of whether physical access to GRs is needed for the trigger to apply. If there were such a requirement, the scope of the Chair’s text would be narrower.

The notes say that “to address this difference of views, the definition is now silent on this issue”. This silence reflects a policy decision by the Chair, and means that the PDR obligation exists in cases where the patent applicant does not have physical access to the GR. This has profound implications. An example shows why.

Assume that the invention of a vaccine is developed using DSI relating to one or more variants of a virus. The variant(s) of the GR would have been “necessary or material to the development of the claimed invention” (i.e., there would be no invention without someone other than the inventor having sequenced the virus) and the invention would “depend on the specific properties of the GR”. So the trigger of the Chair’s text is satisfied.

This means that, where the trigger condition is met, the PDR obligation of signatories applies even where only digital sequence information (DSI) is used in the R&D leading to the invention.

So, a combination of the current definition of the trigger and the fact that physical access is not a requirement means that the PDR applies to inventions using solely DSI and DSI is not excluded as suggested by the notes of the Chair’s text to Article 9.

Given that R&D processes often involve the use of thousands of different sequences, it would make the PDR obligation impossible to comply with Further, unlike other areas of the Chair’s text, there would be no discretion for a signatory to require physical access as a condition of the PDR.

#### Important terms are undefined and unclear.

The fact that the term ‘traditional knowledge’ is not defined is very concerning. The notes indicate it is left to national laws to define or interpret the meaning of traditional knowledge, pending agreement on this matter in the IGC.

However, under the Chair’s text, a PDR is obliged to require disclosure of the source of associated TK (aTK). There is no discretion for signatories not to require disclosure of information relating to aTK.

The Chair’s text seeks to create a sanctionable obligation relating to subject matter which is not defined in the text and often not defined in national law. This is, in our view, unacceptable.

Instead of taking this approach, the instrument should prohibit a requirement of disclosure of aTK until such time as a definition of TK is agreed at an international level and a further definition of aTK is agreed in the context of this instrument.

#### The wording of the Chair’s text does not reflect its intention as expressed in the notes.

Two important examples arising from the extremely important definition of the ‘trigger’ can be given here.

Firstly, the notes on the trigger in Article 3 suggest that where a GR does “not form part of the claimed invention”[[8]](#footnote-8) the trigger (and thus the PDR) does not apply. However, this appears to be incorrect. Again, an example shows why.

Assume that the invention is a compound from a compound library that is tested against a specific bacterium and found to kill it. The patent might claim the compound, but the bacterium would in no way “form part of the claimed invention”. However, the trigger would apply because the bacterium would have been “necessary or material to the development of the claimed invention” and the invention (the compound) would “depend on the specific properties of the GR” because it only works because of the specific properties of the GR.

Secondly, Article 9 clearly suggests that derivatives are not within the scope of the PDR but does not define what is meant by “derivatives”. However, a correct interpretation of Article 3 leads to the conclusion that not only GRs but also “derivatives” are covered under the PDR. Again, we will use an example to show that derivatives are within the scope of the PDR.

Assume that a novel compound is found in a leaf[[9]](#footnote-9) and is found to possess anti-cancer properties. A patent is filed for the compound. The compound is materially/directly based on the GR because the GR was necessary or material to the development of the invention (i.e., the compound would not have been found – indeed, may not have existed – without the GR) and the invention depends on the specific properties of the GR, as it is the specific properties of the GR which led to existence of the compound.

Therefore, the PDR requirement in Article 3 applies to what is a narrow definition of derivatives and the Chair’s text does not reflect the apparent intention.

Indeed, the invention disclosed in any patent which does not claim the GR itself would in one way or the other be derived from the GR and would fall within the trigger, since without the GR the invention would not have been made and the claimed invention would depend on the specific properties of the GR.

There is nothing in the Chair’s text to prevent signatory states from including derivatives in their national laws, however they choose to define them.

#### The Chair’s text does not achieve its stated objectives.

The Chair’s text seeks to develop an instrument which will prevent grant of ‘bad’ patents which are not novel or inventive and improve patent system quality.[[10]](#footnote-10) It is hard to see how disclosure of the source or origin of a GR or aTK will do this. It should be clear to those familiar with patent law that disclosure of the source or origin is unlikely to assist in determining or assessing the prior art which is relevant to novelty or inventiveness (or, indeed, sufficiency). We would expect to see evidence of this being the case if there were any.[[11]](#footnote-11) There is no such evidence. It seems clear that a PDR will not achieve this objective.

Enhanced transparency of the patent system is also an objective of the international legal instrument to be negotiated and created. It is difficult to see the value to the system of transparency of information that is not relevant to that system.

Another stated objective of the PDR system is to enhance efficacy of the patent system. The notes to Article 1 state that “the term “efficacy” also makes it clear that a disclosure requirement implemented at the national level should be effective, practical, easily implementable and not result in overly burdensome transaction costs”.

In his introductory remarks, the Chair alludes to the undesirability of different national systems because they create inherent risks in terms of legal certainty. The importance of legal certainty is correctly referred to on several occasions.

The notes to Article 1 claim that the instrument “does not contain any provisions…that are not relevant to the patent system”. In light of the comments above, that seems to be simply incorrect.

Because the Chair’s text (i) contains insufficient limitations on the scope of a PDR, (ii) is unclear, (iii) leaves much to national law and (iv) does not have the effects that the notes show are intended, it leaves signatories with too much discretion as to how to implement a PDR in national law.

If the Chair’s text forms the basis of an international legal instrument, the inevitable effect will be a proliferation of different and broad PDRs among signatory states. These will all have to be analysed and complied with, resulting in cost and other burdens on innovators, and will delay patent applications. This will inhibit innovation using GRs.

Therefore, the Chair’s text fails to enhance the efficacy of the patent system and also fails to create legal certainty.

**In aggregate, these concerns lead to the conclusion that the approach taken by, and the wording of the text, mean that the Chair’s text would not achieve the objectives set out in the text or the notes to the text.**

1. Specifically, the *Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources* (30 April 2019), prepared by Mr. Ian Goss, former Chair of the World Intellectual Property Organization’s (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“the IGC”). [↑](#footnote-ref-1)
2. We have other more detailed concerns with the text, but they are not addressed in this paper. [↑](#footnote-ref-2)
3. As per Article 1. [↑](#footnote-ref-3)
4. Notably, Articles 5 and 6. [↑](#footnote-ref-4)
5. For example, in Articles 5 and 6. [↑](#footnote-ref-5)
6. [***Economic Impact of Disclosure Requirements in Patent Applications for ´Genetic Resources’-Based Innovation***](https://www.ifpma.org/wp-content/uploads/2023/01/i2023_Economic-impact-DRs-for-GRs-final-report_June2018.pdf), a study commissioned by IFPMA and Crop Life International, and prepared by steward redqueen (June 2018). [↑](#footnote-ref-6)
7. Article 27: Patentable Subject Matter. [***Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”).***](https://www.wto.org/english/docs_e/legal_e/27-trips.pdf)World Trade Organization (WTO) (April 1994). [↑](#footnote-ref-7)
8. The meaning of this term is entirely unclear. [↑](#footnote-ref-8)
9. This is a “derivative” as narrowly defined in Article 2(e) of the Nagoya Protocol, which states that ““derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.” [↑](#footnote-ref-9)
10. It is not clear to us what the difference is between preventing bad patents and patent quality, so we comment on them together. [↑](#footnote-ref-10)
11. Such evidence could include, for example, studies showing that relevant prior art citations are more numerous in those countries which have a PDR than those which do not. [↑](#footnote-ref-11)