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Recommendation for a

COUNCIL DECISION

authorising the opening of negotiations on an international legal instrument relating to intellectual property, genetic resources and traditional knowledge associated with genetic resources

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

In their 2002 Communication to the Trade-Related aspects of Intellectual Property Rights Council (TRIPS Council)[1], the European Union (EU) and its Member States agreed to discuss the introduction of a self-standing disclosure requirement allowing Member States to keep track of patent applications with regard to genetic resources. In 2004 the World Intellectual Property Organisation (WIPO) General Assembly agreed, at the suggestion of the Conference of the Parties to the Convention on Biological Diversity to consider the relationship between access to genetic resources and disclosure requirements in intellectual property rights applications.

Out of this arose WIPO discussions on the disclosure of the origin or source of genetic resources and associated traditional knowledge in patent applications. Those discussions aim at establishing an international disclosure requirement that patent applications for an invention based on genetic resources disclose the country of origin or the source of the genetic resources in question, and where applicable, of the traditional knowledge associated to them.

In 2022, the WIPO General Assembly agreed to hold a diplomatic conference no later than 2024 to conclude an international legal instrument relating to intellectual property, genetic resources and traditional knowledge associated with genetic resources (genetic resources (GR) instrument). To prepare for this, a Special Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore took place on 4 to 8 September 2023. The revised text from this session was transmitted to the Preparatory Committee. of the Diplomatic Conference which took place on 11 to 13 September 2023. The Preparatory Committee approved the draft administrative provisions and final clauses of the basic proposal, the list of invitees and the draft rules of procedure of the Diplomatic Conference. The Preparatory Committee's meeting was adjourned to be reconvened at a future date to consider the draft agenda and the dates of and venue for the Diplomatic Conference.

The Preparatory Committee decided to invite the EU to the Diplomatic Conference as a Special Delegation.

2. LEGAL ELEMENTS OF THE RECOMMENDATION

- **The basic proposal on an international legal instrument relating to intellectual property, genetic resources and traditional knowledge associated with genetic resources (GR instrument)**

The aim of establishing an international GR instrument is to improve the efficacy, transparency and quality of the parts of the patent system that deal with genetic resources and the traditional knowledge associated with them, and to prevent patents from being erroneously granted for inventions that are not novel or inventive with regard to genetic resources and traditional knowledge associated with them.

[1] Communication by the EC and its Member States to the TRIPs Council on the review of Article 27.3(b) of the TRIPs Agreement, and the relationship between the TRIPs Agreement and the Convention on Biological Diversity and the protection of traditional knowledge and folklore.

The scope of the GR instrument, as the basic proposal states, is limited to patents. However, the basic proposal includes a review clause covering a possible extension of the disclosure requirement to other areas of intellectual property (Article 9).

The content of the basic proposal can be divided into (i) substantive provisions and (ii) administrative provisions and final clauses.

As regards the substantive provisions, the key element is the mandatory disclosure requirement contained in Article 3. The basic proposal also foresees sanctions and remedies that would apply in case the disclosure requirement is not respected. In this regard, Article 6 of the basic proposal allows for different measures to be put in place by contracting parties. Other provisions of the basic proposal contain a list of the terms used in the instrument (Article 2), exceptions and limitations to the obligation to disclose (Article 4), a non-retroactivity clause (Article 5), the establishment of information systems (Article 7), or the relationship this instrument should have with other international agreements (Article 8).

The administrative provisions and final clauses contain the general principles of implementation (Article 10), as well as the institutional framework that will govern the instrument: the Assembly, where contracting parties will be represented and that shall deal with all matters concerning the maintenance and development of the instrument, among other tasks, (Article 11), and the International Bureau of WIPO, who shall perform the administrative tasks concerning this instrument (Article 12).

Furthermore, administrative provisions and final clauses provide for rules on the eligibility to become a party (Article 13), the ratification and accession of the instrument (Article 14), the revision and amendments (Articles 15 and 16), the signature (Article 17), the entry into force (Article 18), the effective date to become a party (article 19), the denunciation (Article 20), the reservations (Article 21), the languages (Article 22) and the depositary (Article 23).

- **Union competence**

Without prejudice to the final assessment of the nature of the EU's competence once the negotiating parties have agreed on the text of the GR Instrument at the Diplomatic Conference, a preliminary assessment on the nature of Union competence must be done before negotiations. In this regard, Articles 3(1) and 3(2) of the Treaty on the Functioning of the European Union (TFEU) apply when deciding on EU's competence as far as the GR instrument is concerned.

Under Article 3(1) TFEU, the EU has exclusive competence on matters pertaining to the common commercial policy. International intellectual property commitments can be considered part of the common commercial policy provided they have a specific link to international trade in that they are (i) essentially intended to promote, facilitate or govern international trade and (ii) have direct and immediate effects on it. To assess if this is the case, it is necessary to consider the GR instrument's purpose and content:

– The GR instrument has two main aims: (i) to enhance efficacy, transparency, and quality of the patent system and (ii) to prevent patents from being erroneously granted. These objectives are intended to further promote and facilitate fair and transparent commercial transactions. This is buttressed by recital 4 of the proposal stating that the disclosure obligation at the heart of the GR instrument contributes to legal certainty and consistency, and therefore benefits the patent system. Furthermore, applying uniform standards in this area, by introducing a common disclosure requirement, contributes to the participation of economic operators in

international trade on an equal footing. From all this, it could be understood that the aim of the GR instrument is to improve the efficacy, transparency, consistency and legal certainty of the patent system, thereby promoting, facilitating and governing international trade. The current state-of-play must also be taken into account, as well as possible developments in this area. To this end, the GR instrument includes a review clause that could extend the instrument's scope to other areas of intellectual property law, which would have further effects on international trade.

– Furthermore, it should be assessed whether the GR instrument's key provisions could be regarded as affecting patent protection so much that it would have direct and immediate effects on international trade. In this context, the requirement to disclose the origin of genetic resources in Article 3 of the GR instrument applies to the patent granting procedure and will therefore affect the results of an assessment of compliance with the substantive patentability criteria of novelty and inventive step, which are provided for in Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ('the TRIPS Agreement'), in terms of the relevant prior art to be considered. In this regard, the Court of Justice of the European Union has ruled that Article 27 of the TRIPS Agreement falls within the field of the common commercial policy[2]. Also relevant is that the current wording of Article 6.4 on sanctions and remedies appears to permit the imposition of post-grant sanctions in the case of non-compliance with the disclosure requirement under Article 3 due to fraudulent intent. These could include revoking a patent or rendering it unenforceable. This provision can be considered to establish new grounds for challenging the validity of a patent involving genetic resources, which could be used in patent disputes.

Under Article 3(2) TFEU, the EU has exclusive competence to conclude an international agreement, as long as the agreement in question may affect common EU rules or alter their scope if the commitments concerned relate to an area already covered to a large extent by such rules (without the areas covered by the rules and those the commitments pertain to having to be identical). An analysis done under Article 3(2) TFEU must take into account (i) the areas covered by the rules of EU law and the provisions of the envisaged agreement, (ii) their foreseeable future development and (iii) their nature and content to determine if the agreement is likely to undermine the uniform and consistent application of EU rules and the proper functioning of the system resulting from them. There are various pieces of EU patent law, whose relevance to the GR instrument should be assessed, in particular, Directive 98/44/EC on the legal protection of biotechnological inventions (the Directive 98/44/EC), Regulation (EU) No 1257/2012 implementing enhanced cooperation in the area of the unitary patent protection (the UP Regulation), Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products, Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products and Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products (the SPC Regulations).

– As regards Directive 98/44/EC, the relevant provisions concerned by the GR Instrument are: (i) Article 2(1) stating that 'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced

[2] Judgment of the Court of 18 July 2013, Daiichi Sankyo, Case C-414/11, EU:C:2013:520.

in a biological system, (ii) Article 13, stating that 'where an invention involves the use of or concerns biological material that is not available to the public and which cannot be described in a patent application in such a way as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered inadequate for the purposes of patent law unless: … (b) the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited',(iii) recital 27 stating that 'Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.' Under the provisions of the Directive 98/44/EC, the application as filed should provide the relevant information on the characteristics of the biological material deposited, which may include genetic resources. However, at present, omitting information on the geographical origin of said material does not make its description inadequate, nor does it otherwise prejudice the processing of applications or the validity of rights arising from granted patents. In this sense, including recital 27 in Directive 98/44/EC points to the legislator's intention that the issue of disclosing geographical origin of biological material is to be covered by the Biotech Directive. Moreover, Article 13, read in conjunction with recital 27, implies that the disclosure of the geographical origin of biological material is not relevant for examining the sufficiency of disclosure of inventions, where the deposit system is used for describing such inventions. As stated above, the GR instrument introduces, among other things, a requirement to disclose the origin of genetic resources in patent applications (Article 3), as well as the possibility for the parties to impose sanctions and remedies if this requirement is not fulfilled (Article 6). From this, it is clear that the outcome of the GR instrument negotiation could affect the principles set up in Directive 98/44/EC.

– As regards the UP Regulation, the conditions for the validity of a unitary patent, which as an object of property is to be treated according to applicable national law (Article 7 of the UP Regulation) will be affected by diverging national implementation of Article 6 of the GR instrument on post grant sanctions and remedies. This would result in the conclusion of the GR instrument affecting such common rules for 25 Member States under enhanced cooperation.

– Regarding the SPC Regulations: Supplementary protection certificates (SPCs) are intellectual property rights that make it possible to extend the patent protection of plant protection products and medicinal products subject to a marketing authorisation requirement. It can be presumed that their validity will be affected by the GR instrument's current wording, given the basic patent's revocation invalidates an SPC (Article 15 of the SPC Regulations). This means that any effects of the disclosure requirement on the validity of patents (in line with Article 6 of the GR instrument) will also affect an SPC. It is also important to consider the foreseeable future of the SPC system, in particular given the four legislative proposals the Commission presented on 27 April 2023. These proposals will replace the existing the SPC Regulations by new ones, for medicinal products and plant protection products respectively. Each will include the current national procedure as well as a new centralised procedure for the granting of national SPCs, available where the basic patent is a European patent, and the product has a market authorisation. Two additional proposals relate to the creation of unitary SPCs for medicinal products and plant protection products respectively.

Lastly, it is also important to consider the possible developments this area. The GR instrument includes a review clause that could result in its application being extended to other areas of intellectual property law, such as copyright and plant variety rights. In that respect, it will further affect EU law.

It results from the above that the GR instrument falls within the EU's exclusive competence under Articles 3(1) and 3(2) of the TFEU.

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 218(3) and (4) thereof,

Having regard to the recommendation from the European Commission,

Whereas:

(1) In their 2002 Communication to the Trade-Related aspects of Intellectual Property Rights Council (TRIPS Council), the European Union and its Member States agreed to discuss the introduction of a self-standing disclosure requirement allowing Member States to keep track of patent applications with regard to genetic resources,

(2) In 2004 the World Intellectual Property Organisation (WIPO) general assembly agreed, at the suggestion of the Conference of the Parties to the Convention on Biological Diversity to consider the relationship between access to genetic resources and disclosure requirements in intellectual property rights applications,

(3) Since 2004 WIPO has held discussions on the disclosure of the origin or source of genetic resources and associated traditional knowledge in patent applications,

(4) WIPO general assembly decided to convene a diplomatic conference to conclude an international legal instrument relating to intellectual property, genetic resources and traditional knowledge associated with genetic resources to be held no later than 2024,

(5) The European Union should participate in the negotiations on such international instrument,

HAS ADOPTED THIS DECISION:

Article 1

The Commission is hereby authorised to open the negotiation for an international legal instrument relating to intellectual property, genetic resources and traditional knowledge associated with genetic resources in the context of the World Intellectual Property Organization on behalf of the Union, in consultation with the Intellectual Property Working Party (the special committee).

Article 2

The negotiating directives are set out in the Annex to this Decision.

Article 3

This Decision is addressed to the Commission.

Done at Brussels,

For the Council
The President