National Group: Denmark

Independent Member:

Date: 9 December 2016

Questions

The Groups are invited to answer the following questions under their national laws:

1) Is there a legal requirement in your country that the source and/or country of origin of GRTK must be indicated in patent applications for inventions based on GRTK (***Disclosure Requirement***)?

Yes, Denmark has implemented the requirements found in EUs so-called Biotech-Directive (i.e. DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions).

If yes, please: (i) indicate whether this legal requirement was introduced after 2010 or, if introduced prior to 2010, whether there have been substantial amendments since 2010; (ii) provide concise quotes of the corresponding text from the laws or regulations or a concise summary; and (iii) reply to the following questions a) to j).

(i) This legal requirement was introduced in 2000, by Order 1086, 11/12/2000 in connection with the changes of the Patent Act following the Biotech-Directive (supra point 1), see Danish Patent Act No. 412, 31/5/2000, amending the Patent Act (Consolidated Patent Act 926, 22/9/2000).

(ii) The current version of the rule is found Section 3 in the Order on Patents and Supplementary Protection Certificates No. 25, 17/1/2013 which reads like this:

(5) If an invention relates to or makes use of a biological material, the patent application shall contain information about the geographical origin of the material if the applicant is aware thereof. If the applicant is not aware of the geographical origin of the material, that shall appear from the application. Lack of information about the geographical origin of the material or about the applicant's non-awareness thereof shall not affect the examination and other processing of the patent application or the validity of the rights conferred by the granted patent.

a) Is the Disclosure Requirement found in patent law (including utility model law, plant variety protection law or design law), general IP laws, in legislation implementing the CBD or the Nagoya Protocol, or any other (and if so, what) sources of law?

The Disclosure Requirement is found only in patent law.

b) What "triggers" the Disclosure Requirement, i.e. what relationship between the invention and the GRTK is required?

If the invention relates to or makes use of the GRTK.

c) Is it clear what the concepts of "source" or "country of origin" or "country providing the resource", and "based on genetic resource/traditional knowledge" or "derived from biological resource and associated traditional knowledge" mean, and what information must be included in the patent application?

As stated above the application should name “the geographical origin of the material”.

The Order uses the wording found in the Biotech-Directive and contains no definitions. For this reason, a number of general issues have not been solved and e.g. identifying the origin of material derived directly from *ex situ* biorepositories may be uncertain.

The applicant has to include the geographical origin of the material, if the applicant is aware of the geographical origin. If the applicant is not aware of the geographical origin, but the invention relates to / makes use of biological material, the applicant has to state in the application that the geographical origin is unknown.

d) Is the Disclosure Requirement limited to GRTK of your country or is it applicable also to GRTK obtainable from other countries or geographical regions?

The Disclosure Requirement is applicable to GRTK of all geographical origins.

e) Is disclosure of PIC ("prior informed consent") and/or agreements on "fair and equitable benefit-sharing" required?

No.

f) Are human genetic resources treated differently or the same way as animal or plant genetic resources?

Similar rules (also derived from the Biotech-Directive) are applicable to human genetic resources, with the additional requirement of adding whether the person from whom the biological material originates has given consent.

Section 3 in the Order on Patents and Supplementary Protection Certificates):

> *(6) If an invention relates to or makes use of a biological material of human origin, it shall appear from the patent application whether the person from whom the biological material originates has given his consent to the filing of the application. The information about consent shall not affect the examination and other processing of the patent application or the validity of the rights conferred by the granted patent.*

g) Is "traditional knowledge" separately defined, and is the source of traditional knowledge to be indicated only if it is connected to genetic/biological resources or in general?

No.

h) Are there sanctions for non-compliance (e.g. patent invalidation, revocation or lack of enforceability, patent transfer to the owner of the resource, fines, criminal sanctions etc.)? If yes, please briefly describe any applicable sanctions.

There are no sanctions in patent law. In particular non-compliance cannot be held against the patent's validity, see Section 3 , Order on Patents and Supplementary Protection Certificates excludes sanctions for non-compliance:

> *(5) If an invention relates to or makes use of a biological material, the patent application shall contain information about the geographical origin of the material if the applicant is aware thereof. If the applicant is not aware of the geographical origin of the material, that shall appear from the application.* ***Lack of information about the geographical origin of the material or about the applicant's non-awareness thereof shall not affect the examination and other processing of the patent application or the validity of the rights conferred by the granted patent.***

Anyone who provides false or misleading information to a public authority (such as the DKPTO) may in principle be liable for imprisonment, see Section 162 of the Penal Act. Whereas the rules in the Patent Act on the geographical origin are in principle covered by these provisions, we are not aware of any examples of their application.

i) Is there any ability to amend the relevant text in the patent application after filing to address non-compliance?

There is no requirement for amending the text of the patent application, cf. the above.

j) Is any Disclosure Requirement limited by reference to whether access occurred prior to a particular date, e.g. prior to the date of entry into force of the CBD?

Not mentioned.

The following questions 2) to 14) deal with the effects of the Disclosure Requirement and aspects of the Nagoya Protocol, and the experiences of applicants (and representative of applicants) with those requirements. These questions should be answered by all National and Regional Groups and Independent Members to the extent applicable.

2) Please indicate your experience with the application of the Disclosure Requirement when filing and prosecuting patent applications in your country.

No experience.

3) Please give statistical data on the number of patent applications mentioning source and/or country of origin of GRTK in your country. Is there a specific section of the patent register listing patents and patent applications comprising information on source or country of origin of GRTK? If such data are not available, please give an estimate of the number of such patents and patent applications and indicate the basis of the estimate.

There is no specific section of the patent register listing patents and patent application comprising information on source or country of origin of GRTK.

Other relevant statistics:

Biotechnology makes up 10,24% of all patent applications in Denmark.[1]

The number of total applications for patents in Denmark, including the number of total applications that are defined as "Biotechnology" and "Analysis of biological materials", between 2013 and 2015 (after the Disclosure Requirement came into force in Denmark)[2]:

2013: 1.534 (16)

2014: 1.583 (17)

2015: 1.732 (15)

4) Please indicate whether administrative or judicial decisions on the application of the Disclosure Requirements is available. If yes, please provide a concise summary (or a link to an on-line version) of such decisions.

None as far as we know.

5) Please provide an estimate per patent application of the additional (a) time and (b) cost in legal fees associated with compliance with the Disclosure Requirement in your country.

No experience.

6) Please provide an estimate of the additional time and cost as described in question 5) associated with compliance with any foreign Disclosure Requirement.

Not possible.

7) Has the Disclosure Requirement had an impact on patent valuation (either increasing or decreasing the perceived value of a patent) in your country?

[1] WIPO Statistical Country Profile "Denmark", accessible via: <http://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=DK>

[2] Danish Patent and Trademark Office, 'National Patent Filings', accessible via: < http://www.dkpto.org/media/23032611/statistics%20english%20patent%202015.pdf>

Not to our knowledge.

8) Has the Disclosure Requirement had any effect on R&D activities in your country, e.g., a change in the number of patent applications for inventions in biological technology fields, or an increase or decrease of such activities using biological materials such as plants, animals and microorganisms, etc. from either your country or other countries due to the ease or difficulty of obtaining PIC or MAT ("mutually agreed terms")?

As seen in the statistics under 3, the total number of applications after the Disclosure Requirement came into force has increased a bit. This increase does not show in the number of specific Biotechnology applications, which has remained stable.

The number of Biotechnology and Analysis of biological material applications has in fact been stable for the entire period 2006-2015 (varying between 12 and 19).

9) Are you aware of any benefits or disadvantages, including for third parties, of the Disclosure Requirement in your country? For example, has the Disclosure Requirement improved patent examination, or led to the sharing of financial or other benefits?

No.

10) As a source country or country of origin, does your country have any legal system and/or administrative authorities or agency to provide any type of certificate to provide proof of the source and/or country of origin of GRTK? If yes, which ministry or authority is responsible? Please include also links to websites which would allow accessing information and contacting the responsible local authorities.

Yes, the Danish Nature Agency, see http://eng.naturstyrelsen.dk/.

11) The following questions relate specifically to the Nagoya Protocol.

a) If your country has not (yet) implemented the Nagoya Protocol, please indicate this.

b) The Nagoya protocol stipulates ABS ("access and benefit sharing"). In your country, is there any impact on intellectual property protection and/or enforcement if ABS is not satisfied?

c) The Nagoya Protocol also stipulates PIC ("prior informed consent"). In your country, is there any impact on intellectual property protection and/or enforcement if there is any failure or defect in PIC?

d) The Nagoya Protocol also stipulates MAT ("mutually agreed terms"). In your country, is there any impact on intellectual property protection and/or enforcement if there is any failure or defect in MAT?

Denmark implemented the Nagoya Protocol by Act 1375, 23/12/2012 which entered into force on October 12 2014, see Order 1101, 6/10/2014 and Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union Text with EEA relevance.

There are not as of yet any experiences with neither Act nor Regulation in Denmark.

An unofficial translation of the Danish bill on sharing benefits arising from the utilisation of genetic resources, is available at:

https://www.cbd.int/doc/measures/abs/post-protocol/msr-abs-dnk-en.pdf .

12) Academic research often involves GRTK. Are there any special regulations and/or measures for academics and/or academic institutions such as universities to protect and promote the protection and development of GRTK?

Not that we are aware of.

13) "Traditional medicine" may fall within GRTK. Information relating to traditional medicine is generally not found in the literature or in other written form in the public domain. Does your country permit patent or any other form of intellectual property protection in relation to traditional medicine? If yes, does your country have any specific legislation or examination practice for the protection of traditional medicine? Please include links to websites dealing with these practices or legislation, if appropriate.

Danish law contains no special rules on Traditional medicine.

14) Have there been any authoritative studies in your country on the impact of the Nagoya Protocol? If yes, please provide author(s), title, and information where such studies can be found.

No.

Procedure

It would be most helpful if the National/Regional Groups / Independent Members would fill out the Questionnaire and send their answers to the General Secretariat of AIPPI (**StandingCommittees@aippi.org**) by **17 October 2016.**

For inquiries please contact: Konrad Becker, Chair of the Standing Committee on IP and Genetic Resources / Traditional Knowledge (konrad.becker@bluewin.ch), Maria Carmen de Souza Brito, the next Chair of the Standing Committee on IP and Genetic Resources / Traditional Knowledge (mcarmen@dannemann.com.br), and Catherine Mateu, Chair of the Standing Committee on TRIPS (c.mateu@armengaud-guerlain.com).