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Industry needs for new legislation for IPR/IPP

Work Package 3

Interactions with industry

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EXECUTIVE SUMMARY

In matters concerning IPR/IPP, the careful conclusion was drawn that if there are specific issues for marine biotechnology they relate to the jurisdiction connected to Access and Benefit Sharing (ABS) of raw material. For the remaining part of the marine biotechnology area the technical issues related to IPR/IPP can be considered similar to other biotechnology production.

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ABBREVIATIONS

ABS	Access and Benefit Sharing
CBD	Convention on Biological Diversity
EPO	European Patent Office
IPP	Intellectual property protection
IPR	Intellectual property rights
MBT	Marine Biotechnology
USPTO	United States Patent and Trademark Office

INTRODUCTION

This report details the work covered in part 2 of "Task 3.1 - Industry / Science interactions" in the project Marine Biotechnology ERA-NET (ERA-MBT). In the Description of Work (DoW) for the task, the following is specified for deliverable 3.2:

Potential specific industry / science needs for new IPR/IPP legislation and regulation for uptake of MBT results and technologies will be investigated.

To answer this, the following means were used:

1. In the project, a questionnaire was sent to group of MBT stakeholders including questions related to IPP/IPR legislations and regulations
2. Results from the MBT questionnaire were compared to survey made by DG-Mare (Directorate-General for Maritime Affairs and Fisheries) of the European Commission
3. Interviews with selected MBT stakeholders and people in the IPP/IPR "industry"
4. By attending to "The 8th Berlin Conference on II in Life Sciences: Natural Products" held the 27th of February 2015.

BACKGROUND FOR KNOWLEDGE PROTECTION

Protection of knowledge is an issue that comes up immediately as soon as research results are suggested for commercial exploitation, or good ideas are proposed for economical benefits.

The biodiversity in the marine biosphere is expected to be a rich resource for inventions derived from biological products originating from marine organisms. The biotech industry, including marine biotechnology, has for decades been seeking patent protection of natural products guided by the patentability of the corresponding subject matter according to the IPR legislature and the general praxis of corresponding patent office's such as the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO). This includes patents for isolated genomes and specific genes, gene products, such as enzymes, metabolites and various other substances and molecules including potential drug candidates. Biotech companies often work on a global market but protection through patents is very fragmented, where it is necessary to apply for patent in each country, which multiplies costs and efforts in order to get broad coverage globally. Any actions, through new legislation or otherwise, that reduce the cost of seeking protection through patent applications would be highly beneficial for the biotech industry and favour SMEs and start-up companies.

Since descriptions of inventions become public during the process of patent application, the uncertainty of patentability, strict requirements and high cost of pursuing protection of

biotechnology inventions through patents makes many companies opt for an alternative approach; to keep details of inventions secret and non-public.

Above are general conditions. The question that was aimed at to answer in this report, is if there are special IPR/IPP circumstances connected to marine biotechnology that need attention. The ERA-MBT questionnaire was considered a good opportunity to ask the stakeholders if this could be the case. Further to the results obtained, a comparison is made with the DG MARE study, and follow-up, qualitative interviews with selected stakeholders were performed.

MAPPING OF IPP/IPR MATTERS WITHIN THE MBT ENVIRONMENT

MAIN FINDINGS FROM ERA-MBT QUESTIONNAIRE

A questionnaire was presented on the ERA-MBT webpage and sent by direct mail to more than 900 stakeholders. A total of 127 responses were received within the deadline set. The responses were from 24 countries whereof 94% of these responses originated from European entities. The question on IPP/IPR issues in the survey was: "Are there specific technical IPR/IPP issues for marine biotechnology?"

The ERA-MBT survey did not give any clear indication of MBT specific IPR/IPP issues. Most respondents (22) giving a YES to the question of if there are MBT specific IPR/IPP issues also gave a verbal comment. These were very general, quoting 'uncertainty in IPR/IPP questions', 'unclear legal aspects', 'fuzzy rules concerning the property of the bio-resources', etc. indicating that the European MBT industry might need some "education" on the matter.

Most common responses were on specific problems related to the Access and Benefit Sharing (ABS). The concept of ABS is an objective within the Convention on Biological Diversity (CBD) which seeks to ensure sharing of benefits arising from genetic resources. Some stakeholders participating in the survey mentioned the Nagoya protocol, a supplementary agreement to CBD that provides a legal framework for implementing of the objective on benefit sharing. Such comments on CBD, ABS and Nagoya matters were thus concerned with the raw material and not the wider consideration of marine biotechnology per se.

In general, not much new knowledge surfaced in the answers to this question.

The results can be divided into 3 main categories:

1. ABS / Nagoya and related issues: 12
2. Don't care/don´t know: 4
3. Other: 6

As the answers given by the total population of the survey only gave an indication that there would not be any specific IPR/IPP issues for marine biotechnology (55.3 vs. 44.7%), it could be tempting to have a look at what producing companies answered to the question. Of the 27 respondents being from companies providing specific products being marketed, 16 voted NO to the question, 9 voted yes, and 2 did not answer the question. This gives a score of 64% saying NO and 36% saying YES among the respondents who answered the question. This strengthens the assumption that there are no specific technical IPR/IPP issues for marine biotechnology, still as the number of responses are limited no clear conclusion can be drawn.

COMPARISON WITH DG MARE STUDY

DG MARE made a similar survey containing a questionnaire on some of the issues also raised in the ERA-MBT survey including some on IPP/IPR Issues. The results are published in the publication "Study in support of impact assessment work on Blue Biotechnology". Further referred to as the 'DG MARE study' in the following.

In the DG MARE survey it was stated that regarding intellectual property rights there 'are common challenges for technology sectors including other biotech sectors', but 'these questions are not restricted to the Blue Biotechnology sector'. Also that, 'even if there was an obvious solution to these issues – which there is not – it would clearly not be feasible in to seek to modify Intellectual Property (IP) law just to serve the needs of the Blue Biotechnology sector'.

The DG MARE survey further emphasises under the regulatory review that access and benefit sharing is an area that should be given much more attention in the future.

INTERVIEWS WITH SELECTED STAKEHOLDERS

A qualitative survey was conducted to get more information by discussing with MBT companies and people in the "patent-industry" that have know-how and experience in applying for patents in both Europe and USA. In total four Icelandic MBT companies were contacted all selling their products abroad Iceland. Within the "patent industry" people from four different locations were contacted; at a legal office working with patents in the field, the Federation of Icelandic Industries, the Icelandic Patent Office (IPO) and at the European Patent Office (EPO). In the interviews the following two questions were asked:

1. What are the main problems related to IRR/IPR matters for the MBT industry
2. Are there any specific IPP/IPR problems for the marine biotechnology industry that does not apply for other biotechnology industries?

According to the interviews, there is an indication that there is no specific need for new legislation in the field of Marine Biotechnology but there are some general problems that are common with other biotechnology companies, which want to protect their intellectual properties. Those problems are mainly in relation to the cost and complexity of applying for patents. The new legislation that is taking force in the EU, Unitary patents and the European patent court will be a great step forward in this aspect. (www.epo.org (EU) No 1257/2012 and No 1260/2012). Ratification by the 25 member states is ongoing and has already been accepted by Belgium, Austria, France, Sweden, Denmark and Malta. When this has been implemented it´s not necessary for companies to translate their patent applications in several languages and there is one court for the whole union.

Some participants that were interviewed named the US supreme court decisions from 2013 in the cases of Association for Molecular Pathology vs. Myriad Genetics, Inc. USPQ2d 1972 and Mayo Collaborative Services vs. Prometheus Laboratories USPQ2d 1961 as problem in the field. Based on those decisions the USPTO guidelines for patent-eligibility have fundamentally changed such that subject matter not significantly different from naturally-occurring substances, including genes and

proteins, whether isolated or not, are not patent-eligible. Although the Supreme Court decision regarding claims in Myriad patent was limited to human DNA sequences the new USPTO Interim Guidance Document on March 4, 2014 included the non-eligibility of a broad range of naturally occurring matter. The 16th of December 2014 USPTO published a new Revised Guidance Document. Already the day after, December 17 2017 a new Federal Circuit Decision was issued named Myriad II that made the newly revised Guidance Document out of date. New Guidance has not been published. Others stakeholders that were interviewed said that the Myriad decisions only affected how the patents would be written – that it was possible to "write around it". Whereas the new guidelines have not been published this matter is still unclear.

CONCLUSION

A careful conclusion could be drawn that the main IPR/IPP issues for marine biotechnology relate to the jurisdiction connected to the ABS of raw material. For the remaining part of the marine biotechnology area the technical issues related to IPR/IPP can be considered similar to other biotechnology production. New legislation is under way in Europe that might make it easier to protect knowledge and particularly file patents.

The main conclusions, from the interviews and the questionnaire:

1. The Marine Biotech Industry does not anticipate specific needs for new legislation for IPR/IPP
2. The new IPR legislation that is being implemented in EU will both simplify the patent process and may reduce the cost for protection. This will possibly lead to more emphasis on IP protection in the marine biotechnology area.
3. It is important to "educate" MBT companies about Intellectual properties issues.

FUTURE ASPECTS

The Nagoya Protocol that entered into force on 12 October 2014, is now in an implementing phase in EU and final draft by the EU Commission is expected in October 2015.

The Nagoya Protocol makes it illegal to perform R&D on a genetic resource that has not been accessed in accordance with the Nagoya Protocol. Biotechnology companies and researchers question that the Nagoya protocol will have the positive effect that it was intended to have by encouraging sustainable, equitable, use of biodiversity and instead lead to less use of natural products and hold back development in the biotechnology sector (Goldsmith, 2015). Even though the Nagoya protocol is self does not make any specific reference to the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) or intellectual property rights, some countries have included it or similar in their national patent laws. For example in Switzerland it´s obligatory that patent applications contain information of the genetic resource it directly relies on (Morgera et al, 2012). Brazil and India are another examples (IEEP, Ecologic and GHK, 2012).

It should be taken into account that the Nagoya protocol does not cover the use of marine genetic resources from areas beyond national jurisdiction. Whereas the open oceans and deep seas represent 95 percent of the global biosphere in volume and the sea is around 70% of the earth's area whereof around 60% is beyond national jurisdiction – it´s obvious that large part off the future world marine biotechnology raw materials are not covered by the Nagoya protocol.

The United Nations have a "Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction" also referred to as the "BBNJ working group" where BBNJ is short for "Biodiversity Beyond National Jurisdiction". It is important for the marine biotech industry to actively follow the work of the group to ensure that their views are taken into account and that the problems that the field has with the Nagoya protocol are not repeated in the work of the BBNJ working group.

It has been proposed to liaise work of ERA-MBT with DG MARE on a technology transfer workshop in the margins of what is called the Blue Economy Business and Science Forum. As one of the topics for such a workshop is to examine the differences in patenting rates among EU countries. Apart from a specific workshop as described, it could be of interest to initiate a network among industry stakeholders having interest in IPP/IPR questions.

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