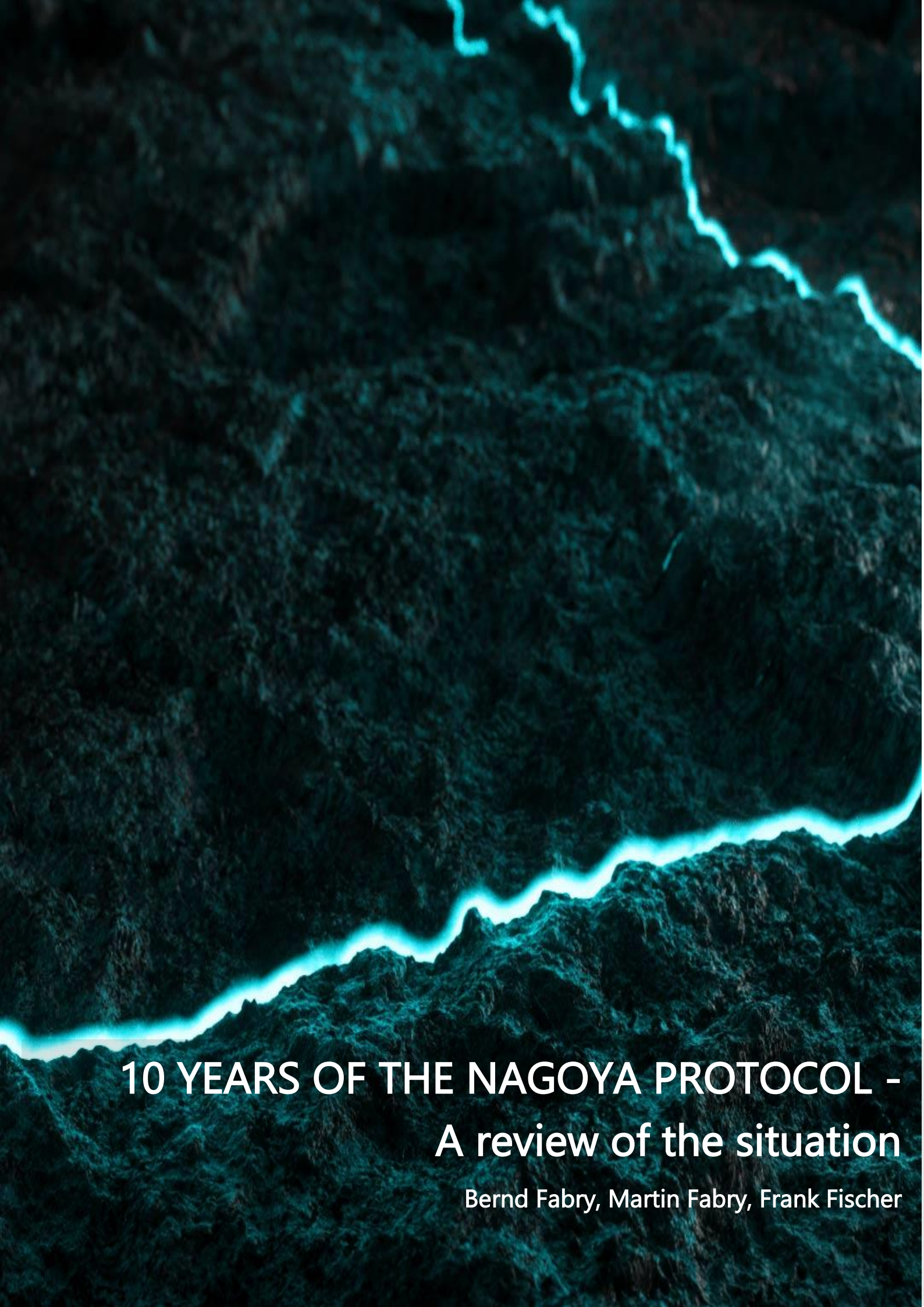

10 YEARS OF THE NAGOYA PROTOCOL - A review of the situation

Bernd Fabry, Martin Fabry, Frank Fischer

10 years of the Nagoya Protocol

A review of the situation

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10 years after the Nagoya Protocol entered into force, the balance sheet is sobering. Despite a comprehensive set of rules, only a fraction of the money that was hoped for has reached the provider countries of genetic resources and traditional knowledge.

What remains is the implementation of the Nagoya Protocol into national law, which varies greatly. The EU regulation also specifies which exceptional circumstances may exist that do not require such self-disclosure. Critical for the future will be whether access to digital sequence information is also to be considered as use under the Nagoya Protocol or not.

By **Bernd Fabry**[a], **Martin Fabry**[b], **Frank Fischer**[c]
a) IP[2] Patentanwalts GmbH, Mönchengladbach (DE)
b) IP[2] Management Ltd, Cambride (UK)
c) Dannemann, Siemsen Bigler & Ipanema Moreira, Sao Paulo (BR)

Dr. Bernd Fabry

is German and European Patent Attorney and Managing Director at IP2 GmbH in Mönchengladbach.

He has decades of experience in the area of IP strategy and is author of the book “Patent Infringement Worldwide”. Since years, Bernd Fabry counts to the IAM 300 most recommended IP strategy attorneys world-wide.

Introduction

Scientific research dealing with the study, modification and use of biological material, and specifically with the genome of plants, animals and humans, takes place largely behind closed doors. In fact, in the vast majority of cases, the public would not notice the fruits of this work until a corresponding sales product is on the shelf.

However, NGOs in particular, but also various government agencies that are critical of some of these developments at best, have found an early indicator that could not be better created: Patent applications. Of course, no research company is going to invest sometimes insane amounts of money in a development without it being adequately protected against unauthorized imitation. From the perspective of patent owners, however, it is regrettable that the

resulting patent applications are disclosed, i.e., made available to the public, as early as 18 months after the filing date. The whole thing therefore happens well before the time when research can provide a marketable product.

Today, it is comparatively easy to find new disclosures through free online searches at the patent offices, either by entering the applicant or a search term. If a manufacturer finds that his development product is denied patent protection - either in opposition proceedings before a patent office or in nullity proceedings before a court - and that imitation is thus possible for any third party free of charge and free of third-party rights, many a research project comes to an abrupt end.

Biopiracy and the international measures taken against it, which led first to the Rio Convention in 1992 and then to the so-called Nagoya Protocol in 2014, are among the hot topics that are sure to attract a great deal of media attention. This paper looks at the situation 10 years after the ratification of the Protocol by 140 member states with regard to access to and protection of genetic resources and traditional knowledge based on them, and what this means for patent applicants.

Martin Fabry PhD

is Patent Associate and Managing Director at IP2 Ltd in Cambridge.

Martin started his PhD in Medical Sciences with Cancer Research UK at the University of Cambridge. After graduation he worked as postdoctoral fellow in computational biology at the Gurdon Institute and European Bioinformatics Institute (EBI) in Cambridge with focus on stem cell development and establishing new technologies for stem cell differentiation.

Basmati: the sin of biopiracy?

With more than 3.2 million square kilometers, India is the seventh largest country on earth and is preparing to replace China as the most populous country on this planet. It is estimated that the subcontinent has more than 5,000 animal species on land and in its waters; no one has yet attempted to determine the number of plant species. Thus, India is blessed with a gene pool that is roughly comparable in the world; only Brazil may be able to keep up. It is therefore no surprise that the existing genetic reservoir aroused the appetites of large pharmaceutical companies decades ago, which have made use of these resources, both robustly and unlawfully, to create "new" products from them for the benefit of mankind and its shareholders, in particular "new" foods and medicines. Many of us still remember the images from the 1990s, when so-called scouts roamed the jungles and collected whatever animals and plants they

could get their hands on. The centuries-old Indian knowledge of shamans and medicine men was deliberately tapped and the basis for industrial developments and enormous money flows was created, which benefited only the industrialized nations; for the countries whose resource sources were exploited, at best crumbs remained[1]. On the other hand, verbal cudgels such as the catchword "neo-colonialism" are not very helpful to objectify the sometimes very emotional discussions.[2]

Not the first, but certainly the most prominent example of what appears at first glance to be a particularly brazen case of biopiracy occurred in 1997, when the US Patent Office granted the American company RiceTec Inc a patent on a rice plant that was characterized, among other things, by structural features such as the starch index and the content of 2-acetyl-1-pyrroline in the grains (US 5,663,484). The starch index in particular was of importance here, as it had been identified as a parameter for how the rice behaved during cooking. Following this observation, RiceTec had then produced, through selection and breeding, new varieties that were superior to the known basmati rice varieties, according to the applicant. The cross consisted of one of 22 specified known basmati lines and at least two of the 15 known semi-dwarf long grain varieties, which are listed in the International Rice Research Institute (IRRI) databases as distinct, i.e. distinguishable from each other, and therefore notably not wild varieties.

The patenting triggered a wave of indignation in India and was soon treated as a violation of national pride, since basmati rice had been cultivated at the foot of the Himalayas thousands of years ago. In particular, the granting of the patent was seen not only as an inadmissible exploitation of the biological heritage of Indian farmers, but also as an import ban on Indian exports to the USA, which at that time amounted to a good 350 MUS$. Last but not least, it was also a case of misleading the consumer, since the RiceTec products were

Frank Fischer

is Brazilian Patent Attorney and Partner at Dannemann Siemsen Bigler and Ipanema Moreira.

He has decades of experience in Brazilian patent law and counts since years to the IAM 1000 most recommended patent attorneys worldwide.

[1] J.M.Finger, P. Schuler, „Poor Peoples Knowledge", World Trade Bank Report, S. 159-207 (2004), ISBN 0-8213-5487-6

[2] J. McGown, „Out of Africa", Edmonds Institute (2006) ISBN 1-930169-49-3

not Basmati rice from India and the US products were of a different quality.[3]

The patent was challenged by the Indian government in a nullity suit in 2020, after the Research Foundation for Science Technology (today: NA-VDANYA) had already asked the Supreme Court - which had no jurisdiction at all - to revoke the patent protection.

But the case was not that simple.

At that time, the question of whether this was a case of biopiracy was irrelevant, as there were no legal barriers to protection[4]. Nevertheless, RiceTec had overshot the mark in its legitimate efforts to obtain protection for its new varieties. Instead of protecting only the relevant varieties (claims 8, 9, 11-13), protection was claimed - in good patent attorney fashion - for all rice varieties possessing certain structural and functional characteristics, which - accidentally or deliberately - also included the new varieties. In the re-examination process, the patent was therefore finally limited to the claims that were directed to the new varieties. These are still sold today by RiceTec under the names "TEXMATI" or "American-Style Basmati Rice". [5]

The long road from the Rio Conference to the Nagoya Protocol[6]

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[3] BASMATI is now protected as a word or figurative mark in much of the world; the owner is the Indian Agricultural and Processed Food Products Export Development Authority (APEDA) , e.g. US 88312496, but is in opposition proceedings.

[4] In fact, this is still true today, as the U.S. has not signed the Nagoya Protocol.

[5] This was not the first case of alleged or actual biopiracy in India: for example, a patent (US 5,401,504) on turmeric in its use as a wound treatment was granted to two Indian-born researchers, Suman K. Das and Hari Har P. Cohly of the University of Mississippi, in March 1995. The Indian Council for Scientific and Industrial Research (CSIR) then filed a nullity suit on the grounds that turmeric has been used for thousands of years to treat wounds and rashes and that the claimed therapeutic indicia is not novel. In doing so, the CSIR relied on an ancient Sanskrit text published as early as 1953 in the Journal of the Indian Medical Association. The USPTO subsequently cancelled this and other patents related to turmeric.

[6] Glossary:
ABS = Access and Benefit Sharing
CBD = Convention for Biodiversity

On June 5, 1992, the United Nations Conference on Environment and Development adopted the UN Convention on Biological Diversity (CBD, also known as the "Rio Convention"). Article 15 of the CBD for the first time required the respective nation states to establish a system that

o grants access to genetic resources on the basis of mutually agreed conditions; or

o grants access on the basis of prior informed consent; and

o ensures the equitable sharing of benefits arising out of the utilization of genetic resources.

In connection with the creation of national regulations to ensure the obligations of equitable benefit-sharing, interventions in the national patent regulations have been demanded, especially by countries known for their biological wealth, namely the indication of the origin of the genetic resources included in a patent as part of the patent application. In the view of these countries, this indication of origin was intended to prevent "biopiracy". In addition, it was seen as a means of monitoring compliance with national laws and obligations to share benefits.

The EU Commission had also initially sympathized with the requirement of indications of origin in patent applications, but then saw no current need for action. AIPPI, on the other hand, considered contractual regulations to ensure prior information and consent for access to and use of genetic resources to be imperative. In this context, there was also an explicit call to designate statutory bodies to regulate access to these resources. [7]

At the subsequent United Nations Conference on Biological Diversity, held in Bonn in 2008, a further decision in principle was taken on biopiracy: Binding regulations on the use of natural resources from poorer countries and their share of profits were to be created by 2010. These were finally adopted on 29 October 2010 at the 10th

COP = Conference of the Parties
DSI = Digital Sequence Information
PIC = Prior Informed Consent
MAT = Mutually Agreed Terms

[7] AIPPI, Jahrbuch 2001/II, S.445-446 (Q159)

Conference of the Parties to the UN Convention on Biological Diversity, which was attended by 193 states, with the Nagoya Protocol. After 50 states and the EU ratified the protocol on July 14, 2014, it entered into force 90 days later on October 12, 2014.

The content of the Nagoya Protocol

The Nagoya Protocol is part of the Biodiversity Targets (also called "Aichi Targets") formulated for the period until 2020, which should define the framework for the conservation and sustainable use of biological diversity. The agreement specifies in particular Article 15 of the CBD with regard to access to genetic resources and the fair and equitable sharing of benefits arising from their use ("Access and Benefit Sharing" (ABS)). The provisions of the Convention also apply to traditional knowledge, which can be regarded as "the sum of know-how, skills and practices developed, maintained and transmitted from generation to generation within a community and in a traditional context. However, there is as yet no internationally valid definition.

With regard to access to genetic resources and the associated traditional knowledge, the agreement stipulates that national regulations must be adopted for this purpose. For this purpose, it is recommended to use the ABS Clearinghouse platform, where users can provide information on access and profit sharing.[8]

To a certain extent, the Nagoya Protocol represents the implementing provisions for the goals set by the CBD. However, the main addition is the requirement for all Parties to establish monitoring bodies to ensure that the use of genetic resources and traditional knowledge on their territory is carried out in compliance with the ABS regulations of the respective provider countries. Currently, 140 countries have ratified the Protocol (Fig. 1).

[8] [8] (https://absch.cbd.int/en/about/),

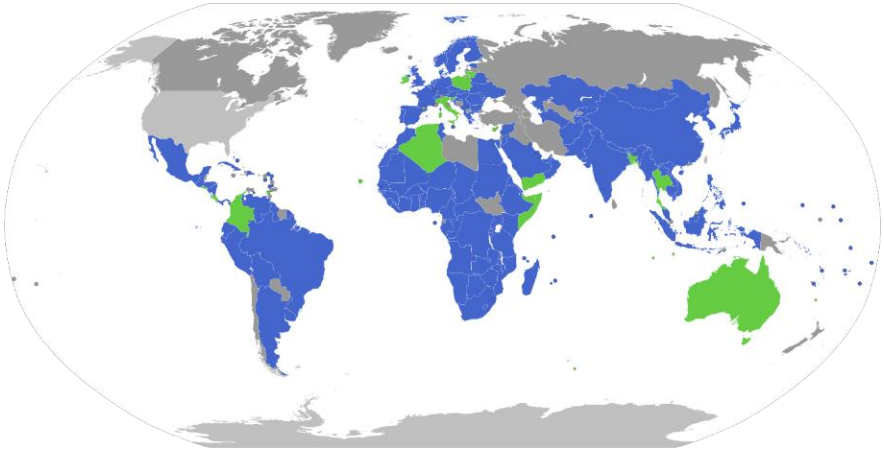

Fig.1 States Parties to the Nagoya Protocol[9]

The signatory states are marked in blue, the states that have signed but not yet ratified the agreement are marked in green, and the non-signatory states, which include the USA, Canada, and Russia, are marked in gray.

Implementation of the Nagoya Protocol in the EU

Regulation (EU) No. 511/2014 ("EU ABS Regulation") implements the control obligation under the Nagoya Protocol uniformly for all EU Member States. It has been in force since October 2014 and has been directly applicable in the member states since then.The regulation essentially prescribes the obligations of users of genetic resources in the EU and how these must be controlled by the member states.

However, the EU ABS Regulation only applies if the following criteria are met:

- The material used in the EU is genetic resources and/or traditional knowledge related to them;
- The use takes place within the meaning of the EU ABS Regulation;
- The use takes place in the EU;

[9] https://de.wikipedia.org/wiki/Nagoya-Protokoll#/media/Datei:NagoyaProtocol.svg

- The resources used are subject to the sovereign rights of a State that has ratified the Nagoya Protocol and has adopted appropriate access regimes;
- The access took place after the Nagoya Protocol entered into force (12.10.2014);
- The resources are not freely available through other multilateral regulation.

Furthermore, Art. 4 of the Regulation stipulates that users of genetic resources or traditional knowledge have to fulfill due diligence obligations. Corresponding declarations ("Due Diligence Statements") can be submitted, for example, via the online portal DECLARE of the EU Commission. Such a self-disclosure is thus obligatory under EU law and must be submitted both at the time the user receives external funding for the relevant research and when the final phase of product development from which the use results is reached. Each EU member state must establish monitoring bodies to verify compliance and set penalties for violations.

Implementation of the Nagoya Protocol in national law

All EU countries regulate access to genetic resources individually; the control obligations, on the other hand, are uniformly prescribed by the aforementioned EU Regulation. No. 511/2014 of 16.4.2014. By the way, the EPC does not provide any regulation for the implementation of the Nagoya Protocol and at present it is not expected that there will be any additional regulations in this respect.

Germany. Germany has transposed the Nagoya Protocol into national law, but has not enacted any further regulations. Thus, access to genetic resources is not dependent on the prior conclusion of an Access and Benefit Sharing (ABS) agreement with the country from which the resource originates, in which a Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) are agreed. Instead, the relevant provisions for Germany are those of the "Act on Obligations under the Nagoya Protocol" (NagProtUmsG) of 1.7.2016. According to § 6, the Federal Agency for Nature Conservation is responsible for

implementation, which has the following powers according to §§ 1(3) and 2(2):

- Inspection of documents
- Taking samples
- Carrying out inspections
- Seizures
- Prohibition of use.

The text of the law refers to the use of biological material as well as indigenous knowledge for research and industrial purposes and makes no reference to patent law. Furthermore, there is no provision for a voluntary obligation on the part of users to provide information, i.e. the powers presuppose that the BfN itself takes action and requests information. If this is refused, administrative fines of up to EUR 50,000 may be imposed (§ 4(3)). However, this does not mean that users are free to provide the relevant information or to refrain from doing so, since the EU ABS Regulation applies here as a higher-level law, which makes precisely this self-disclosure mandatory.

Neither the EU Regulation nor its implementation in national German law contains a specific reference to patent law. Section 34a PatG forms this bridge. According to this, a patent application should contain information on the geographical place of origin if the invention involves or uses biological material of plant or animal origin. If this is the case, the DPMA informs the BfN, which can then take action. The Patent Act also does not provide for any sanctions in the event that an applicant fails to provide the relevant information.

United Kingdom. In March 2015, the UK adopted the Nagoya Proto-col (Compliance) Regulations 2015 (Statutory Instrument 2015 No. 821) to implement EU Regulation No. 511/2014, which places enforcement of the EU Regulation in the hands of inspectors who also impose civil penalties for failure to comply with the EU Regulation's due diligence, record keeping, and due diligence and compliance statements. Any person guilty of such an offense may, if

convicted, be sentenced to a fine or imprisonment of up to two years, or both.

Switzerland. A similar situation is found in Switzerland. In December 2015, the Federal Council passed the "Nagoya Ordinance" to further implement use measures in the country. These measures require users to demonstrate, as part of due diligence, that genetic resources were accessed in accordance with the ABS regulations of the provider country. In addition, users must report compliance with this due diligence requirement to the Federal Office for the Environment when a product developed from genetic resources is marketed or receives marketing authorization. Users who violate these provisions face fines of up to 100,000 Swiss francs, and their products may not be approved.

India. In November 2014, new "Guidelines on Access to Biological Resources and Related Knowledge and Benefit Sharing Arrangements" were adopted before the Indian Biodiversity Authority. These outline the financial obligations of users for certain types of activities that must be included in ABS agreements, and specify how the fruits of development activities are to be shared with the government and the wider community. Under India's ABS regulations, any party seeking an intellectual property right related to the use of genetic resources inside or outside India must first obtain permission. Those who fail to do so face imprisonment of up to five years.

Brazil. On November 17, 2015, Brazil's Biodiversity Law (Federal Law 13.123) came into force. It aims to simplify the process for scientific research and facilitate commercial development by requiring the development and implementation of an electronic registration system for users.[10]

Under the provisions of said Law, which is further regulated by the Federal Decree No. 8,772/2016, published on May 11, 2016, establish rules for the access to genetic heritage samples and associated traditional knowledge with the intent to research or technological development. Both regulations substitute the Provisional Measure No. 2.186-16 of the year 2001 (preceded by the Provisional Measure

[10] B. Fabry, F. Fischer, Mitt. 2010, p 346 - 351 (Heft 7-8)

No. 2052 of the year 2000) at that point considered one of the first legislations related to the subject matter in the world.

According to the current rules any access to the Brazilian genetic heritage or associated traditional knowledge will have to be registered at the SisGen database (National System for Management of Genetic Heritage and Associated Traditional Knowledge). The activities that shall be registered at SisGen include:

- any natural person or national, public or private legal entity,
- the access made by any foreign entity associated or not with a national institution for scientific and technological research, public or private;
- shipment of genetic heritage component samples abroad with the purpose of access.

The registration shall be made prior to shipping or to the request of any intellectual property right, commercialization of the intermediate product, disclosure of results, final or partial, in scientific publications or in the media, or to the notification of finished product or reproductive material developed as a result of access.

Once a product is derived from said access, an authorization will have to be requested at the Executive Office of the National Council of Genetic Resources – CGEN, which is a collegiate body that is formed by members of the government and society with a deliberative, normative, consultative and appeals nature, responsible for coordinating the development and implementation of policies for managing access to genetic heritage and associated traditional knowledge and the distribution of benefits. As of the request for registration, an agreement establishing the sharing of the benefits will have to be filed within one year.

Generally speaking, the sharing of benefits in the case of economic exploitation of a finished product or reproductive material originating from access to genetic heritage, the sharing of benefits will be 1% calculated on the annual net revenue obtained from the economic exploitation of the product. This amount shall be deposited in the National Fund for Benefit Sharing - FNRB, which is a governmental entity related to the Ministry of the Environment.

Mexico. In October 2014, Mexico declared by decree that the Nagoya Protocol has the force of law. Since the issuance of the decree, the Secretariat of Environment and Natural Resources ("SEMARNAT") has been engaged in legislating the specific implementation of the Protocol. Until then, Mexico will apply both the Protocol and previous legislative measures establishing ABS requirements. These measures include the General Law on Environmental Protection and Conservation, which authorizes SEMARNAT to require consent and benefit sharing before users can access biological resources.

South Africa. In May 2015, the Department of Environmental Affairs issued revised ABS regulations requiring a "bioprospecting permit" and an executed benefit-sharing agreement for commercialization of the country's "indigenous biological resources." The revisions are intended to harmonize international and domestic permitting requirements and provide more transparent provisions for the discovery phase of non-commercial research and the management of the country's bioprospecting trust fund. The new regulations impose penalties on anyone found guilty of a violation and provide for imprisonment of up to 10 years.

Expectation and disillusionment

Many biodiversity-rich developing countries in particular had high expectations of the Nagoya Protocol. There was talk of "green gold" and with it the hope that in the future the utilization chain from the genetic resource to the marketable product could be completely traced and thus also controlled. After more than 10 years, the balance sheet is predominantly negative: neither has it been possible to halt the loss of biological diversity worldwide, nor have significant amounts of money flowed into developing countries on the basis of the Nagoya Protocol. Therefore, many countries are of the critical opinion that the Protocol still does not reflect reality.

An ambitious new global framework for biodiversity should therefore be developed at the UN Biodiversity Conference in 2021.Above all, overarching long-term biodiversity targets should be defined to ensure that the world's ecosystems are restored, resilient and adequately protected by 2050. The EU in particular had set itself the task

of driving the new developments and adopted the Biodiversity Strategy 2030 to this end. In addition to transforming at least 30% of Europe's terrestrial and marine areas into effectively managed protected areas and far-reaching plans to restore nature, it was intended in particular to promote systems of taxation and pricing to better reflect the real environmental costs, including the costs of biodiversity loss, and to ensure that biodiversity was truly integrated into public and economic decision-making processes.[11] Indeed, in December 2022, the UN Biodiversity Summit COP15 in Montreal ended with a final declaration in which participants pledged to place 30% of their land under protection by 2030. Certainly, an important goal, but in the final document there is no reference to the Nagoya Protocol and the goal of a more equitable management of genetic resources and traditional knowledge. It seems as if these demands have simply been lost under the wheels of climate change and the status quo of 2016.

Digital Sequence Information (DSI)

Whereby this is not entirely true.

The rapid progress in the life sciences, such as next generation sequencing, metagenome studies, metatranscriptome research or the synthesis of nucleic acids, has led to increasingly efficient and cheaper processes, as can be seen from the exploding number of patent applications in these fields. Fig. 2 shows the development of the number of new applications in the field of Cas protein engineering (the figures for 2022 were not yet complete at the time of the survey).

[11] https://ec.europa.eu/commission/presscorner/detail/de/qanda_20_886

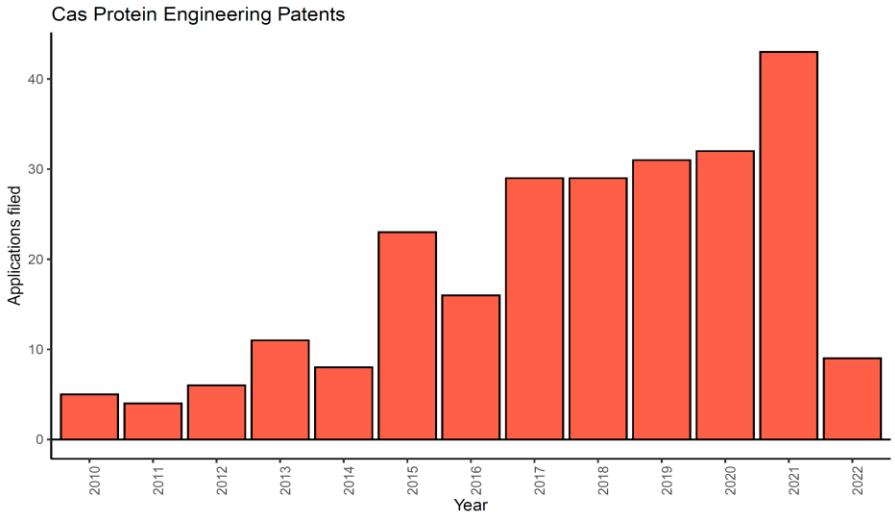

Fig.2
Development of Login Numbers Cas Protein Engineering

With the help of DSI, genetic diversity can now be characterized comprehensively and genetic material can be used without ever having to hold it in one's hands. At present, it is assumed that there are more than 100,000 substances available in nature for the synthesis of about 12,000 listed plant active ingredients, for which digital sequence information may already be sufficient.[12]

This is why the importance of digital information of genetic and biological resources has increased so much recently. The USA, the EU and Japan in particular have set themselves the goal of providing open-source access to this data.

The fronts are forming, with on the one hand the demand for a regulatory instrument for DSI and on the other hand the open access to DSI for scientific progress and international cooperation opposing each other. The German Biotechnology Industry Association, for example, sees the inclusion of DSI in the Nagoya Protocol as a brake on investment and fears the relocation of relevant research to countries such as the USA or Russia, which have not ratified the protocol. Instead, bilateral agreements are recommended to avoid further overburdening the protocol.[13]

[12] Pflanzenforschung.de 2013
[13] BioTech Brief 1/2019, Deutsche Industrievereinigung Biotechnologie

Clarity is now to be provided by a working group, the establishment of which was decided at the Montreal summit. At present, it is assumed that developments based on DSI will be assessed similarly to the use of the specific genetic resources.[14] It remains to be seen what this means for patent applicants. It is conceivable that it will no longer be sufficient to state in sequence listings only the organism from which the sequence originated, but also the way in which the sequence was obtained. In any case, it is foreseeable that the argumentation that one has not worked with a concrete genetic resource, but only with its - publicly accessible - sequence, will no longer be sufficient to evade the obligations of the Nagoya Protocol.

Consequences for patent applicants

Whether a patent application must contain a reference to the origin of a specifically used genetic resource or the associated traditional knowledge depends on whether the invention originates from a research project for which the EU ABS Regulation requires such self-disclosure. In practice, the patent attorney will be well advised to have his client answer the following questions before processing an invention disclosure:

1. Is the invention based on or does it include genetic resources and/or traditional knowledge relating thereto?
2. Is it intended to be used in the EU?
3. What is the origin of the resource and/or traditional knowledge used?
4. How long has access to the resource or traditional knowledge been available?
5. Is the resource or traditional knowledge freely available under other bilateral or multilateral agreements?

A few comments on this:

[14] https://www.cbd.int/dsi-gr/whatdone.shtml

- The first question is of course the most important, but in practice will often cause the greatest headache for the client. When is a genetic resource a source covered by the Nagoya Protocol? The EU ABS Regulation defines a genetic resource (GR) as any material of plant, animal, microbial or other (non-human!) origin containing functional units of heredity, or derivatives of a genetic resource (e.g., enzymes, proteins, metabolites) with actual or potential value. The definition in Sec. 34a Patent Act deviates from this, as it only refers to "biological material". But according to Sec. 2a (3) No. 1 PatG, this biological material is defined quite analogously as material that contains genetic information and can reproduce itself or be reproduced in a biological system. Thus, there are no differences between the definitions of the EU Regulation and the Patent Act and, in particular, not every plant raw material falls under the provisions of the Nagoya Protocol.
- If the patent application is filed as a national application in an EU state, as an EP or PCT application giving rise to priority, use in the EU can be assumed.
- If the invention relates to or involves genetic resources, the question of where it comes from can sometimes be difficult to answer, especially if the raw material was not obtained directly from the providing country. However, ignorance is not an excuse for not providing information. This is where the duty of care prescribed by the EU comes into play, i.e. the declarant is obliged to investigate the origin of the raw material and, in case of doubt, will have to justify why it was impossible for him to provide the corresponding self-disclosure. Ultimately, the knowledge is also important for the applicant. If he can prove that the resource originates from a country that has not (yet) ratified the Nagoya Protocol (e.g., Thailand) or has not imposed any access restrictions, a corresponding indication of origin is not necessary or does not have any further effect.
- The question of timing is open to interpretation. Specifically, it is a question of whether access occurs prior to the entry into force of the Nagoya Protocol and is thus free, or only after; in this case, the Nagoya standards would then apply. However,

the Protocol leaves unanswered the question of how to proceed if access occurred before the effective date but product development (= use) occurred after. Furthermore, how are cases to be assessed in which there was a first access and a first use before the cut-off date, and a second access and a second use afterwards? There is some evidence that in the first case there is no obligation under the Nagoya Protocol, but in the second case there is.

- The last question concerns possible exceptions. A genetic resource may be free to use if, for example, it is exempted by the International Seed Convention or another multilateral agreement.

On the Brazilian perspective

The Brazilian legislation has provided some guidance of what needs to be registered as falling with the scope of "genetic heritage". As discussed in "VASCONCELOS, R. M. de. Regulatory frameworks applicable to research and development activities. Brasília, DF: Embrapa, 2016. p. 11-76., Chapter 1)[15], the following shall be covered:

a) Plant, animal or other species, including domesticated ones, found in *in situ* conditions in the national territory, on the continental shelf, in the territorial sea and in the exclusive economic zone.

b) Microorganisms isolated from substrates collected in the national territory, in the territorial sea, in the exclusive economic zone or on the continental shelf.

c) Plant, animal and microbial or other species maintained in *ex situ* conditions, provided that they have been collected in *in situ* conditions in the national territory, on the continental shelf, in the territorial sea and in the exclusive economic zone (Comprises a band that extends from 12 to 200 nautical miles, counted from the baselines that serve to measure the width of the territorial sea).

d) Spontaneous populations of introduced species, which have acquired distinctive characteristics in the country.

[15] https://ainfo.cnptia.embrapa.br/digital/bitstream/item/157337/1/Marcos-regulatorios-aplicaveis-as-atividades-de-pesquisa-e-desenvolvimento-2016.pdf

e) Traditional local or creole varieties.

f) Locally adapted or creole breeds.

Covered by the current legislation are the activities of access and economic exploitation of finished products or reproductive material initiated after November 17, 2015. Activities that were in progress on that date and that were achieved by Provisional Measure No. 2,186-16, 2001 are also covered.

Furthermore, the registration at SisGen shall occur prior to the filing of any Patent Application.