3 Defining commercial and non-commercial research and development under the Nagoya Protocol and in other contexts

Caroline von Kries and Gerd Winter

Introduction

There are many ways to define criteria for the categorisation of research and development (R&D) activities as they are applied to the study and further elaboration of genetic resources (GR). Also, in other contexts it seems difficult to develop a consistent classification of research, although it is of relevance in different areas of science (biotechnology, biology, chemistry) and in different areas of application of the knowledge resulting from the research (pharmacy, agriculture, engineering). This may be due to the fact that a number of factors influence and are influenced by research classification: the flow of benefits to the provider of research material, the allocation of funding to the researcher, the application of intellectual property rights on the resulting knowledge, the different possible actors using the classification, the extent to which research output shall or shall not be published, and any privileged protection of research through basic rights.[1]

The following study will start by analysing the contextual use of the various terms that are related to the distinction between non-commercial and commercial. In a second section, the explored terminological variants shall be the starting point for interpreting the terms commercial/non-commercial as they are used in the Nagoya Protocol. Finally, the proposed interpretation shall be tested in view of the relevant provisions of the Nagoya Protocol followed by a short summary of the main results of the study.

Categorisation in different contexts

When discussing the definition of terms, some basic considerations should be kept in mind:

- a definition does not objectively exist but is a convention that is first of all informed by the context and the goal in and for which the term is used and that may regularly be adapted if social developments challenge the nature of research

1 On the European level: Art. 13 Charta of Fundamental Rights of the European Union; on the national level: p.ex. Article 5.3 of the German Grundgesetz.

- the lawmaker is largely free to define a term he/she uses in a given law
- when a definition concerns two opposite terms (like black and white), there are often clear cases belonging to one or the other side (black or white), but there are also often overlapping "grey" cases; in the legal sphere, however, grey cases should be avoided if different legal consequences are tied to the opposite terms.

Terms related to the organisation conducting research

A possible categorisation of research is related to the entity that executes the research activity or that finances a research project. This may be called the *institutional approach*. On the one hand there is the public sector, such as universities and other public research institutions. They are mainly funded by public budgets. The choice of project objectives and content is generally at the discretion of the individual researcher. The research results are normally published. On the other hand there is the private sector, meaning private enterprises and private research institutions. The research is mainly funded by private budgets. The choice of project objectives and content are rather determined by potential commercial gains. Research results are kept secret if this is required in view of commercialisation. But there are also "grey" cases, such as private non-profit entities, private entities conducting basic research, public entities which are partly funded by private sources, as well as public–private partnerships.

Terms related to the content of research

Another possible categorisation is related to the research activity as it unfolds in the chain of research and development; it may be called the *content-related approach*.

Basic/applied research

Research is often categorised as basic (or fundamental/pure) and applied research. The OECD's *Frascati Manual*, for instance, distinguishes between basic research, applied research, and experimental development. It serves as a standard for R&D surveys and data collection. According to the manual,

> basic research is "experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts without any particular application or use in view".
>
> applied research is "also experimental or theoretical work undertaken primarily to acquire new knowledge but it is directed primarily towards a specific practical aim or objective".
>
> experimental development is "systematic work drawing on existing knowledge gained from research and/or practical experience which is directed to

> producing new materials, products or devices, to installing new processes, systems and services or to improving substantially those already produced or installed".
>
> (OECD 2002, 23)

Other terms are also in use characterising the content of research. For instance, concerning state aid control, the European Commission, in a paper on the legality of state aid for research and development, which was regulated in Article 87 of the pre-Lisbon EEC Treaty (EU Commission 1986), differentiated between fundamental research,[2] industrial basic research[3] and applied research and development.[4] The Commission ruled that state aid for fundamental research goes beyond the scope of the application of Article 87 of the EEC Treaty and thus the control of the Commission. Rather, "the control of state aid must be had to the need for resources to be channelled to the industries contributing to improved European competitiveness" (EU Commission 1986, 5). This content-related distinction thus serves to draw a line between the scope of the Commission's competence to monitor competition-related measures and the unlimited competence of the Member States to regulate matters of (fundamental) scientific research.

The difference between fundamental and applied research is also brought forward to solve a constitutional problem: the question whether and to what extent applied/industrial research should be protected by constitutional basic rights. Research is, for instance, constitutionally protected by Article 13 of the CFR and Article 5.3 of the German Grundgesetz. The German Federal Constitutional Court takes a restrictive view, declaring: "The guarantee of scientific freedom is justified by the consideration that it is the science which is detached from ambitions of social benefits and political usefulness that serves state and society best".[5] Likewise some authors hold that only basic research deserves special constitutional protection because economic motives might impair scientific standards (Dickert 1991, 85; Blankenagel 2001, 44). Other authors argue that industry also carries out research which is neither manipulated nor unqualified and shall thus be protected under constitutional law (Kamp 2004, 70; Bernstorff 2011, 270).

Research/development

"Research" is often connected to "development," such as in the common abbreviation R&D. For instance, in an opinion on the "European Research Area," the

2 ". . . enlargement of scientific or technical knowledge not linked to industrial or commercial objectives".

3 ". . . original theoretical or experimental work whose objective is to achieve better understanding of the laws of science or engineering as they might apply to an industrial sector or a particular undertaking".

4 ". . . investigation or experimental work based on the results of basic industrial research to acquire new knowledge to facilitate the attainment of specific practical objectives such as the creation of new products, production processes or services".

5 Judgement of 1 March 1978, BVerfGE 47, 327 (370).

European Economic and Social Committee distinguished basic research, application-oriented research, "encyclopaedic" research (e.g. "to complete our knowledge about substance properties, new substances, active substances, etc."), technological development and product and process development (EESC 2000, para 7.1).

Terms related to the economic yield from research

There are various terms indicating whether research is or is not aimed at economic gain. They are closely related to the distinction between basic and applied research but differ because they are concerned with exchange value while the latter looks at use value. The categorisation listed here can be called *yield-related approach*.

Precompetitive/competitive

Research is sometimes qualified as precompetitive or competitive, such as in European documents on the enhancement and support of research and innovation (p.ex. EESC 2000).

"Precompetitive/competitive" is sometimes synonymously used with "fundamental/applied" or "non-commercial/commercial". Research is considered precompetitive when it is "of unknown and/or unlikely value," whereas it is competitive if it is "of known commercial value" (DOW MicroB3 2011).

The said distinction was introduced in order to better target the funding of appropriate kinds of research. For instance, a proposal by the EU Commission concerning an initiative for innovative medicines (EU Commission 2007), which observes bottlenecks in drug development, suggests supporting precompetitive pharmaceutical research and development. It states that "in this context 'precompetitive pharmaceutical research and development' should be understood as research on the tools and methodologies used in the drug development process." In the pharmaceutical sector in general, an emerging interdependency between "competitive and precompetitive knowledge" in drug discovery is observed (Collaborative Drug Discovery (CDD) 2012).

Precompetitive research is seen as a necessary step before moving on to competitive development, regardless of which institution carries it out (EESC 2007 on Lisbon Strategy, 4; EU Commission 2011, 34; EU Commission 2008, 588). The European Economic and Social Committee stated that "in many particularly relevant areas of research, costly infrastructure and a large apparatus are essential to securing fundamentally new findings and technological progress, and they provide technological development (at the precompetitive stage) with novel options for improvements and innovation. Such infrastructures are the basis and catalyst for top-level research" (EESC 2008, 1).

Scientific/significant for commercial purposes

Another term looks more specifically at the way research results can be used. For instance, in UNCLOS, Part XII, on marine scientific research, a distinction is drawn between "marine scientific research" and "marine scientific research with

direct significance for the exploration and exploitation of natural resources" (Article 246.1 and 246.5 (a) UNCLOS). The former activity shall be carried out "exclusively for peaceful purposes" and "in order to increase the benefit of all mankind" (Article 246.3 UNCLOS).

The meaning of "with direct significance" is further explained in a guidance paper by the United Nations Division for Ocean Affairs and the Law of the Sea. It suggests that "direct" should be understood as meaning that a project "can reasonably be expected to produce results enabling resources to be located, assessed and monitored with respect to their status and availability for commercial exploitation" (Secretary General 2005, 10).

Yielding non-monetary/monetary benefits

According to Article 5.1 Nagoya Protocol, "benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources". Article 5.2 classifies benefits to include monetary and non-monetary ones, and the Annex to the Nagoya Protocol further specifies different kinds of the two classes. The list indicates that monetary benefits involve the payment of money, while non-monetary involve benefits in kind. To be more precise, some of the listed benefits do not arise "from" the utilisation of the genetic resources (as, for instance, payments of royalties and R&D results), but rather as an exchange "for" the consent of their utilisation, such as up-front payments, research funding, collaboration in research activities and participation in product development.

Notwithstanding this fact, the Protocol notes that benefits do accrue in the process and from the results of utilising genetic resources, and it is interesting to note that the Protocol suggests categorising them. The purpose of introducing the distinction is however not to attach any legal effect to it. It appears to simply alert contracting parties of the fact that there can be multiple benefits, and that providers and users should be aware of that when negotiating mutually agreed terms of benefit sharing.

Terms related to the availability of research results

The categorisation of research in terms of availability of research results can be called the *functional approach*. The most common distinction is that between keeping knowledge under one's private disposition and making it publicly available.

There is a wealth of legal documents which mention the distinction between private and public availability of research results, both on the national and international levels. To name just one international example, Article 244 UNCLOS asks states and international organisations to "make available by publication and dissemination through appropriate channels [. . .] knowledge resulting from marine scientific research." By contrast, research which is "of direct significance for the exploration and exploitation of natural resources" must not be regarded as

subject to the publication requirement.[6] The coastal state can however require publication as a precondition for granting its research consent.

Privatisation of knowledge can be searched and ensured by various legal mechanisms: The form of the knowledge may be protected by copyright, which excludes its publication by others. The content of the knowledge (if it is an invention, new and commercially applicable) may be protected by patent rights. Privatisation is also obtainable through the protection of trade secrets. Inversely, an author may waive his/her copyright and allow further publication of his/her work by introducing it into the public domain. Concerning patent rights, he/she may desist from applying for such rights or provide use licenses at no or low royalties.

Interpreting commercial/non-commercial in the context of the Nagoya Protocol

Against the background of the various terms and definitions, we will now explore what the Nagoya Protocol might mean when it employs, in Article 8 (a), the distinction between commercial and non-commercial research. As a starting point for suggesting an interpretation, the objectives of the access and benefit-sharing concept in the CBD and NP should be identified. These objectives are that providers shall have a share in the benefits drawn from genetic resources (GR) and traditional knowledge (TK), and that they can use their sovereign rights of regulating access to GR and TK in order to ensure ex ante that benefit sharing takes place. On the other hand, users shall be allowed to accede to and work on GR and TK. The distinction between commercial and non-commercial is introduced for the sake of structuring the modalities of access regulation, benefit sharing, compliance enforcement and monitoring. It should help, in particular, to distinguish between facilitated and normal access conditions, between non-monetary and monetary benefits, between different kinds of monitoring (such as reporting duties and checkpoints), and between different instruments of ensuring compliance in effect (such as through administrative supervision or the enforcement of contracts).

It may be noted that several States have indeed introduced national ABS legislation recognizing simplified measures for non-commercial research according to Article 8 NP, such as Brazil, Indonesia, Australia, Ethiopia and Ecuador (see table in IUCN 2012, 120/121).

Applying first the *institutional approach*, "non-commercial/commercial" could be defined as to mean research by public or private institutions. However, as already pointed out, the private or public institutional setting may often indicate but does not per se determine what kind of research (basic or applied, of economic value or not) will be conducted and what kinds of benefits (non-monetary/monetary) will accrue. Therefore, in view of the objectives of the terms, the institutional approach is not appropriate.

Better suited seems to be the *content-related approach* and the *yield-related approach*, which are based on the distinction of the term "basic" (or fundamental/

6 See von Kries and Winter on "Harmonising ABS conditions under UNCLOS and CBD/NP", Ch. 4 in this volume.

applied, research/development, precompetitive/competitive, scientific/commercial and non-monetary/monetary). They would perceive the working on GR and TK as a process from basic research via the development of products to their patenting and marketing. This perception has well characterised R&D in the past. However, with the advent of genomics and the extension of the intellectual property concept to nature-forms, the "old" distinction has been blurred (Kamp 2004, 63, 64). Already at the stage of analysing the genome, their functions (and thus applicability of uses) may be identified. A gene and its function can be patented and thus made a source of royalty payments. The synthesis of the gene and the gene itself can be offered as marketable services and products. Inversely, a researcher whose final purpose is application and commercialisation may, as a first step, be willing to do research for the pure gain of new knowledge and share this freely with the research community (Kamp 2004, 54). There is, of course, still a wide array of "basic" research in the sense that its results do not yet have a commercial value, such as biological research on organisms and ecosystems, but economic value nowadays emerges at earlier stages than before. The early phase of fundamental research can thus not automatically be associated with non-commercial research. Hence, the distinction between commercial and non-commercial should not be attached to the traditional sequence of steps of R&D.

We are thus left with the fourth option – the *functional approach*. It appears indeed to be the most appropriate. The potential economic value of a genetic resource should not be determinative, but rather the intention, whether that value be realised or not. Arico and Salpin (2005, 33) also suggest the functionality criterion when they conclude that "the difference of regime lies in the treatment of research results". The UN Secretary-General stresses that "the difference between MSR and bioprospecting therefore seems to lie in the use of knowledge and results of such activities, rather than in the practical nature of the activities themselves" (Secretary General 2005, para. 202; also Treves 2008, 1).

Distinguishing between the public domain on the one hand and privatisation for capitalisation on the other, the functional definition captures benefits whenever they emerge. If the benefits are in the public realm – most often these will be non-monetary benefits – access is open to the public, providers being free to make use of them like anybody else. Provider states may feel that this is not sufficient reward for them. But then they may demand to somewhat restrict the publication of results or ask for privileged access to the public domain. In contrast, if the benefits are in the private realm – they will normally be monetary benefits – the provider must secure a share bilaterally by way of setting conditions in the access permit and contract.

Testing the functional definition in the Nagoya Protocol

We will now discuss whether the functional definition of commercial/non-commercial research is compatible with the relevant provisions of the Nagoya Protocol. We will in turn examine the regulation of access, the sharing of benefits, the assurance of compliance, and monitoring.

Regulation of access

In relation to the regulation of access, Article 8 NP is relevant which states:

> "In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:
>
> (a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for *non-commercial* [emphasis added] research purposes, taking into account the need to address a change of intent for such research; . . ."

The terms "non-commercial research" and, by implication, "commercial research" are used here at the stage of acceding to GR (and, incidentally, also TK). The aim of the paragraph is to simplify the regulatory regime of access if non-commercial research is envisaged.

It should be noted that Art. 8 (a) NP has research in mind that "contributes to the conservation and sustainable use of biological diversity". This corresponds to the system of objectives of the CBD. The sharing of benefits from the utilization of genetic resources is not an absolute right but is contextualised by the two other objectives, the conservation of biodiversity and sustainable use (Art. 1 CBD). Likewise, the sovereign rights of states over their natural resources as recognized by Art. 15.1 is immediately followed by the duty enshrined in Art. 15.2 to "endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses". This means that facilitation of access is strongly related to the objective that knowledge should be generated which helps to conserve and sustainably use the resources. Such knowledge can best serve these goals if it is publicly available. Thus, it appears to be public domain research which is meant by "non-commercial" in Art. 8 (a) NP.

As said earlier, "to conduct . . . development" (*viz.* of products) can also be non-commercial. Although Art. 8 (a) NP only refers to research, states should nevertheless consider simplifying access also for activities aiming at the "development" of products, the use of which is publicly available and free.

Looking from the provider state perspective it may not always be attractive to just be part of the general public and have as such free access to the knowledge and products. After all, it was its resources that were provided to the public. However, by appropriate clauses in the access consent and/or agreement the provider state may ask for special conditions, like prior information on knowledge to be published, duties of users to explain results, inclusion of personnel in the research, etc.

There is a risk, however, that published knowledge will result in products and monetary benefit drawn from them without the provider state being able to track this down to the GR/TK provided by it. In order to cope with this risk, the provider state may require the user to transfer come-back clauses to third parties using knowledge from the public domain. As this is difficult to implement, the provider state may alternatively ask the user to keep the knowledge private for both the provider and the user, based on trade secret protection or even joint patenting.

All these variants of provider strategies are still related to the functional definition, notwithstanding whether the provider opts for the public domain or the privatisation of knowledge. Thus, the functional definition appears to be the most suitable concerning the access regime.

This result is also supported by the suggestion of the ABS-Working Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches (WG-ABS 2008). The non-commercial research was characterized by this group as follows:

a) willingness to disclose the scope and methods of research projects,
b) eagerness to engage provider country research institutions and researchers in projects,
c) willingness to provide access to research results to the provider country and international research community,
d) interest in providing training and technical assistance to provider countries with the goal of building their national research capacities,
e) commitment to transparency and open sharing of benefits, without proprietary ownership of any potential commercial benefits stemming from the research, and
f) explicit agreement to a default benefit-sharing arrangement for unanticipated commercial benefits, or willingness to inform provider countries if any unanticipated potential commercial benefits are uncovered and to renegotiate the ABS agreement to include a new benefit-sharing arrangement for commercial intellectual property rights.

In conclusion, we propose that the terms "non-commercial" and "commercial" be understood in the functional sense, i.e. by looking at whether the GR material and knowledge are to be publicised or privatised. This means that a provider state should require in its PIC and MAT that the researcher promises to submit any research results to the public domain. If this is the case, the provider state does not need to precisely circumscribe and restrict the allowed kinds of research. For instance, traditional taxonomy as well as modern genomics would be part of the allowed research activities. Moreover, it would be of no concern if access is sought by public or private research institutions or financed through public or private sources. Of course, a come-back clause would have to be included for cases of change of intent from public domain to privatisation.

It is, in the opinion of the authors, also sufficient to rely solely on the functional criterion. Greiber et al. (2012) however suggest adding a content-related criterion to it. In this view commercial research

- is normally designed to produce at least some results and benefits that will have real or potential commercial value, and
- creates benefits that are held privately rather than entered into the public domain and are restricted in different forms (Greiber et al. 2012, 118).

While the second attribute circumscribes the functionality discussed above, the first recurs to the substantive approach that relates to the content of the research activity. We do not consider this necessary because (1) public domain research also produces results with potential (financial) value, since it is inherent in the object of research ("genetic resources" are genetic material of actual or potential value); (2) commercial research can also be "basic" as a first step producing "only" non-monetary benefits; and (3) the formulation is rather imprecise in using vague terms such as "normally" (what are the exceptions?), "at least some results" (how many to fulfil this criterion?), "will have . . . value" (no precise time period). The application of this attribute is thus difficult to handle.

Benefit sharing

Concerning the regulation of benefit sharing Article 5.1 NP is relevant which says:

> "In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and *commercialization* [emphasis added] shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms".

The provision introduces the obligation to share benefits resulting from GR. The activities generating benefits are the utilisation and subsequent applications and commercialisation. (Subsequent) commercialisation is here juxtaposed to utilisation (i.e. according to Article 2 NP, any research and development including biotechnology) and (subsequent) application. This appears to indicate that the substantial definition which refers to the valorisation chain of GR is the one meant in this paragraph.

However, this would imply that benefits from earlier phases in the valorisation chain cannot be "commercial". For instance, patents on genes identified in the course of basic research that yield license money would not qualify as commercial benefits. Though they would still be subject to the benefit-sharing obligation, the terminology would be very confusing because these clearly monetary benefits would qualify as non-commercial. This would be understandable with regard to access fees, fees to be paid to trust funds, and research funding (Annex to the NP No. 1 a), f) and h)), because such payments should cover the costs of research, collections, data banks, etc. and are thus elements of managing the public domain. But the patenting of genes etc. is a business operation that should be captured by the term "commercial". It is therefore more appropriate to employ the functional definition also in the realm of Article 5. This would mean that the words "as well as subsequent applications and commercialisation" is only to be understood as a

reminder and even emphasis that the "subsequent" steps in the valorisation sequence are also included, but that it is not excluded that commercialisation may also occur at the stage of fundamental research.

The adoption of the functional definition would also help to solve a riddle posed by paragraphs 2 and 5 of Article 5. These paragraphs are concerned with genetic resources held by indigenous and local communities (ILCs) as well as with TK of ILCs. They extend the obligation to share benefits from these particular resources only for the utilisation of GR and TK (i.e. R&D including biotechnology) but do not – other than in paragraph 1 – mention the stages of subsequent application and commercialisation. The omission may be explained by the difficulty the negotiating parties expected concerning the tracing of benefits back to local GR and TK, but this does not justify cutting back the sharing obligation to benefits from nonapplied basic R&D. This shortcoming can be solved if the functional definition is applied. It would allow regarding benefits capitalising on the utilisation of local GR and TK (i.e. R&D plus biotechnology) as commercial and thus also subject to the benefit-sharing obligation. Moreover, it would also allow including the "subsequent application and commercialisation" into the notion of utilisation. This would be perfectly in line with the mother convention of the NP, the CBD, because its Article 15.7 extends the benefit-sharing obligation to "the benefits arising from the commercial and other utilization of genetic resources". Likewise, Article 8 (f) CBD refers to benefits from any "utilisation" meaning that also commercial utilisation is covered. It is hardly imaginable that within the Nagoya negotiations the resource states were willing to retire from a position they had already seized under the CBD. Thus, the cited provisions of the CBD remain intact, complementing the somewhat amputated provisions of the NP and supporting the making use of the functional definition of commercial/non-commercial.

Duty to ensure compliance

Concerning the duty to ensure compliance, the relevant provision is Article 15.1 NP which says:

> Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

Article 15 does not explicitly make use of the terms commercial/non-commercial. It may however be considered as implicitly doing this because other than in Article 5.1 NP it does not mention "subsequent applications and commercialisation". This is widely understood to mean that the obligation of user states to ensure compliance in effect (and not just by monitoring) only extends to

non-commercial utilisation (i.e. R&D plus biotechnology) (Buck & Hamilton 2011; cf. Kamau, Fedder & Winter 2010). The same would be true in relation to TK of ILCs, because the pertinent Article 16 NP also does not refer to "subsequent applications and commercialisation".[7]

This interpretation unduly privileges the capitalisation of GR and TK. It would mean that the user state is only required to supervise R&D processes but not the patenting and marketing of products derived from them. In consequence, the duty to ensure benefit sharing would exclude from its realm precisely those benefits which are the most sought after by provider states, i.e. monetary benefits from the placing of R&D results on the market. This may be seen as a negotiation success of user states, but it is one that is one-sided and likely to create mistrust among provider states.

Against this, the application of the functional definition would provide a more equitable solution. Its beneficial role already probed in relation to Article 5 (1) NP could be extended to Article 15. In other words, the material duty to share benefits (Article 5) and the enforcement duty to ensure benefit sharing (Article 15) would run parallel and relate to both the phase of R&D and "subsequent application and commercialisation", because any capitalisation, be it early or late in the valorisation sequence, would be covered. In conclusion, user states are obliged to ensure compliance with provider state access legislation in relation not only to R&D but also to the obtaining of property rights and the placing on the market of R&D results.

That this solution is being accepted by state practice shows the EU Regulation No. 511/2014/EU which in Article 7 (2) provides that "at the stage of final development of a product developed via the utilisation of genetic resources or traditional knowledge associated with such resources, users shall declare to the competent authorities . . . that they have fulfilled the obligations under Article 4", which are to comply with provider state access requirements.

Duty to monitor

The duty to monitor is regulated by Article 17.1 NP which lays out:

> To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:
>
> (a) The designation of one or more checkpoints, as follows:
> (i) Designated checkpoints would collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate;

7 Special attention was not paid to GR of ILCs by Articles 15 to 18 NP. This means that Article 15.1 is applicable, requiring that user states see to compliance with any provider state requirements, but that they do not bear a self-standing duty to ensure benefit sharing with ILCs.

(ii) – (iii) . . .
(iv) Checkpoints must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, inter alia, any stage of research, development, innovation, pre-commercialization or commercialization.

The provision asks for monitoring by states – and notably by user states – through the designation of checkpoints. These checkpoints shall collect information inter alia concerning the utilization of GR (i) and, more specifically, information at any stage of research, development, innovation, pre-commercialisation and commercialisation (iv). By alluding to the sequence of steps it appears that this provision once more uses the content-related definition of "commercial/non-commercial". But it would certainly not exclude that commercialisation can already occur at earlier steps. It is therefore suggested that the functional definition should also command Article 17 NP. This implies that the mentioning of "pre-commercialisation" and "commercialisation" is not constitutive of the term but only a reminder and emphasis that all aspects of the utilisation of GR, and in particular the last steps, shall be covered by the monitoring.

A beneficial implication of this suggestion is that it gives subparagraph (i) a useful effect which would otherwise be missing. For if one understood the words "pre-commercialisation" and "commercialisation" in the substantial sense, this would mean that information on them, while still having to be collected, would be of no avail because there was no corresponding duty to ensure compliance in effect for which the information could be used. The information would, so to

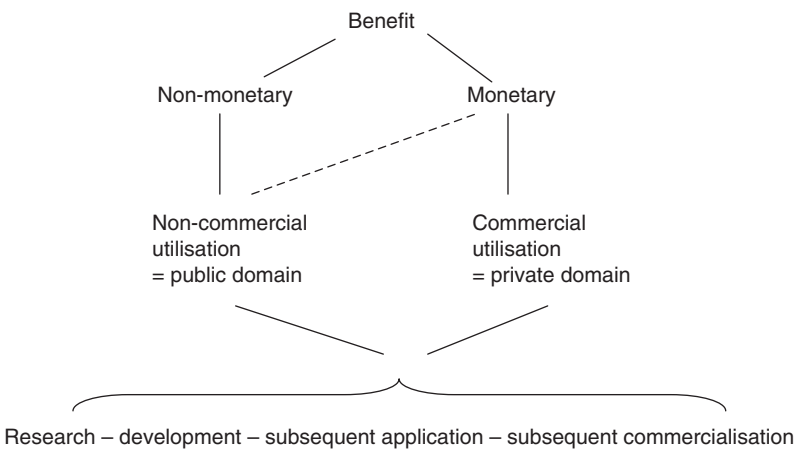

Figure 3.1 Overview of terminology
Source: *Own illustration*

speak, hang in the air. In contrast, with the functional definition such information would be about commercial utilization and thus be valuable for enforcing compliance, related also to later stages of the valorisation chain.

Conclusion

It is an impossible task to develop an abstract categorisation of research without respecting the objectives of the special field of research and research policy. This is due to inconsistent terminology in the legal texts, different approaches to research classification within and between research disciplines, and a different understanding of the dimension of the freedom of research on the European and national levels.

Classifying the types of research and development according to the functional approach will, as we have seen, best solve the tension between non-commercial and commercial utilisation of GR as regulated by the Nagoya Protocol. It is the intention to release R&D results to the public domain or keep them proprietary which predetermines (a) if access shall be simplified or not, (b) if non-monetary or monetary benefits shall be provided to the provider state, (c) to which extent states shall ensure compliance and (d) to which extent states have a duty to monitor.

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