Discussion paper

IP and access to publicly funded research results in health emergencies

Policy, law and practice in Europe

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WIPO

Discussion Paper on IP and Access to Publicly Funded Research Results in Health Emergencies

The discussion paper on the topic of access to publicly funded research results in health emergencies was produced as one of the activities under WIPO's COVID-19 Response Package.

This chapter of the discussion paper was prepared by Mr. Sven Bostyn, Associate Professor, Biomedical Innovation Law, Faculty of Law, University of Copenhagen, Denmark. His insights are focused on policy, law and practice in Europe.

The views and opinions expressed in the paper are of the author and do not necessarily reflect those of WIPO or its Member States.

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IP and access to publicly funded research results in health emergencies. Policy, law and practice in Europe[±]

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Executive summary

Considerable public funding is poured every year into a variety of technological developments. Occasionally, this funding has led to important developments, such as with the COVID-19 pandemic. The results here were astonishing, given few people could have imagined it was possible to develop and bring to market successful vaccines in under a year. Innovation is critical to knowledge-based societies, and indeed to the world, and systems that foster it must be improved. Public funding can be of irrefutable importance.

An area that has remained underresearched is the instruments that governments and institutions (as grantors of public funding) can deploy to access the intellectual property (IP)-protected results of publicly funded research. This study looks at the relationship between such research and access to IP rights-protected technologies. It examines the tools that can be used by governments to influence access to largely patent-protected technology that benefited from public funding. The focus is predominantly on Europe, primarily the European Union and its member states. Acknowledging the inevitable opacity and complexity of public funding, and inventions made with such funding, should not detract from the ambition to provide an overview of potential instruments that governments could use. The fact there is frequently no direct one-to-one relationship between public funding and an end product encompassing intellectual property rights (IPRs) fully funded by public resources is no excuse for not studying policy levers that can influence the behavior of recipients of such funding. Public funders have a duty to serve the public good. They must, therefore, evaluate how the public (national and international) can benefit in the optimal way from investments and innovation made with taxpayer money.

This study will provide an overview of the instruments and the policy levers that governments and public funding bodies can deploy to gain access to IP-protection technologies in case of health emergencies. It will not make value judgments about the tools available to governments. The typology of policy instruments covers, in a first category, statutory direct effect instruments such as compulsory licenses, obligations to grant licenses to the government, obligations to license the technology to third parties in certain limited situations, and emergency legislation. A second category includes statutory instruments that have an indirect or secondary effect, such as open science and open data policies. The third category is contract-based tools comprising voluntary licensing, advance market

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commitments (AMCs, also called advance purchase agreements or APAs in Europe) and research grant contracts.

The instruments governments can use to influence behavior can be applied simultaneously in many, though not all, situations. This study does not claim to provide an exhaustive overview of all instruments that can be used in the context of public funding but covers the most commonly available.

It concludes that there is an extensive catalog of instruments available. Many of those statutory instruments relating to non-voluntary licensing (whether compulsory licenses, government use or ex officio mandatory licenses, or emergency use licenses) do not differentiate between whether the IPRs for which licenses will be granted result from public funding or not. In Europe, the pandemic accelerated in-depth thinking and action on the tools governments should have at their disposal to secure access to IP-protected technologies, introducing obligations to license to governments who have provided public funding.

In the view of the author, legislative actions taken in Europe in response to the COVID-19 pandemic show a general willingness to adapt legal frameworks regarding access to patented technologies in health emergency situations, regardless of whether such technologies have been solely developed with public funding or not. In particular, according to the EU emergency legislation, in the event of a public health emergency at the EU level, the European Commission can require access to IP protected technology if such technology pertains to relevant medical countermeasures, which have been financed, at least in part, by the Commission.

The European Commission has also proposed the EU-wide compulsory licensing system for crisis situations, which encompasses but is not limited to health pandemics. Under the system, when determining the remuneration to be paid to the right holder, the European Commission shall consider whether the right holder has received public support to develop the invention.

Some member states have, to varying degrees, also adapted their research grant contract templates to include emergency situations. It could be argued that, irrespective of any research grant contract stipulations, national or EU-wide emergency legislation might override contractual provisions of such grant contracts, though that is not a given.

Various proposals and enacted EU legislation refer to publication or declaration by public funding recipients of the amounts received as a factor in calculating licensing fees in case of compulsory licensing, which measures can arguably also be applicable, to licenses granted to third parties in case of lack of production of vital products by such recipients.

Voluntary contractual arrangements, including APAs/AMCs, can also be used to include a variety of rights and obligations, such as obligations to license technology to third parties, in return for providing the financing under such agreements. Even though available documentation relating to those contracts in Europe seems to suggest that no such obligations were included in the APAs (also confirmed by the fact that no licenses were granted to third parties), knowing the precise nature of all clauses within the APAs remains difficult as these are largely secret.

It is hoped this study will inspire governments and policymakers to look to toolboxes already filled with policy instruments to influence the behavior of public funding recipients who have additionally benefited from an IP and proprietary knowledge portfolio that is at least in part

developed and/or commercialized with such funding. Admittedly, though, many statutory instruments do not differentiate between IPRs obtained with public funding or not.

1 Introduction

Every year, considerable public funding is poured into a variety of technological developments. Occasionally,[1] this funding leads to important developments.[2] With the most recent health emergency, the COVID-19 pandemic, massive amounts of public funding were made available to develop much-needed vaccines. The results have been astonishing. Few could have imagined it was possible to develop and bring to market successful vaccines in under a year. Innovation is critical to knowledge-based societies, and indeed to the world, and systems that foster it must be improved or at least maintained. This study does not claim that innovation successes during the pandemic were entirely attributable to public funding but that it was, nonetheless, crucial. Public-private partnerships are vital in this connection.

There is no lack of research on legal aspects of the pandemic but one that has remained underresearched is the instruments that governments and institutions, as grantors of public funding, can deploy to gain access to the IP-protected results of publicly funded research. Further, the relationship between publicly funded research and access to patent-protected technologies that have, at least in part, been developed with public funding, and/or where the public funding has contributed to the development of such technologies, is equally poorly researched. This study attempts to fill this gap, focusing on the relationship between publicly funded research and access to patent-protected technologies. More precisely, it examines the tools that can be used by governments to influence behavior of patent holders who benefit from public funding.

Before the instruments available to funding governments are appraised, it is necessary to explain what this study defines as publicly funded research (see section 5). The inevitable opacity surrounding the link between public funding and inventions made with such funding is also discussed (see section 5).

It is rare that public funding is the sole financial source in the creation of IPR-protected end products such as medicinal products. Often, the recipient of such funding will already have a proprietary-based portfolio of technology, and it will be difficult to extricate the results obtained with public funding from those already obtained, or obtained simultaneously without public funding. This poses difficult questions for policymakers as to how to deal with access to publicly funded IP-protected research. This is complicated further given that the purpose of using a tool against the innovator (or forcing the innovator to share IPRs obtained for technology that has been, in part, publicly funded) will, in most cases, be to gain access to the end product to which the public funding only contributed in part. In the case of pandemics, this would be for public health purposes.

In the context of the COVID-19 pandemic, there is a clear link between the development of successful vaccines and the public funding received to develop and market these vaccines.[3] Further evidence can be found in patent activity,[4] where many of the patent filings originated

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[1] This study makes no attempt to quantify the degree of commercial success resulting from public funding.

[2] For example, see public funding provided in the United States of America to Moderna and in Germany to BioNTech that led to the development of mRNA technology, which has been proved to deliver some of the best functioning vaccines.

[3] See section 4; and Bostyn, S.J.R. "Access to drugs, patents and pandemic crisis: a tale of (non-) inclusivity." *Research Handbook on Intellectual Property and Inclusivity*, C. Sappa (ed.). Edward Elgar, 2024 (forthcoming) (hereinafter, Bostyn, "Access to drugs, patents and pandemic crisis").

[4] World Intellectual Property Organization. *COVID-19 vaccines and therapeutics: Insights into related patenting activity throughout the pandemic*. WIPO, 2023. <https://www.wipo.int/edocs/pubdocs/en/wipo-pub-1075-23-en-covid-19-vaccines-and-therapeutics.pdf>.

from universities and public research institutions. However, much of the technology underlying the vaccines, such as mRNA technology and other vaccine platform technology, was developed prior to the receipt of public funding during the pandemic.[5]

The difficulties in distinguishing between the development of proprietary technology resulting from public funding and private funding should not detract from the ambition to provide an overview of the instruments that governments could use.

The study is structured as follows: section 2 contains statistical data on EU member states' public funding of research and development (R&D); section 3 discusses R&D intensity in the European Union compared with competitors; section 4 provides insight into EU public spending during the COVID-19 pandemic; section 5 introduces the typology of legal instruments governments can use to influence the behavior of funding recipients (many of which have a broader applicability); sections 6 to 8 analyzes legal instruments; and section 9 draws conclusions.

2 EU member states public budget funding of R&D

The European Union is part of the "club" of the most research-intensive regions of the world. Public funding of R&D as a percentage of gross domestic product (GDP) is slightly above that of the United States of America (0.74 per cent (average) compared with 0.67 per cent) but below Japan (1.69 per cent) and the Republic of Korea (1.38 per cent). The numbers (see table 1 and figure 1) refer to the so-called government budget allocations for R&D (GBARD), which cover government-financed R&D performed in government establishments and also in the other three national sectors (business enterprise, private non-profit, higher education), as well as to the rest of the world sector.[6]

[5] Bostyn, S.J.R. "Access to therapeutics and vaccines in times of health pandemics: how exclusivity rights can affect such access and what we can do about it." *Intellectual Property Quarterly* No. 4 (2020): pp. 227–270.
[6] Eurostat, Government budget allocations for R&D (GBARD).

Table 1 Government budget allocations for R&D, 2012–2022 (% of GDP):

	2012	2022
EU[e]	0.69	0.74
Belgium	0.64	0.69
Bulgaria	0.24	0.22
Czechia	0.64	0.57
Denmark	1.00	0.82
Germany	0.88	1.11
Estonia[e]	0.81	0.72
Ireland	0.43	0.19
Greece	0.39	0.74
Spain	0.60	0.59
France	0.72	0.68
Croatia	0.71	0.65
Italy	0.54	0.66
Cyprus	0.36	0.41
Latvia	0.15	0.24
Lithuania	0.36	0.33
Luxembourg	0.57	0.56
Hungary	0.34	0.31
Malta	0.27	0.21
Netherlands	0.72	0.79
Austria[d]	0.77	0.81
Poland[b]	0.35	0.42
Portugal	0.35	0.33
Romania	0.21	0.14
Slovenia	0.52	0.54
Slovakia	0.40	0.38
Finland	1.03	0.90
Sweden	0.83	0.73
Norway	0.78	0.75
Switzerland	0.84	0.98
Serbia	:	0.39
Türkiye	0.34	0.36
Albania	:	0.06
Japan[d]	0.74	1.69
South Korea[p]	1.11	1.38
United States	0.72	0.66

(b) break in time series
(d) definition differs
(e) estimated
(p) provisional
(:) data not available

Source: Eurostat (online data code: GBA_NABSFIN07)

eurostat

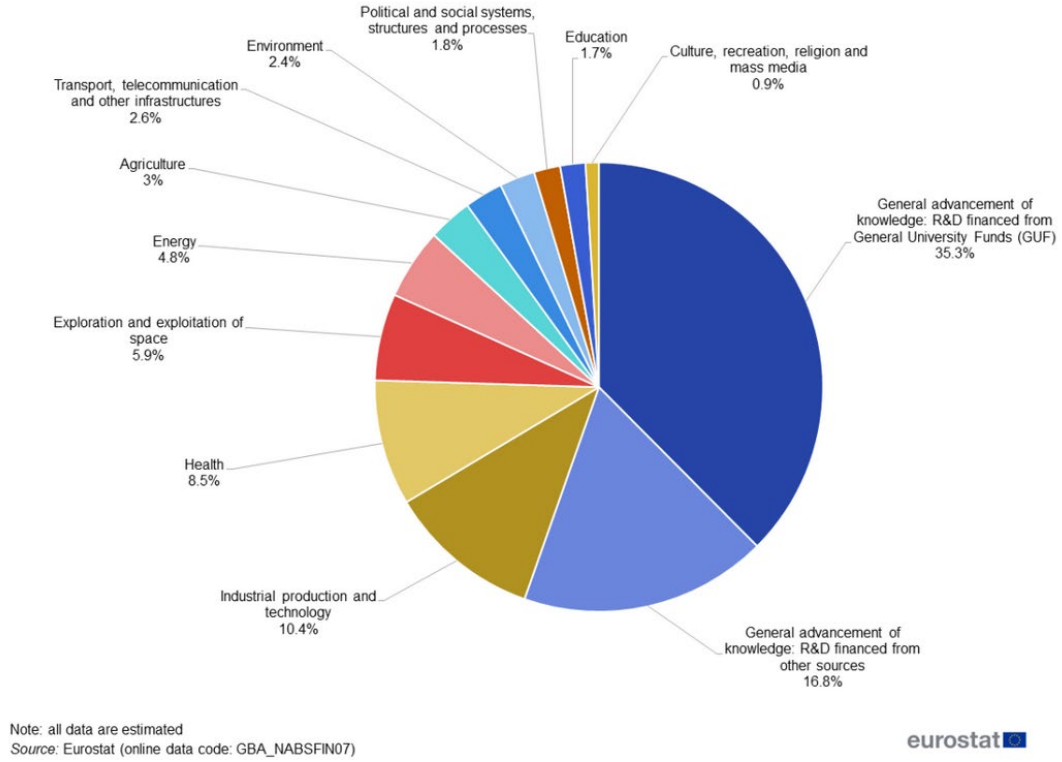
Source: Eurostat, Statistics explained, Government budget allocations for R&D (GBARD), ec.europa.eu. European Union, Jan. 2024.

Figure 1 provides an overview of the distribution of GBARD by sector, according to the NABS 2007 classification (nomenclature for the analysis and comparison of scientific

programmes and budgets).[7] It can be observed that the bulk of GBARD in the European Union goes to university research, and that spending on health is 8.3 per cent.

It must be emphasized that the statistics do not pinpoint how much of GBARD is spent on, for instance, developing health technologies, as part of the funding for such technologies will have been captured by university research, whereas R&D could be financed from other sources and health categories.

Figure 1 Distribution of government budget allocations for R&D by NABS, 2022 (%)



Source: Eurostat, Statistics explained, "Government budget allocations for R&D (GBARD)", *ec.europa.eu*. European Union, Jan. 2024.

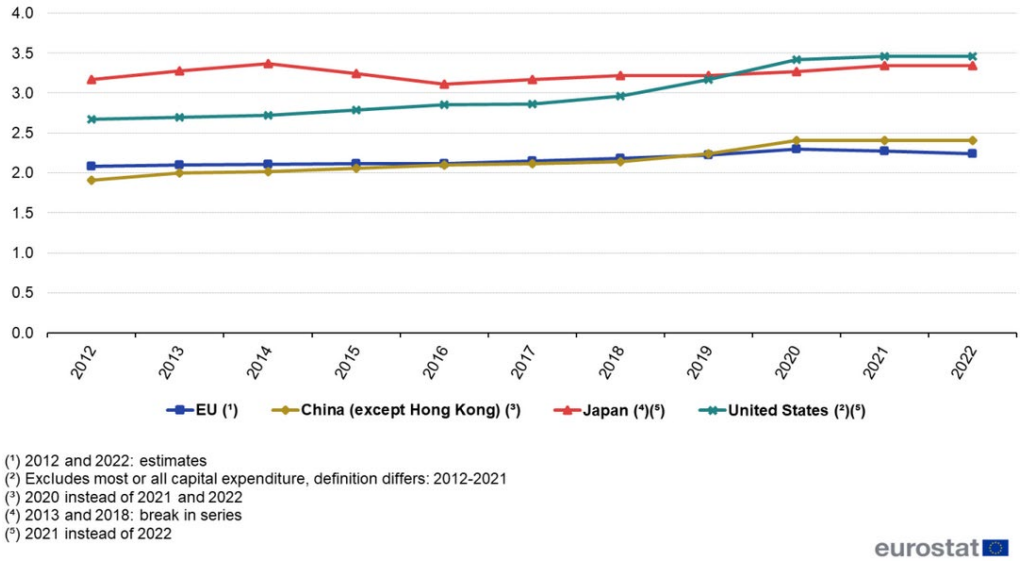
3 EU gross domestic expenditure on R&D

Section 2 discussed public R&D spending. The picture looks rather different when looking at EU gross domestic expenditure on R&D (GERD), which includes expenditure on R&D by business enterprises, higher education institutions, and government and private non-profit organizations. It stood at 354 billion euros in the European Union in 2022, equating to an average of 792 euros R&D expenditure per inhabitant.[8] Expressing GERD in terms of percentage of GDP provides the R&D intensity. In other words, the ratio of GERD to GDP is known as R&D intensity.[9]

[7] ShowVoc, ESTAT Nomenclature for the analysis and comparison of scientific programmes and budgets.
[8] Eurostat, R&D expenditure by sector of performance.
[9] *Ibid*.

The R&D intensity ratio for the European Union in 2022 was 2.23 per cent (see figure 2), below the main R&D intensive trade partners, including the United States of America (3.46 per cent, 2021 data), Japan (3.34 per cent, 2021 data) and China (2.41 per cent, 2020 data).[10]

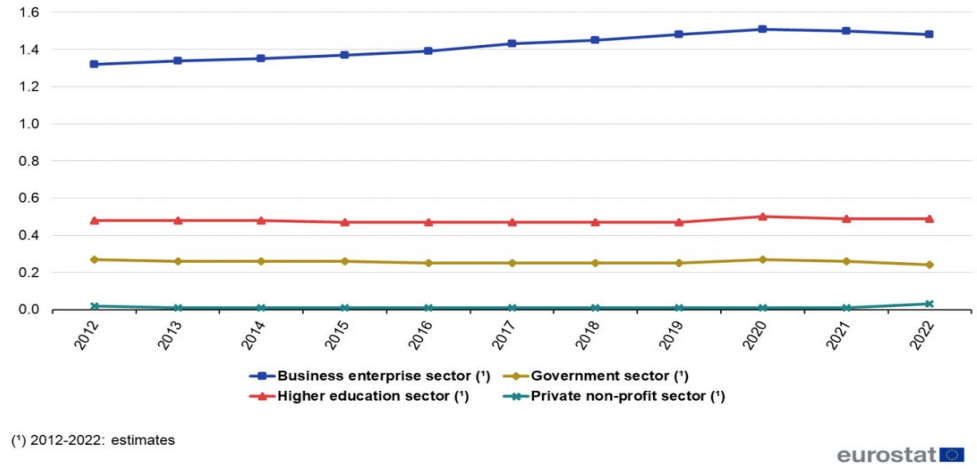
Figure 2 Gross domestic expenditure on R&D, 2012-2022 (% relative to GDP):



Source: Eurostat, Statistics explained, "R&D expenditure by sector of performance", *ec.europa.eu.* European Union, Jan. 2024.

Looking at GERD by sector of performance (business enterprise, government, higher education, private non-profit) shows the business sector is responsible for the highest R&D intensity (1.48 per cent of GDP in 2022).[11] The higher education sector was second (0.48 per cent), and the government sector third (0.24 per cent). The private non-profit sector accounted for a mere 0.02 per cent of GDP (see figure 3).

Figure 3 Gross domestic expenditure on R&D by sector, EU, 2012-2022 (% relative to GDP):



Source: Eurostat, Statistics explained, "R&D expenditure by sector of performance", *ec.europa.eu.* European Union, Jan. 2024.

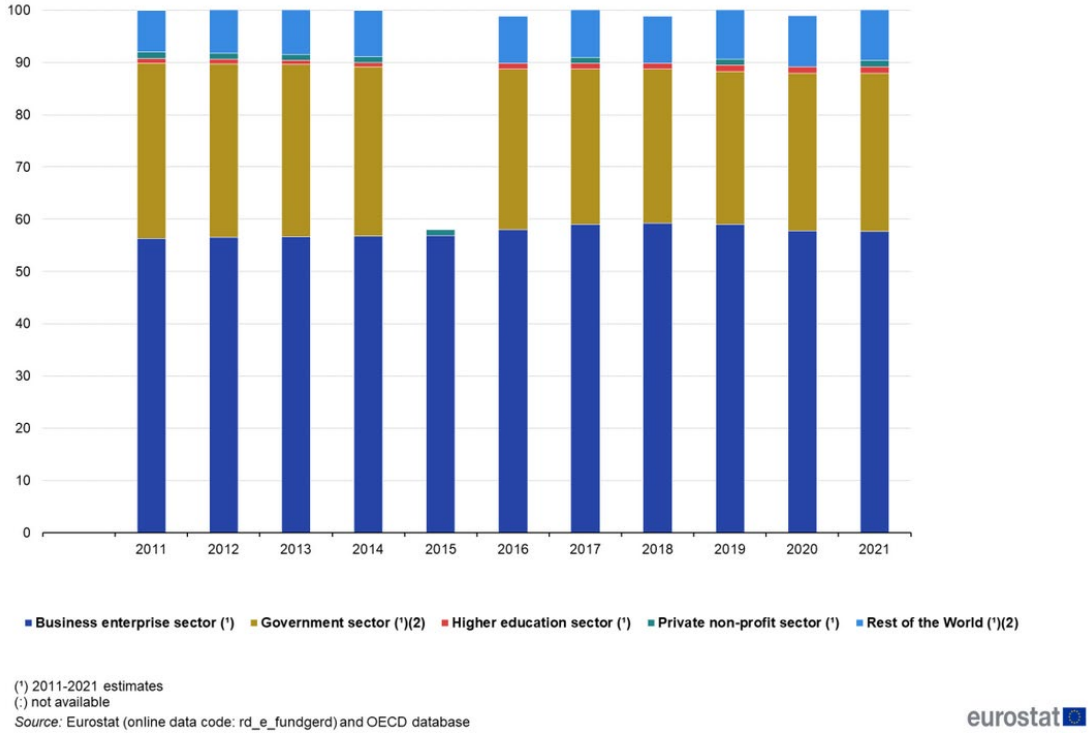
[10] *Ibid.*

[11] Divisions used by Eurostat.

Comparing the R&D intensity of the business sector reveals that the European Union lags behind the Republic of Korea (3.9 per cent), the United States of America (2.68 per cent), Japan (2.62 per cent) and Switzerland (2.26 per cent).[12]

Looking at R&D expenditure by source of funds shows that more than half (57.7 per cent) of the total expenditure within the European Union in 2021 was funded by business enterprises, almost one third (30.3 per cent) by government, and a further 9.7 per cent by the rest of the world (foreign funds). Funding by the higher education sector in 2021 was relatively small, at 1.2 per cent of the total (see figure 4).[13]

Figure 4 Gross domestic expenditure on R&D by source of funds, EU, 2011-2021 (% of total):



Source: Eurostat, Statistics explained, "R&D expenditure by sector of performance", *ec.europa.eu.* European Union, Jan. 2024.

4 EU public spending in the COVID-19 pandemic

Globally, the pandemic triggered vast amounts of public funding in R&D and advance market commitments (AMCs) for COVID-19 vaccines. In the first year, 2020, only 5 per cent of funding went to therapeutics, while 95 per cent went to vaccines. According to analysis by the kENUP Foundation,[14] the public sector (covering most parts of the globe) dedicated at least 93 billion euros to COVID-19 in 2020, with more than 88.3 billion euros spent on vaccine companies.

Most of the funds, about 86.5 billion euros, were used to conclude AMCs. In return for the right to buy a specified number of vaccine doses in a given time frame, governments will

[12] *Ibid*.
[13] *Ibid*.
[14] More information is available on the kENUP website, https://www.kenup.eu.

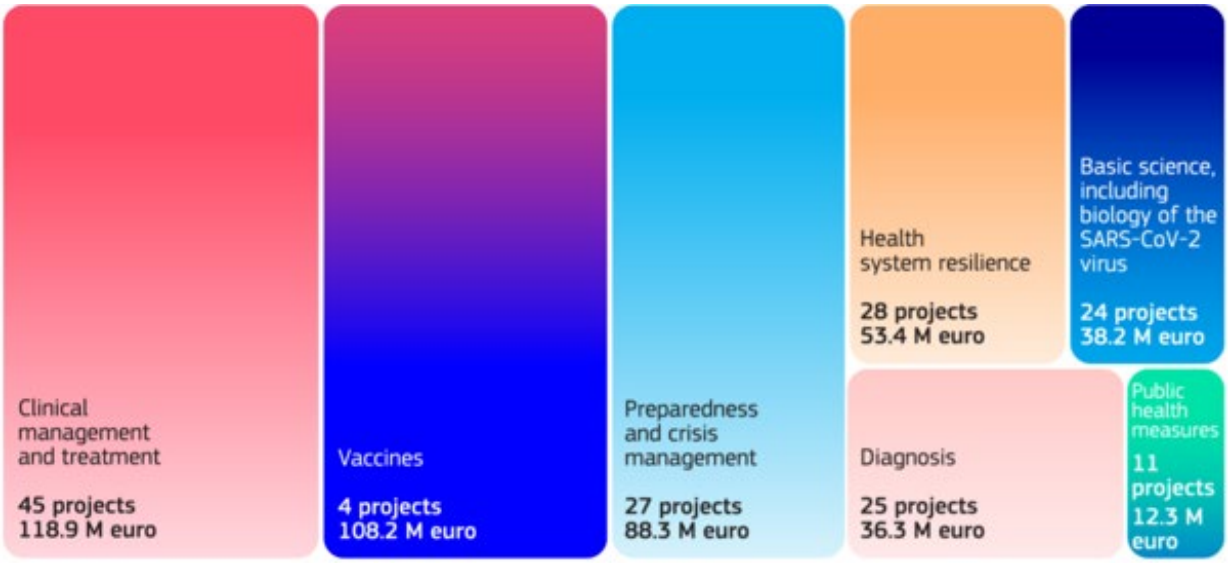
finance part of the up-front costs faced by vaccines producers in the form of AMCs. Just 7 per cent of funds were spent through preferred loans or conventional grants.[15]

The European Union

According to data collected up to 2022, the European Union's Horizon 2020 programme[16] granted funding of more than 660 million euros for COVID-19 related research[17] (see figure 5 for 2020 funding[18]).

The European Commission has invested 469 million euros in 105 COVID-19 research projects, with funding for 45 clinical trials taking the biggest share (118.9 million euros).[19]

Figure 5 Spending on COVID-19 research in Horizon 2020 projects:



Spending on COVID-19 research in Horizon 2020 projects

Source: Goda Naujokaitytė, "How the EU spent €469M on COVID-19 research in a year", *Science|Business* (sciencebusiness.net).

The Coronavirus Global Response, launched by the President of the European Commission, Ursula von der Leyen, is a global action for universal access to affordable vaccination, treatment and testing. It is the EC's response to the call for action by the World Health Organization (WHO), with governments and partners, on April 24, 2020, during which 15.9 billion euros was pledged, including 4.9 billion euros by the European Investment Bank, in partnership with the European Commission. .[20]

[15] covidX, Progress updates.
[16] Horizon 2020 (budget nearly 80 billion euros) was the European Union's research and innovation funding programme from 2014 to 2020. It was succeeded by the Horizon Europe programme (budget 95 billion euros for the period 2021–2027).
[17] COVID-19 coronavirus outbreak and the EU's response - Consilium (europa.eu)
[18] Science|Business Network, How the EU spent €469M on COVID-19 research in a year.
[19] *Ibid*.
[20] Coronavirus Global Response (archive-it.org).

For the APAs (AMCs are also called advance purchase agreements in Europe), the Commission financed part of the up-front costs from the 2.7 billion euros Emergency Support Instrument[21] that was activated to support its member states.

Apart from this central level, member states and other European countries separately funded pandemic-related research and development. A sample of that funding is provided in this study. The choice of countries was based more on the ease of retrieving data from public sources than on any message or insinuation about country performance. It is difficult to find this kind of information in an organized fashion, and it was beyond the scope of this study to delve into complete statistical data for all public funding in each EU member state or other European countries.

Germany

Since 2020, through its Bundesministerium für Bildung und Forschung (BMBF) federal research fund, Germany has supported COVID-19 research with a total of 1.8 billion euros.[22] Of this, 375 million euros went to BioNTech for the development of a new mRNA vaccine, on top of earlier funding of 17 million euros for mRNA technology.[23]

BMBF has also made available 70 million euros to research COVID-19 therapeutics,[24] and a further 138 million euros for financing clinical trials with candidate therapeutics (the latter in cooperation with the federal health ministry (Bundesministerium für Gesundheit, or BMG).[25]

United Kingdom

UK Research and Innovation (UKRI) is a non-departmental public body sponsored by the Department for Science, Innovation and Technology (DSIT). It brings together seven disciplinary research councils, Research England, which supports research and knowledge exchange at higher education institutions in England, and the innovation agency, Innovate UK.[26]

According to the COVID-19 research tracker, a live database by UK Collaborative on Development Research and the global research collaboration GloPID-R,[27] UKRI funded research with more than 1.4 billion US dollars to June 2023.

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[21] European Commission, EU vaccines strategy.
[22] Germany, Federal Ministry of Education and Research, Coronaviren im Fokus: Die BMBF-Forschungsförderung (Coronaviruses in focus: BMBF research funding).
[23] *Ibid.*, BMBF-Sonderprogramm zur COVID-19-Impfstoff-Forschung (BMBF special programme for COVID-19 vaccine research)
[24] *Ibid.*, Forschung und Entwicklung dringend benötigter Therapeutika gegen SARS-CoV-2 II (Research and development of urgently needed therapeutics against SARS-CoV-2 II); and Forschung und Entwicklung dringend benötigter Therapeutika gegen SARS-CoV-2 (Research and development of urgently needed therapeutics against SARS-CoV-2).
[25] *Ibid.*, Förderung der klinischen Entwicklung von versorgungsnahen COVID-19-Arzneimitteln und deren Herstellungskapazitäten (Promote clinical development of near-supply COVID-19 medicines and their manufacturing capacities).
[26] More information is available on the UK Research and Innovation website < https://www.ukri.org/who-we-are/about-uk-research-and-innovation/our-organisation/ >.
[27] UK Collaborative on Development Research (UKCDR), COVID-19 Research Project Tracker.

Vaccine delivery funding

Aside from public funding into the research and development of new vaccines and therapeutics, the European Union and its member states have provided funding for vaccine delivery. The APAs/AMCs financed by the EU were already mentioned. A sample overview is provided (selecting some of the most populous countries in Europe and the largest foundation contributors) of the funding that the European Union and its member states, alongside other European countries, have committed to Gavi, the Vaccine Alliance,[28] and the Gavi COVAX Advance Market Commitment (AMC).[29,30] All figures are for the period 2021 to 2025, and the data have last been updated on June 30, 2023.

In relation to vaccine delivery funding, the EU has provided Gavi and the Gavi COVAX AMC with a total of 1.394 billion US dollars in contributions[31] and pledges (384.6 million US dollars as direct contributions and 1.0094 billion US dollars to the Gavi COVAX AMC).[32]

Germany[33] has provided 2.1838 billion US dollars (716.1 million US dollars in direct contributions and 1.4677 billion US dollars via the Gavi COVAX AMC).

France[34] has provided 793.2 million US dollars (252.7 million US dollars in direct contributions, 338.1 million US dollars via the Gavi COVAX AMC and 202.4 million US dollars through the International Finance Facility for Immunisation (IFFIm)[35]).

Italy[36] has provided 816.8 million US dollars (111.9 million US dollars in direct contributions, 547.6 million US dollars to the Gavi COVAX AMC and 157.3 million US dollars through the IFFIm).

The United Kingdom[37] has provided 2.6438 billion US dollars (1.3482 billion US dollars in direct contributions, 125.3 million US dollars via the Gavi COVAX AMC, 535.3 million US dollars through the IFFIm, 603 million US dollars via the IFFIm (Gavi COVAX AMC) and 32.1 million US dollars through the Gavi Matching Fund[38]).

The Bill and Melinda Gates Foundation[39] has provided 1.8072 billion US dollars (1.526 billion US dollars via direct contributions, 236.2 million US dollars to the Gavi COVAX AMC and 45 million US dollars via the Gavi Matching Fund).

For reference, the United States of America[40] has provided 4.89 billion US dollars (890 million US dollars in direct contributions and 4 billion US dollars to the Gavi COVAX AMC).

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[28] More information is available on the Gavi website, <https://www.gavi.org/>.
[29] Gavi, Gavi COVAX AMC.
[30] See Bostyn, Access to drugs, patents and pandemic crisis.
[31] Direct contributions include grants and agreements from donor governments, foundations, corporations and organizations.
[32] Gavi, Donor profiles, European Union.
[33] *Ibid.*, Donor profiles, Germany.
[34] *Ibid.*, Donor profiles, France.
[35] The IFFIm is a mechanism that creates immediately available cash resources by using government pledges to back the issuance of bonds on the capital markets. See Gavi. "Overview 2000–2037." *gavi.org*. Gavi, the Vaccine Alliance, 2024. <https://www.gavi.org/investing-gavi/funding/overview-2000-2037>.
[36] Gavi, Donor profiles, Italy.
[37] *Ibid.*, Donor profiles, United Kingdom.
[38] The Gavi Matching Fund is a three-way philanthropic programme where donors match contributions from corporations, foundations, customers, members, employees and business partners. See Gavi, Overview 2000–2037.
[39] Gavi, Donor profiles, The Bill & Melinda Gates Foundation.
[40] *Ibid.*, Donor profiles, United States of America.

5 Tools governments have in relation to publicly funded research and access to patented technologies

This section, and those following, will discuss the tools that governments have in relation to publicly funded research and access to patented technologies, explaining those that provide access to such technologies.

Some observations regarding study delimitations are required. First, the term public funding here refers to public funding granted to private companies or institutions as a direct grant to carry out research and/or R&D, funding granted in the context of APAs/AMCs,[41] and research grants or other means of financing research, such as via the European Investment Bank and other institutions. Public funding in this context is not meant to include other types of (indirect) public funding such as tax relief, funding received via health insurance systems, and financial returns that do not belong in the first category. It is difficult to distinguish between types of funding, given there are various financial streams considered to be public funding, but it should be clear which fall within the scope of this study.

A second observation regards the exact connection between receiving public funding, patenting activities, and any tools public funders would consider using to gain access, and/or provide third parties access, to the technologies and products (in part) developed with such funding. There is an inevitable opacity surrounding the link between public funding (as defined above) and inventions made with such funding. Public funding can rarely be allocated fully to the creation of an IP-protected product; for instance, a pharmaceutical product. There are several reasons for this, including the incremental nature of technological innovation, where previous innovations are built upon. One vaccine as a final product will likely be protected by multiple IPRs, such as patent rights, because it is the result of many building blocks, with patent protection obtainable for several of those.[42] This means that in most cases innovation created with public funding will, at best, have assisted in constructing the next step to a broader technology. Further, the public funding recipient will often already have a proprietary portfolio of technology and/or will further develop one, and it will be difficult to extricate the results obtained with public funding from those obtained already or obtained simultaneously without public funding.

This poses difficulty for policymakers in dealing with access to publicly funded IP-protected research. Questions include whether public funding recipients should be obliged to grant access to proprietary patent and/or trade secret-protected technology to which the public funding has only partially contributed. This is further complicated given the purpose of using a tool against the innovator, or forcing the innovator to share IP rights obtained for technology that has been in part publicly funded, will in most cases be to gain access to the end product (to which the public funding only contributed in part); in the case of pandemics, for public health purposes.

For example, assume that public funding has contributed to the development and marketing of a IPRs-protected COVID-19 vaccine. At least part has come from public sources. Assume further a situation where a government wishes the public funding recipient (who is the developer of the vaccine) to grant a license to a third party because the vaccine developer cannot meet demand. Assume the government has a choice here between issuing a compulsory or other type of ex officio mandatory license, and forcing a voluntary license on the funding recipient for the IPR-protected technology that has been publicly

[41] For more information, see section 8.3.

[42] For examples on the COVID-19 pandemic, see Bostyn, Access to therapeutics and vaccines in times of health pandemics.

funded. By issuing a compulsory or other type of mandatory license, all IPRs can be included in the license (depending on whether all statutory requirements have been fulfilled to that effect), and in such a scenario it does not matter which part of the technology leading to the IPRs has been publicly funded or not. Such a scenario evidences the intrusive nature of compulsory and other mandatory licensing but can be justified by a public interest concern.

If a different type of licensing agreement is envisaged by the government, different questions arise. How effective can a voluntary license system be if it only covers the IPR-protected technology that has been publicly funded, for which a government could hypothetically make a case that such a license would be based on fairness? Based on the statutory provisions, it would seem that governments in Europe, and/or the European Commission, can impose obligations to license to third parties' IPR-protected technology that pertains to the IPR-protected end product, even if that end product is the result of both private and public funding. This is not surprising, again, merely evidencing the intrusive nature of compulsory or other types of mandatory licensing. It must be emphasized, however, that these provisions are untested.

In the context of the COVID-19 pandemic, there is a clear link between the development of the much-needed, successful vaccines and public funding received to develop and market them (see section 4). But this is only to a limited extent. Much of the foundation technology underlying those vaccines, such as mRNA technology and other vaccine platform technology, preexisted the public funding received during the pandemic.[43]

The difficulties in distinguishing between development of proprietary technology resulting from public funding and private funding should not detract from the ambition to provide an overview of the instruments available to governments. This can inspire further thinking, and leads to the third observation that this study will provide an overview of the tools that European governments have (or do not have) to gain access to IPR-protected technologies where public funding has at least been part of the funding mix.

The subsequent sections will examine a variety of such tools. As the scope of this study is limited to health emergencies, the tools discussed are limited to those that can be used in such a context. However, many policy instruments and measures can also be implemented in other areas where governments believe access to technology, at least partly developed with public funds, is critical.

This study distinguishes between a variety of policy instruments that can be utilized to achieve the desired results for the above hypothesis, as follows:

- Statutory instruments that directly mandate access to IP-protected technologies; for example, compulsory license, obligations to grant licenses to the government and to third parties under certain conditions, and emergency legislation (see section 6).
- Statutory instruments that have indirect effect, called soft law statutory tools; for example, open science and open data policies. Can be hybrid, as even though they may contain certain firm obligations, implementation can be subject to exceptions (see section 7).
- Contract-based tools that subject recipients to certain contractual obligations; for example, voluntary licensing, APAs/AMCs and research grant contracts (see section 8).

[43] *Ibid*.

In the author's view, the classification captures most types of instrument levers that governments could use to gain access to IP-protected technology that has at least been subject to some form of public funding as defined.

6 Statutory licensing tools

6.1 Introduction

One way of influencing the behavior of public funding recipients is through the use of statutory licensing tools. Regimes can take multiple forms, such as voluntary licensing, the obligation for public funding recipients to grant licenses for the inventions made with such funding to the government, the threat of being subject to compulsory licenses in the public interest or for other statutory reasons, and the obligation to grant licenses to third parties under certain conditions.

Voluntary licensing will be discussed in section 8, this section being limited to mechanisms that are not based on a decision by the recipient to voluntarily grant licenses.

6.2 Compulsory and other types of non-voluntary licensing

6.2.1 General considerations

Compulsory licensing is a tool with a much wider reach than to gain access to government-funded research. It is in effect a statutory instrument that governments and/or courts can use to force patent right holders to share technology with third parties by means of granting a license to third parties to work the patented technology. It is rather intrusive, which probably explains why in Europe it has been threatened but rarely used.[44, 45]

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[44] One example is the threat by the Dutch government – not exercised – to grant compulsory licenses to BRCA gene patents for patent-protected diagnostic tests. It argued the cost for breast cancer tests was excessive. The patent holder's business model consisted of asking users to send samples to a limited number of licensed labs, with the result sent to the requesting physician. Regarding access to cheaper medicines, see also Dutch Council for Public Health and Society. "Ontwikkeling nieuwe geneesmiddelen: Beter, sneller, goedkoper." (Development of new medicines: better, faster and cheaper.) *raadrvs.nl*. Council for Health and Society, 2017. <https://www.raadrvs.nl/documenten/publicaties/2017/11/09/ontwikkeling-nieuwe-geneesmiddelen>.

[45] Compulsory licensing originated mainly in the concept of non-working of the patent, and in many national patent acts is still a ground for the granting of compulsory licenses (see. e.g.United Kingdom, Patents Act 1977 sect. 48(1)).
The concept of non-working has become closely related to the issue of supply. The working requirement developed to include elements of sufficient supply in the domestic market as a basis for a compulsory license (see Ullrich, H. "Mandatory licensing under patent law and competition law: different concerns, complementary roles." Compulsory Licensing Practical Experiences and Ways Forward, Hilty and Liu (eds.). Springer, 2015, pp. 343–344.)
The concept of compulsory licensing to combat abuse developed later (See Reichman, J.H., and C. Hasenzahl. *Non-voluntary Licensing of Patented Inventions*. United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, 2003.).
The idea of abusing the patent right as a ground for compulsory licensing is, of course, not that distant from the original concept of non-working. In both, the underlying idea is that it is deemed unfair for the patent holder to use their patent in a way that is not conducive to public interest, which is to have (to some extent) access to the technology. That leads, then, to the compulsory license in the public interest that is common to many national patents acts today. (Germany, Patent Act 1980 sect. 24; the Netherlands, Patents Act 1995 art. 57.).
There is no general public interest compulsory licensing provision under United Kingdom law. The Patents Act 1977 sect. 48A contains a more specific list of situations where a compulsory license can be triggered:
"(1) In the case of an application made under section 48 above in respect of a patent whose proprietor is a WTO proprietor, the relevant grounds are –
(a) where the patented invention is a product, that a demand in the United Kingdom for that product is not being met on reasonable terms;

Compulsory licensing is not limited to technologies that have been developed with government funding and can be granted for all kinds of technology, whether publicly or privately funded, provided conditions under the applicable law are met. The statutory regime does not discriminate between publicly funded and privately funded IPRs. But as it can encompass technology that has been publicly funded, and as compulsory licensing schemes are linked by legislatures to IP-protected technologies, including those that are publicly funded, at least in part, it is relevant. The COVID-19 pandemic has led to a shift in thinking on the use of compulsory licenses to gain access to health technologies, and has resulted in a legislative proposal at EU level, evidence that legislatures have determined the use of compulsory licensing schemes should at least be considered in cases of emergency.

In some countries, compulsory licensing is supplemented with other types of non-voluntary licensing such as government use licenses or ex officio licensing.[46] See section 6.2.3 for types of non-voluntary licensing practices.

In Europe, compulsory licensing used to be a matter for European Union member states only, and no European Union-wide compulsory licensing system existed. Gradually, legislation entered at EU level, prescribing in which circumstances and under which conditions certain types of compulsory licenses can be granted. This left the general legislative framework of member states in place.[47]

Legislative developments have opened the scope of compulsory licensing to the entire EU territory as put forward in the Proposal for a Regulation of the European Parliament and of

(b) that by reason of the refusal of the proprietor of the patent concerned to grant a licence or licences on reasonable terms –
(i) the exploitation in the United Kingdom of any other patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered, or
(ii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;
(c) that by reason of conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced."

[46] See Crown use in the United Kingdom (Patents Act 1977 sects. 55–59); and France, Code de la propriété intellectuelle 1992, arts. L613-16–L613-18.

[47] Two examples are relevant. The first relates to compulsory cross-licensing obligations under Article 12 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. OJ L 213, 30.7.1998, pp. 13–21., prescribing in which situations and under which conditions a compulsory cross-license should be granted to patent holders or plant variety right applicants/holders in case they could not practice their rights without infringing, respectively, a plant variety right or patent. These licenses remain governed by national law. (For more information, see Bostyn, S.J.R. "Patenting plants, plant variety protection and inclusion of plant breeders: is it achievable?" *Research Handbook on Intellectual Property and Inclusivity*, C. Sappa (ed.). Edward Elgar, 2024 (forthcoming).)
The second example concerns compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, thereby implementing Article 31bis of the TRIPs Agreement. EU member states are obliged to grant such compulsory licenses if all conditions prescribed in Regulation (EC) No. 816/2006 of the European Parliament and of the Council of 17 May 2006 have been fulfilled. These licenses are, in principle, only targeting a specific IP right holder in a specific EU member state or states. As this system is governed by an EU regulation, its provisions have direct applicability in member states without the need to transpose those provisions into national law (as is the case with EU directives).

the Council on compulsory licensing for crisis management,[48] which is a novel development.[49,50,51]

[48] See section 6.2.2.

[49] It is helpful to add a brief background on the legal systematic organization of compulsory licensing systems in European jurisdictions. In these countries, as members of the World Trade Organization (WTO) and hence complying with the TRIPS Agreement, in principle, a compulsory license can only be granted after the patent holder refuses to grant a license under reasonable terms. A voluntary license must first be negotiated, and once that has been unsuccessful, a compulsory license can be filed for and granted (TRIPS Agreement art. 31(b)). One major issue is to determine what is understood by reasonable terms, something to be determined by the courts. (For more details on Article 31 TRIPS, see Ho, C. *Access to Medicine in the Global Economy.* Oxford University Press, 2011, pp. 125–155; Gervais, D. *The TRIPS Agreement: Drafting History and Analysis*. 4th edition. Sweet and Maxwell, 2012; and Le, V.A. *Compulsory Patent Licensing and Access to Medicines: A Silver Bullet Approach to Public Health?* Palgrave Macmillan, Cham, 2022.)

[50] Under limited circumstances, the requirement to negotiate a voluntary license first can be waived, as can be seen in Article 31(b) of the TRIPS Agreement. But this is limited to narrowly defined circumstances, such as health emergencies, which would be applicable in the case of COVID-19-related licenses. Even though the principle under the TRIPS Agreement is that such compulsory licenses should be granted for predominantly domestic use (See TRIPS Agreement art. 31(f). Limitation is not applicable to compulsory licenses granted as a result of a finding of anticompetitive behavior; see art. 31(k).), an exception can be found in Article 31bis ((See Trips Agreement art. 31bis)) introduced by the Doha Declaration (World Trade Organization. "Declaration on the Trips Agreement and public health." wto.org. Nov. 20, 2001.). That provision is applicable only to the granting of compulsory licensing for export to least-developed countries (Annex to the TRIPS Agreement art. 1(b)). In Europe, the concept of granting compulsory licenses for export to countries outside the European Union as per Article 31bis has been implemented by Regulation (EC) No. 816/2006.
One further issue is that in many jurisdictions, including the European Union, there is hitherto no alignment between the compulsory licensing tool and the ex post rights obtained via data and market exclusivity triggered by obtaining a marketing authorization (MA) for a medicinal product (See Bostyn, Access to therapeutics and vaccines in times of health pandemics, pp. 266–267. It is beyond the scope of this chapter to detail the legal concepts; for more information, see De Jongh, T., et al. Effects of Supplementary Protection Mechanisms for Pharmaceutical Products. Technopolis Group, 2018, pp. 61–73, downloadable at <https://www.technopolis-group.com/wp-content/uploads/2020/02/Effects-of-supplementary-protection-mechanisms-for-pharmaceutical-products.pdf>; and Bostyn, S.J.R. "Personalized medicine, intellectual property rights and human rights." Intellectual Property and Human Rights, Torremans, P.L.C. (ed.). Kluwer Law International, 2020, pp. 945–950.). In Europe (and many other jurisdictions) one can bring a medicinal product on the market only after extensive clinical trials accumulating in a MA granted by the regulator. In the majority of cases this would be the European Medicines Agency (EMA), though there is still competence at national level for certain categories of drugs. In Europe, the grant of an MA comes with ex post rights obtained via data and market exclusivity. Generic manufacturers cannot file for a generic MA during the period of the data exclusivity and, once that has lapsed, they cannot enter the market until the market exclusivity period has lapsed. The regime entails eight years of data exclusivity (officially called regulatory data protection), and two years of market exclusivity (market protection) on top of that.

[51] Obtaining a compulsory license does not automatically void or suspend the effect of data and market exclusivity rights, making it de facto impossible for compulsory licensees, or at least the MA holder benefiting from the products produced under such license, to practice the license. That is because they need to apply for an MA themselves prior to marketing the products. Such application for an MA will be refused in case data exclusivity is still in force, or alternatively, marketing the products will be impossible to the extent that market exclusivity is still in force. This is a known issue that has been raised for many years but has not been generally fixed (See European Commission. "Tamiflu application and data exclusivity in an emergency compulsory licence situation." Letter from the European Commission to Mr Greg Perry, EGA-European Generic Medicines Association. Feb. 20, 2006. The letter further states: "Community pharmaceutical acquis does not currently contain any provision allowing a waiver of the rules on data exclusivity and marketing protection periods.").
In Europe, a waiver system has been introduced for compulsory licensing for manufacture and export to countries outside the European Union, as per Article 31bis of the TRIPS Agreement. According to that system (see Regulation (EC) No. 816/2006 art. 18.), compulsory license applicants may avail themselves of the so-called scientific opinion procedure under Article 58 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004, or any similar procedure under national law applicable to generic companies. If the applicant uses that procedure, and it concerns a generic version of a reference product still benefiting from data exclusivity and market protection (also called market exclusivity), these protection periods will not apply. This system is only applicable to licenses for export to least-developed nations, and is not of general applicability to all compulsory licenses.

6.2.2 Compulsory licensing for crisis management in the European Union

The European Commission recently proposed a draft regulation covering compulsory licensing for crisis management.[52]

It may be useful to briefly describe the legislative process at EU level. The European Commission has the sole right to initiate proposed legislation. The process for such statutory instruments requires a plenary vote by the European Parliament at first reading, in most cases involving a (considerable) number of amendments. This amended and adopted text is subsequently sent to the European Council of ministers for further consideration. If the Council does not accept the text as adopted by the Parliament, a text as amended by the Council is sent back to the European Parliament for a second reading. The Parliament can reject this, and then the proposed legislation will not enter into force. It may also propose further amendments, and the adopted amended text is sent to the Council again, who can accept or reject the amended text. In the case of a rejection, the Conciliation Committee is convened, composed of an equal number of members of the Parliament and Council representatives. It must agree on a text acceptable to both institutions. A joint text from the Conciliation Committee is sent for a third reading to the Parliament. If it rejects or fails to act on it, the proposal ends. Alternatively, it adopts the text. At the Council, the same examination of the joint text takes place, with identical options. To be enacted, both the Parliament and Council must adopt the joint text. If not, the proposal ends.[53]

On March 13, 2024, the European Parliament adopted the proposal at first reading with amendments.[54] The underlying principles can be summarized as follows: the Commission may grant a Union compulsory license where a crisis or emergency mode listed in the annex to the draft regulation[55] has been activated or declared in accordance with one of the Union acts listed in that annex.[56,57] What exactly constitutes a crisis or emergency mode is not made entirely clear but it covers health emergencies. Initiating the compulsory licensing procedure is done by means of a notice published in the *Official Journal of the European Union*, including information on the discussions on the granting of a Union compulsory license in the context of a Union crisis or emergency mechanism. The notice should also help the Commission identify the IPRs concerned, the rights holders and potential licensees.[58]

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[52] Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006. COM(2023) 224 final.

[53] Council of the European Union, The ordinary legislative procedure.

[54] This study discusses the draft regulation and its provisions as per the European Commission proposal, with reference to some European Parliament amendments. See European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (COM(2023) 224 – C9-0151/2023 – 2023/0129(COD)). P9_TA(2024)0143. The adopted text is at the time of writing (as of April 25, 2024) still with the European Council of ministers, who must take a position on the proposal with amendments.

[55] Annex to the Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006. COM(2023) 224 final.

[56] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on compulsory licensing for crisis management and amending Regulation (EC) 816/2006, COM(2023) 224 final, art. 4.

[57] The text adopted by the European Parliament made a substantial amendment in that a compulsory license can be granted only if an agreement on a voluntary license fails (agreement, or the lack thereof, should be reached within four weeks. European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (COM(2023) 224 – C9-0151/2023 – 2023/0129(COD)). P9_TA(2024)0143, art. 1(1) as amended.

[58] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on compulsory licensing for crisis management and amending Regulation (EC) 816/2006, COM(2023) 224 final, recital 23 of the preamble to the regulation.

Such a compulsory license will be non-exclusive and non-assignable, have a scope and duration limited to the purpose for which it is granted, and to the scope and duration of the crisis or emergency mode in the framework of which it is granted. It will be subject to remuneration,[59] and the territorial scope limited to the territory of the Union. The license may cover a patent application, and will extend to the patent thus granted, provided the grant takes place while the compulsory license is still valid. It will also cover supplementary protection certificates,[60] provided the transition from patent protection to that conferred by a supplementary protection certificate takes place while the Union compulsory license is valid.[61] The European Commission will consult an advisory body prior to the granting of the license,[62] though its opinion is not binding.[63]

The opinion of the advisory body will account for the following:

> "(a) the nature of the crisis or emergency;
> (b) the scope of the crisis or emergency and how it is expected to evolve;
> (c) the shortage of crisis-relevant products and the existence of other means than a Union compulsory licence that could adequately and swiftly remedy such shortage." [64]

The right holders will be heard to gather their arguments but it is the Commission that decides whether to grant a compulsory license.

For the purposes of this study, there is an interesting provision in the proposal, in terms of determining the size of the remuneration paid in return for the compulsory license. Article 9 states that having received public funding will be taken into account when determining adequate remuneration:

> "1. The licensee shall pay an adequate remuneration to the rights holder. The amount of the remuneration shall be determined by the Commission and specified in the Union compulsory licence.
> 2. The remuneration shall not exceed 4 per cent of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence.
> 3. When determining the remuneration, the Commission shall consider the following:
> (a) the economic value of the relevant activities authorized under the Union compulsory licence.
> (b) whether the rights holder has received public support to develop the invention.
> (c) the degree to which development costs have been amortized by the rights holder.
> (d) where relevant, the humanitarian circumstances relating to the granting of the Union compulsory licence.

The text adopted by the European Parliament has added more stringent conditions for the European Commission, to the effect that the "initiation of any compulsory licensing procedure should first involve the identification of the intellectual property rights concerned, the rights-holders concerned, as well as potential licensees, with the involvement of the national authorities responsible for issuing compulsory licenses under their national patent laws". This will put an additional burden on the European Commission regards issuing a compulsory license, as identifying all IPRs can be complex and time consuming indeed, and the amendment states this should be done prior to issuing the compulsory licensing procedure.

[59] The text adopted by the European Parliament imposes the obligation to disclose trade secret protected information, subject to adequate remuneration.

[60] Supplementary protection certificates (SPCs, often labelled patent term extensions in other jurisdictions) are mechanisms to compensate at least partially for the loss of effective patent term during the regulatory marketing approval process. Unlike products in unregulated markets, a pharmaceutical product can only enter the market (and a patent relating to that can only be enforced) after a MA is granted, which may take years. See De Jongh, 2018, p.

[61] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on compulsory licensing for crisis management and amending Regulation (EC) 816/2006, COM(2023) 224 final, art. 5.

[62] *Ibid*., art. 6.

[63] *Ibid*., art. 7(2).

[64] *Ibid*., art. 7(1).

> 4. If the published patent application for which a compulsory licence has been granted does not subsequently lead to the granting of a patent, the rights holder shall refund the remuneration paid under this article to the licensee."

In other words, any compulsory license issued against a patent right holder for a protected pharmaceutical product will be subject to a royalty,[65] but, in setting the remuneration, any public funding received by the right holder is taken into account. In the view of the author, this can be interpreted to mean that the remuneration will likely be reduced if such funding has been received. One must recognize that the decision of the Commission (as a decision of an EU agency) is subject to appeal at the General Court.[66]

The territorial scope of the draft regulation is limited to the European Union, implying that only EU member states will be able to benefit from the measures in the draft. There is no extraterritorial effect and countries outside the European Union cannot, therefore, invoke the measure or benefit from it.

Finally, the issue of data and market exclusivity in the case of compulsory licenses for medicinal products is tackled in the proposal. It aims to introduce a provision in new pharmaceutical legislation, in particular, the provisions dealing with data and market exclusivity. In regard to a compulsory license being granted by a relevant authority in the Union to address a public health emergency, data and market protection (as it is called in the proposal) will be suspended for the duration of the compulsory license.[67,68] The proposal suggests suspending exclusivity only in cases of compulsory licenses granted in the context of health emergencies, not of general applicability to all compulsory licenses for pharmaceutical products.[69]

6.2.3. Government use and ex officio licensing

The non-voluntary and compulsory licensing landscape in Europe is not always easy to understand as it contains a patchwork of statutory regimes. While specific situations would

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[65] The proposal refers to the general concept of crisis-relevant products, which according to *ibid*, art. 3(a) means "products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union."

[66] Interestingly, the proposal is silent on this. It does refer to the right to appeal decisions by the European Commission to issue penalties. However, the General Court should have jurisdiction based on Art. 256 juncto Art. 263 TFEU (Treaty on the Functioning of the European Union of 13 December 2007, consolidated version (OJ C 202, 7.6.2016, pp. 47-360)) for decisions taken by the European Commission issuing a compulsory license.

[67] Art. 80(4) of the Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, COM(2023) 192 final: "By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party to address a public health emergency, the data and market protection shall be suspended with regard to that party insofar as the compulsory licence requires, and during the duration period of the compulsory licence."

[68] The text of art. 80(4) of the proposal recently adopted by the European Parliament at first reading reads somewhat differently, without touching upon the very principle of the suspension: "4. By way of derogation from paragraphs 1 and 2, when a compulsory licence has been granted by a relevant Member State authority in the Union under conditions laid down in Union law and in compliance with international agreements to a party, the data and market protection shall be suspended with regard to that party insofar as the compulsory licence requires, and during the duration period of the compulsory licence in the Member State(s) where the compulsory license has been granted." European Parliament legislative resolution of 10 April 2024 on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM(2023) 192 – C9-0143/2023 – 2023/0132(COD)), P9_TA(2024)0220, Texts adopted - Union code relating to medicinal products for human use - Wednesday, 10 April 2024 (europa.eu). Whether the Council of ministers will adopt this amended text is yet to be seen.

[69] See Bostyn, Access to drugs, patents and pandemic crisis.

give rise to compulsory licensing in one country, those very situations will require a government use or ex officio licensing scheme. All these regimes have in common that the license is non-voluntary, but they may differ in their operational details. Indeed, countries have at their disposal compulsory licensing, and some have other layers of non-voluntary licensing, such as government use and ex officio licensing. It is not always clear from a legal systematic view how these regimes differentiate themselves from each other. They have in common that these are forms of non-voluntary licensing, wherein governments can request access to the IPR-protected technology for government use, or for use by a third party on behalf of the government. In this respect, they are akin to compulsory licenses. They do not, however, necessarily contain all the legal systematic requirements and conditions of compulsory licensing regimes. Several studies appear to equate them to compulsory licenses while acknowledging operational differences,[70] but for this study it was deemed appropriate to treat them separately. As with compulsory licensing, the provisions have general applicability, and make no distinction in principle between publicly funded and privately funded IP-protected technology.

Government use and ex officio licensing are practices where governments have the right to claim a license to the invention made by a third party for public/government use, and/or have the right to grant a license to a third party on behalf of the government in specific circumstances. This is typical for national security/defence or other interests of the state, situations where the patent holder does not develop the technology any further, and/or in situations where the patent holder could not meet demand in crisis situations.

A selection of statutory provisions in European jurisdictions is now briefly discussed.[71]

United Kingdom

In the United Kingdom, there are Crown use rights. Crown use allows government departments to make, use, import, sell or offer to sell, etc. the patented product for services of the Crown.[72] It must be emphasized that Crown use can be applied to all patents, not just those that benefited from public funding. More precisely, the UK statute does not refer to public funding as a requirement for invoking Crown use, given 'the services of the Crown' is explained as encompassing, among other things, "the production or supply of specified drugs and medicines".[73] Section 59 of the Patents Act 1977 contains a wider list of situations where use for the services of the Crown can be invoked, in particular referring to use during

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[70] "While the beneficiaries of these two forms of licenses are different and such licenses may have operational distinctions, generally, the term 'compulsory licensing' is often used to refer to both forms of authorization. Moreover, conditions to be respected in the grant of these both forms of licenses involve similar aspects." See Standing Committee of the Law of Patents. "Draft reference document on the exception regarding compulsory licensing." *wipo.int*. World intellectual Property Organization, 2019. <https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-main1.pdf>.

[71] See Standing Committee on the Law of Patents. "Exceptions and limitations to patent rights: compulsory licenses and/or government use (part II)." *wipo.int*. World intellectual Property Organization, 2014. <https://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_5_rev.pdf>.[72] See United Kingdom, Patents Act 1977 sect. 55

[72] See United Kingdom, Patents Act 1977 sect. 55

[73] *Ibid*., sect. 56: "(2) In this Act, except so far as the context otherwise requires, "the services of the Crown" includes –
(a) the supply of anything for foreign defence purposes;
(b) the production or supply of specified drugs and medicines; and
(c) such purposes relating to the production or use of atomic energy or research into matters connected therewith as the Secretary of State thinks necessary or expedient; and 'use for the services of the Crown' shall be construed accordingly." Specified drugs and medicines are further explained in sect. 56(4).

[74] United Kingdom, Patents Act 1977 sec. 59(1). For a discussion on sec. 59 Patents Act 1977, IPCOM GmbH & Co Kg v Vodafone Group Plc & ors [2021] EWCA Civ 205 (February 19, 2021).

emergency (provisions predate the COVID-19 pandemic[74]). Under those provisions, Crown use includes:

"[P]ower to use the invention for any purpose which appears to the department necessary or

expedient –

(a) for the efficient prosecution of any war in which Her Majesty may be engaged;

(b) for the maintenance of supplies and services essential to the life of the community;

(c) for securing a sufficiency of supplies and services essential to the well-being of the community;

(d) for promoting the productivity of industry, commerce and agriculture;

(e) for fostering and directing exports and reducing imports, or imports of any classes, from all or any countries and for redressing the balance of trade;

(f) generally for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community; or

(g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any country or territory outside the United Kingdom which is in grave distress as the result of war;

and any reference in this Act to the services of the Crown shall, as respects any period of emergency, include a reference to those purposes."

In principle, a remuneration must be paid for Crown use.

The Netherlands

Compulsory licensing provisions in the Netherlands can be found in articles 57–58a of the Dutch Patents Act 1995. The legal system provides, amongst others, for compulsory licensing for non-use and in the public interest. The statute also contains a separate type of non-voluntary licensing, which is a license in the interest of public defence.

Article 59 of the Dutch Patent Act states:

> "Bij koninklijk besluit kan, indien het belang van de verdediging van het Koninkrijk dit vordert, op gemeenschappelijke voordracht van Onze Minister en van Onze minister, wie het rechtstreeks aangaat, worden bepaald, dat de Staat bevoegd is in dat besluit nauwkeurig te omschrijven handelingen, waartoe de houder van een in dat besluit aan te wijzen octrooi ingevolge de artikelen 53 en 54a gerechtigd is, zelf te verrichten of door anderen te doen verrichten. Deze bevoegdheid geldt voor de gehele duur van het octrooi, tenzij in het besluit een kortere duur is bepaald."
>
> (It may be determined by Royal Decree, if the interests of the defence of the Kingdom so require, on the joint recommendation of Our Minister and of Our Minister whom it may directly concern, that the State shall be authorized to perform, or to have performed by others, acts to be specified in such decree, which the holder of a patent to be designated in such decree is authorized to perform himself or by others pursuant to sections 53 and 54a. This power shall apply for the entire term of the patent, unless a shorter term is specified in the decree.[75])

[74] United Kingdom, Patents Act 1977 sec. 59(1). For a discussion on sec. 59 Patents Act 1977, IPCOM GmbH & Co Kg v Vodafone Group Plc & ors [2021] EWCA Civ 205 (February 19, 2021).

[75] Translated with DeepL.com, free version.

France

The compulsory licensing provisions relating to patents in France can be found in articles L613-11 to L613-14 in the Code de la propriété intellectuelle 1992.[76] The system is limited to non-use only, and for the license for export as per Regulation (EC) No. 816/2006.[77] For other situations, types of ex officio licenses can be granted, as follows.

Article L613-16 covers the ex officio license in the interest of public health, and is hence limited to medical and diagnostic processes and products:

> "Si l'intérêt de la santé publique l'exige et à défaut d'accord amiable avec le titulaire du brevet, le ministre chargé de la propriété industrielle peut, sur la demande du ministre chargé de la santé publique, soumettre par arrêté au régime de la licence d'office, dans les conditions prévues à l'article L613-17, tout brevet délivré pour:
>
> "a) Un médicament, un dispositif médical, un dispositif médical de diagnostic in vitro, un produit thérapeutique annexe;
> b) Leur procédé d'obtention, un produit nécessaire à leur obtention ou un procédé de fabrication d'un tel produit;
> c) Une méthode de diagnostic ex vivo.
>
> "Les brevets de ces produits, procédés ou méthodes de diagnostic ne peuvent être soumis au régime de la licence d'office dans l'intérêt de la santé publique que lorsque ces produits, ou des produits issus de ces procédés, ou ces méthodes sont mis à la disposition du public en quantité ou qualité insuffisantes ou à des prix anormalement élevés, ou lorsque le brevet est exploité dans des conditions contraires à l'intérêt de la santé publique ou constitutives de pratiques déclarées anticoncurrentielles à la suite d'une décision administrative ou juridictionnelle devenue définitive.
>
> "Lorsque la licence a pour but de remédier à une pratique déclarée anticoncurrentielle ou en cas d'urgence, le ministre chargé de la propriété industrielle n'est pas tenu de rechercher un accord amiable."
>
> (If the interests of public health so require, and in the absence of an amicable agreement with the patent owner, the Minister responsible for industrial property may, at the request of the Minister responsible for public health, subject by decree to the ex officio license system, under the conditions set out in article L613-17, any patent granted for:
> a) A medicine, a medical device, an in vitro diagnostic medical device or an ancillary therapeutic product;
> b) A process for obtaining them, a product necessary for obtaining them or a process for manufacturing such a product;
> c) An ex vivo diagnostic method.
>
> Patents for these products, processes or diagnostic methods may only be subject to compulsory licensing in the interests of public health when these products, or products derived from these processes, or these methods, are made available to the public in insufficient quantity or quality, or at abnormally high prices, or when the patent is exploited under conditions contrary to the interests of public health or constituting practices declared to be anticompetitive following a final administrative or judicial decision.

Where the purpose of the license is to remedy a practice declared to be anti-competitive, or in cases of urgency, the Minister responsible for industrial property is not obliged to seek an amicable agreement.[78])Article L613-18 expands the circumstances in which an ex officio license system can be triggered to cover the national economy, Article L613-19 to meet national

[76] Art. L613-15 contains two provisions relating to other types of mandatory licensing.
[77] See section 6.2.1
[78] Translated with DeepL.com, free version.

defense requirements, and Article L613-19-1 expands the system to semiconductor technology.

As per Article L613-17, for each ex officio license, any qualified third party may file a request with the minister responsible for IP to obtain a license to work the patent.

6.3 Emergency and pandemic preparedness legislation

A major shift in the approach to compulsory licensing, or at least in forcing right holders to grant licenses in specific situations, was prompted by the COVID-19 pandemic. In Europe, that was evident in the first embodiment of so-called emergency legislation, which was swiftly enacted in several EU member states. The type of instruments had, in most cases, the look and feel of compulsory licenses or related instruments.[79] Subsequently, these new laws were not further put into effect for vaccines and therapeutics, being replaced by APAs.[80]

For instance, Germany, in March 2020, adopted a new amendment to its Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen – Infektionsschutzgesetz – IfSG (Act on the Prevention and Control of Infectious Diseases in Humans),[81] which gives special powers to the Federal Ministry of Health, among other things, setting aside the effect of patents. According to Section 5, the ministry can order that:

> "[U]nder s. 13(1) of the Patent Act that an invention relating to one of the products mentioned in No. 4 […] shall be used in the interest of public welfare or in the interest of the security of the Federal Republic of Germany; the Federal Ministry of Health may instruct a subordinate authority to make such an order."[82]

Under Section 13(1) of the Patent Act:

> "(1) The patent shall have no effect in a case where the Federal Government orders that the invention is to be used in the interest of public welfare. Further, it shall not extend to a use of the invention which is ordered in the interest of the security of the Federal Republic of Germany by the competent highest federal authority or by a subordinate authority acting on its instructions."[83]

This means patent holders can maintain their rights but cannot enforce them against ministries invoking the provision.

France has taken radical measures. Under Law No. 2020-856 of July 9, 2020, Article 1(IX),[84] the Public Health Code (Code de la santé publique) was amended to include

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[79] Hybrid pieces of legislation (at least to some extent and in some countries), covering not only compulsory licenses but also other measures.

[80] See section 8.3.

[81] "Infektionsschutzgesetz vom 20. Juli 2000 (BGBl. I S. 1045, Bundesgesetzblatt BGBl. Online-Archiv 1949 - 2022 | Bundesanzeiger Verlag), ("Infection Protection Act of July 20, 2000 (Federal Law Gazette I p. 1045)", as amended). IfSG - nichtamtliches Inhaltsverzeichnis (gesetze-im-internet.de)

[82] Klopschinski, S. "Update on patent-related measures in Germany in view of Corona pandemic." Kluwer Patent Blog, April 2, 2020. <http://patentblog.kluweriplaw.com/2020/04/02/update-on-patent-related-measures-in-germany-in-view-of-corona-pandemic/?doing_wp_cron=1596741304.5864660739898681640625>

[83] *Ibid.*

[84] LOI n° 2020-856 du 9 juillet 2020 organisant la sortie de l'état d'urgence sanitaire (1) - Légifrance (legifrance.gouv.fr) (LAW no. 2020-856 of July 9, 2020 organizing the end of the state of health emergency). Abrogated by LOI n° 2022-1089 du 30 juillet 2022 mettant fin aux régimes d'exception créés pour lutter contre l'épidémie liée à la covid-19 (1) - Légifrance (legifrance.gouv.fr) (LAW no. 2022-1089 of July 30, 2022 putting an end to the exceptional regimes created to combat the epidemic linked to covid-19).

measures, among other things, constricting people's freedom of movement but also the following:

> "En tant que de besoin, prendre toute mesure permettant la mise à la disposition des patients de médicaments appropriés pour l'éradication de la catastrophe sanitaire." (to the extent necessary, take any action allowing the provision of medicines to patients with a view to eradicate the health pandemic).[85]

The emergency legislation measures go beyond the grant of compulsory or non-voluntary licensing, and offer wide ranging powers to governments, including the right to set aside patent rights.

At the European level, the European legislature has also enacted legislation to organize pandemic preparedness,[86] which must be distinguished from the EU legislative proposal on compulsory licensing for crisis management (see section 6.2.2).

Interesting for this study are the provisions relating to the obligation of recipients of European Commission financing, who are also patent right holders, to provide licensing under fair and reasonable conditions,[87] of IP and know-how pertaining to such countermeasures. That obligation is triggered if an economic operator (grant recipient) abandons their development effort or is unable to ensure sufficient and timely delivery under the terms of the agreement.

Indeed, Council Regulation (EU) 2022/2372 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at the Union level aims, according to the preamble, to:

> "[E]stablish an instrument of economic policy fundamental to avoid the adverse economic consequences of health crises, such as negative growth, unemployment, market disruptions, fragmentation of the internal market, and impediments to swift manufacturing – consequences which have been witnessed on a large scale in the context of the COVID-19 pandemic – with a view to ultimately safeguarding the economic stability of the Union and of its Member States."[88]

Medical countermeasure, as used in the regulation, is defined as follows:

> "[M]edicinal products for human use as defined in Directive 2001/83/EC of the European Parliament and of the Council, medical devices as defined in point 12 of this Article and other goods or services that are necessary for the purpose of preparedness for and response to serious cross-border threats to health."[89]

Article 8(9) states:

> "9. Where the Commission provides financing for the production and/or development of crisis-relevant medical countermeasures, the Commission shall have the right to require the

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[85] France, Code de la santé publique art. L3131-15(I)(9), Article L3131-15 - Code de la santé publique - Légifrance (legifrance.gouv.fr). The statute makes no specific reference to existing provisions in the Code de la propriété intellectuelle (Intellectual property code) relating to compulsory and ex officio licensing, leaving the extent to which those provisions could be overridden unclear.

[86] Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. OJ L 314, 6.12.2022, pp. 64–78.

[87] Reference is made to "provided financing" and "financial support", suggesting the licensing system can be triggered in all cases where some financial funding has been provided by the Commission. The wording does not suggest a precondition that medical countermeasures are entirely financed by the Commission.

[88] Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, recital 2.

[89] See Council Regulation (EU) 2022/2372, *op cit*., art. 2(3) in conjunction with art. 3(10) of Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No. 1082/2013/EU (Text with EEA relevance). OJ L 314, 6.12.2022, pp. 26–63.

> licensing, under fair and reasonable conditions, of intellectual property and know-how pertaining to such countermeasures, if an economic operator abandons their development effort or is unable to ensure their sufficient and timely delivery under the terms of the agreement concluded. Further conditions and procedures relating to the exercise of that right may be set out in specific agreements with economic operators."

Recital 16 explains it thus:

> "Appropriate intellectual property tools are needed to mitigate the risks of abandonment of development efforts, or supply issues, concerning crisis-relevant medical countermeasures during a public health emergency, especially where public authorities have provided financial support for the development and production of such countermeasures. The Commission should therefore be able to require the licensing, under fair and reasonable terms, of intellectual property rights and know-how pertaining to such countermeasures, the development and production of which the Commission has financed, in justified exceptional cases, as a safety net and an incentivising element. When facilitating the licensing of intellectual property and know-how pertaining to such countermeasures, the Commission should take into account the upfront financing by the Union or Member States of the development and the production of such countermeasures."

It can be observed that the licensing obligation is for the IPRs pertaining to the financed countermeasures. In light of the fact that countermeasures can refer to medicinal products, and that the provision also refers to conditions relating to abandoning development of such countermeasures, or being unable to supply them in sufficient quantities, this should probably be understood as the entire product, even if the end product has only been part-financed by the European Commission. The regulation is applicable in the territory of the European Union and its member states, for the benefit of the same.

The licensing obligations under Council Regulation (EU) 2022/2372 show similarities to the government use and ex officio licensing obligations discussed in section 6.2.3.[90]

6.4 Reporting public financial support requirement in new EU pharma package

An interesting provision can be found in the European Commission's proposals for a substantial overhaul of the medicinal product regulation system in Europe.[91] It is beyond the scope of this study to discuss those wide-ranging proposals.

The proposal for a directive on a new Union code relating to medicinal products for human use stipulates in Article 57 an obligation for an MA applicant to declare any direct financial support received from a public authority or publicly funded body relating to activities for the R&D of the medicinal product.

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[90] Licensing obligations under Council Regulation (EU) 2022/2372 equally show similarities to the licensing provisions introduced in the United States of America with the Bayh-Dole Act (Bayh-Dole Act. Section 6(a) of Pub. L. 96–517, Dec. 12, 1980, 94 Stat. 3018, incorporated into 35 U.S. Code Chapter 18, sects. 200–212). For an overview, see Ouellette, L.L. "IP and public research in health emergencies: US policy, law and practice." *wipo.int*. World Intellectual Property Organization, Mar. 7, 2024. <https://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_ge_24/wipo_ip_ge_24_discussion.pdf>.

[91] Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC. COM(2023) 192 final; Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM(2023) 193 final.

Article 57, on responsibility to report on public financial support, states:[92]

> "1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.
> 2. Within 30 days after the marketing authorisation is granted the marketing authorisation holder shall:
> (a) draw up an electronic report listing:
> (i) the amount of financial support received and the date thereof;
> (ii) the public authority or publicly funded body that provided the financial support referred to in point (i);
> (iii) the legal entity that received the support referred to in point (i).
> (b) ensure that the electronic report is accurate and that it has been audited by an independent external auditor;
> (c) make the electronic report accessible to the public via a dedicated webpage;
> (d) communicate the electronic link to such webpage to the competent authority of the Member State or, where appropriate, to the Agency.
> 3. For the medicinal products authorised under this Directive, the competent authority of the Member State shall communicate in a timely manner the electronic link to the Agency.
> 4. The marketing authorisation holder shall keep the electronic link up to date and, as necessary, update the report annually.
> 5. The Member States shall take appropriate measures to ensure that paragraphs 1, 2 and 4 are complied with by the marketing authorisation holder established in their country.
> 6. The Commission may adopt implementing acts to lay down the principles and format for the information to be reported pursuant to paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2)."

The text of Article 57 recently adopted by the European Parliament at first reading[93] reads slightly different compared to the original European Commission proposal:

> "1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority, publicly funded body or philanthropic or not-for-profit organisation or fund, irrespective of its geographic location, and any indirect financial support received from any public authority or publicly funded body of the Union or its Member States in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.
> 2. Within 30 days after the marketing authorisation is granted the marketing authorisation holder shall:
> (a) draw up an electronic report listing:
> (ii) the entity that provided the financial support referred to in point (i);
> (iii) the legal entity that received the support referred to in point (i).
> (iiia) where relevant, any independent legal entity from which it obtained a licence in relation to, or acquired the medicinal product in its previous phases of development, and at which stage of the research and development process. The marketing authorisation holder shall, to the extent possible, include in the report information on funding received as referred to paragraph 1 specific to the relevant medicinal product.
> (b) ensure that the electronic report is accurate and that it has been audited by an independent external auditor;
> (c) make the electronic report accessible to the public via a dedicated webpage;
> (d) communicate the electronic link to such webpage to the competent authority of the Member State or, where appropriate, to the Agency.

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[92] Art. 57 of the Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC. COM(2023) 192 final.

[93] European Parliament legislative resolution of 10 April 2024 on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (COM(2023)0192 – C9-0143/2023 – 2023/0132(COD)), P9_TA(2024)0220, Texts adopted - Union code relating to medicinal products for human use - Wednesday, 10 April 2024 (europa.eu). Whether the Council of ministers will adopt this amended text is yet to be seen.

> 3. For the medicinal products authorised under this Directive, the competent authority of the Member State shall communicate in a timely manner the electronic link to the Agency.
> 4. The marketing authorisation holder shall keep the electronic link up to date and, as necessary, update the report annually.
> 5. The Member States shall take appropriate measures to ensure that paragraphs 1, 2 and 4 are complied with by the marketing authorisation holder established in their country.
> 6. The Commission shall adopt implementing acts to lay down the principles and format for the information to be reported pursuant to paragraph 2, by [12 months from the date of entry into force of this Directive]. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).
>
> 6a. The Agency shall provide on its website the links to the information communicated to the Agency in accordance with paragraphs 2 and 3, sorted, where relevant, by medicinal product and by Member State.

The rationale for introducing such a provision can be seen as a logical consequence of introducing provisions relating to compulsory licensing and other licensing rights to "countermeasures" where public funding was received for the development of those countermeasures. Indeed, the obvious use of this proposed requirement is to facilitate the use of both enacted and proposed legislation where the existence of received public funding will entail certain obligations or limitations, in this case, the European emergency legislation in place in Council Regulation 2022/2372[94] and the draft Regulation on compulsory licensing and crisis management.[95] In that sense, it is a necessary measure to ensure that received public funding can be traced, facilitating the licensing rights and obligations being put into effect.

This provision, however, can also constitute a useful basis for future policy choices that the European Union and/or its member states might want to pursue. For instance, it could be a useful tool in the evaluation of leverage in negotiations between governments and recipients of such public funding, such as in the case of APAs/AMCs or other forms of licensing. It is also worth observing that the provision aims at public funding being disclosed to the public at large, not only public bodies. The intention is to see details of the funding received by the MA applicant published on a dedicated webpage, available to the wider public. Accuracy of the information provided is subject to audit by an external independent auditor.

7 Soft law statutory tools

7.1 Introduction

Soft law statutory tools prescribe or stimulate disclosure of information relevant to the innovation in question, but (in terms of this study) would not bind right holders to grant licenses to third parties. Even though they cannot directly contribute to a particular patent-protected technology becoming available to third parties for the duration of the patent, such tools help disseminate underlying data and knowledge, potentially valuable in knowledge sharing and transfer. They can in that sense also influence the options for owners of know-how to retain it secret.

In Europe, much effort has been applied to developing open science and open data policies. Though some might have hoped these would displace traditional IPRs, this has not – and is unlikely – to happen. At best, they are a tool to assist in the wider dissemination of scientific

[94] See section 6.3.
[95] See section 6.2.2.

and technological knowledge, given traditional IPRs remain important in investment-heavy areas. As Lemley suggests, and limiting ourselves to the patent system, the prospect of attaining no exclusivity in areas where the production of the knowledge (largely information which is, as such, non-exclusive and non-rival)[96] comes at considerable financial and intellectual effort could at least be an indication such innovations would not have come about without some form of exclusivity.[97]

7.2 Open science, open access and open data

Since 2000, much of the focus in Europe has centered on open science and open access as a tool to spread knowledge globally. European legislators likely considered that the correct course of action was to ensure that knowledge obtained with public research funding was shared with third parties as another means of stimulating innovation. This has led to the so-called open science policy. It is beyond the scope of this study to elaborate on the vast amount of literature relating to this domain.[98] According to the European Commission, open science can be defined as follows:

> "Open Science is a system change allowing for better science through open and collaborative ways of producing and sharing knowledge and data, as early as possible in the research process, and for communicating and sharing results. This new approach affects research institutions and science practices by bringing about new ways of funding, evaluating and rewarding researchers. Open Science increases the quality and impact of science by fostering reproducibility and interdisciplinarity. It makes science more efficient through better sharing of resources, more reliable through better verification and more responsive to society's needs."

The Commission has organized the policy thus:

> "Open science policy has developed progressively in the EU. It concerns all aspects of the research cycle, from scientific discovery and scientific review to research assessment, publishing and outreach; its cornerstone being open access to publications and research data. Since 2016, the Commission organises its open science policy according to eight 'ambitions':
>
> "1. Open Data: FAIR (Findable, Accessible, Interoperable and Re-usable data) and open data sharing should become the default for the results of EU-funded scientific research.
> 2. European Open Science Cloud (EOSC): a 'federated ecosystem of research data infrastructures' will allow the scientific community to share and process publicly funded research results and data across borders and scientific domains.
> 3. New Generation Metrics: New indicators must be developed to complement the conventional indicators for research quality and impact, so as to do justice to open science practices.
> 4. Future of scholarly communication: all peer-reviewed scientific publications should be freely accessible, and the early sharing of different kinds of research outputs should be encouraged.
> 5. Rewards: research career evaluation systems should fully acknowledge open science activities.
> 6. Research integrity: all publicly funded research in the EU should adhere to commonly agreed standards of research integrity.
> 7. Education and skills: all scientists in Europe should have the necessary skills and support to apply open science research routines and practices.

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[96] Nordhaus, W.D. *Invention, Growth and Welfare: A Theoretical Treatment of Technological Change*. Cambridge, Massachusetts: MIT Press, 1969; and Dam, K.W. "The economic underpinnings of patent law." *The Journal of Legal Studies* (1994): pp. 247–271.

[97] Lemley, M.A. "Faith-based intellectual property." *UCLA Law Review* vol. 62 (2015): pp. 1328–1346.

[98] See Miedema, F. *Open Science: The Very Idea*. Springer Dordrecht, 2022.

8. Citizen science: the general public should be able to make significant contributions and be recognised as valid European science knowledge producers."[99]

The FAIR principles can be defined as follows.[100]

Findable
The first step in (re)using data is to find them. Metadata and data should be easy to find for humans and computers. Machine-readable metadata are essential for automatic discovery of datasets and services:
F1. (Meta)data are assigned a globally unique and persistent identifier.
F2. Data are described with rich metadata (defined by R1 below).
F3. Metadata clearly and explicitly include the identifier of the data they describe.
F4. (Meta)data are registered or indexed in a searchable resource.

Accessible
Once the user finds the required data, they need to know how they can be accessed, possibly including authentication and authorization:

A1. (Meta)data are retrievable by their identifier, using a standardized communications protocol.
A1.1 The protocol is open, free and universally implementable.
A1.2 The protocol allows for an authentication and authorization procedure, where necessary.
A2. Metadata are accessible, even when the data are no longer available.

Interoperable
The data usually need to be integrated with other data. In addition, the data need to interoperate with applications or workflows for analysis, storage, and processing:

I1. (Meta)data use a formal, accessible, shared and broadly applicable language for knowledge representation.
I2. (Meta)data use vocabularies that follow FAIR principles.
I3. (Meta)data include qualified references to other (meta)data.

Reusable
The goal of FAIR is to optimize the reuse of data. To achieve this, metadata and data should be well described so they can be replicated and/or combined in different settings:

R1. (Meta)data are richly described with a plurality of accurate and relevant attributes.
R1.1. (Meta)data are released with a clear and accessible data usage license
R1.2. (Meta)data are associated with detailed provenance.
R1.3. (Meta)data meet domain-relevant community standards.

The FAIR principles refer to three types of entities: data (or any digital object), metadata (information about that digital object), and infrastructure. For instance, principle F4 defines that both metadata and data are registered or indexed in a searchable resource (the infrastructure component).[101]

The goal of open science and open data is to ensure scientific information and data become available in the widest possible manner and to the widest possible audience. Despite commendable ambitions, however, a tension remains between the desire to see the results

[99] European Commission, Open science.
[100] It is beyond the scope of this study to give a full overview of open data policies. For more information, see Wilkinson, M.D. *et al*. "The FAIR guiding principles for scientific data management and stewardship." *Scientific Data* vol. 3 (2016).
[101] More information is available on the Go Fair website, <https://www.go-fair.org/fair-principles/>.

of creative and inventive effort being shared in the widest possible manner, and the equally present desire to be able to recoup the cost of creating those works and inventions. IPRs, in particular patent rights, can coexist with the open science and open data policies but, in the view of the author, are not fully compatible. In certain situations, the availability of scientific information and data will be delayed if patent rights need to be filed. But the COVID-19 pandemic demonstrated that the two can co-exist to a large extent; for example, once patent positions have been decided, scientific developments and data can be published, or alternatively, in the public interest, patent positions are not taken and instead the scientific results are published.[102] In investment-intensive technology sectors, it is not unusual to see patent positions being taken.

Most literature discussing the interrelationship between open science and IPRs has focused on copyright law.[103] In the context of copyright, the policy of open access is an efficient way of ensuring knowledge is spread to as many people as possible. Equally it poses many questions,[104] though that discussion is beyond the scope of this study.

It is realistic to view the relationship between open science and IPRs as one of partners[105] trying to achieve the best of both worlds; that is, retaining an incentive mechanism to stimulate innovation but respecting the interests of society in being able to use creative and inventive labor.

The open science ambition results in large amounts of scientific information becoming available to a wider public, facilitating technology and knowledge transfer, while the IPR positions taken give innovators the prospect of returns on investments made to create new technologies.

8 Contract-based tools

8.1 Introduction

Contract-based tools allow parties to agree on a variety of rights and obligations. For public funders, they can be used to demand a range of concessions from funding recipients for the benefit of the public. The tools can be powerful, though their success will, at least partly, depend on the leverage the public funder can exercise beyond providing funding for research or some other output. As a contract tool, success is also influenced by the understanding of the various options, and/or poor implementation/negotiation of such options. Information asymmetry between parties in negotiating the contracts will also affect the end result. For instance, if a public body negotiates a contract to prefinance vaccine production, the vaccine manufacturer has information supremacy, given it knows how much it will cost to manufacture a single dose, it knows the value and volume of its (secret) know-how, and has sophisticated insight into its IP portfolios. This information will be largely unknown or not sufficiently known to the public funder. Further, the public funder has the

[102] An example is the publication of the gene sequence of the first variants of the SARS-CoV-2 virus, which facilitated research and development of new vaccines.
[103] European Commission, Directorate-General for Research and Innovation. *Open Science and Intellectual Property Rights: How can they Better Interact? State of the Art and Reflections*. Publications Office of the European Union, 2022. <https://data.europa.eu/doi/10.2777/347305>.
[104] See Gruessing, E., et al. "Drivers and obstacles of open access publishing. A qualitative investigation of individual and institutional factors." *Frontiers in Communication* vol. 5 (2020).
[105] See ALLEA, Aligning intellectual property rights with open science

common good to deal with, and all the pressures that entails, which are of far less strategic importance to private companies.

In this section, various typologies of contracts used in the European Union are discussed. This is not an exhaustive list, as the number of variations is almost limitless, and not all information on such contracts can be found in public repositories. This is not helped by the scattered approach in the European Union, with many countries barely sufficient on the information publicly available.

The typologies discussed are as follows:

- Voluntary licensing
- APAs/AMCs
- Contract templates in EU countries and at the European Commission relating to research grant contracts

8.2 Voluntary licensing

Voluntary licensing is always an option to gain access to protected technology whether it was publicly or privately funded. Such a license depends on the volition of the licensor to grant access to the technology protected by patents and/or trade secrets, which will be limited, and/or come with sometimes onerous terms. The author observes that there is little evidence to show that during the COVID-19 pandemic, companies controlling exclusive rights in vaccine technology were willing to grant access to this technology. One notable exception is the production license granted to the Indian company, Serum Institute India.[106] Other licenses were largely limited to finishing and filling licensing,[107] which can be granted without the need to provide access to exclusive technology.

Public funders can enter voluntary licensing agreements with public funding recipients that allow access to IPR-protected technologies.[108] Voluntary licensing can also take place in the context of other contractual arrangements, such as APAs/AMCs (see section 8.3), and public funding grant agreements (see section 8.4). Patent pooling and ensuing licensing agreements are also an example of contractual arrangements where voluntary licensing of IPR-protected technology takes place. And as with most measures discussed in this study, the scope and applicability cover situations where there has been public and/or private funding for the IPR-protected technology entering the patent pool. One example is the so-called Medicines Patent Pool (MPP). In the words of the organization:

> "The Medicines Patent Pool (MPP) is a United Nations-backed public health organisation working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries. Through its innovative business model, MPP partners with civil society, governments, international organisations, industry, patient groups and other stakeholders, to prioritise and licence needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations. To date, MPP has signed agreements with ten patent holders for thirteen HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals and a tuberculosis treatment. MPP was

[106] The Economic Times, AstraZeneca & Serum Institute of India sign licensing deal for 1 billion doses of Oxford vaccine.
[107] For example, Pfizer, Pfizer and BioNTech announce collaboration with Biovac to manufacture and distribute COVID-19 vaccine doses within Africa; Novartis, Novartis signs new initial agreement with BioNTech to support fill and finish of the mRNA Pfizer-BioNTech COVID-19 vaccine; and BioProcess International, Sanofi to fill-finish up to 200m doses of Moderna's COVID vaccine.
[108] For example, the research grant agreements between funders and recipients. See section 8.4.

> founded by Unitaid, which serves as sole funder for MPP's activities in HIV, hepatitis C and tuberculosis."[109]

Under this voluntary pool system, patent holders agree to license their technology to the MPP, and the latter subsequently sublicenses the patented technology to generic pharmaceutical manufacturers. Among other agreements, the MPP has been successful in closing licensing agreements for Paxlovid (nirmatrelvir and ritonavir),[110] where Pfizer owns the IP rights, and for Lagevrio (molnupiravir), owned by Merck.[111]

Public funders can include such arrangements in their grant agreements with developers of what later becomes IPR-protected technology, ensuring access to the funded technology. Because of its voluntary nature, whether such arrangements are feasible in a given situation will depend on many factors, leverage of the parties being an important one.

8.3 APAs/AMCs[112]

Advance purchase agreements (APAs), referred to as advance market commitments (AMCs) in certain jurisdictions, notably the United States of America, are a form of procurement agreement, where one party, the sponsor, prototypically a government or public body, commits to pay to another party, such as a vaccine developer/manufacturer, an amount of money in return for the supply of a named quantity of products; in the case of COVID-19 pandemic, vaccines. In the context of pandemics, it is a rather specific type of procurement agreement, and regarding COVID-19 vaccines, they have been an embodiment of public-private partnerships.

Such agreements, especially in the context of pandemics, can be labelled pull incentives, given their aim is to expedite the bringing to market of specific products. Lead time to produce a vaccine, as a biological product, can be long.[113] That is problematic in health emergencies. Generally, pharmaceutical companies will not start up a vaccine production process until the marketing authorization (MA) has been granted, or at least up to the moment when there is a positive expectation it will be granted in the near future. The reasoning is that producing vaccines without the prospect of obtaining an MA would make little business sense.

The conundrum is that holding back production will, in practical effect, mean that vaccines only get to people months after the MA has been granted, and in the case of a pandemic or other serious disease outbreak, time is of the essence. APAs provide an efficient solution to this dilemma. Under an APA, a government, international organization or other public body will lock in quantities and price per unit, potentially providing advance payment, thereby taking away at least part of the financial risk for producers. This allows them to start production well in advance of obtaining the MA. The main financial risk is that payment received in advance will have to be refunded if no MA is obtained. But pharmaceutical companies can hedge their risk, and start production, which they would otherwise likely be unwilling to do.

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[109] More information is available on the Medicines Patent Pool website, https://medicinespatentpool.org/.
[110] Medicines Patent Pool, Nirmatrelvir.
[111] *Ibid*., Molnupiravir.
[112] Parts of this section are derived from Bostyn, Access to drugs, patents and pandemic crisis.
[113] Lead times normally reach from several months to three years. See Plotkin, S., *et al*. "The complexity and cost of vaccine manufacturing – An overview." *Vaccine* vol. 35, issue 33 (2017): pp. 4064–4071.

APAs are not a new concept, and have been used for vaccines against neglected diseases and influenza.[114] They can be a powerful tool to ensure expedient access to vaccines or other medical treatments is guaranteed.

As a voluntary contract, they can contain a wide variety of provisions besides the supply and payment of vaccines or other products. Governments can use them to impose obligations on manufacturers or allow them certain exemptions.[115] It is possible to impose duties for manufacturers to grant licenses to third parties, or set minimum quantity requirements with penalty clauses, among other things.[116] As far as is known, such obligations were not imposed on the manufacturers in the first COVID-19 vaccines related to APAs. In practice, it is difficult to know what is included in a particular procurement contract, as they are, in principle, secret.[117]

As governments provide substantial funds under APAs/AMCs, they can be in a position to negotiate obligations on the part of the recipient (being the counterpart in the APA/AMC); for instance, to grant licenses to third parties. It is worth public funders exploring the possibilities under APAs/AMCs in preparing for future crises.

8.4 European Union and national contract template provisions on licensing of results as a consequence of public grants

It is useful to examine how public funding governments/bodies approach the relationship between the funding they provide and access to the technology that is at least being partly produced with said funding. The question arises as to how to measure that approach. Scrutinizing research grant contract templates is a useful parameter to evaluate the extent to which funding governments try to influence the behavior of funding recipients in accessing the funded technologies.

A non-exhaustive search of European Commission and national research grant contract templates was conducted, and their terms in relation to IP rights analyzed. The sample is not necessarily representative of all EU member states.[118]

A distinction must be made between funding granted through European Commission facilities, such as Horizon Europe and other EU programmes, and funding provided by the EU member states.

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[114] Turner, M. "Vaccine procurement during an influenza pandemic and the role of advance purchase agreements: Lessons from 2009-H1N1." *Global Public Health* vol. 11, issue 3 (2016): pp. 322–335; Berndt, E.R., *et al*. "Advance Market Commitments for vaccines against neglected diseases: Estimating costs and effectiveness." *Health Economics* vol. 16, issue 5 (2007): pp. 491–511; Berndt, E.R., and J.A. Hurvitz. "Vaccine advance-purchase agreements for low-income countries: Practical issues." *Health Affairs* vol. 24, No. 3 (2005): pp. 653–665; and Barder, O., *et al*. *Making markets for vaccines: From ideas to action*. Center for Global Development, 2005.

[115] One not elaborated is the inclusion of liability waivers for pharmaceutical companies. In procurement contracts with the UK government, such a liability waiver was included. See Brodies, COVID-19 vaccines and civil liability.

[116] For more information on APAs/AMCs, see BOSTYN, Access to drugs, patents and pandemic crisis.

[117] For analysis of some APAs signed in Europe, see Slade, A., and N. Hawkins. "Intellectual property rights and advance purchase agreements in a crisis." *Intellectual Property Quarterly* (2023): pp. 1–32.

[118] The decision to use contract templates was influenced by information available in public repositories and the presence of interesting features, though this is not necessarily representative of government practices in other countries.

EU Annotated Grant Agreement

The Annotated Grant Agreement (AGA), a user guide that explains to applicants and beneficiaries the EU Model Grant Agreement for EU funding programmes 2021–2027, was studied, limited to the provisions related to IPR and know-how.[119]

The EU Model Grant Agreement is the basis on which the actual grant agreements are developed and signed. The funding contract between the granting body (the European Commission or one of its agencies) and the beneficiary/beneficiaries is the grant agreement. Besides the grant agreement, there is also the consortium agreement, which specifies the rights and obligations of the parties within the consortium.

For the purposes of this study, the grant agreement is the most relevant, as it defines the rights and obligations between the funding body and recipient. The EU Model Grant Agreement constitutes the best springboard, given it acts as the template for the grant agreements. The relevant material can be found in Article 16 and annex 5, Specific Rules. Article 16(2) states:

> "16.2 Ownership of results
>
> "The granting authority does not obtain ownership of the results produced under the action.
>
> "'Results' means any tangible or intangible effect of the action, such as data, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights."

The basic principle, therefore, is that the granting authority does not obtain ownership of the results. However, one must also look at Article 16(4):

> "16.4 Specific rules on IPR, results and background
>
> "Specific rules regarding intellectual property rights, results and background (if any) are set out in Annex 5."

Annex 5 is a complex document, giving several options that can be included in grant agreements. The clauses of agreements relating to IPRs depend on the type of EU programme the grant refers to. For Digital Europe Programme (DEP) and European Defence Fund (EDF) programmes, the following principles apply:

> "[Exploitation of results
>
> "Beneficiaries must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to exploit their results directly or to have them exploited indirectly by another entity, in particular through transfer or licensing.]"[120]

Surprisingly, there is no obligation to license the technology to the granting body, or for use on behalf of it, if no exploitation has taken place within the four years.

> "Access rights for the granting authority EU institutions, bodies, offices or agencies [and national authorities] to results for policy purposes
>
> "The beneficiaries must grant access to their results – on a royalty-free basis – to the granting authority, other EU institutions, bodies, offices or agencies, for developing, implementing and monitoring EU policies or programmes. [Such access does not extend to beneficiaries' background.]
>
> "Such access rights are limited to non-commercial and non-competitive use.

[119] European Commission, AGA, Annotated Grant Agreement (document studied is a draft).

[120] Text between brackets refers to terms/conditions that are an "option for programmes with specific IPR rules".

> "[The access rights also extend to national authorities of EU Member States or associated countries, for developing, implementing and monitoring their policies or programmes in this area. In this case, access is subject to a bilateral agreement to define specific conditions ensuring that:
> - the access will be used only for the intended purpose and
> - appropriate confidentiality obligations are in place.
>
> "Moreover, the requesting national authority or EU institution, body, office or agency (including the granting authority) must inform all other national authorities of such a request.]"

Even though there is an obligation to grant a royalty-free license to the granting authority – and, as can be seen in the clause between brackets, optionally to national authorities – for the results (excluding background) for policy purposes, the template does not explain what a "policy" purpose could encompass. It is also not clear whether there is a right to sublicense. The use may not be commercial and competitive, however. For instance, if a policy purpose was to grant access to the results to third parties in lower income countries, to develop digital diagnostic technology (the "results") themselves, that would not comply with the conditions under the license, as the use may not be commercial and competitive. Sharing that technology with third parties for researching the development of such digital diagnostic technology might not be commercial. Surely, though, questions will arise over non-competitive once the resulting diagnostics are brought to market in such countries, even if that is done in a non-commercial fashion (for instance, government organized and not for profit).

> "[Access rights for the granting authority to results in case of a public emergency
>
> "If requested by the granting authority in case of a public emergency, the beneficiaries must grant non-exclusive, world-wide licences to third parties – under fair and reasonable conditions – to use the results to address the public emergency.]
>
> "[Access rights for third parties to ensure continuity and interoperability
>
> "Where the call conditions impose continuity or interoperability obligations, the beneficiaries must make the [materials, documents and information] [and] [results] produced in the framework of the action available to the public (freely accessible on the Internet under [open licences] [or] [open source licences]).]
>
> "Access rights for national authorities to the special report for use by/for armed forces or security or intelligence forces
>
> "For Research Actions, the beneficiaries must grant access to the special report – on a royalty-free basis – to national authorities of EU Member States or associated countries for use by/for their armed forces or security or intelligence forces (including in the framework of cooperative programmes).
>
> "'Special report' means the specific deliverable summarising the results of a research project and providing information on the basic principles, aims, outcomes, basic properties, tests performed, potential benefits, potential defence applications and expected exploitation path of the research towards development. It may also include information on the ownership of IPRs.
>
> "Access to the special report will be granted by the granting authority, after having ensured that appropriate confidentiality obligations are in place.
>
> "Access rights for third parties to further develop results
>
> "For Research Actions, the beneficiaries must grant access – on a royalty-free basis – to results which are necessary for the execution of other EU grants or contracts between national authorities of two or more EU Member States or associated countries and one or more beneficiaries, to further develop together results generated by the action.

> "In this case, access is subject to a bilateral agreement to define specific conditions ensuring that:
> - the access rights will be used only for the intended purpose and
> - appropriate confidentiality obligations are in place.]"

Fair and reasonable conditions are further defined as:

> "Appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged."

The emergency use worldwide license is a new provision in the template for EU grant contracts, brought about by the COVID-19 pandemic. It allows third parties to gain access to the results of publicly funded research under fair and reasonable conditions. If an EU EDP or EDF grant leads to results that fall within the scope of what is needed to tackle the public emergency, such results would be caught by this clause. It is not clear how it could be implemented if the results achieved are intrinsically linked to other, earlier proprietary or IP-protected developed technology, given questions remain as to whether the contract imposes an obligation to also include that technology in the license. Indeed, Article 16 of the template defines results as,

> "[A]ny tangible or intangible effect of the action, such as data, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights".

The problem lies in understanding the exact scope of this definition. Should results be understood to mean purely the "effect of the action", which could, for instance, be a building block of a broader technology platform for vaccines, or does it also cover the end product achieved with the "effects of the action".

For Horizon Europe and Euratom (HE) and Research Fund for Coal and Steel (RFCS), the following special provisions relating to IPRs may apply:

> "Exploitation of results
>
> "Beneficiaries which have received funding under the grant must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to exploit their results directly or to have them exploited indirectly by another entity, in particular through transfer or licensing.
>
> "[If, despite a beneficiary's best efforts, the results are not exploited within one year after the end of the action, the beneficiaries must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results.]"

Once again, there is no obligation to license the technology to the granting body, or for use on behalf of it, if no exploitation has taken place within the four years, and the Horizon Platform has not led to any interested parties.

> "[Additional exploitation obligations
>
> "Where the call conditions impose additional exploitation obligations (including obligations linked to the restriction of participation or control due to strategic assets, interests, autonomy or security reasons), the beneficiaries must comply with them – up to four years after the end of the action (see Data Sheet, Point 1).
>
> "Where the call conditions impose additional exploitation obligations in case of a public emergency, the beneficiaries must (if requested by the granting authority) grant for a limited period of time specified in the request, non-exclusive licenses – under fair and reasonable conditions – to their results to legal entities that need the results to address the public

> emergency and commit to rapidly and broadly exploit the resulting products and services at fair and reasonable conditions. This provision applies up to four years after the end of the action (see Data Sheet, Point 1).]"

Fair and reasonable conditions are further defined as per above. The clause does not specify whether such a license is worldwide, whereas the clause for the programmes discussed earlier does make that clarification. And, it seems the emergency license provisions can only be triggered for the HE and RFCS programmes if the call conditions impose exploitation obligations in a public emergency. If such conditions are not imposed in the call, then the clause cannot be triggered. It is not clear why the licensing provisions for the HE and RFCS programmes for emergency situations should be different from those programmes discussed earlier.

In conclusion, there are provisions in the EU Annotated Grant Agreement ensuring access to funded technologies. The template provides for an obligation to license the results of the funded project in case of public emergency, but some of wording is not clear, and the IP approaches between funding programmes could be improved.

Dutch Research Council

The Dutch Research Council (NWO) standard consortium agreement template[121] makes no mention of any obligation to grant a license to the granting authority. Somewhat surprisingly, it does not provide for licensing obligations in case of public emergency.[122]

Clauses comprising rights to background and results are covered in the traditional fashion.

Interestingly, however the parties organize their IP arrangements, all contractual provisions must comply with the so-called 10 principles for socially responsible licensing as laid down by the Netherlands Federation of University Medical Centres (NFU).[123]

Those 10 principles are:

> "1. Academic institutions strive to ensure that research contributes to societal and/or economic development.
> 2. Academic institutions retain the right to continue using their own results and to let them be used for research and education.
> 3. Academic institutions make licensing agreements exclusively with parties that can reasonably be expected to continue developing the knowledge and are committed to doing so.
> 4. Academic institutions verify that partners with whom they have arranged a licensing agreement do not have societal objectives that are in conflict with their own.
> 5. Academic institutions ensure that no traditional or indigenous knowledge or inventions based on it are included under intellectual property rights without appropriate agreements being made with the rights holders.
> 6. Academic institutions, when applying these principles, take those parties that are directly concerned into account and ensure that they are adequately informed of the wishes and interests of those interested parties.
> 7. Protection and licenses must not conflict with the legal task and societal mandate of academic institutions.
> 8. Licenses stimulate the development and use of technology and knowledge and bestow rights that are clearly defined and limited. Consideration must be given to both the commercial interests of the current partner and any other future applications. Plus unintentionally including future results or the results of others must be avoided.

[121] NWO, Consortium agreement.
[122] Consortium agreement, art. 4 and annex.
[123] NFU, Ten principles for socially responsible licensing.

> 9. In certain countries, licenses provide space to encourage or ensure marketing access or development, where possible. They can also offer possibilities to encourage or ensure application in certain sectors.
> 10. Licenses ensure that the price-setting of the final products and/or services does not endanger accessibility."

There has been criticism that the Dutch government did not adhere to clause 10 regarding COVID-19 vaccines, for which it, partly through NWO funding, provided substantial funding.[124] This study does not make judgment on such criticisms.

German Federal Ministry of Education and Research ancillary provisions for grants

The Federal Ministry of Education and Research's ancillary provisions for grants[125] were also studied, with the following observations. The public funding recipient can retain the IPRs in the results obtained, and hasexclusive exploitation rights, implying they can decide whether and under which conditions licenses will be granted, and know-how shared, among other things.[126]

But there are also restrictions, as laid down in clauses 3.4. and 3.5 of the ancillary provisions. Exploitation outside the European Economic Area (EEA)[127] and Switzerland requires written consent of the funding grantor. There is also a specific clause relating to granting a license in the public interest to the grantor:

> "3.4.2. Auf Verlangen des ZG [Zuwendungsgeber] hat der ZE [Zuwendungsempfänger] dem ZG in Fällen eines öffentlichen Interesses an den Ergebnissen und den urheberrechtlich geschützten Teilen der Ergebnisse ein nicht ausschließliches, übertragbares Verwertungsrecht einzuräumen. Auf Verlangen des ZG ist der ZE verpflichtet, dem ZG ein ausschließliches Verwertungsrecht einzuräumen, wenn dies zur Wahrung der öffentlichen Sicherheit erforderlich ist. In diesen Fällen entschädigt der ZG den ZE bis zur Höhe seines nachgewiesenen Eigenanteils zuzüglich der gesetzlich geschuldeten USt."
>
> (At the request of the G [Grantor], the GR [Grant Recipient] shall grant the G a non-exclusive, transferable right of exploitation in cases of public interest in the results and the copyright-protected parts of the results. At the request of the G, the GR is obliged to grant the G an exclusive exploitation right if this is necessary to safeguard public safety. In such cases, the G shall compensate the GR up to the amount of its proven own share plus the legally owed VAT.[128])

The template appears to limit the obligation to grant a license to the granting authority in cases of public interest, but is silent on what is meant by public interest, which likely implies it can be interpreted flexibly. This is confirmed by scrutiny of the case law and literature relating to the German compulsory license in the public interest,[129] in which the "public

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[124] Somo, How can we make publicly funded corona vaccines accessible to all.
[125] Germany, Federal Ministry of Education and Research. "Neufassung der Nebenbestimmungen für Zuwendungen auf Ausgabenbasis des Bundesministeriums für Bildung und Forschung zur Projektförderung(NABF)." (New version of the ancillary provisions for grants on an expenditure basis of the Federal Ministry of Education and Research for project funding.) *bmbf.de*. Dec. 2022 < Dritte Änderung der Bekanntmachung über die Nebenbestimmungen für Zuwendungen, Bundesanzeiger vom 21.12.2022, Änderung der Bekanntmachung - BMBF>. For the original text of the ancillary provisions (which are also the ones relevant for this study), see < Bekanntmachung über die Nebenbestimmungen für Zuwendungen. Bundesanzeiger vom 18.10.2017 Bekanntmachung - BMBF > *bmbf.de*. Oct. 2017.
[126] Clauses 3.1 and 3.2 of the ancillary provisions.
[127] EEA comprises the European Union and three of the four European Free Trade Association (EFTA)countries (Iceland, Liechtenstein and Norway).
[128] Translated with DeepL.com, free version.
[129] Germany, Patent Act 1980 sect. 24.

interest" concept can be assumed to be like the one in the present contract template. Technical, economic, sociopolitical and medical reasons can all justify a public interest:[130]

> "d) Als besondere Umstände, die die Annahme eines öffentlichen Interesses rechtfertigen, kommen deshalb unabhängig von der mißbräuchlichen Ausübung des Patentrechts auch andere Umstände in Betracht, vor allem technische, wirtschaftliche, sozialpolitische und medizinische Gesichtspunkte (Benkard, aaO, § 24 Rdn. 17 ff. m.w.N.; Horn, Mitt. 1970, 184,185; Schulte, aaO, § 24 Rdn. 8). Dabei ist das Wohl der Allgemeinheit vor allem auf dem Gebiet der allgemeinen Gesundheitspflege zu berücksichtigen. Die Frage, unter welchen Voraussetzungen ein öffentliches Interesse vorliegt, das die Erteilung einer Zwangslizenz gerade an diesen Lizenzsucher gebietet, hängt von den Umständen des Einzelfalls ab und ist im Einzelfall unter Abwägung der schutzwürdigen Interessen des Patentinhabers und aller die Interessen der Allgemeinheit betreffenden maßgeblichen Gesichtspunkte zu entscheiden." [131]
>
> (Therefore, other circumstances, in particular technical, economic, socio-political and medical aspects (Benkard, loc. cit., § 24 para. 17 et seq. with further references; Horn, Mitt. 1970, 184,185; Schulte, loc. cit., § 24 para. 8), may also be considered as special circumstances justifying the assumption of a public interest, irrespective of the abusive exercise of the patent right. In this context, the public good must be taken into account, particularly in the area of general healthcare. The question under which conditions a public interest exists which requires the granting of a compulsory license to this particular license seeker depends on the circumstances of the individual case and must be decided on a case-by-case basis by weighing up the interests of the patent proprietor worthy of protection and all relevant aspects relating to the interests of the general public.[132])

The contract terms do not refer to any remuneration that should be due. Clause 3.5.2 of the ancillary provisions also requires that the grant recipients guarantee free access for research purposes of the results of the research in Germany and the European Union:

> "3.5.2: [Die ZE hat:] die Ergebnisse — ggf. nach Anmeldung der gewerblichen Schutzrechte — der Forschung und Lehre in Deutschland und den Mitgliedsstaaten der EU auf Anfrage unentgeltlich zur Verfügung zu stellen, wenn sichergestellt ist, dass die Ergebnisse für einen nichtwirtschaftlichen Zweck verwendet werden. Anfragen zu Informationen, die dem nicht veröffentlichten Teil III des Sachberichts zum Verwendungsnachweis (Erfolgskontrollbericht) zu entnehmen sind, braucht der ZE nur auf der Grundlage einer Vertraulichkeitsvereinbarung zu beantworten."
>
> ([the GR must:] make the results available free of charge to research and education in Germany and the member states of the EU upon request – if necessary after registration of the industrial property rights – if it is ensured that the results are used for a non-economic purpose. Requests for information contained in the unpublished Part III of the report on the utilisation of funds (performance review report) need only be answered by the GR on the basis of a confidentiality agreement.[133])

In summary, the German model agreement does not provide for automatic licensing rights by the granting authority. There is the potential for the granting body to obtain a non-exclusive transferable right to exploit the results achieved in the public interest. Given this is a broadly defined concept, it could result in a flexible and wide-ranging right to obtain a license. Also noteworthy is the obligation to provide free access, for research purposes, of the results of the research funded. Despite the fact this sounds interesting, and could include otherwise 'secret-kept' know-how developed with the public funding, it can be difficult to prove precisely what has emanated from the funding, and what was privately funded preexisting knowledge.

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[130] See also, KRAßER, R., *Patentrecht*, 5th edition , Munich: Beck, 2004, 862-63.

[131] German Federal Court of Justice (BGH), Interferon-gamma, X ZR 26/92, 5 December 1995, para A.II.1.d), BGHZ 131, 247, at 254.

[132] Translated with DeepL.com, free version.

[133] *Ibid*.

9 Conclusions

This study researched the policy instruments that governments and government bodies can deploy to influence the behavior of public funding recipients. It was made clear from the outset that the relationship between public funding and IPR-protected products is, at best, opaque, and only rarely can end products be attributed fully to public funding. But that there is, in many cases, no direct relationship between public funding and an end product encompassing IPRs being funded in full by public resources is no excuse not to study policy levers that can influence the behavior of the recipients of such funding. Even if an end product is not covered fully by public funding, it is still good practice to analyze the tools that governments can deploy to gain access, or ensure that third parties gain access, to technologies funded at least in part by the public purse.

The study concludes that there is already a wide catalog of available instruments. Many statutory instruments relating to non-voluntary licensing (whether compulsory licenses, government use or ex officio mandatory licenses and emergency use licenses) do not distinguish whether the IPRs for which licenses will be granted result from public funding or not.

In Europe, the pandemic accelerated in-depth thinking and action relating to the tools governments should have at their disposal to secure access to IP-protected technologies, introducing obligations to license to governments that have provided public funding. Legislative action in Europe shows a willingness to force public funding recipients to provide access to funded technologies in certain situations, even if the products and technologies to which governments claim access have not been solely developed with public funding. In particular, EU emergency legislation can require access to funded technologies and accompanying IP-protected technology if such technology pertains to countermeasures such as medicinal products that have at least been in part publicly funded.

The European Commission has also proposed a compulsory licensing system for crisis situations that encompasses but is not limited to health pandemics. Under it, a new type of EU-wide compulsory license could be granted to ensure access to IP-protected technologies, with a view to producing products necessary to tackle the crisis. With respect to publicly funded technologies specifically, the proposal states that, when determining the remuneration to be paid to the right holder, whether public support to develop the invention was received or not shall be considered.

EU member states have, to varying degrees, also adapted their research grant contract templates to include emergency situations, though not all. Further reflection in this regard could be useful. Arguably, irrespective of any research grant contract stipulations, national or EU-wide emergency legislation might override the provisions of such grant contracts, even though that is not necessarily a given.

Various types of voluntary contractual arrangements, including APAs/AMCs, can also be used to include rights and obligations, including obligations to license technology to third parties in return for providing the financing under such agreements.

It is hoped this study will inspire governments and policymakers to look to toolboxes already filled with policy instruments to influence the behavior of public funding recipients, who have benefited from an IP and proprietary knowledge portfolio that is at least in part developed and/or commercialized with the assistance of such funding. Admittedly, many such statutory

instruments do not differentiate between IPRs obtained with public funding and those that are not.