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A Preliminary Index of SARS-CoV-2 Diagnostic Testing Patents

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Contents

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Abstract

Diagnostic testing for COVID-19 is an important part of the management of the pandemic. A diagnostic test-based policy response assumes the existence of diagnostic kits on a large scale, their availability at the point of care, an efficient way to administer the tests to the economically and socially active population, and the analysis and communication of the results. Overall, information produced by a diagnostic testing strategy is a key input to individual and public health decision making.

In this paper, we attempt to answer the question of where knowledge prerequisites to produce SARS-CoV-2 diagnostic tests are located in the world. We compile background knowledge on virology, particularly concerning the various options of diagnostic testing for known Coronaviruses with information retrieved from the corpus of patent documents. More specifically, we extract keywords from this field of expertise and we query these keywords in patent application filings. We construct an indicator of inventive activity in the area of Coronavirus diagnostic tests, and we decompose it across several dimensions - time, location of inventors, and thematic classifications. Our reasoning is that previous knowledge in the field might prove crucial for the development and deployment of diagnostics for SARS-CoV-2.

In the current pandemic, the knowledge prerequisites for the production of diagnostic tests are pertinent to a wide range of issues. The knowledge that is encapsulated in the patenting activity, which we document, can potentially be far-reaching if it becomes widely available to the scientific and industrial actors engaged in applied biomedical research. We present, without evaluating, a number of policy options.

1 Introduction

The global economy is currently managing the COVID-19 pandemic and making efforts for its resilience. Epidemiological management efforts go hand in hand with coordinated plans for rebound, reallocation, and structural change. This effort could potentially harness the diagnostic testing capabilities at a large scale. Acquiring more information on the extent of SARS-CoV-2 infection in various populations is fundamental for the management of the global pandemic.

Information produced by diagnostic testing is a key input to individual and public health decision making. On the individual level, the value of information on whether one is infected or not is self-evident. The established characteristics of the SARS-CoV-2 so far, such as the gestation period and the diverse patterns of symptoms, including asymptomatic infection, render diagnostic testing indispensable for reducing individual uncertainty on infection status. Depending on the criteria of aggregation, either horizontal (such as the regional concentration of the infection) and vertical (such as different age groups), more information obtained by diagnostic testing is a crucial input to the public health response strategy.

To be effective, testing requires technological solutions to an extent sufficient to cover much of the affected global population. However, bringing large quantities of diagnostic tests to the point of care is an issue that is pertinent to a wide range of considerations, namely to innovation, production, and the coordination of the administration of diagnostic tests. In this paper, we touch upon one aspect of diagnostic testing production, based on the analysis of patent data.([1])

The pharmaceutical and biotechnology sectors spend considerable resources on knowledge production, as reflected e.g. by R&D expenditures.([2]) Complex products such as diagnostic test kits require capabilities that are specialised in several domains, and involve multiple stages of knowledge-intensive modular production. Thus, complex products such as diagnostic tests may bring together manufacturing stages that involve intermediate goods (for instance, complementary substances for the necessary chemical reactions to produce results). The analysis of results of diagnostic testing might also require specialised skills found in laboratory manpower.

Therefore, there is a general question of assembling the value chain that will connect various stages of R&D, production, and distribution of diagnostic tests.([3]) The patterns of international specialisation of these different parts of the value chain is an equally complex issue, which is determined by a combination of factors like the global income distribution, the development stages of innovative and productive capacity, the availability of public and private finance and marketing business activities. In this paper, we consider knowledge production as reflected by patented knowledge as one of the stages of this value chain.

To discover diagnostic testing capabilities, we compile background knowledge on biomedicine pertinent to Coronaviruses and related viruses that cause contagious diseases to animals and to humans. We rely on a corpus of documents that consists of official announcements of the WHO and other institutions, which make the connection between previously prevalent Coronaviruses such as SARS-CoV and MERS-CoV with SARS-CoV-2. We document the two different categories of diagnostic testing, namely, DNA/RNA-based tests and serological tests. These two tests operate in different ways. The former detects fragments the genetic material of a virus, while the latter detects the presence of antibodies, i.e. molecules produced by the immune system of the infected host organism.

The compilation of this background knowledge allows us to extract keywords which we then use to query the body of patent applications. This set of keywords defines a semantic content which delimits the field of diagnostic testing and vaccines for Coronaviruses. Through elementary text analysis, we obtain the patent applications submitted for consideration to various national and international patent offices, pertinent to the semantic content of SARS-CoV-2 diagnostic testing. We show that an index of inventive activity thus compiled is sensitive to the outbreak of coronavirus epidemics.([4])

([1]) This question is embedded in the larger discussion about global value chains, which we do not review here; see, for instance, Antras and Chor (2013) and Costinot, Vogel, and Wang (2013).

([2]) For instance, among the global top private R&D spenders measured by the EU R&D Industrial Scoreboard, the share of pharmaceutical and biomedicine industries is 18.5% on a total private R&D investment of 824 billion EUR in EU27 plus UK (figures in nominal terms, referring to 2018. Source: Hernandez et al (2019, 2020)).

([3]) This question is embedded in the larger discussion about global value chains, which we do not review here; see, for instance, Antras and Chor (2013) and Costinot, Vogel, and Wang (2013).

([4]) In economic theory, the protection of intellectual property rights is necessary since knowledge is non-rival and can thus be used by competing firms in the market, thereby diluting the individual firm incentives for knowledge investment. This fundamental reasoning first presented by Arrow (1962) and Nelson (1959) still constitutes the departing point of any economic analysis of innovation. The

We map an index of innovative activity, in terms of patents, across different regions of the world. We find that overall, there is a strong position of regions outside the EU27 active in the field of Coronavirus diagnostic tests, without neglecting the leading position of France and the Netherlands in patenting activity in the field. Hence, we see that knowledge prerequisites for diagnostic test production are dispersed across different IPR protection regimes.

Contagious diseases, such as the current pandemic, introduce fundamental externalities in all aspects of the economy, society, and challenges to public policy responses. One of the channels of contagion is caused by physical proximity of individuals and the physical movement of population within or across cities, regions, and national boundaries — or, more broadly, the movement of human population in the physical space. An element of the definition of a pandemic according to the World Health Organisation, is that the susceptible population, as defined in epidemiological models, is indeed the world population.

In essence, if the market for diagnostic tests is the global population, public health becomes a global commons, much like the environment. Hence, in an abstract sense, global public health considerations in the current epidemic impose a reasoning on the interpretation of our data that is similar to the one applied on innovative activity directed to the preservation of the environment.([5])

Private sector innovative activity surges whenever there is a market incentive to do so, either in cost-cutting grounds, or in the sense of putting new products in the market. For instance, Popp (2012) examines patent data on energy-saving technologies and finds that there is a surge in innovative activity for conservation of energy inventions when oil prices are increasing. Private investments in innovation for energy conservation is a key action for both the preservation of the environment as well as for confronting the adverse effects of climate change. However, as economic theory shows, there is sometimes an imperfect alignment between private incentives and the conservation of global commons. Economic theory has given arguments for public policy action in this context. For instance, Acemoglu, Aghion, Bursztyn, and Hemous (2012) build on these ideas to provide policy instruments for enabling the private sector in its effort to innovate in dealing with environmental issues and climate change, operating both at the production side as well as the market for privately produced goods.

In the situation created by a global pandemic, a similar line of reasoning might be in operation, precisely because of the vast implications of the all-encompassing externality that affects all potential users of the information produced by diagnostic testing. The private, market-driven incentives for innovation linked to the problem of the preservation of the environment might be similar to those for innovation linked to the problem of managing the adverse effects of a pandemic.

The protection of intellectual property rights (IPRs) is generally recognised as one of the main drivers to fostering innovation. According to classical economic theory, patents are a distortion introduced by the legal system granting assignees temporary monopoly rights to the market exploitation of their invention.([6])

Given that patent protection is granted for a limited time, IPR law and international treaties establish a tradeoff between this temporary distortion in the market, precluding competition, and the dynamic gains from bringing new products to the market to respond to consumers' needs. The mechanism applies universally to all knowledge-based industries and hence, those active in the biotechnology and pharmaceutical sectors.

Additionally, the legal context governing patented knowledge requires its public announcement. In this sense, the ideas codified in patents might be considered as free to circulate in a non-competitive manner internationally. However, IPRs enforcement is restricted to national boundaries. Moreover, the capacity for large-scale diagnostic testing production and distribution at the point of care might be asymmetric in different regions of the world, which poses significant problems in the management of the pandemic. We comment on the possible policy implications in the last part of the paper.

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protection of property rights is a fundamental determinant of economic development and foreign direct investment flows; see, for instance, Awokuse and Yin (2010) among others.

([5]) Public health considerations have previously called for exceptions and special treatment in international arrangements concerning trade and cooperation. Goldberg (2010) provides a thorough discussion of these issues in the context of trade flows of pharmaceuticals produced by companies in developed countries aiming at treating diseases prevalent in the developing world. We do not survey or comment on this literature.

([6]) The protection of intellectual property rights is necessary since knowledge is non-rival and can thus be used by competing firms in the market, thereby diluting the individual firm incentives for knowledge investment. This fundamental reasoning first presented by Arrow (1962) and Nelson (1959) still constitutes the departing point of any economic analysis of innovation. The protection of property rights is also acknowledged as a fundamental determinant of economic development and foreign direct investment flows; see, for instance, Awokuse and Yin (2010) among others.

Our analysis is a preliminary step. Further research should clarify the incentives for knowledge production, the re-use value of this knowledge and possible spill-overs to other sectors, its market outreach, as well as the global dispersion of knowledge, and the value chain components of diagnostic testing, *inter-alia*.

The rest of the paper is structured as follows. We first provide a thorough background on the technology of diagnostic testing, based on field knowledge from virology. We then present the patent keyword search strategy that we employed, resulting in an index of inventive activity. We then provide a list of policy options, and discuss their pertinence towards increasing the capacity for diagnostic testing in EU27. The last section concludes.

2 The Technology of SARS-CoV-2 Diagnostic Testing

The Coronaviridae Study Group of the International Committee for the Taxonomy of Viruses has classified the coronavirus responsible for the ongoing pandemic as a human pathogen under the name "Severe Acute Respiratory Syndrome Coronavirus 2", causing "Coronavirus Disease 19" in March 2nd, 2020.([7]) Nevertheless, coronaviruses affecting humans have been identified and submitted to genome sequencing in the past. Several of these coronaviruses are responsible for diseases associated with mild symptoms, while others are fatal; see Table 1.

Andersen et al (2020) review the genomic data on the composition of Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) and Middle-East Respiratory Syndrome Coronavirus (MERS-CoV) which can cause severe diseases and compare it with the sequencing SARS-CoV-2, finding similarities.([8]) Thus, our empirical strategy is based on the assumption that previous knowledge production encapsulated in patent applications provides the extent of capabilities to produce diagnostic testing and vaccine production instruments.

Correspondingly, in this Section, we compile field knowledge from virology pertinent to the two strands of knowledge that relate to the development of the two different ways of detecting the infection of an organism from a Coronavirus. ([9])

2.1 The Pathogen: SARS-CoV-2

A virus is a microbe containing genetic material encased in an outer protein shell called a capsid.([10]) The genetic material is a sequence of either RNA or DNA which serves as a blueprint for the reproduction of the virus. Viral particles (virions) enter cells through transmembrane receptors. They access the nucleus of the cell, and they inject their genetic material. The material surrounding the nucleus (cytoplasm) then provides the necessary machinery for the reproduction of the virion particles, multiple times. The new virions escape from the cell, resulting in its eventual destruction.([11]) Eventually, this process expands to tissues, which in turn may lead to failures of whole organs, thereby manifesting a disease ranging from mild symptoms like the common cold to as severe as being fatal.([12])

A genome of SARS-CoV-2 has first been sequenced by Wu et al (2020) who submitted it on the 10th of January, 2020 as entry MN908947.3 to GenBank, the open-access initiative of the International Nucleotide Sequence Database Collaboration hosted by the National Center for Biotechnology Information in the United States.([13]) The presence of viral genetic material in the human body forms the basis for the first technological alternative of diagnostic testing production, that of NAAT-based tests, as we explain below.

The SARS-CoV-2 virus belongs to a family which is characterised by the mechanism via which it binds to ACE receptor of the host cell membrane. This attachment results in destroying the cell, in various ways that we do not document.([14])

The intrusion of a virus activates parts of the human immune system, which launches a concerted effort to counteract the reproduction of the virus in the cells. This effort is partly undertaken by *antibodies*, which are molecules that circulate freely in the host blood and bind themselves to the virus. The coupling of antigens

([7]) See Gobalenya et al (2020) for the official declaration to the scientific community and the general public.

([8]) The National Institute of Allergy and Infectious Diseases (NIAID, United States) states on its website that "much of NIAID's work on COVID-19 is an expansion of its work on Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS)", and that "thanks to research investments into the SARS and MERS outbreaks, NIAID scientists and grantees are better prepared to develop diagnostics, therapeutics and vaccines against COVID-19." [Link]

([9]) Field knowledge on Coronaviruses, particularly SARS-CoV-2 is rapidly evolving. Our compilation here is based on publicly available sources and publications at the time of the writing of this paper (April 2020).

([10]) We use the term "microbe" based on the following excerpt by Crawford (2011, Chapter 1): "By the beginning of the 20th century, viruses were defined as a group of microbes that were infectious, filterable, and required living cells for their propagation, but the nature of their structure remained a mystery. [...] However, it was not until the invention of the electron microscope in 1939 that viruses were first visualized and their structure elucidated, *showing them to be a unique class of microbes*. [...] Viruses are not cells but particles." (Emphasis added). We do not comment on taxonomy terms of microbes, or whether a virus is a microbe at all, as this is beyond the scope of this paper.

([11]) Animal and plant viruses circulate in wildlife animal and plant ecosystems, respectively. Animal and plant viruses have different penetrating abilities linked to the manner that the virus is attacking a cell.

([12]) The current Coronavirus attaches itself to lungs, entering through the tract of human mouth, ears, and eyes.

([13]) As Wu et al (2020) mention, the first patient of the now-known COVID-19 has been clinically identified on December 12th, 2019.

([14]) Andersen et al (2020) cite particularly the cell component called "receptor ACE2". This receptor acts as a bay to Coronaviruses in cells, and recently confirmed to be the case of SARS-CoV-2.

and antibodies results, among other things, in staling the viral genome reproduction and its eventual destruction, and the subsequent host disease recovery.([15])

Table 1: Indicative sources of information on human Coronaviruses (Source: adapted from Lim et al (2016) and World Health Organisation website; own elaboration).

Discovery	Strains	Host	Disease
1966	HCoV-229E	Bats	Mild respiratory syndromes (common cold) (Lee and Traynor, 2016)
1967	HCoV-OC43	Cattle	
2003	SARS-CoV	Palm Civets, Bats	South-Asia Respiratory Syndrome. First infected humans in the Guangdong province of southern China in 2002. Symptoms are influenza-like and include fever, malaise, myalgia, headache, diarrhoea, and shivering (rigors). An epidemic of SARS affected 26 countries and resulted in more than 8000 cases in 2003.
2004	HCoV-NL63	Palm Civets, Bats	First identified in the Netherlands, has been shown to infect mainly children, manifesting as mild upper respiratory symptoms (Abdul-Rasool and Fielding, 2010).
2005	HcoV-HKU1	Mice	First characterized in Hong Kong in January 2005 in the respiratory specimens of 2 adults with pneumonia. (Vabret et al., 2006)
2012	MERS-CoV	Bats, Camels	Middle-Eastern Respiratory Syndrome. Typical MERS symptoms include fever, cough and shortness of breath. Pneumonia is common, but not always present. Approximately 35% of reported patients with MERS-CoV infection have died.

The corpus of biomedical research that studies the genetic composition of Coronaviruses is large.([16]) For the purposes of our data retrieval strategy, we rely on a corpus of documents structured around the timeline of the occurrence of human Coronaviruses reported in Table 1. ([17])([18])

2.2 Diagnostic Testing

In sum, there are two broad categories of diagnostic tests that can be performed on humans, based on two different manifestations of the infection caused by the virus.([19])

([15]) Immunity is the presence of antibodies, either as a result of the penetration of the virus to the human body, or before, in principle prior to the development of a viral disease. Hence, immunity is obtained either by vaccination or by recovery antibodies. At the time of this writing. (April 2020), there is still research on the immunity characteristics of SARS-CoV-2.

([16]) The emerging field of data science applied to large repositories of genetic sequences aims at relating features of data with manifestations of the disease, clinical response preparation, and potential correlates to these different strands of evidence. We do not review this literature as it is beyond the scope of this article, and since the international effort to produce results on these fronts is currently underway.

([17]) Andersen et al (2020) cite particularly the cell component called "receptor ACE2". This receptor acts as a bay to coronaviruses in cells, and recently confirmed to be the case of SARS-CoV-2.

([18]) Immunity is the presence of antibodies, either as a result of the penetration of the virus to the human body, or before, in principle prior to the development of a viral disease. At the time of this writing, there is still research on the immunity characteristics of SARS-CoV-2.

([19]) We do not discuss antigen tests, as this class of tests were not under our purview at the time of the writing of this paper (April 2020).

First, the **Nucleic Acid Amplification Tests** (NAATs) that are used to detect a particular organism such as a virus by its DNA or RNA fragments, in terms of their nucleic acid patterns. Although it can be performed in any tissue, existing SARS-CoV-2 tests are administered by capturing a specimen by a throat swab. The quantity of the genetic material contained in the test swab is increased (amplified) by a technique called PCR (polymerase chain reaction) so that it can be studied in a laboratory context. The statistical properties of this type of tests can render them reliable, provided the viral load is sufficiently high, which is usually not the case in the early stages of the infection.

Second, the category of **serological tests** which necessitate blood samples to detect the existence of antibodies against the virus, those that counter the effect of a virus when the latter has invaded a host and started reproducing itself.

Serological tests aim at detecting antibodies. Specifically, these antibodies are produced by the human immune system to attack the protein coat of the Coronavirus. In addition, "spike (S) proteins" are transmembrane signaling proteins attached on the capsid of the virus. As alluded to above, the presence of these antigens in the human organism results in the activation of the human immune system, which releases the antibodies to attack the virus once it enters the human body.

Some antibodies are members of the immunoglobulin (Ig) class, particularly IgA, IgG, and IgM. The identification of the presence of these antibodies enables the inference of the point in time at which an individual was infected – in some cases, even if she or he is without symptoms (asymptomatic). This way individuals who have been infected by a particular virus in the past and have meanwhile recovered can potentially be identified at a later stage.

Overall, both the time of the infection in the past, as well as the presence of the virus in the human organism, render diagnostic testing a statistical decision making problem which adheres to certain properties.([20]) The biomedical research related to clinical trials and diagnostic test development produces results on the power of the tests, such as the sensitivity of the test to produce reliable results and their specificity, including error rates of false positives or false negatives. In the case of SARS-CoV-2, these properties are subject to active research by the international scientific community.

2.3 Patent Data

Against the backdrop of domain knowledge presented in the previous Section, we proceed to presenting out text analysis methodology. The methodology consists of selecting text features for a keyword search on the corpus of patent filings as reported in PATSTAT 2019 (Autumn). The keyword search is performed on titles and abstracts, for patents classified under specific IPC categories. Overall, our methodology is a hybrid, consisting of sequential refinement of a Boolean keyword search strategy.([21])

First, we base our keyword search strategy on the work of the World Intellectual Patent Organisation (WIPO) on patent landscaping of vaccines for selected infectious diseases (WIPO, 2012) and on patents related to pandemic influenza preparedness (WIPO, 2011). We aim at retrieving the filings related to diagnostic tests for general types of Coronaviruses, including potential medical instruments and diagnostics of SARS-CoV and MERS-CoV viruses and antibodies.

We retrieved all patents that are classified in at least one of the International Patent Classification (IPC) categories outlined in Table 2. The top-level category "Medicinal preparations containing antigens or antibodies" is narrowed down to the two sub-categories "Orthomyxoviridae" and "Coronaviridae". We thus eliminate the retrieval of false positive matches of innovations pertinent to general purpose antigens and antibodies diagnostics for a large population of viruses. ([22])

([20]) For an exposition and a discussion of these statistical properties, see Manski (2019).

([21]) Capturing the boundary of a semantic content with such a lexical heuristic strategy is an established methodology in the literature; see, for instance, Benson and Magee (2013) and references therein.

([22]) While the choice of scope is arbitrary, we believe that our strategy captures a considerable part of the capabilities by looking at these already broad categories, as we explain below. We do not employ a validation procedure at this stage.

Table 2: IPC Classification Version 2020.1 (English)

IPC Classification	IPC Classification	Title
Top Level	A61K 39/00	Medicinal preparations containing antigens or antibodies
	A61K 39/145	Orthomyxoviridae, e.g. influenza virus
	A61K 39/215	Coronaviridae, e.g. avian infectious bronchitis virus
Top Level	C07K 14/00	Peptides having more than 20 amino acids; Gastrins; Somatostatins; Melanotropins; Derivatives thereof
	C07K 14/005	From viruses
	C07K 14/08	RNA viruses
	C07K 14/11	Orthomyxoviridae, e.g. influenza virus

Table 3: Stems of terms used in the title of filings

diagnost*	vaccin*	test*	sars	H5N*
blood	serum	antibod*	mers	coronav*
H1N*	molecul*	immunoglobulin M or G or A	igm or igg or iga	Spike *protein
serolo*	ident*	Ards	nl63	hku1
hcov229	hcovoc43	oc43	229e	pcr
rrtppcr	polymerase chain reaction	nucleic acid amplification	rna amplification	

Table 4: Stems of terms used in the abstract of filings

diagnost*	vaccin*	test*	sars	H5N*
blood	serum	antibod*	mers	coronav*
H1N*	molecul*	immunoglobulin M or G or	igm or igg or iga	Spike *protein

		A		
serolo*	ident*	Ards	nl63	hku1
hcov229	hcovoc43	oc43	229e	pcr
rrtppcr	polymerase chain reaction	nucleic acid amplification	rna amplification	

We refine this set by identifying the patent filings that contain in the title at least one of the keywords depicted in *Table 3*. These terms together define a semantic content that is pertinent to the development of two kinds of diagnostic tests and related vaccines against strains of Coronaviruses that have appeared in past epidemic outbreaks.

Specifically, we choose to include keywords that have pertinence to SARS-CoV and MERS-CoV, and in addition to the H5N* and H1N* to capture so-called influenza A viruses. Our desk research (as of April 2020) shows that diagnostic testing technologies for H5N* and H1N* viruses are also based on various PCR techniques (such as RT-qPCR).([23]) Hence, we decide to include antigens and antibodies for this class of viruses, in addition to coronaviridiae. Inclusion of these extra codes and terms expanded the sample size for our analysis. At this point, we do not undertake a validation of the results, in terms of the aimed semantic content.

We then filter the patent applications that contain in their abstract combinations of at least two terms taken from the list in *Table 4*.

The data come with qualifications, both technical and conceptual. Overall, the set of keywords defines a semantic content from a lexical point of view, a basic procedure in text analytics. Hence, the main obstacle to the keyword search queries we perform is that patent applications pertinent to different strains of Coronaviruses may codify knowledge to produce diagnostic tests for those viruses that are affecting *exclusively* animals and not humans (zootic as opposed to enzootic, respectively), and which thus may or may not be pertinent to the sought after capabilities.([24]) Another challenge is the possibility to have patent filings in languages other than English with pertinence to the semantic content we define here, or the existence of false positives in our sample.([25])

These challenges may result in the intrusion of different terms that may exhibit different degrees of relevance to the aimed semantic content. We address some of these challenges by an iterative procedure. ([26]) We arrive at the set of keywords alluded to above by extracting a set of patent filings given an initial set of keywords used in keyword Boolean search on the corpus of patent filing abstracts. This set of documents is filtered by a tf/idf heuristic procedure, yielding a set of potentially new terms that are relevant to the semantic content of the initial document corpus and not included in the initial set of keywords. The terms are ranked according to tf/idf scores and included into the final keyword set, as reported in Tables 3 and 4 above.([27])

([23]) See Klug et al (2019) for a textbook overview and elementary concepts, and Glick et al (2010) for an advanced review, among others.

([24]) Applications for veterinary medicine against Coronaviruses affecting birds or animals (zootic) like cattle were also identified in the initial search. Our field knowledge research hints that in the majority of cases of these patent applications, there is an aim for industrial development of medicines addressing human patients.

([25]) In addition, the data contained in PATSTAT include patent applications that have been filed until the end of 2019, which precludes the possibility of having a glimpse on the current development of the inventive activity with respect to the unfolding epidemic.

([26]) The iterative procedure we employ has led to the inclusion of the terms “dog” and “canine”, for instance. In addition, we identify applications for veterinary medicine against Coronaviruses affecting birds or animals like cattle. We choose to include these terms, to capture the potential in identifying complementary capabilities for diagnostics aiming at human population use.

([27]) There are two additional qualifications for the reading of our results. The first relates to the absence of standardisation of the name and other identification information of patent applicants in PATSTAT. This absence of standardisation introduces the possibility of erroneous double counting. Our Table is based on a first count of different assignees after an initial grouping of different versions of names and identification information. Secondly, the ownership structure of different assignees is known to be a tree-like structure. We leave the definite disambiguation of the names and the ownership structure for future work.

2.4 Results

The final sample of patent filings so obtained consists of 993 records corresponding to 566 unique INPADOC families, for a total of 1,508 assignees, either institutional actors or individual inventors, residing in 36 different countries going back to the 1960s.([28])

Among these records, six are classified as utility models, while 172 from the remaining documents are patent applications that have been filed via the Patent Cooperation Treaty (PCT) route. Utility models are application filings less stringent in patentability requirements, in the sense that they represent minor innovations compared to those of patents.

In addition, 284 out of the 993 records correspond to 284 single member patent families while the remaining 711 are grouped together into 282 families. The term *patent family* designates the *same* invention filed in multiple patent offices and institutions across the world. Hence, 284 out of 993 records correspond to a patent that has been filed in only one patent office across the world, whereas 282 other inventions were followed by subsequent filings in the same or other patent office. We choose to retain all records, since part of our objective is to discover capabilities across the world.

Figure 1 documents the evolution of the yearly patent filing count on our sample. We interpret this count as an indicator of inventive activity aiming at an industrial response to the emergence of pandemics caused by human Coronaviruses, and potential complementary production and distribution capabilities.

Recent years have experienced a surge in patents related to human Coronaviruses, coinciding with the emergence of epidemics attributed to these viruses. The excess patent filing count observed in 2013 is related to the SARS epidemic that has affected large parts of South-Eastern Asia, and similar patterns are observed for other human Coronaviruses related to epidemics. Furthermore, in Figure 2 we document the cumulative count for patent applications that mention one of the viruses that have appeared during the past twenty years. After an epidemic outbreak, the inventive activity measured by our index increases. The more serious the Coronavirus infection in terms of symptoms as documented in Table 1, the more increases the inventive activity which we measure in our sample. We consider this as preliminary evidence of directed technical change in the innovation activity, which is linked to the extent of the Coronavirus epidemics that they are destined to address.

The majority of patent assignees are for-profit, private sector companies. In Table 5, we summarise the institutional affiliation of assignees. ([29])For-profit companies, including private sector laboratories, comprise the second largest category of assignees. Medical research is indispensable for the production of vaccines and diagnostic testing. Moreover, clinical trials that follow strict protocols of the scientific method in order to obtain licensing of new pharmaceutical products and equipment are conducted in large hospital systems. This is reflected in our sample.

Table 5: Institutional Identity of Inventors (subsample of valid cases)

Sector	Company	Hospital	Individual	Non-Profit	University
Private	634	6	858	0	254
Public	17	0	0	166	19

([28]) INPADOC which stands for International Patent Documentation is an international patent classification, grouping together filings at different intellectual property offices which refer to the same invention.

([29]) This affiliation is natural for individuals, since a portfolio of inventions may be used as a career advancement instrument, apart from securing intellectual property rights in view of engaging in entrepreneurial activity.

Figure 1: Yearly count of patent filings in our sample (Source: PATSTAT)

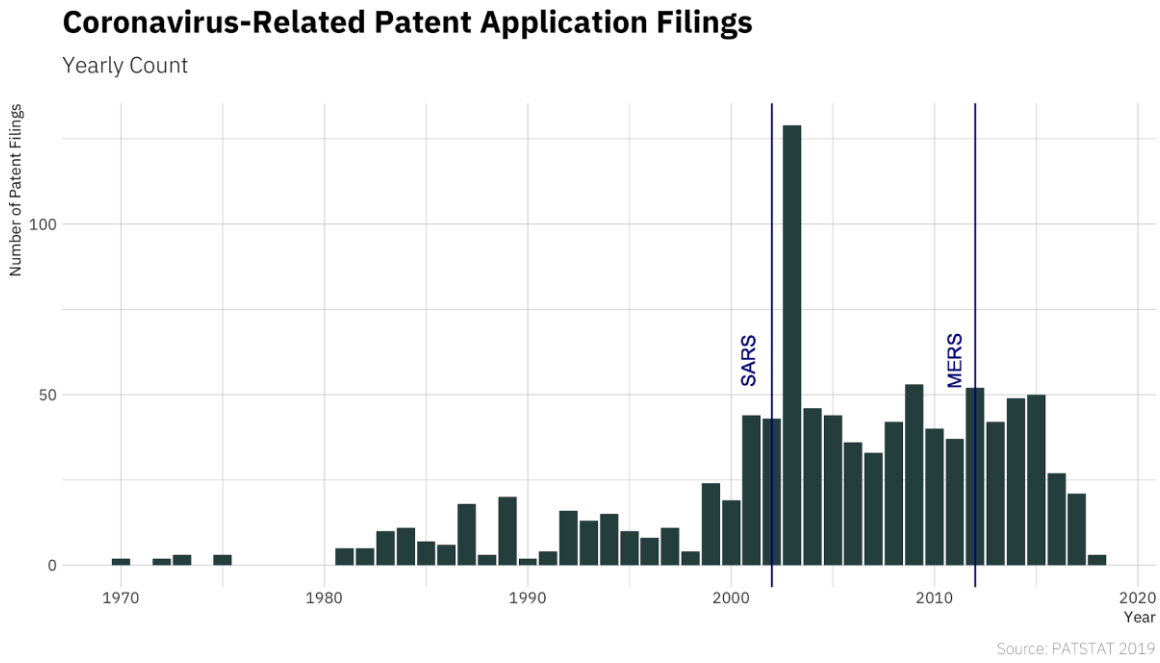
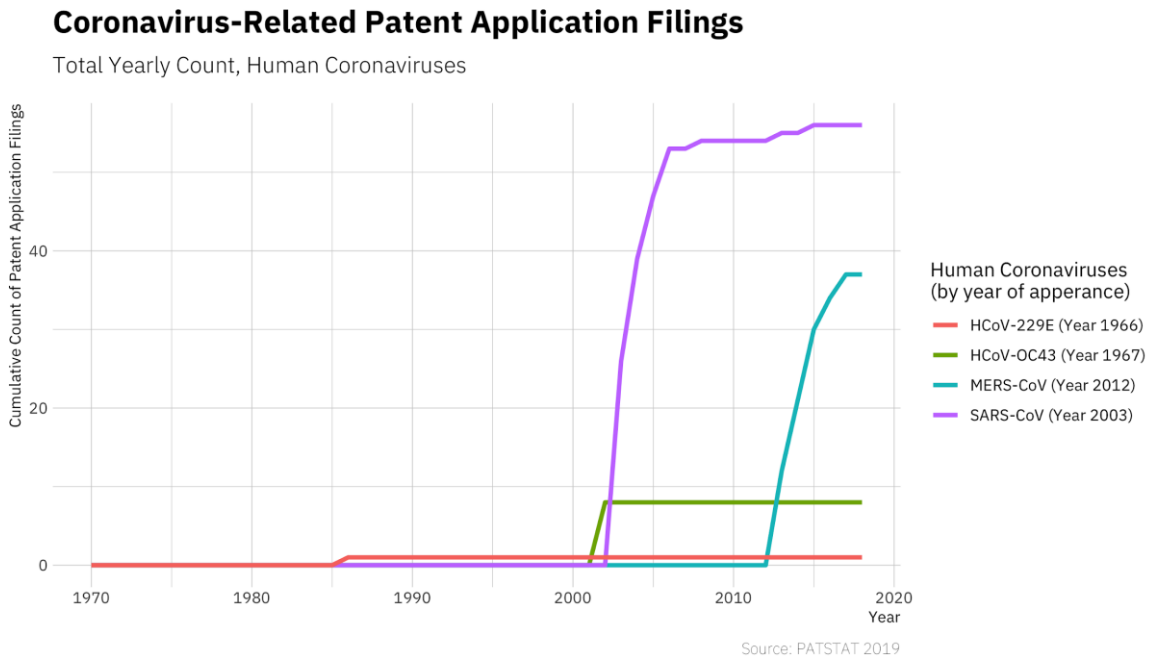


Figure 2: Yearly count of patent filings in our sample (Source: PATSTAT)



2.5 Territorial Dispersion of Knowledge

Protection of intellectual property rights, particularly through patents, has a strong national or territorial character. However, an inventor who files an application in a national office may seek to find protection by IPR law in other countries as well. The potential for reaching a global market, or for producing parts of a product

in an assembly line that is dispersed across multiple intellectual property rights protection jurisdictions motivates the filing to multiple patent offices.

We find that the bulk of applicants declare residence in the United States which, along with China and Japan, amounts for more than 60% of all applicants in our sample. The EU27 amounts to 18% of filings in our sample, of which half has been filed by the entities located in the Netherlands and France. In Table 7, we summarise the distribution of unique patent families across patent institutions (patent offices).([30])

Our count statistics based on patent families captures the effect of subsequent filings in offices other than that of the country of residence, aiming at extending the protection rights of the invention at jurisdictions other than the one of the assignee. The motive for a company is to secure its position in a foreign market raising barriers to competitors or possible imitators.

Figure 3: Location of inventive activity in our sample

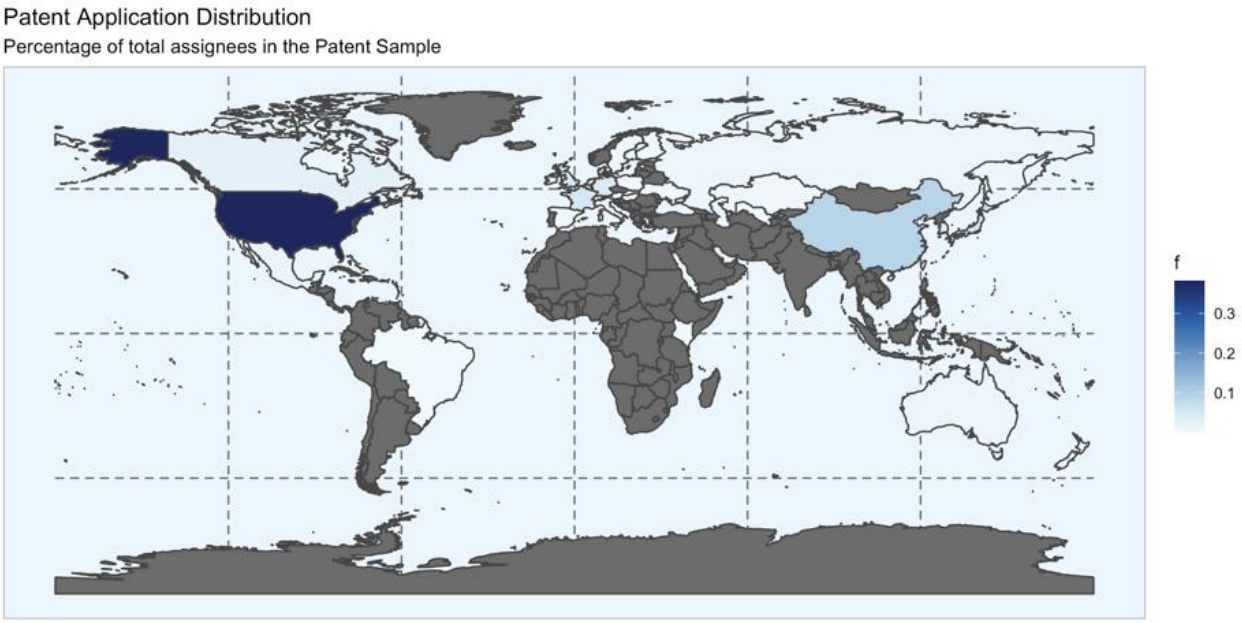


Table 6: Frequencies of Assignees per Country

Country	Assignees	Percentage
United States	762	40.4%
China	179	9.5%
Japan	115	6.1%
Netherlands	109	5.8%

([30]) A patent family is a grouping of patents from various patent offices across the world that refer to the same invention and to the same assignee.

France	97	5.1%
United Kingdom	82	4.4%
Germany	80	4.2%
Denmark	69	3.7%
South Korea	56	3.0%
Rest of the world		17.8%

Figure 4 and *Table 7* jointly describe the structure of patented innovative activity across the world in our sample. The United States is the originator of inventions that are filed for protection in multiple institutions such as the Patent Cooperation Treaty and the European Patent Office, and to national patent offices like Canada. There are two potential factors that explain this pattern. The first is the potential to expand the markets for products based on these inventions, and the second is the existence of subsidiaries of US companies in other countries than the US, or vice versa. On the contrary, China appears to be inward looking in its patenting activity.

In EU27, the most active patent filing is observed by the Netherlands, who contribute filings to both the United States USPTO and the EPO. Russia and Japan are key notable players in the field, as well as South Korea.

Overall, our index shows that there is a strong position of regions outside the EU27 active in the field of Coronavirus diagnostic tests, without neglecting the leading position of France and the Netherlands in patenting activity in these fields.

The evidence presented in grouped form in Table 8 corroborates to this conclusion. First, main world regions appear to be in relative inwardness in the development of knowledge pertinent to diagnostic tests. This is the case for Japan and China, and to a lesser extent for EU27. At the same time, the EU27 region as a whole appears to be leading on the front of international cooperation, by having 8.7% of patent bundles developed by US-based inventors, and 6.1% by inventors that reside in the Rest of the World as defined in Table 8 and Table 9. This preliminary finding should be reviewed once the international ownership structure of the patent assignees is established; nevertheless the observed pattern is commensurate with that obtained from previous analysis on the international activities of firms developing advanced technologies; see Gkotsis (2015), and Gkotsis and Vezzani (2016).

Table 7: Distribution *of unique INPADOC patent families (bundles) across patenting institutions and authorities*

International Patent Institutions	Count	Large Patent Offices	Count	National Patent Offices	Count
Patent Cooperation Treaty (PCT)	29	United States	28	France	5
European Patent Office	15	Canada	18	Spain	4
Eurasian Patent Organisation	7	China	16	United Kingdom	4

		Mexico	14	Brazil	2
		Australia	11	Malaysia	2
		South Korea	10	Philippines	2
		New Zealand	10	Germany	1
		Japan	6	Denmark	1
		Taiwan	6	Jordan	1
		Russia	5	Ukraine	1

Figure 4: Patent application distribution of INPADOC patent bundles (families) across country patent offices and international patent institutions.

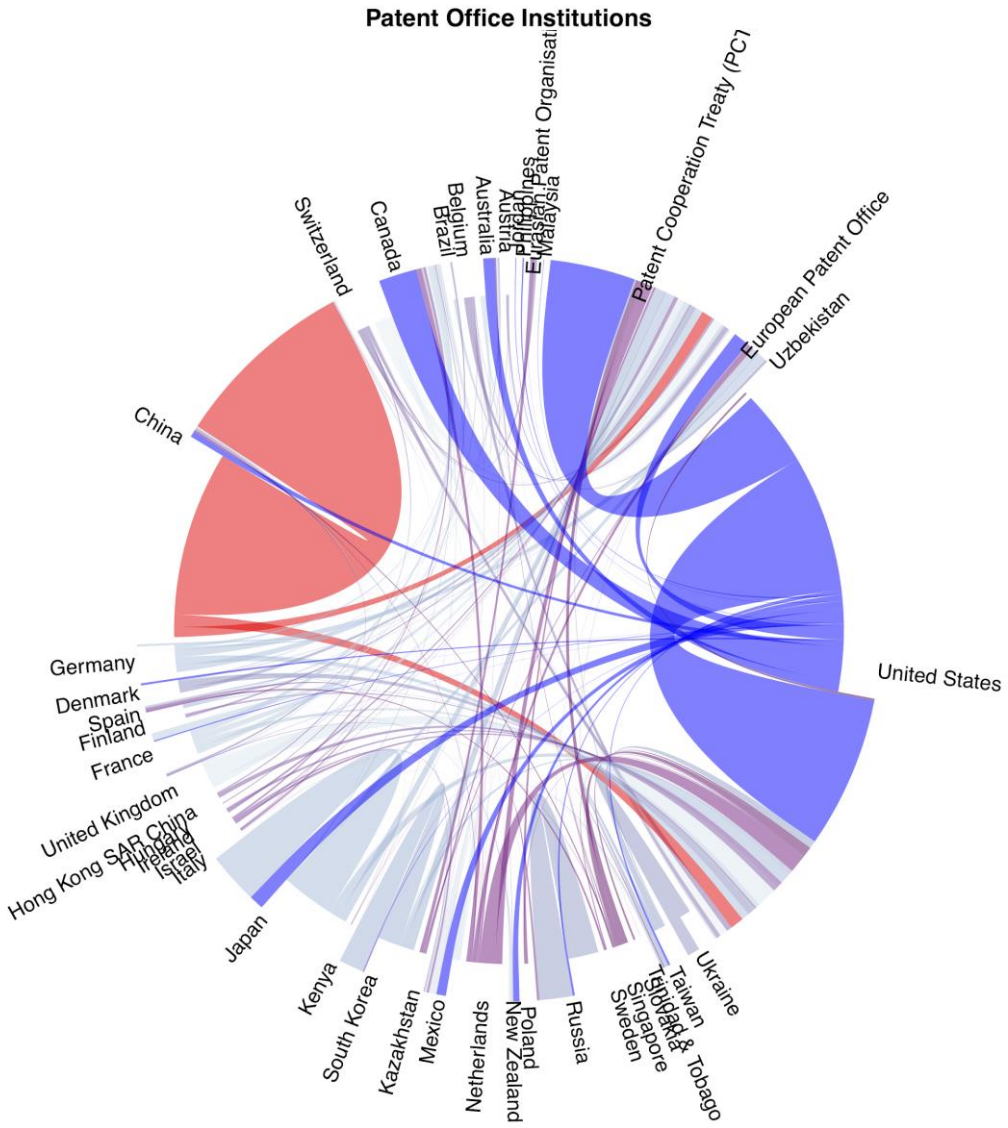


Table 8: Share of Patent Families (bundles) by World Region of Assignee Developed Abroad – All Fields of Invention

Share of patent families by world region of assignee developed abroad					
	Inventor region				
Region	China	EU27	Japan	Rest of the World	United States
China	93.3%	0.2%		2.0%	4.5%
EU27	1.3%	83.9%		6.1%	8.7%
Japan			97.5%	1.5%	1.1%

Rest of the World	1.0%	2.7%	0.2%	85.6%	10.5%
United States	1.4%	2.0%	0.6%	3.4%	92.6%

Table 9: Share of Patent Families (bundles) by World Region of Assignee Developed Abroad – Inventions Related to Diagnostic Tests

Share of patent families on diagnostics by world region of assignee developed abroad					
	Inventor region				
Region	China	EU27	Japan	Rest of the World	United States
China	100.0%				
EU27		95.4%		1.3%	3.3%
Japan			100.0%		
Rest of the World		0.7%		92.1%	7.2%
United States				2.4%	97.6%

3 Discussion and Policy Options

3.1 Background: International Innovation and Production Networks

The outbreak of the epidemic has found the global economy in an advanced stage of globalization of which the conspicuous characteristic has been the progressive unbundling of production, innovation, and distribution tasks.([31]) Activities are physically separated and located in different parts of the world, mainly to obtain cost benefits or/and gain access to local markets and specialised knowledge.([32]) For the global production value chains, modular product design and manufacturing enables the unbundling of final products into components, which in turn can be manufactured in a regional, national, or most often international system consisting of plants in different locations and sophisticated supply chain management. Modularisation of the innovation workflow and new forms of connecting R&D teams, tapping into regional sources of knowledge, skills, labor, and capital have led to similar phenomena for innovation networks.

Both the global production and innovation networks are closely intertwined; location decisions however might be motivated differently.([33]) For the location of production value chains of these companies, access to markets, local supply chains and availability of skilled labour are important. For innovation networks, quality and access to researchers and specialised knowledge are important. For the location of both production and innovation activities of such large multinational companies, proximity to existing activities is a clear asset. In all of these activities, however, the investment motive is strong, the stronger is the protection of intellectual property rights. In our empirical analysis, we focused on the aspect of IP rights protected by patents, as a first step towards understanding the global value and supply chains for the production of SARS-CoV-2 diagnostic tests.

When looking specifically at the R&D activities in the global innovation networks, there is a question on whether there is considerable global dispersion or not. Depending on sectoral characteristics, earlier stages of R&D are often located in top-notch innovation ecosystems, while innovations of higher Technology-Readiness Level stages (development, market adaptation) are located closer to the market.([34]) Results of the global distribution of innovation activities for pharmaceuticals have suggested recently an increasing shift of activities at the later stages of the innovation process (higher TRLs) towards Asia, for cost-, regulation- and market size considerations.([35]) More applied innovative activities (e.g. TRL 7-9) are often driven towards regions with large market demand, while early stage research activities (TRL 1-3) generally occur in traditionally more advanced regions (EU-Japan-US triad), that are endowed with a highly-skilled labour force, strong research institutions and universities. Besides, co-location is found for some R&D sub-functional specificities: some later-TRL activities (e.g. TRL 8 or phase 3 trials) need close connection to manufacturing facilities. Overall, there are patterns of specialisation that we do not capture, and that we leave for future research.

3.2 SARS-CoV-2 Diagnostic Tests

Our preliminary index is based on an established premise from economic theory, namely that new knowledge can be generated by R&D activities that recombine existing stocks of knowledge and ideas so as to produce new ones.([36]) The identity of patents grantees is important, inasmuch as an applicant might exploit knowledge related to tests for Coronavirus pathogens, vital for innovations to produce tests for SARS-CoV-2. We rely on

([31]) For instance, early in the COVID-19 pandemic, there were press reports that the capacity to produce masks and basic consumables for healthcare and clinical support has been insufficient. This more than anecdotal evidence on the shortage of elementary equipment was attributed to the outsourcing of production outside the EU, mainly to Southeastern Asia.

([32]) We retain a descriptive definition of a value chain encompassing all the activities a firm undertakes to deliver a product to the market, typically ranging from the initial development stage, resource acquisition, production to the outbound logistics, sales and post-sales services.

([33]) For instance, Potters & Grassano (2019) present a survey of the top European R&D investing companies which shows that the global production value chains are even more dispersed than the innovation networks.

([34]) A common approach here is the analysis of the research, development and innovation (R&D&I) stages divided in different levels of Technological Readiness Levels (TRL stages), as initially introduced by NASA.

([35]) See Dosso et al (2019) for more information.

([36]) Our contribution is to generate data for future analyses that can address these issues, along the lines of Weitzman (1988) and those of Bloom et. al. (2020). We do not address the interesting but much broader issue of whether new knowledge can be produced out of existing stocks of knowledge with ease so that it can respond to emergencies. We focus on the specific questions we pose in the introduction of this paper.

published expert opinion, our literature review of academic research, and official announcements by expert competent institutions to discuss this issue. We do not cover the entire literature on the subject.

3.3 Capabilities

Our analysis of patenting activity shows that while there are important regional centers for the production of pertinent knowledge outside the EU27, mainly the United States and China, there appears to be substantial capacity within the EU27 to innovate on this type of diagnostic tests.

Our index of patent application filings might also be interpreted as an indicator of where the capabilities to develop and to potentially produce and distribute testing kits are located, and where a related industrial ecosystem might be found.

Many countries are mobilising their capacity for producing and distributing diagnostic tests. South Korea and Iceland are examples of countries where the knowledge was available in the private sector and where, through close collaboration with the public sector, the production of testing kits has been upscaled and deployed.

We do not capture several components of these capabilities, for example:

First, there is the possibility that some innovations are not patented or applied for intellectual property protection, and hence they exist outside the purview of our sample.

Second, there is the possibility that we capture innovations that are still in the research stage and far from the production and market stage, and hence they cannot be deployed in the short- to medium-term response to the pandemic. As this is a rapidly unfolding situation, we cannot comment on how strong this impediment will prove to be in the near future.

Third, we are not able to evaluate how essential certain patents might be towards bringing viable solutions to the market. Some patents might constitute a factual bottleneck towards widespread use of techniques covered by other patents.

Experimentation, the use of background knowledge and prior art, the exploitation of freely available information such as the genetic sequencing of SARS-CoV-2 are thought by many to be key enablers to producing and deploying diagnostic testing. This is one of the main motivations for having included in our sample all patent application filings, granted and non-granted, in addition to utility models. The extent to which the patents captured in our index are incorporating elements from different strands of information, such as open-data on the genetic sequencing, is unknown at this stage, and hence it can't be evaluated by our methodology.

On April 7th, 2020, the WHO listed the first two diagnostic tests for emergency use during the Covid-19 pandemic.([37]) This Emergency Use List "is intended to assist interested procurement agencies and [WHO] Member States on the suitability for use of a specific IVD [In-Vitro Diagnostics], based on a minimum set of available quality, safety, and performance data." (Source: WHO)

3.4 Policy Levers

What policy levers are at the disposal of the Union to accelerate the production of SARS-CoV-2 testing at a massive scale?

There is an instrument at the disposal of patent jurisdictions. There is legal provision allowing countries to raise patent barriers, suspending protection and granting the right to produce a patented product to a third party, or use the product itself without the consent of the patent owner, whenever needed. These provisions for compulsory licensing([38]) were first allowed by the Paris Convention on the protection of IPRs and were amended in 1995 by the World Trade Organisation in the form of the TRIPS agreement (trade aspects of intellectual property rights). Production under compulsory licensing should in principle be limited to the supply

([37]) https://www.who.int/news-room/detail/07-04-2020-who-lists-two-covid-19-tests-for-emergency-use (link accessed April 2020). As of October 20th, 2020, the official list has been growing, as it can be seen at the official website of the WHO [https://www.who.int/diagnostics_laboratory/EUL/en/] Link Accessed October 22nd, 2020.

([38]) https://www.wto.org/english/thewto_e/glossary_e/compulsory_licensing_e.htm

of the domestic market for a limited duration of time, while the patent owner retains the right to be paid. Important exceptions to the general conditions of IPR law apply in cases of national emergencies, or other circumstances of extreme urgency, speeding up the process and raising the non export clause of pharmaceuticals produced under compulsory licensing. ([39])

Most European countries have already integrated rules on granting compulsory licenses in their IP legislation according to the EU Biotech Directive (98/44/EC) and the EU regulation on compulsory licensing of patents relating to manufacture of pharmaceutical products for export to countries with public health problems. To our knowledge, and at the time of this writing, in the context of the current epidemic no country has proceeded to compulsory licensing actions.

An alternative policy action, namely the acquisition (buy-back) and opening-up of the patented knowledge to be put in the public domain have been suggested in the public debate. The majority of these patents belong to private institutional actors. International coordination on this issue would mean the cooperation of foreign national authorities and international institutions in actually giving the green light for such a move.

The repercussions of either policy option are difficult to evaluate, and we do not undertake such an evaluation here. However, two potential repercussions might arise as follows. The compulsory licensing unilateral approach might potentially result in a topical treatment of the pandemic, in that some countries will produce tests and manage the epidemic in their territory. Alternatively, there is a question on the distortions that the buy-back action might introduce, even if it is considered as a temporary action with specific time limits. Feasibility of the two will also depend on the actual ownership of the relevant patents and progress of the research regarding the disease. Once again, the evaluation of either policy action is beyond the scope of the present paper and it is left for future research.

This type of interventions will come into play once there is a real access problem to technological knowledge and a general high public interest at the same time. However, there are still issues pertinent to patent law that could potentially hamper research on the development of diagnostic testing, especially in the case of biotechnology-based tests.

3.5 The Experimental Use Doctrine

In the EU the European Patent Convention (EPC) ([40]), establishes the law of patentability in all EU countries and states that inventions with a potential industrial application are in general patentable. The EPC goes a step further in excluding from the patentable inventions methods for treating the human body, diagnostics practised on humans and inventions whose commercial exploitation could raise moral issues([41]). The EU Biotechnology Directive([42]) which was enacted in 1998 governs Intellectual property rights for inventions in the field of biotechnology making specific provisions for the case of processes involving biological material isolated from its environment or biological material produced artificially. Diagnostic methods not practised in the body and genetic diagnostics are also covered (Cooper and Rochelle, 2017).

Besides, national laws of EU countries make a clear distinction between the use of patented inventions for research purposes (research on a patented invention) including research necessary to fulfil premarket clearance requirements which are permitted and research with a patented invention which is not. Researchers in the EU are also free to research genes protected by patents provided they are not using them for the function described in the patent (Cooper and Rochelle, 2017).

On the other hand, in the US, the experimental use exception formed part of the US patent law for many years and protected scientists by allowing them to use patented inventions for basic research only. Recent changes in the America Invents Act (AIA), coupled with court rulings against the use of patents for specific research activities, have cast doubts about the viability of the doctrine and there is currently an ongoing debate about the repercussions this could have on scientific research especially in life sciences; see, e.g., Kostolansky and Salgado (2018). Another complication arises by the US antitrust law which does not enforce parties with an exclusive position in the market to license their patented inventions, thus eliminating competition and taking advantage of their leading position as it happened with Myriad Genetics and their patents on the BRCA 1 and 2 gene sequences. These genes mutate in a way which is useful for breast cancer diagnostic testing. The company was refusing to license the test to other laboratories, it was asking for

([39]) In November 2001 the Doha Ministerial Declaration recognised the particular vulnerability of the least developed countries and of countries lacking production capacity of pharmaceuticals.
([40]) The EPC entered into force in 1977 and was amended in 2000.
([41]) Other exclusions include inventions discoveries, scientific theories, and mathematical methods.
([42]) Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions.

licensing fees above market price and was taking aggressive litigation action against competitive developers. As a consequence of the Myriad BRCA 1 and 2 breast cancer testing case the OECD developed the general licensing guidelines for genetic inventions.([43]) In the EU the European competition law offers a safeguard to public interest by stating that no party with an exclusive position may refuse to license a patented invention if by doing so it would block the launch of a new product for which there is consumer demand or would eliminate all competition.

([43]) http://www.oecd.org/sti/emerging-tech/guidelinesforthelicensingofgeneticinventions.htm (Accessed October 2020)

4 Conclusions and Further Research

While this report shows the main locations of technological knowledge relevant to the diagnostic testing capabilities, a firm-level, plant-level, or regional-level analysis of individual inventors and assignee institutions will reveal the full extent of the innovation ecosystem that produces knowledge necessary for diagnostic test production.

A number of intelligence tools may help in this respect. We have already mentioned the EU R&D Industrial Scoreboard (Hernandez et al (2019, 2020)). Another intelligence tool that employs a validated, comprehensive methodology at the disposal of researchers and policy makers is the EU R&D Innovation Radar (see, among others, De Prato, G., Nepelski, D. and Piroli, G. (2015)) that could shed light to the issue of private-public sector interactions, as well as issues such as the output additionality of public support, or the enabling character of the origins of funding. ([44]) Overall, more information is needed to assess key enablers of innovation, innovators, and their regional dispersion and transfer of knowledge, and we leave this for further research.

Policy options have to consider to what degree existing knowledge can be more effectively explored and exploited, as well as existing test kit manufacturing production lines can scale-up towards large test production. These difficulties may prove to be important, and they may provide further qualifications in the interpretations of our results.

In addition to the development and production capacities, there is a margin of action for the public sector to ensure the necessary framework conditions to maximise the efficiency of its testing capabilities. These framework conditions are not only IPR regimes, but also linked to the public health sector: medical personnel and laboratories that can help improve testing protocols, workflows and respond to increased pressure for testing analytics.

A final aspect is related to regulation regarding tests, and the information they produce in a general sense. The EU In-Vitro Diagnostics Regulation coming into effect in May 2022 covers general types of genetic-based diagnostics, like the ones we have captured in our sample. ([45])The Regulation covers medical software and genetic tests. The rationale for covering software stems from the need to satisfy safety standards for labs-on-a-chip innovations, digital medicine apps, predictive medicine applications and other digital solutions that with the proliferation of IoT, wearable computing, and bioengineering are reaching the final users through the market. In this last aspect, the importance of the flow and sharing of information, particularly data that emerge from large-scale deployment of diagnostic testing might prove itself to be of relevance. ([46]) On this aspect as well, further research is needed to exhibit the benefits of such an approach.

([44]) In our index, we have not computed the origins of funding, the contribution of public sector R&D support subsidies and related schemes, or the contribution of knowledge from public sector entities. These may be important key enablers for the industry. For instance, in South Korea, private institutions account for 90% of the medical system and 90% of the testing capacity. We leave this investigation for future research.

([45]) In anticipation of the Regulation coming into effect in 2022, actors subject to such provisions might have started to make complementary investments for regulatory compliance. Examining how this regulation can help in the current situation might also be a policy option. We do not comment on this front, and we leave this point for future research.

([46]) See Duch-Brown, Martens, and Müller-Langer (2017) for a thorough exposition of the economics of ownership, access, and trade of data. Sharing diagnostic testing information across Member States, for instance, through initiatives of the European Commission in the context of the European Interoperability Framework might prove to be a key enabler in the public sector response at an EU-wide scale. See Vaccari et al (2020) for such a potential instrument and the implementation technology at the availability of governments in the Union.

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List of figures

List of tables

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